# The 'Over-researched community'

## An exploration of stakeholder perceptions and ethical analysis

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# DECLARATION

This dissertation is submitted in partial fulfilment of the requirements for the degree of Master of Arts (Research Psychology). University of KwaZulu-Natal, Pietermaritzburg, South Africa.

I declare that this dissertation is my own unaided work. All citations, references and borrowed ideas have been duly acknowledged.  It is being submitted for the degree of Master of Arts (Research Psychology) in the Faculty of Humanities, Development and Social Science, University of KwaZulu-Natal, Pietermaritzburg, South Africa. None of the present work has been submitted previously for any degree or examination in this or any other University.

Signed

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26 November 2010

As the candidate's supervisor, I have approved this dissertation for submission

Signed

Prof. D. R. Wassenaar

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# Dedication

In loving memory of my dad Gabriel Angus Koen 1936-2007. Who didn't see the fruition of this work but taught me so much about honesty, fairness and integrity.

# ABSTRACT

Research in resource-limited, multi-cultural contexts raises complex ethical concerns. The term 'over-researched community' (ORC) has increasingly been raised as an ethical concern and potential barrier to community participation in research. However, the term lacks conceptual clarity and is omitted from established ethical guidelines and academic literature. In light of the concern being raised in relation to vitally needed HIV prevention research in developing countries, a critical exploration of the meaning of the notion was undertaken.

Guided by Emanuel et al.'s (2004) eight principles for ethically sound research in developing countries, this study explored the relevance and meaning of the terms 'over-research' and 'over-researched community' through a thorough review of ethical guidance documents and analysis of key stakeholder perspectives. In-depth interviews were conducted with 23 resource persons from research ethics committees, community advisory boards and research organisations in South Africa. Interviews were transcribed and translated where necessary and data were analysed thematically.

'Over-research' was found to reflect a conglomeration of ethical concerns, often being used as a proxy for existing ethical concepts. 'Over-research' might be interpreted to mean exploitation. However, exploitation itself could mean a range of different things. 'Over-research' seemed fundamentally linked to disparate positions and perspectives between different stakeholders in the research interaction, arising from challenges in inter-stakeholder relationships. Analysis of the data suggests that using the term may lead to an obscured understanding of real or perceived ethical transgressions, making it difficult to intervene to address the underlying concerns. It is recommended that the term not be used in research ethics discourse. However, because it represents other legitimate concerns, it should not be dismissed without careful exploration

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# A     INTRODUCTION

Approximately eighty percent of the world's population lives in developing contexts, where access to healthcare and other social benefits is severely constrained by limited resources (Nuffield Council on Bioethics [NCOB], 2002). Health research, frequently conducted in developing contexts by external sponsors, has contributed significantly to the understanding, prevention and treatment of ill-health, through medical, social and behavioural interventions (NCOB, 2002).

The rapidly expanding global Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome [HIV/AIDS] pandemic, despite increased access to HIV treatment, has generated an imperative for the development of increased options for HIV prevention (Merson, O'Malley, Serwadda, & Apisuk, 2008). Since the developing world, sub-Saharan Africa in particular, bears the burden of the epidemic, with 68 % of new infections and 72 % of all AIDS-related deaths, globally in 2008 (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2009), there is a critical need for increased research efforts to develop prevention methods which are suited to these contexts.

Research in developing countries and resource-limited settings is a complex undertaking, particularly, when sponsored by developed country organisations. It raises many complicated and contentious ethical concerns, including those related to exploitation and research with vulnerable populations (cf. Emanuel, Wendler, Killen & Grady, 2004; Hawkins & Emanuel, 2008).

The issue of the 'over-researched community' (ORC) is increasingly raised as an ethical concern regarding research with groups of people, especially in developing and resource-limited contexts. The term is often used informally in popular discourse (cf. Mellville, 20 March 2007), although, it has been used by gatekeepers of research as a reason for denying researchers access to communities (cf. Nattrass, 2006). Concerns about communities being 'over-researched' are increasingly cited in relation to health and HIV-related research in developing countries (cf. Essack, et al., 2009; Heise, Shapiro & West-Slevin, 2008; Nattrass, 2006).

From a conceptual perspective, although the term 'over-research', seems a fairly self-explanatory concept, interrogation of the notion reveals this simplicity to be deceptive. The notion as a gatekeeping criterion seems primarily to be used pejoratively, implying that too much research has been conducted.  However, what constitutes 'too much' research?  And , what is it about 'over-research' that is ethically worrisome?

In most cases of its use, the term is not directly addressed, but used with its meaning taken for granted (cf. Matheson, Howden-Chapman, & Dew, 2005; Mavhunga & Dressler, 2007). Apart from a single article linking 'over-research' to so-called 'research fatigue' and reasons for refusal to participate in qualitative research, there is no formal body of literature exploring the issue of 'over-research' (cf. Clark, 2008). There is also little (if any) mention of the term in the accepted international guidelines for ethical research. It does not appear that the notion is explicitly defined anywhere in the existing literature or ethical guidance.

It remains unclear what the term 'over-research' actually means  - whether it refers to existing challenges regarding research in developing or resource limited settings, which are already dealt with in existing normative frameworks, or whether it represents a concern which has emerged over time and is absent from these frameworks.

## 1    Aim

The principal objective of this study was to explore the relevance and meaning of the term "over-researched community" (ORC) as an ethical construct. At the heart of this objective are two questions: (1) Is 'ORC' a discrete ethical concern or does it reflect other existing concerns in research ethics? and (2) How do the various stakeholders involved in the research enterprise make sense of this term when it is used?

## 2    Background

Electronic searches of academic databases (including EbscoHost, PsycInfo and PubMed Central) were conducted for articles dealing with the issue of 'over-research' or 'over-researched communities'. Bibliographic resources on 'over-research' and 'over-researched communities/populations' using the Kennedy Institute of Ethics' National Reference Center for Bioethics Literature[1] (NRCBL) were also explored. Apart from one article (cf. Clark, 2008), which sought to explore how researchers accounted for so-called 'research-fatigue' and 'over-research' in qualitative studies,  neither search strategy found academic articles directly discussing the notion of 'over-research', or critically engaging with its meaning. While Google searches on the topic found some mentions of 'over-research' and 'over-researched communities' in the grey literature, such as meeting reports and presentation slides, these were usually in the context of explanations for poor response rates or a lack of willingness to participate in research, and also lacked a critical engagement with the meaning of the notion of 'ORC'. Further, the reliability and credibility of such sources is questionable, and none addressed the concept directly. The notion was also referred to, tangentially, in other literature around community engagement (cf. Flicker, Travers , Guta, McDonald, & Meagher, 2007); again, none explicitly explored the concept. Where the term was used, the concerns raised could be argued to provide some insights

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[1] http://bioethics.georgetown.edu/

into the meaning of 'over-researched communities'. However, this could not be claimed to constitute a comprehensive analysis of the use of the term.

## 2.1    ORC in ethical guidance

While none of the standard ethical guidance documents explicitly use the term 'over-research,' or address it in any specific way, several allude to the notion, usually under the topic of fair selection.

The Belmont Report, discussing justice, suggests that

> The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.(Belmont Report, 1979, B-3).

The closest reference to the notion of 'over-research', seems to be in the commentary on the Council for International Organisations of Medical Sciences [CIOMS] (2002) guidance point 12, in which a concern about the 'over-use' of certain populations is raised, directly in relation to a discussion of fair selection. This is argued to be "a perception, sometimes correct and sometimes incorrect, that certain groups of persons have been overused as research subjects."  What the commentary to guidance point 12 suggests is that "such overuse has been based on the administrative availability of the populations," or "because they were conveniently available to researchers." Another major factor influencing the idea of over-use in this commentary is the selection of those from "the lowest socioeconomic classes....,[who are] subordinate members of hierarchical institutions, ... [and] impoverished groups." The commentary also suggests that:

> Not only may certain groups within a society be inappropriately overused as research subjects, but also entire communities or societies may be overused. This has been particularly likely to occur in countries or communities with insufficiently well-developed systems for the protection of the rights and welfare of human research subjects. Such overuse is especially questionable when the populations or communities concerned bear the burdens of participation in research but are extremely unlikely ever to enjoy the benefits of new knowledge and products developed as a result of the research.

The South African Medical Research Council [SA MRC] (2001) Guidelines on the recruitment and selection of healthy volunteers (7.1.2) caution against the "excessive use of any volunteer", however they do not expand on this. The SA MRC (2001) guidance point regarding research on patients (7.2) includes a separate sub-point (7.2.5) regarding "Protection against excessive requests":

> Some groups of patients, such as those with rare diseases, may be at risk of exploitation through frequent requests to take part in research that may not directly benefit them. Investigators must be sure that such patients, or patients who are readily available and compliant, are not exploited for the sake of convenience and that they do not feel obliged to participate in research as a condition of receiving care."

Here the suggestion is that frequent requests to participate in potentially non-beneficial research is *exploitation*, or 'over-research'. The concern is about 'exploitation' or 'over-use' on the basis of convenience or compliance. The MRC guidelines appear to link 'over-research' to exploitation.

The only set of guidelines which use the phraseology 'over-researched community' are the Indian Council of Medical Research Guidelines (2006, p.46), in connection with child involvement in research however.  The guidelines however do not expand on the concept at all.

## 2.2    ORC in literature

In the absence of a formal body of literature directly addressing the notion of the 'over-researched community', it remained to examine how the term is used, when, and if, it is used, in the literature.

Clark (2008) in his assessment of research fatigue and claims of 'over-research' being mobilised as reasons to avoid engagement in qualitative research, notes that the concept "has received relatively little attention within [the literature examining direct challenges to research engagement], despite being all too familiar to many researchers" (p. 955). Concerns about  the 'over-researching' of communities can be found for example, in research with: indigenous or aboriginal populations (cf. Boyer et al., 2007; Lawrence, 2007; Ng'ong'ola, 1997; Preis, 1996), minority ethnic groups (cf. Afshar, Franks, Maynard & Wray, 2002; Elam et al., 2003; Feldman, Freese  & Yousif, 2002; Pemberton, Alty, Boylan & Stevens, 2006), African American populations (cf. Peters, 2004), the elderly (cf. Seymour et al., 2002) homosexual groups (cf. McLean & O'Connor, 2003), female commercial sex workers (cf. Coy, 2006; Sanders, 2006), rural communities in South Africa (cf. Tapela, Maluleke & Mavhunga, 2007), vulnerable communities (cf. Frankish, 2006), survivors of human rights violations in South Africa (cf. Kagee, 2004), HIV-positive individuals (cf.de Bruyn, 2005) and communities hosting HIV prevention research (Essack et al., 2009; Heise, Shapiro & West Slevin, 2008; Nattrass, 2006; Thiessen, et al., 2007).

Most articulations of the notion of 'over-research' might be interpreted to suggest that communities feel 'over-researched' because of a lack of feedback from researchers (cf. Tapela et al., 2007), a lack of tangible outcomes, a perception of a lack of benefit to local communities (cf. Thiessen et al., 2007), and lack of perceptible impact or change as a result of their participation (cf. Clark, 2008).

> Now in South Africa it is more research done on the African population . . . why are other population groups not selected? For example we know that in (X), that area is over researched, and it is always, it is always Africans... . . . there is a lot of research that has been taking place in (X), but you look at the socio-economic status and the health and it has not improved. And people are starting to say, even the communities themselves, are starting to say, why are you researching us when there is no development in our areas? . . . We should actually see an improvement in terms of the lives for the people who are being researched over and over and over again" (Government respondent Quoted in Essack et al., 2009).

Concerns, under the heading of 'over-research', such as the following, have been raised:

In several African countries, there are some research centres that are internationally known. These centres of excellence are mostly situated in poor rural areas and all the major studies are conducted in these centres as well as their surrounding areas. Some of these areas are now over-researched and most of the literature is from these areas. In some situations this phenomenon has resulted in the stigmatisation of the communities. An example is the Hlabisa community in South Africa who are now referred to as the "AIDS People" since most of the studies on HIV in South Africa have been conducted in that community. The communities in these areas serve as "Human Laboratories" and end up bearing all the burdens of research. Researchers need to ask themselves the reason why they have chosen a particular area for their study. Is it because the people are too receptive or is it to take advantage of the existing infrastructure? Certainly burdens and benefits from research need to be shared out equally among all communities (Ndebele, 2003, p. 20).

In addition to suggesting concerns about the misrepresentation of communities in research (cf.), it was implied that adopting research strategies which fail to acknowledge the ethical integrity of communities could lead to communities feeling 'over-researched' (cf. Flicker et al., 2007). Furthermore, "having a long-term commitment is also important in terms of the communities that are being researched. If meaningful relationships are not established, and research subjects or institutions begin to feel used, and become 'over researched,' the viability of projects in the future may be threatened" (Thomlinson, Swartz & Landman, 2003, p.542).

In relation to HIV prevention research, Heise et al. (2008) suggest that the 'over-researching' of communities is a valid concern, and might have significant implications for the scientific integrity of studies, however, they do not expand further on precisely what this concern means. Heise et al. (2008) also imply that where 'over-research' results in the suspension of research efforts in a community, the community may be deprived of needed benefits.

Subsequent to the closure of the Cellulose Sulfate (CS) Microbicide trial in 2007, concerns were raised about whether certain sites were 'over-researched', as it was argued that "some participants come out of one trial and immediately go into another" (Dhai, 2007 in Smith, 2007, p.14). Concerns raised by communities regarding their selection for HIV prevention research emerged in "the context of the debate that communities are over-researched" (Frohlich, 2007 in Robinson, 2007, p.4). However, where the need for research to address priority issues is clear to communities, concerns about 'over-research' might be avoided (Frohlich, 2007 in Robinson, 2007).

## 3    Rationale

Examining the usage of the term 'over-research' in literature provides some insight into the ethical concerns to which it refers. For example, that it has something to do with issues regarding the distribution of the burdens and benefits of research, the selection of the research population, respect for participants and communities, community participation, research with vulnerable populations, research into socially sensitive issues (like HIV/AIDS) and general concerns about exploitation.

However, the term 'over-research' remains conceptually and definitionally amorphous, seeming to refer simultaneously to various ethical concerns. In none of the instances of its usage is there a clear and explicit definition of 'over-research'.

The apparent lack of academic literature dealing directly with the notion of 'over-research' and 'over-researched communities', made a systematic and thorough exploration of the use of the term in the literature challenging.

Moreover, the few references made to the notion of the 'ORC' seem to suggest that it represents a conglomeration of disparate ethical concerns. As such, the concern about 'ORC' is difficult to address as it is not clear what the precise problem is. As Hawkins and Emanuel (2008, p.14) argue, "specifying what constitutes [an ethical concern like 'ORC'] is critical not only for correctly labelling a situation or relationship but for devising the appropriate remedy. Unless, we know what the problem is, it is very hard to know what the right solution is."

Together with the challenges posed by the high mutability of the HI virus and the numerous complex social factors associated with HIV, the development of effective biomedical and behavioural HIV prevention methods will require the recruitment of thousands of participants into research worldwide (Heyward, MacQueen & Goldenthal, 1998). Given the desperate need for options to curb the spread of HIV, it is crucial that communities in the most burdened settings are willing to participate in research, both now and in the future. As such, understanding and addressing potential barriers to community involvement in research efforts, like 'over-research', is essential (cf. Kegeles, et al., 2006). Since the term 'over-research' is used by research stakeholders, and is often raised as a concern at research-related and bioethics-focused workshops (e.g. see Mamotte, Wassenaar, Koen & Essack, 2010), this lack of clarity and systematic treatment of the notion lends support to the need for further exploration. Any term used to describe concerns in the ethics of research requires clarity, in order to ensure that these concerns can be adequately understood and appropriately dealt with, without distraction or confusion (cf. Emanuel, 2004, 2005; Hawkins & Emanuel, 2008).

## *Outline of dissertation*

In order to elucidate the notion of the 'over-researched community' (ORC), in the absence of literature directly addressing it, this dissertation begins with a review of the development of research ethics. This review will situate the emergence of increasing ethical concerns about communities in research and outlines the evolution of existing ethical issues in research, which might have bearing on the notion of 'over-research'.  Existing ethical issues in research include vulnerability, exploitation, and concerns

about research in developing countries. This review also explores whether or not the notion of the 'ORC' reflects an existing concept in the evolution of research ethics. Barriers to community engagement in research and issues relating to the research context in South Africa are also reviewed. Following this is an outline of the empirical study. As the notion of 'over-research' has not received much theoretical attention, this study was exploratory and thus adopted a qualitative approach. Respondent perspectives on the notion of the 'ORC', clustered according to a framework for ethical research conduct (Emanuel et al., 2004), are then presented. Discussion of the major cross-cutting themes from respondent perspectives in relation to the literature, then follows, with some conclusions and recommendations.

# B    BACKGROUND & LITERATURE REVIEW

## 1.    *Evolution of research ethics*

Research ethics is not a static field. Changing global political and societal trends, have elicited shifts in perspectives on research and research ethics (Emanuel & Grady, 2006; Mastroianni & Kahn, 2001). Ethical concerns in research with human participants and the mechanisms for addressing them have evolved over time through various phases, or paradigms, which incorporate different approaches to research oversight and the protection of research participants (Emanuel & Grady, 2006). Specific scandals in the conduct of research with human participants, together with the development of new technologies, have led to the development of ethical guidelines, frameworks, standards and policies, each with varying foci and emphases. Concurrently there has been the emergence of new ethical concerns and ideas, and the redefinition of existing ethical issues and principles in response to the changing context in which research is conducted (Benatar & Singer, 2010; Emanuel & Grady, 2006).

## 1.1    *Researcher Paternalism*

Approaches to research prior to, and during the second world war, were 'unashamedly utilitarian', justifying individual sacrifice in research by the contribution a study might make to the 'greater good' (Emanuel & Grady, 2006). In the absence of any formal, internationally recognised and enforced code of research ethics, or requirement for informed consent or review of research by an independent committee, the primary protection for research participants was the integrity of the researcher (Emanuel & Grady, 2006). Researchers were seen as having the participants' best interests at heart, and were considered best placed to make judgments on their behalf about the appropriateness of risk-benefit ratios (Emanuel & Grady, 2006). Researchers, on the grounds of their professional training and knowledge, adopted a stance of 'strong paternalism', making most decisions about research participation for individuals, ostensibly in their best interests with little consultation with the participants themselves (Beauchamp & Childress, 2001; Emanuel & Grady, 2006).

Researcher paternalism was congruent with the paternalistic relationship between physicians and patients, dominant at the time in therapeutic settings. It was generally accepted that physicians, based on judgements of the potential impact of certain information on patients, would decide how much information to disclose to their patients, and would frequently influence a patient's decision to undergo specific treatment or not (Emanuel & Grady, 2006). Furthermore, the judgements of medical professionals were rarely, if ever questioned by patients or lay members of the public, as they were considered to lack the rational expertise and competence to make decisions in their own best interests (Emanuel & Grady, 2006).

## 1.2 Historical Abuses

Historically, research was also frequently conducted in populations of people, who were considered a burden to society, such as prisoners, the mentally handicapped or those in psychiatric institutions or orphanages, and was justified as a means by which these groups could make a valuable contribution to society (Emanuel & Grady, 2006).

### 1.2.1 Nazi experiments

The atrocities to which prisoners in Nazi concentration camps during World War II were subjected, under the guise of 'scientific experiments', were grounded in an extreme version of the utilitarian philosophy of individual sacrifice for societal benefit (Lott, 2005; Loue, 2000; Weindling, 2008). Racial and social groups, defined as racially inferior, 'undesirable' and as placing a burden on the healthy population, were targeted for imprisonment in concentration camps, which allowed brutal treatment and deliberate killing for the purposes of scientific research (for comprehensive reviews see Weindling, 2008).

#### 1.2.1.1 The Nuremberg Code

At the end of the Second World War, surviving Nazi doctors were prosecuted for war crimes at the Nuremberg Trials (Annas & Grodin, 2008; Loue, 2000). In response to the numerous atrocities conducted in the 'guise of scientific research', the military tribunal judges articulated the *Nuremberg Code* (Annas & Grodin, 2008; Emanuel et al., 2003). The code outlined ten criteria for acceptable research with human participants and emphasised voluntary informed consent (IC), by competent individuals, as a central protection for research participants (Annas & Grodin, 2008; Emanuel et al, 2003; Loue, 2000).

As the first internationally promulgated code of its sort, the *Nuremberg code* is argued to have heralded the birth of modern research ethics (Annas & Grodin, 2008; Lott, 2005).
Despite representing a significant development in the ethics of research with human participants, the *Nuremberg Code* had little effect on global research practices (Annas & Grodin, 2008). The prevailing view was that the *Code* was only applicable to totalitarian regimes such as that of the Nazis (Annas & Grodin, 2008; Emanuel & Grady, 2006).

### 1.2.2 Ethical scandals in the United States

In the 1970s numerous cases of unethical research conducted in the United States were revealed, and it became clear that unethical research was not isolated to totalitarian regimes (Ashcroft, 2008).The unethical experiments revealed, were mostly conducted on poor, ill and powerless people, who were unlikely to benefit from participation, and in some cases, were unaware that they were part of research (Loue, 2000). Although a few of these unethical experiments had been started before the promulgation of the *Nuremberg Code*, many were only initiated after its formulation (Loue, 2000).

The ethical scandals included the Jewish Chronic Disease Hospital (JCDH) Study[2] in which chronically ill, elderly hospital patients were injected with live, laboratory-cultured cancer cells, without their knowledge or consent, in order to assess their bodies' immune reactions (Arras, 2008; Lott, 2005). In the Willowbrook hepatitis experiments[3], residents of the Willowbrook School for mentally retarded children were deliberately infected with hepatitis via food contaminated with faecal matter, in order to study the course of the disease and to determine if immunity could be induced (Loue, 2000; Lott, 2005; Robinson & Unruh, 2008). These studies called into question the view, that researchers, on the grounds of the contribution they made to science, had rights to make unilateral decisions regarding the bodies of others and the norm of researcher discretion regarding the ethical integrity of research (Arras, 2008). Concerns about benefit to those bearing the burden of research, worries about the selection of vulnerable populations for research, and the need for voluntary informed consent were also highlighted (Arras, 2008; Loue, 2000; Lott, 2005; Robinson & Unruh, 2008). Questions were also raised about coercion and parental consent for enrolling children into research, and researcher responsibilities to address the background conditions, which fuel the condition that is the subject of research (Loue, 2000; Lott, 2005; Robinson & Unruh, 2008).

The Tuskegee Syphilis Study[4] of the natural course of untreated syphilis among African-American males, is one of the most infamous examples of unethical research, and has had a significant impact on the field of research ethics (Emanuel et al., 2008; Lott, 2005). The study was government sponsored and continued from 1932 to 1972 (Brandt, 1978; Jones, 2008; Lott, 2005). For the 40 years that this study continued, treatment, even when it became widely available, was deliberately withheld from participants, because it would have ended the study, and diagnostic procedures, such as spinal taps, were misrepresented as treatment to encourage participation (Brandt, 1978; Jones, 2008; Loue, 2000).

It was only following public outrage in response to media coverage of the Tuskegee study in 1972 that the study was eventually stopped (Brandt, 1978; Jones, 2008; Lott, 2005; Loue, 2000). Moreover, it was only in the wake of legal action undertaken by a civil rights leader on behalf of the surviving study participants and the families of the deceased, that the surviving men eventually received the treatment to which they were entitled (Jones, 2008). It was only in 1997 that the families and participants received a formal apology from the U.S. president (Jones, 2008).

The Tuskegee Syphilis study highlighted concerns about informed consent, access to treatment and the complexities of conducting research among groups of people unfamiliar with medicine and health

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[2] For more detail see Arras (2008)
[3] For more detail see Robinson & Unruh (2008)
[4] For more detail see Jones (2008)

research. The study has had far-reaching consequences regarding the public perception of medical research, particularly among black communities in the U.S., as exploitative (Jones, 2008; Loue, 2000).

### 1.2.3 Social Science Research

Ethics in social science research has been given significantly less attention in the academic literature and in regulatory protections for research participants than biomedical research, presumably based on the assumption that social scientific research poses comparatively less risk of significant harm to research participants (Haggerty, 2004; Hoeyer, Dahlager & Lynoë, 2005; Moreno, 2001; Wassenaar, 2006). However, social science research has generated ethical controversy and public debate in several instances and the ethical issues raised have relevance for both clinical and behavioural research (Levine & Skedsvold, 2008).

Perhaps the most well known social science studies to generate ethical debate are Millgram's studies of obedience, conducted in the early 1960s, in which participants were instructed to administer painful electric shocks to another individual for mistakes made in a sham memory test (Haggerty, 2004; Levine & Skedsvold, 2008; Moreno, 2001). Although the individual being shocked was an actor and no shocks were actually delivered, if they were some of these would most likely have been lethal (Haggerty, 2004; Levine & Skedsvold, 2008; Moreno, 2001).

In Zimbardo's study of social-psychological behaviour in a simulated prison environment, participants became so emotionally involved in their roles as 'warders' or 'prisoners', that they began to behave abusively towards one another, and Zimbardo was forced to terminate the study prematurely because of concerns about the potential physical and psychological consequences of allowing such behaviour to continue (Haggerty, 2004; Levine & Skedsvold, 2008; Moreno, 2001).

In the 'tearoom trade' study in the late 1960's, a researcher covertly observed the behaviour of men who engaged in casual homosexual encounters in a public restroom, and then recorded their licence plate numbers, which he then matched to names and addresses in official records (Haggerty, 2004; Loue, 2000; Moreno, 2001). Later, the researcher approached these men at their homes in order to obtain information about their personal lives and found that most were outwardly heterosexual and many were married (Haggerty, 2004; Loue, 2000; Moreno, 2001).

These studies raised questions about the ethics of deception in research, the ethics of covert observation, and concerns about privacy and confidentiality (Haggerty, 2004; Levine & Skedsvold, 2008; Moreno, 2001; Wendler & Miller, 2008). The potential for study information to result in significant psychological, emotional, social and even legal harm, was also highlighted (Haggerty, 2004; Loue, 2000; Levine & Skedsvold, 2008; Moreno, 2001).

## *1.3 Regulatory Protectionism*

With the exposure of the abuses perpetrated in the interests of science, it became clear that researchers, who were usually focussed on advancing science and their own careers, were not, especially concerned with participants' best interests. Researchers often seemed to experience conflicts of interest between the ratio of risks to benefits for individual participants and the social value of the research (Arras, 2008; Emanuel & Grady, 2006). The paternalistic 'researcher knows best' approach seemed to be a mechanism for limiting information to, and actively deceiving, relatively powerless participants, in order to recruit them into, and retain them in, studies (Arras, 2008; Brandt, 1978; Emanuel & Grady, 2006; Jones, 2008). Ironically, the social value, often used to justify studies was dubious in many cases, given existing evidence and researchers failing to manage factors, which compromised scientific integrity and led to meaningless results (Emanuel & Grady, 2006). Clearly, researcher integrity could not be relied upon as the primary protection for research participants (Emanuel & Grady, 2006). It was agreed that the self-regulation of research activity by researchers, and the utilitarian justification of individual sacrifice for societal good, were no longer acceptable (Arras, 2008; Beauchamp, 2008; Emanuel & Grady, 2006; Jones, 2008; Loue, 2000).

In light of the scandals that had taken place, the United States introduced legislation and established a commission (US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research) in 1974 in order to explore the ethical issues in both behavioural and biomedical research, and to develop ethical guidelines for regulating the conduct of research. The outcome of this process was the establishment of formal ethical requirements and regulations for the conduct of research, outlined in the *Belmont Report* (Arras, 2008; Beauchamp, 2008; Emanuel & Grady, 2006; Loue, 2000).

### 1.3.1 The Belmont Report

Grounded in the history of research abuses, the perspective on research informing the drafting of the *Belmont Report* was that, although research could be valuable and necessary, it was fundamentally dangerous and threatening to the wellbeing of individual participants (Emanuel & Grady, 2006; Levine 1996 in Beauchamp, 2008). As such, research participants were viewed as vulnerable and in need of protection from the risks and burdens of research (Emanuel & Grady, 2006; Beauchamp, 2008). A protectionist stance was adopted in the ethical oversight of research, and many groups were excluded from research on the grounds of their 'vulnerability'.

Independent review, in which research and ethical decision-making authority was given to independent review bodies, and individual informed consent, emphasising individual autonomy, were proposed as the best measures for protecting participants (Emanuel & Grady, 2006; Beauchamp, 2008).

The Belmont Report represented a statement of a framework of general moral principles to guide the ethical conduct of research and the analysis of ethical problems (Beauchamp, 2008; U.S. National Commission, 1979). The ethical principles outlined in the Belmont Report (1979) are embodied in various forms in the provisions outlined in all of the subsequently developed guidelines, regulating research involving human participants, and delineate researcher obligations to participants (Macklin, 2004).

The framework outlined in the Belmont Report (1979) incorporates three basic ethical principles determined to underpin ethical research: *respect for persons*, *beneficence,* and *justice*, and links each of these respectively to specific, regulatory requirements: *informed consent, assessing the ratio of risks to benefits in order to ensure that it is favourable,* and *fairness in the selection of research participants* (Beauchamp, 2008; Emanuel & Grady, 2006).

## 1.3.2   Principles of research ethics

### 1.3.2.1          *Respect for persons*
The principle of respect for persons requires that "individuals [are] treated as autonomous agents" (Belmont Report, 1979, B-1). Individuals capable of understanding, reasoning and deliberating and making independent decisions, and who are capable of acting out these decisions intentionally, might be considered autonomous, and their autonomy must be respected (Beauchamp & Childress, 2001). An individual's right to have opinions, to make choices and to take actions that are consistent with his personal values and beliefs, must be upheld (Beauchamp & Childress, 2001; Belmont Report, 1979, B-1). Furthermore, confidentiality and privacy must be maintained (Beauchamp & Childress, 2001; Belmont Report, 1979, B-1)

The principle of respect for persons requirement that "subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" finds expression in the procedural requirement of obtaining informed consent (IC) from prospective research participants (Beauchamp, 2008; Beauchamp & Childress, 2001; Belmont Report, 1979, C-1). Meaningful IC should include the disclosure of all information pertinent to prospective participants' decision-making, tailored to the individual's level of competence to ensure that there is adequate understanding of the information on which to base an informed decision. Furthermore, in order to be valid, IC must be voluntary or under "conditions free of coercion and undue influence", and participants must be free to withdraw from a study should they so choose (Belmont Report, 1979, C-1 Beauchamp & Childress, 2001; Lindegger & Richter, 2000).

### 1.3.2.2          *Beneficence and nonmaleficence*
The principle of beneficence (Belmont Report, 1979, B-2), refers to an obligation to act for the benefit of others, and incorporates the principle of nonmaleficence, which is an obligation to avoid inflicting harm on others, and is sometimes considered to be a distinct ethical principle (Beauchamp & Childress,

2001). Beneficence requires positive action, not only in doing or promoting good and maximising benefits, but also preventing and removing or minimising risks; nonmaleficence requires adhering to the maxim 'do no harm' or refraining from negative action (Beauchamp & Childress, 2001; Belmont Report, 1979, B-2).

In common parlance, beneficence connotes general acts of kindness, charity, or altruism which are not strictly obligatory acts, however, in the context of research ethics, there is some disagreement about whether 'beneficence' constitutes a moral obligation or duty to act for the benefit of others' welfare, or whether it is supererogatory – morally praiseworthy but not strictly obligatory (Beauchamp & Childress, 2001; Belmont Report, 1979, B-2; Stobie & Slack, 2010). While the position adopted in the Belmont Report (1979) is that beneficence is obligatory, other approaches to research ethics seem to support the view that beneficence is supererogatory, arguing that beneficence is a virtuous ideal and that a failure to act beneficently does not constitute a moral violation (Beauchamp & Childress, 2001; cf. CIOMS, 2002; Stobie & Slack, 2010).

Broadly, general beneficence, which applies to all people simply by virtue of their common humanity, constitutes a duty if, by engaging in the potentially beneficent activity, it is possible to prevent some negative outcome, without sacrificing anything of comparable or greater moral significance (Singer, 1972 in Beauchamp & Childress, 2001; Siegel, 2008). If however, performing the beneficent act would place an individual at risk of sacrificing something, as significant or of even greater significance than would be gained through the act, then beneficence would be supererogatory (Beauchamp & Childress, 2001; Stobie & Slack, 2010). It is argued that all people have a general duty of beneficence to support others to address their true needs but not to the extent that they place their own needs at risk, and consequently come to need the beneficence of others (Beauchamp & Childress, 2001; Kant, 1996 in Siegel, 2008).

In certain circumstances, all people have specific obligations to act beneficently towards those in need (Beauchamp & Childress, 2001). While it is clear that there is an increased obligation to engage in beneficent action towards those with whom special moral relationships have been developed (through friendship, family or business relationships), everyone has a duty to rescue, or in some way help those in urgent need, when it is clear that no-one else will assist and when enacting the duty of rescue would not be excessively risky, or require significant sacrifice (Beauchamp & Childress, 2001; Siegel, 2008; Hawkins, 2006; 2008). In situations in which an individual's action is needed, and if undertaken is likely, to prevent a significant harm to another, is relatively simple or low cost to perform, and the benefits to the person being aided will greatly outweigh any costs to the provider, then there is an obligation to engage in such action (Beauchamp & Childress, 2001). The classic example used to illustrate these 'Good Samaritan' obligations is that of a passerby who notices a child drowning in a pool. All the

passerby has to do to save the child's life is pull him out of the water, and since no-one else is around and this is a relatively easy rescue, the passerby has a moral duty to save the child (Beauchamp & Childress, 2001; Hawkins, 2006). It is noted that, in some cases researchers may be the best placed, if not only, parties able to provide assistance for urgent needs, at little cost to themselves, and as such are obligated to act beneficently to meet these needs (Hawkins, 2006; 2008; Richardson & Belsky, 2004; Siegel, 2008). Furthermore, the obligations of beneficence that researchers have to participants may be intensified based on the depth of the relationship established between these parties (Beauchamp & Childress, 2001; Belsky & Richardson, 2004; Richardson & Belsky, 2004; Hawkins, 2006; 2008).

The principle of beneficence gives rise to the requirement to refrain from perpetrating intentional harm on individuals in the research setting (this is sometimes referred to as nonmaleficence), and the requirement that an independent body (such as an institutional review board or a research ethics committee) assess the risks and benefits of a study to ensure that the risks of harm in the research are reasonable in relation to the potential benefits (Beauchamp, 2008; Belmont Report, C-2). The Belmont Report (1979, C-2), stipulates, in accordance with the principle of beneficence, that participants should be fully informed of the systematically identified risks and potential benefits of the study, and, that research should not expose participants to risks in excess of those to which they might be exposed in the course of their daily lives nor should participants be allowed to consent to such excessive risks (Beauchamp, 2008). The range of possible harms (and benefits) was extended to include , in addition to physical harm, psychological, legal, social and economic harms (and corresponding benefits) (Belmont Report, 1979, C-2). Furthermore, while a certain degree of risk is an inevitable aspect of research, steps to minimise and offset this risk must be undertaken (Belmont Report, 1979, C-2). Although the position of beneficence expounded in the Belmont Report (1979, C-2) includes the notion of promoting benefits, the primary conception is of research as potentially harmful and the focus is on minimising risk and avoiding harm.

### 1.3.2.3 Justice

*Justice* requires that individuals receive what is owed to them, and that burdens are not imposed on individuals unduly (Beauchamp & Childress, 2001; Belmont Report, 1979, B-3). A formal conception of justice is that equals should be treated equally and unequals unequally (Beauchamp & Childress, 2001; Belmont Report, 1979, B-3). The principle of *justice*, as it is applied to research, is most frequently 'distributive', and is concerned with fairness in the distribution of both the burdens and benefits of research (Beauchamp & Childress, 2001; Belmont Report, 1979, B-3).

There are various approaches to determining distributive 'fairness'. Utilitarian approaches view fairness as that which maximises the greatest good overall (Beauchamp & Childress, 2001). Libertarian approaches do not focus on the substantive outcomes of the distribution of the burdens and benefits,

but see fairness as located in the procedures undertaken to determine the distribution (Beauchamp & Childress, 2001). From a communitarian perspective distributive fairness is not fixed but depends on the background conditions and  context in which the transaction takes place, and under different circumstances different distributional allocations might be considered fair (Beauchamp & Childress, 2001; Carse & Little, 2008). Egalitarian theories of justice propose that fairness requires some degree of equality in the distribution of burdens and benefits (Beauchamp & Childress, 2001).

The Belmont Report (1979, B-3) also outlined several formulations of justice, noting that each "mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit." In the context of research, 'equity' is noted to be a key notion in ensuring a fair distribution of burdens and benefits, requiring that no single group bear a disproportionate degree of benefits or burdens of research (Macklin, 2004).

The principle of justice finds pragmatic expression in the requirement that the procedures for selecting participants for research are fair so as to promote a just distribution of the ensuing burdens and benefits (Beauchamp, 2008; Belmont Report, 1979, C-3). Although the position on distributive justice articulated in the Belmont Report (1979, B-3) includes the fair distribution of the benefits of research, the principal concern is the unfair distribution of burdens and the dominant focus is on the prevention of any further exploitation of groups defined as 'vulnerable' (Beauchamp, 2008; Beauchamp & Childress, 2001; Mastroianni & Kahn, 2001).

The principle of justice demands that those individuals most capable of bearing the burdens of research should be selected prior to those already burdened by illness or environmental factors. Moreover, "research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research" (Beauchamp, 2008; Belmont Report 1979, B-3).

### 1.3.3   Other Regulatory protections

Since the *Belmont Report*, there has been a flurry of ethical guidelines, ethics discussion documents and policies guiding the conduct of research at both national and international levels including the Declaration of Helsinki [DoH] (most recently revised in 2008), which influenced the establishment of the system of independent review (see also Ashcroft, 2008; Williams, 2008), the CIOMS ethical guidelines for multinational research (1982, 1993,2002) (see Bhutta, 2002; CIOMS, 2002; Idänpään-Heikillä & Fluss, 2008), and the UNAIDS (2000, 2007) guidelines focussing on biomedical HIV prevention research (see Guenter, Esparza & Macklin, 2000;  WHO-UNAIDS, Expert Group, 2004a, 2004b; WHO-UNAIDS-AAVP Expert Group, 2007). The revised UNAIDS guidelines incorporate an increased emphasis

on community participation and collaborative partnership (cf. UNAIDS, 2006). South Africa specific guidelines include the South African Department of Health [SA DOH] (2004, 2006) guideline documents and the SA MRC guidelines (2001, 2003).

### 1.3.4 Independent ethical review

The requirement for the ethical review of all proposed research with human participants by an independent body, prior to its conduct, has become a core international standard for the ethical conduct of research (cf. CIOMS, 2002, Guideline 2; SA DOH, 2004, 2006; SA MRC, 2001, Guideline 9; UNAIDS-WHO, 2007, GP4). Research ethics committees (RECs) are argued to be critical to maintain ethical standards of practice in the course of research, to protect participants from harm and exploitation, to ensure that research is not conducted without adequate attention to informed consent, and, to overcome potential conflicts of interest between the rights of the participants and the value of research to society (CIOMS, 2002, Guideline 2; Emanuel et al., 2004; SA DOH, 2004, 2006; SA MRC, 2001, Guideline 9)

## *1.4    Participant Autonomy*

In spite of its emphasis on informed consent and respect for persons, protectionist approaches to ethical oversight, in the significant role assigned to independent review bodies in making decisions about research, were arguably paternalistic. Regulatory protectionism placed limitations on the autonomy of individuals from 'vulnerable' groups, and effectively excluded certain groups from research on the grounds of their vulnerability (Emanuel & Grady, 2006).

### 1.4.1 The AIDS movement

The emergence of the rapidly expanding health crisis of the HIV/AIDS epidemic in the early 1980s,a disease for which there was no cure, resulted in a sense of urgency regarding the development of effective treatment and demands for enhanced research efforts (Dresser, 2008; Emanuel & Grady, 2006; Killen, 2008; Mastroianni & Kahn, 2001).

HIV positive individuals, facing the prospect of severe illness and death, were willing to try even unproven, potentially risky, but equally, potentially beneficial, treatments (Emanuel & Grady, 2006; Killen, 2008). Research came to be viewed as a source of potential benefits to which individuals should be allowed access, as opposed to a threat from which protection was required (Emanuel & Grady, 2006; Mastroianni & Kahn, 2001). AIDS activist groups in the U.S. demanded, that just as the burdens of research should be fairly distributed so too should  the benefits, and that justice in research was not only about protection from research risks, but also the fair opportunity for inclusion in research (Emanuel & Grady, 2006; Mastroianni & Kahn, 2001; Killen, 2008).

There was already the view, with regard to life-threatening illnesses like cancer, that standard treatment modalities were largely ineffective and that research participation represented an opportunity to access more advanced, and potentially more effective therapies (Levine, 1994; Mastroianni & Kahn, 2001). However, the benefits of these therapies were largely limited to the individuals who participated in the studies, and, these were primarily white adult males (Mastroinni & Kahn, 2001). The regulatory protections in place effectively excluded certain 'vulnerable' groups, including women, racial minorities and economically disadvantaged people from research participation in order to protect them from harm and exploitation. However, these protections simultaneously prevented these groups from accessing needed benefits (Dresser, 2008; Emanuel & Grady, 2006; Mastroianni & Kahn, 2001). As opposed to a protective measure against research risks and potential exploitation, the exclusion of certain groups from research, was itself viewed as exploitative, harmful and unjust (Emanuel & Grady, 2006; Mastroianni & Kahn, 2001). AIDS treatment research often represented the only opportunity for infected individuals to stand a chance of receiving the only known therapy for preventing opportunistic infections and delaying death (Emanuel & Grady, 2006; Killen, 2008; Levine, 1994; Mastroianni & Kahn, 2001). Activists argued that clinical research represented a form of healthcare and worked to overcome the regulatory obstacles to the participation of women and ethnic minorities in research, in order that they might access the potential benefits of research (Emanuel & Grady, 2006; Killen, 2008; Mastroianni & Kahn, 2001).

The AIDS movement effectively forced a reconsideration of certain regulatory protections and resulted in a revised emphasis on, and expanded interpretation of the original philosophical principles underpinning modern research ethics, which were outlined in the Belmont Report (1979) (Beauchamp & Childress, 2001; Dresser, 2008; Emanuel & Grady, 2006; Killen, 2008; Mastroianni & Kahn, 2001). Activists advocated participant autonomy as primary, outweighing the paternalistic approach of protectionism (Dresser, 2008; Emanuel & Grady, 2006; Killen, 2008). Individuals were argued to have the right to autonomous control of their decisions about what risks and potential benefits were acceptable to them, and to be in the best position to make decisions about their own needs and interests (Dresser, 2008; Emanuel & Grady, 2006; Killen, 2008). Beneficence as a positive obligation was emphasised in a shift from simply acting to avoid the risks of research to actively promoting the potential benefits of research to society and individual participants (Dresser, 2008; Emanuel & Grady, 2006). Furthermore, beneficence to groups represented by research participants was emphasised, and resulted in increased mandates for including representatives of 'vulnerable' groups in research (Dresser, 2008; Grady, 1998). The AIDS movement's demands for expanded access to research fundamentally altered the conception of justice in research, from justice as protection to justice as access, and from justice as the fair distribution of burdens in research to the fair distribution of benefits (Emanuel & Grady, 2006; Mastroianni & Kahn, 2001; Weijer, 1996).

Although the re-evaluation of fundamental ethical principles, prompted by the AIDS movement in the U.S., is to some degree reflected in more recent ethical guidance for example in more consideration being given to the benefits of research and to their fair distribution, most national and international ethical and regulatory guidelines have maintained some degree of a protectionist stance towards the involvement of human participants in research (Moreno, 2001).

## 1.5    Limitations of demands for increased access to research

The limitations of extreme advocacy for participant autonomy and emphasis on the benefits of research, however, began to emerge as research progressed (Dresser, 2008; Emanuel & Grady, 2006). Emphasis on research as healthcare and access to potentially beneficial new interventions effectively resulted in a blurring of the lines between research and treatment, complicating the definition of the role of the health researcher and potentially exacerbating the therapeutic misperception (Appelbaum & Lidz, 2008; Emanuel & Grady, 2006; Killen, 2008; Levine, 1994). It was argued that, individuals may have false expectations of therapeutic benefit from research participation. Decisions to participate on the basis of these beliefs might compromise the validity of their consent, and thus limit their autonomy (Appelbaum & Lidz, 2008; Dresser, 2008). While increased access to research clearly expanded the range of individuals who could potentially benefit from participation, following several adverse events in some AIDS treatment trials, it became apparent that emphasis on the benefits alone fails to adequately acknowledge that research participation does involve certain risks and burdens (Dresser, 2008). Also, expanded access to research and its attendant benefits was noted to do little to enhance the just distribution of social resources if no measures are implemented to ensure the sustainability of access beyond the duration of the study (Dresser, 2008).

## 1.6    Globalisation of health research

Growing awareness of the social determinants of health, the recognition that health is a critical component of development, has led to the view that health research represents a key factor in addressing global inequities through helping to ensure access to evidence-based healthcare which makes judicious use of limited resources (Benatar, 1998; 2002; Benatar & Singer, 2010; Bhutta, 2002; Kahssay & Oakley, 1999; Volmink & Dare, 2005). Health research conducted in developing countries, where there is a general lack of access to healthcare, could represent an important source of healthcare, would provide evidence for interventions to address conditions specifically affecting these countries, would help to determine effective methods for implementing these interventions, and could contribute to building the capacity of local professionals, and so may be of significant benefit (Benatar & Singer, 2010; Bhutta, 2002; Shapiro & Benatar, 2005; Volmink & Dare, 2005; Whitworth et al., 2008).

Despite health research becoming increasingly globalised and a significant increase in the number of pharmaceutical industry sponsored clinical trials conducted in developing countries since 1995 (Flaherty, Nelson & Stephens, 2000; Glickman, et al., 2009; Macklin, 2004; Shah, 2006; Thiers, Sinskey

& Berndt, 2008) health in the developing world has not improved, and in many cases is deteriorating (Benatar & Singer, 2010).

A critical factor appears to be the lack of attention and resources devoted to research to address the problems of the developing world (Benatar & Singer, 2010; London, 2008). In what has become known as the '10/90' gap, it was noted that, although diseases of poverty account for over 93% of premature deaths globally, 90 % of global resources are spent on research on conditions primarily affecting the developed world, with only 10% allocated to the diseases accounting for the largest proportion of morbidity and mortality (Commission on Health Research for Development, 1990) The health research agenda remains skewed in favour of the wealthy populations of the developed world, who are able to achieve significant health gains because their needs have been the predominant focus of health research and so the fruits of this research are directly applicable to them (Benatar & Singer, 2010; London, 2008).

In light of increased awareness of global health inequities, the globalisation of health research has raised concerns about the potential exploitation of people from vulnerable, resource-constrained, groups (Emanuel & Grady, 2006; National Bioethics Advisory Commission [NBAC], 2001; Wertheimer, 2008b).

## 1.7    Concerns about research in developing countries

Research conducted by developed world researchers in developing countries has been characterised as 'mosquito research' or 'parachute/ safari research', where researchers collect data in developing countries but leave little behind, or as 'scientific colonialism', where the exploitative relationships between colonies and colonists, are replicated in research contexts with the use of developing country resources to meet developed world priorities (Edejer, 1999; Macklin, 2004; Costello & Zumla, 2000). Although arguably evolving to a more partnership-oriented model of research engagement, externally funded and managed research remains controversial (Edejer, 1999).

Intense public debate surrounding placebo-controlled trials (PCTs) conducted in the late 1990s in developing countries, of a less intensive, and less expensive, version of the developed world regimen (076) to prevent the vertical transmission (mother-to-child-transmission [MTCT]) of HIV/AIDS[5], fore-grounded ethical concerns about research in developing countries (Bhutta, 2002; Hawkins & Emanuel, 2008; Macklin, 2004; NBAC, 2001; NCOB, 2002). The studies were strongly criticised as unethical for their use of placebo-controls when an effective treatment regimen had been established and was the standard of care for pMTCT in developed countries (cf. Angell, 1997; Lurie & Wolfe, 1997). Others contended that, since the standard of care for pMTCT in the developing world was no treatment at all,

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[5] For more detail see Appendix C

the use of placebo-controls did not render the participants worse off than they would otherwise have been, and PCTs were the most efficient method of establishing a regimen that was more effective than no treatment at all, and which could be implemented in the context (cf. Abdool Karim, 1998; London, 2000, Resnick, 1998; Varmus & Satcher, 1997). However, it was argued that "residents of impoverished, postcolonial countries, the majority of whom are people of colour, must be protected from potential exploitation in research. Otherwise, the abominable state of health care in these countries can be used to justify studies that could never pass ethical muster in the sponsoring country" (Lurie & Wolfe, 1997). Concerns were raised that allowing the conduct of placebo-controlled trials in developing countries that would not be permitted in the developed world, would create a morally unacceptable 'double standard' in international research, which could see researchers increasingly seeking out impoverished populations in order to conduct research more efficiently and with fewer restrictions (cf. Angell, 1997; Carse & Little, 2008; Lurie & Wolfe, 1997; Macklin, 2004). Allowing a double standard of this sort, was argued to imply that participants in developing countries were not of equal value to their developed country counterparts (cf. Angell, 1997; Lurie & Wolfe, 1997).

In what became known as the 'standard of care debate' (cf. Abdool Karim, 1998; Annas & Grodin, 1998; Bayer, 1998; Crouch & Arras, 1998; Grady, 1998; Glantz, Annas, Grodin & Mariner, 1998; Lie, 1998; Resnick, 1998), the trials generated acrimonious, and ongoing, discussions, not only about placebo-controls and standards of care, but also about informed consent and fair benefits in international research, fundamentally underpinned by concerns about exploitation in resource-limited settings (Benatar & Singer, 2010; Hawkins & Emanuel, 2008).

### 1.7.1  Exploitation

"The central issue at stake when developed countries perform research on subjects in developing countries is exploitation" (Annas & Grodin, 1998, p.560).

The ethical controversy, which erupted, in response to the placebo-controlled trials of AZT for pMTCT in developing countries, sparked heightened concern about the potential for the exploitation of people in developing countries by researchers from developed countries (Emanuel & Grady, 2006; Wertheimer, 2008b).

Exploitation is argued to be the fundamental ethical concern underlying all clinical research, and has become a major concern about research conducted in resource-limited settings (cf. Carse & Little, 2008; Hawkins & Emanuel, 2008; Wertheimer, 2008a).

While the concept of exploitation provides a unifying rubric to draw together the seemingly disparate and often contradictory ethical issues that arise in research, exploitation is itself noted to be a complex and somewhat vague ethical concern (Grady, 2009; Hawkins & Emanuel, 2008; Macklin, 2003, 2004;

Wertheimer, 2008a). "Although there is virtually universal agreement that exploitation is wrong, there are sharp disagreements on what constitutes exploitation" (Macklin, 2003, p.473).

Exploitation in the context of research is generally framed as one party taking unfair advantage of another. This may be that the exploiter treats the exploited party 'instrumentally' or as the 'mere means' to advance his own interests, and/or, because the terms of the transaction between the parties are unfair and the exploiter receives a disproportionate benefit relative to the burdens borne by both parties (Carse & Little, 2008; Hawkins, 2008; Macklin, 2004; Siegel, 2008; Wertheimer, 2008a).

'Unfairness', in transactions between parties, which benefit the exploiter in some way, is central to defining exploitation in research, and there are various ways in which transactions may be unfair (Carse & Little, 2008; Hawkins, 2008; Siegel, 2008; Wertheimer, 2008a). Transactions may be unfair in terms of how they are conducted, or in terms of their outcomes.

### 1.7.1.1 Procedural unfairness

Transactions between parties may be procedurally unfair, in that something in the process of the interaction is unfair, for example, when there are problems in the informed consent process, or there is a lack of respect for participants (Hawkins, 2008; Siegel, 2008; Wertheimer, 2008a). A procedural account of exploitation essentially reflects a Kantian perspective on exploitation, which argues that exploitation occurs when there is a failure to respect the dignity of another in an interaction (Hawkins, 2008; Siegel, 2008; Wertheimer, 2008a). From this perspective, exploitation occurs when the party perpetrating the exploitation fails to acknowledge, or actively undermines the exploited party's autonomy, such that he consents to a transaction to which he could not, or should not, rationally consent (Carse & Little, 2008). Failing to address issues that compromise an individual's capacity to provide meaningful consent, or manipulating someone into agreeing to participate in research, through coercion or deciet, might be considered exploitative (Siegel, 2008).

### 1.7.1.2 Outcome unfairness

Exploitation is also understood as unfairness in the outcomes of a transaction, in terms of the distribution of goods between the parties involved (Hawkins, 2008; Wertheimer, 2008a). It is clear that one party benefiting from harming, or rendering another worse off, constitutes exploitation (Wertheimer, 2008a; 2008b). However, situations in which the outcomes are mutually advantageous, that is, both parties benefit relative to their situations prior to the transaction, can also be exploitative, when levels of benefits are unfair. Determining what is an unfair level or distribution of benefits is however, complex (Wertheimer, 2008a; 2008b).

## 1.7.2 Vulnerability

Claims of exploitation are often associated with concerns about vulnerability (Wertheimer, 2008a, 2008b). Exploitation is suggested to occur when "wealthy or powerful individuals or agencies take

advantage of the poverty, powerlessness, or dependency of others by using the latter to serve their own ends (those of the wealthy or powerful) without adequate compensating benefits for the less powerful or disadvantaged individuals or groups" (Macklin, 2003, p.475).

The vulnerability, and need for the enhanced protection of specific groups was of particular concern following the exposure of the numerous ethical abuses in the 1970s (Emanuel & Grady, 2006; Grady, 2009; Iltis, 2009; Lott, 2005). The Belmont Report (1979, B-3; C-3) argued that certain vulnerable groups had historically borne a significant proportion of research burdens for little benefit to themselves, and might "continually be sought as research subjects... because of their easy availability, their compromised position, or their manipulability".

All international ethical guidelines adopt a protectionist approach to the involvement of 'vulnerable groups' in research (Levine et al., 2004, Macklin, 2004). The Declaration of Helsinki (2008, para.9) notes that, "some research populations are particularly vulnerable and need special protection," and CIOMS (2002, Guideline 13) argues that, "special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied".

Ethical guidelines for research with human participants designate a broad range of groups as 'vulnerable', so broad in fact that it has been argued that "so many categories of people are considered vulnerable that virtually all potential human subjects are included" (Levine et al., 2004, p.46). The list of populations considered to be potentially vulnerable in research is extensive, including an assortment of diverse populations. Some of the groups identified as vulnerable include but are not limited to pregnant women, children, racial minorities, the economically disadvantaged, the very sick, the institutionalized, already burdened populations, those in subservient or inequitable power relationships, and captive[6] and convenient populations (cf. Belmont Report, 1979, B-3, C-3; CIOMS, 2002 Guideline 13, Commentary; Lott, 2005; Moreno, 1998). Macklin (2003) proposes, that not only

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[6] Captive and convenient populations, including prisoners, soldiers and to some extent, students, are considered vulnerable because of concerns that certain features of the 'captive' environment limit their ability to fully exercise autonomy (Bonham & Moreno, 2008; Lott, 2005; Mastroianni & Kahn, 2001; Moreno, 1998). Captive groups are separated from general society in some way, are noted to have limited choices and are frequently selected for research purposes because they are readily available (Bonham & Moreno, 2008; Moreno, 1998). Researchers might favour working with captive populations because they are better able to control factors which could impact on the research, able to more easily access and obtain information about the study population and are less likely to lose participants to follow-up in a clinical study because, the population members can be easily located (Bonham & Moreno, 2008; Moreno, 1998). However, there are concerns that individuals in captive settings may be particularly susceptible to coercion for fear of retribution should they decline to participate in research, or that they may be unduly influenced to agree to highly risky research for benefits most other reasonable individuals would not accept (Bonham & Moreno, 2008; Lott, 2005; Mastroianni & Kahn, 2001; Moreno, 1998)

individuals or groups of individuals, but countries or communities as a whole, could be considered vulnerable to exploitation.

Because they lack access to healthcare, social resources and tend to have lower levels of formal education and familiarity with research, socio-economically disadvantaged populations are considered vulnerable to exploitation (Denny & Grady, 2007; Grady, 2009). As such, communities and participants from developing or resource-limited contexts are frequently considered 'vulnerable' and in need of special protections from exploitation in research (Denny & Grady, 2007; Macklin, 2003; SA MRC 2003).

SA DOH guidelines (2004, 5.12; 2006, 2.3.11) note that, "South Africa is home to a number of vulnerable communities" which require additional attention by research ethics committees (RECs) to protect their welfare. These guidelines identify communities with "limited economic development; inadequate protection of human rights; discrimination on the basis of health status; limited ability of individuals in the community to provide informed consent; limited availability of healthcare and treatment options; and the inadequate understanding of scientific research", as vulnerable.

The involvement of 'vulnerable groups' in research has been an area of particular debate in research ethics (cf. Denny & Grady, 2007; Grady, 2009; Levine et al., 2004). The protectionist approach considers all individuals belonging to so-called vulnerable groups as inherently vulnerable and requires "extensive protection, even to the point of excluding them from activities which may harm them" (Belmont Report, 1979, B-1). This position has been criticised as failing to distinguish between individuals within groups, who might have personal characteristics which influence the need for specific protections in research or make such protections redundant (Grady, 2009; Levine et al., 2004). Furthermore, excluding individuals who might benefit from research might be unfair, and unjustifiably paternalistic (Denny & Grady, 2007; Grady, 2009).

### 1.7.4   Concerns about informed consent

Typically, individuals with limited resources, such as those from developing countries, are considered vulnerable to impaired decision-making, which limits their ability to provide meaningful consent for research participation (Benatar, 2002; Denny & Grady, 2007; Dickens & Cook, 2003; Grady, 2009; Hawkins & Emanuel, 2008; Levine, 2008). Of particular concern is that obtaining meaningful voluntary IC from individuals in developing countries may be especially challenging (cf. Annas & Grodin, 1998). In some cases, there are concerns that, owing to the challenges of obtaining IC in these contexts, investigators may be tempted to forgo the IC process altogether (Hawkins & Emanuel, 2008).

#### *1.7.4.1        Difficulties in understanding*

Concerns are raised that individuals from socio-economically disadvantaged contexts may enrol in research without a full appreciation of the risks (Denny & Grady, 2007). Arguably inadequate

understanding of key study information, which leads to decisions based on incomplete or misunderstood information, compromises participants' capacity to provide meaningful, voluntary informed consent. A more thorough understanding might lead participants to make different decisions (Denny & Grady, 2007; Grady, 2009).

Even participants from well-resourced settings , may struggle to fully understand of complex research-related concepts like 'placebo' and 'randomisation', and to completely appreciate what complicated medical procedures entail  (cf. Elbourne, Snowdon & Garcia, 1997; Featherstone & Donavan, 1998; 2002). However, socio-economically disadvantaged populations are likely to have lower levels of formal education and associated lower levels of health and research literacy (Denny & Grady, 2007; Grady, 2009). As such, these individuals may have difficulty understanding specific health or research-related concepts, may not fully comprehend what certain procedures entail, and thus may fail to fully comprehend the risks of research participation (Denny & Grady, 2007; Grady, 2009).

Given global inequities, disadvantaged populations in developing countries are even more likely to lack familiarity with research and to struggle to comprehend challenging scientific concepts (cf. Fitzgerald et al., 2002; Kass, Maman & Atkinson., 2005; Leach et al., 1999; Pace et al., 2005). Furthermore, difficulties in communicating complex scientific concepts to potential participants are compounded when participants and researchers speak different languages, as is common in international research, and there is a need to translate these concepts into local languages, which may not have the vocabulary to accommodate these terms (Kass & Hyder, 2001; Marshall, 2006; 2007; Molyneux, Peshu & Marsh, 2004). In many cases "there are no commonly used, universally understood terms for research," and this basic difficulty "poses a substantial communication barrier between researchers and laypersons for discussing biomedical research", particularly when it comes to the more complex concepts of placebo and randomisation (Molyneux, et al., 2004 p.2553).

### 1.7.4.1.1    *Therapeutic misconception*

The conceptual and terminological complexities of explaining or translating scientific research to participants, contribute to what is termed the 'therapeutic misconception' (Molyneux et al., 2004). The therapeutic misconception describes a situation in which participants do not fully comprehend the distinction between *research about*, and *treatment for* a particular condition – that is, research participants believe that the study to which they have consented is designed to benefit them directly, even when it is a placebo-controlled trial (Appelbaum et al, 1987; Henderson et al., 2007; Kimmelman, 2007). The therapeutic misconception not only creates barriers to the comprehension required for meaningful IC, but also increases the potential for mistrust and perceptions of injustice and betrayal when research participation does not produce the expected benefits (Lavery et al., 2010).

In some instances, the words used for research when translated into local dialects are identical to those used for medicine or treatment (Kass & Hyder, 2001; Marshall, 2006; 2007).This might fuel the therapeutic misconception and is likely to result in miscommunication, misunderstanding and unrealistic expectations about individual studies (Lavery et al., 2010; Molyneux et al., 2004).

While the therapeutic misconception may also be a concern in research conducted in relatively well-resourced settings, in resource-limited settings it is further complicated by a general lack of access to medical care (Marshall, 2007). The fact that the research organisation may be the only facility with adequate medical capacity and resources, may make it more difficult for community members to distinguish research from general healthcare provision (Molyneux, et al., 2004). It has been suggested that many participants in research from resource-limited settings, are motivated to participate in research because they believe that they will access treatment or care for the conditions from which they suffer (Kass et al., 2005). Moreover, despite attempts by researchers to emphasise information to the contrary, members of resource-limited communities may perceive a research unit to be an aid agency because of its access to funding and resources, which often exceed those of the existing public facilities (Molyneux et al., 2004). Benatar (2002) however, argues that seeking healthcare may be a rational motivation for research participation in resource-limited contexts.

### 1.7.4.2 Concerns about voluntariness

Concerns have also been raised about the ability of potential participants, particularly those in developing countries, to exercise voluntariness in decisions about research participation (Barsdorf & Wassenaar, 2005; Pace & Emanuel, 2005). 'Voluntariness' refers to the capacity of research participants to make fully autonomous voluntary decisions, free from coercion, undue influence or pressure from another (Barsdorf & Wassenaar, 2005; Beauchamp & Childress, 2001). Where participants do not fully comprehend, or do not believe that they are entitled to refuse study participation, the voluntariness of their consent may be undermined (cf. Abdool Karim, Abdool Karim, Coovadia & Susser, 1998; Lynoe, Hyder, Chowdry & Ekstrom, 2001). Voluntariness is argued to be compromised by factors including poverty, low socio-economic status, limited access to medical care and other resources, limited recognition of human rights and certain cultural decision-making patterns (Benatar, 2002; Kass et al., 2005).

Social position and power inequities between researchers and potential participants, which are particularly common in developing or resource-limited contexts, are also argued to have a significant impact on voluntariness (Marshall, 2006). It has been shown that "a posture of acquiescence or subordination is more likely to occur when the person seeking consent of someone to a research project has more education or higher social status than the research participant" (De Costa et al., 2004). Furthermore, this difference in socio-economic and educational standings between researchers and participants may lead to socially desirability, or participants behaving according to what they

believe to be socially normative in a given situation in order to create a favourable impression (Lindegger & Richter, 2000). Social desirability is a recognised threat to the validity of a study. While social desirability is not unique to resource-limited contexts, in such contexts participants may not only behave in such a way as to create a favourable impression, but may also fear negative consequences should they not go along with what they perceive to be the wishes of the researchers (Lindegger & Richter, 2000). Added to this, even in developed countries it has been shown that participants are reluctant to question medical authority, deferring to the apparent educational and hierarchical superiority of doctors and researchers (Appelbaum et al, 1987; Gikonyo et al., 2008; Kass, Sugarman, Faden & Schoch-Spana, 1996). Furthermore, the voluntariness of a potential participant's consent may be affected by normative cultural and gender roles, and the legacies of colonialist and other oppressive regimes may play a role in the capacity of participants to provide voluntary consent to research participation (Benatar, 2002; Marshall, 2006).

### 1.7.4.2.1    Undue Inducement

There is also a concern that the services, care and other goods, offered as part of research will act as an 'undue inducement', or impairment to rational decision-making, resulting in individuals, irrationally disregarding the risks and burdens of a study, simply to receive these benefits (Denny & Grady, 2007; Emanuel, 2004; 2005; Emanuel, Currie & Herman, 2005; Grady, 2009; Levine, C., 2008). It is argued that, while individuals may fully comprehend all relevant information pertaining to study participation, the goods offered as part of study participation may be so irresistible to those who generally lack resources, that they fail to pay adequate attention to the risks of participation or to give them appropriate weight in making decisions to participate (Denny & Grady, 2007; Emanuel, 2004; 2005; Emanuel, et al., 2005; Grady, 2009). Socio-economically disadvantaged individuals are argued to stand to gain more from study participation than more well-off participants, in light of their pre-study circumstances. This might lead them to consent to excessively risky research, that better-off individuals would reject (Emanuel, 2004; 2005; Emanuel, et al., 2005). Such concerns imply doubts that the study in question has received competent ethical review in order to ensure that risks are acceptably low (Emanuel, 2004; 2005; Emanuel, et al., 2005). Despite the concerns, there are no empirical data to suggest that socio-economically disadvantaged individuals are more likely to disregard risks for increased benefits, (Bentley & Thacker, 2004; Grady, 2009). However, a usual response to concerns about 'undue inducement', is to reduce the rewards offered in research involving individuals from resource-limited settings, ostensibly to reduce their decision-impairing likelihood (Grady, 2009).

### 1.7.4.2.2    Coercion

Furthermore, there are worries that "in the absence of health care, virtually any offer of medical assistance (even in the guise of research) will be accepted as 'better than nothing' and research will almost inevitably be confused with treatment, making informed consent difficult " (Annas & Grodin, 1998, p.562). Participants in developing countries are argued to perceive research participation as their

only option to access needed and otherwise unavailable, medical care, and "that offering the trial participants access to extensive services that are not otherwise available to them may be coercive in itself, especially among vulnerable populations" (De Zoysa, Ellias & Bentley, 1998, p.573). Coercion refers to a threat, which unfavourably reduces a person's options in order to force a certain course of action or to make a certain choice irresistible (Hawkins & Emanuel, 2005). In circumstances in which participants are perceived to have no other choice but to participate in research, concerns are raised that their decision to participate is coerced and that they are consequently exploited (Hawkins & Emanuel, 2005). It is however noted that 'coercion' is frequently used incorrectly and is often conflated with other ethical concerns including 'exploitation' and 'undue inducement' (Hawkins & Emanuel, 2005). While coercion involves a threat and a narrowing of options, 'undue inducement' is a concern about an inappropriate offer, which, however inappropriate, in fact serves to increase a person's options (Emanuel, 2004; 2005; Hawkins & Emanuel, 2005). In resource-limited contexts, lacking access to medical care or other resources, benefits from research participation serve to increase participants' potential options, and cannot be considered coercive (Hawkins & Emanuel, 2005). Furthermore, not all choices made in the context of limited options constitute coercion, and not all cases of coercion constitute exploitation (Carse & Little, 2008; Hawkins & Emanuel, 2005; Wertheimer, 2008b).

### 1.7.5 REC capacity

In 1996, in the absence of a competent mechanism of ethical review, Pfizer used the outbreak of a meningitis epidemic in Nigeria as an opportunity to conduct a risky, trial among severely ill children, of the efficacy of the yet untested drug Trovan in comparison to standard therapy (cf. Chima, 2006; Loewenberg, 2008; Shah, 2006; Stephens, 2000). The trial, which failed to inform parents about the experimental nature of the drug, left several children dead and others severely harmed by their meningitis infections (Shah, 2006; Stephens, 2000). Furthermore, the trial resulted in heightened suspicion of western medicine and research in Nigeria (cf. Jegede, 2007).

Ethical review of research by an independent body is an important aspect of ensuring that research abides by ethical guidelines and does not take unfair advantage of participants and host communities (Chima, 2006; Macklin, 2004). A frequently cited concern is that a competent system of ethical review may be lacking in many developing countries, and this could lead developed country researchers, seeking to avoid the stringent regulations and bureaucratic process of ethical review, to target populations in these countries for research that would not be approved in the developed world (Hawkins & Emanuel, 2008; Macklin, 2004 NCOB, 2002, 2005).

In certain developing countries, the number of individuals with the capacity to provide competent ethical review of research protocols may be limited, and these individuals may simultaneously be involved in the research under review because of general limited capacity, and this could create a conflict of interest (London, 2002; Milford, Wassenaar & Slack, 2006; NCOB, 2002). RECs in developing

countries may also feel subtle but powerful pressure to approve research that has been approved in the sponsoring country (London, 2002).

## 1.7.6 Concerns about fair benefits in research in developing countries

Another major concern regarding research in developing countries is that, owing to cost and infrastructural challenges, the products and interventions tested in resource-poor communities, will primarily benefit wealthier populations in the developed world, who can afford them. Thus, the benefits are not likely to be available to those who have borne the burdens of the research (cf. Lurie & Wolfe, 1997; Angell, 1997; Annas & Grodin, 1998).

Recognition of the problem of the 10/90 gap stimulated calls for increased involvement of the developing world in health research, largely through collaborative research activities between developing and developed countries (London, 2008; Wolitz, Emanuel & Shah, 2009). However, even with increased research involvement, developing countries and host communities might still fail to benefit from the fruits of the research and may thus be exploited (cf. Annas & Grodin, 1998; Glantz et al., 1998).

Defining what would constitute fair benefits for research participation has generated a fair amount of debate (cf. IJsselmuiden et al., 2010; London, 2005; London & Zollman, 2010; Participants, 2004) , and disagreement persists about what should be provided to participants and host communities, during and after research (Grady et al., 2008).

Initial approaches to ensuring that host communities receive fair benefits in exchange for research participation and thus avoiding exploitation were embodied in the 'responsiveness' and 'reasonable availability requirements', articulated in CIOMS (2002) and the Declaration of Helsinki (2000, 2008). Since their original formulation, the reasonable availability and responsiveness requirement have been endorsed in various ethical guidance and discussion documents, as an essential requirement of ethical research in developing countries (cf. CIOMS, 2002, Guideline 10; DoH, 2008; NBAC, 2001; UNAIDS-WHO, GP 19).It has been argued that "medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research" (DoH, 2008, B-17).

### 1.7.6.1 The responsiveness requirement

The responsiveness requirement argues that in order for research to benefit host communities, it must address their needs and priorities (CIOMS, 2002, Guideline 10). While insisting that research must be responsive to a country's particular needs and priorities, helps to ensure an increased likelihood of benefit for host countries and communities, because it does not specify how much each party receives,

'responsiveness' is not sufficient to overcome exploitation as unfairness in the distribution of benefits (Wolitz, Emanuel & Shah, 2009). Nevertheless, conducting unresponsive research may constitute treating people disrespectfully, as 'mere means', because it does not generate social value locally and thus *"threatens to use the world's poor and vulnerable as… [the] laboratory"* of the developed world (Carse & Little, 2008, p.219).

### *1.7.6.2    The Reasonable Availability Requirement*

In addition, to responsiveness, the 'reasonable availability requirement' represents an influential attempt at ensuring fair benefits to research participants and host communities (Emanuel, 2008). It is argued that: "the ethical requirement of 'responsiveness' can be fulfilled only if successful interventions or other kinds of health benefit are made available to the population" (CIOMS, 2002, Guideline 10, Commentary). Furthermore, "if the knowledge gained from the research in [a developing host] country is used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical"(CIOMS, 2002, Guideline 10 Commentary), and, "if the results of a clinical trial are not made reasonably available in a timely manner to study participants and other inhabitants of a host country, the researchers might be justly accused of exploiting poor, under-educated subjects for the benefit of more affluent populations of the sponsoring countries" (Crouch & Arras, 1998, p.29). Being responsive to the needs and priorities of a host community is therefore argued to entail "making any product developed ... reasonably available to them, and as far as possible leav[ing] the population in a better position to obtain effective healthcare and protect its own health" (CIOMS, 2002, General Ethical Principles).

### *1.7.6.3    Criticisms of responsiveness & reasonable availability*

The 'responsiveness' and 'reasonable availability' requirements in international research, represent important evolutions in research ethics in that they suggest that researchers and sponsors have responsibilities not only to individual research participants, but to populations too (cf. CIOMS, 2002, Guideline 10, Commentary).

However, ensuring that research is responsive to the health needs and priorities of a community is complex (cf. London, 2008). Not all health needs are considered priorities and "communities can... differ in their health priorities, even when significant members of their populations have common health needs" (London, 2008, p.738). Furthermore, questions have been raised regarding how such needs and priorities are established. Research agendas are noted to be significantly skewed in favour of the developed world and consequently may not reflect the needs of developing countries, but rather the externally established priorities of funders (cf. Benatar & Singer, 2010; Benatar & Vaughn, 2008; Edejer, 1999; Ali, Hill, Kennedy, & IJsselmuiden, 2006; Macklin, 2004; NCOB, 2002).

Recent commentary on the 'responsiveness requirement' has highlighted different interpretations of what it means for research to fulfil this requirement (cf. London & Kimmelman, 2008; Sewankambo &

IJsselmuiden, 2008; Wolitz et al., 2009). Research might be considered responsive to the health needs of a community, only if it is part of a broader sustainable intervention that will expand the capacity of health-related infrastructure within a community, and might not be responsive if it primarily provides communities with supplementary benefits and not sustainable benefits that can be used to address health needs (London & Kimmelman, 2008). Although early phase clinical trials and research which seems to lack local applicability is typically considered unresponsive, it has also been suggested that such research, in building local scientific and health delivery capacity may actually be responsive to local health needs (Sewankambo & IJsselmuiden, 2008).

Also, since both parties to an exploitative transaction may benefit in some way, a critical issue in addressing exploitation is not just that a benefit is guaranteed, but that the level and distribution of the benefits are fair (Wertheimer, 2008a). Requiring effective interventions to be made reasonably available does not address the issue of fairness in the distribution or the level of benefit received, but simply ensures that a specific type of benefit is provided (Participants, 2004). The reasonable availability requirement also represents a narrow conception of benefit, suggesting that the only way in which participants and communities might benefit from research is through receiving the intervention under study (Participants, 2004). Host communities and research participants might very well view other benefits of research participation as more important (Participants, 2004).

Furthermore, 'reasonable availability' is only applicable to successful Phase III intervention studies, which suggests either that other types of clinical and health-related research do not produce benefits for populations in developing countries and so should not be conducted there, or that other benefits must be possible (Participants, 2004). In addition, even in Phase III studies, reasonable availability guarantees participants and communities an uncertain benefit because trials may fail to produce a successful intervention and on this narrow conception of benefit would mean that there is a lack of benefit in many studies (Participants, 2004).

Because reasonable availability specifies how participants and host communities should benefit from research participation, the requirement is somewhat paternalistic, suggesting that participants and host communities cannot decide for themselves how they would like to benefit (Participants, 2004).

### 1.7.6.4 The Fair Benefits Framework

The *'Fair Benefits Framework'* represents an alternative approach to ensuring fair benefits in research (Participants, 2002, 2004). The *Fair Benefits* approach advances the view that avoiding exploitation entails ensuring that those who bear the risks and burdens of research participation are also the recipients of the benefits (Participants, 2002, 2004). The framework is proposed as a supplement to the usual considerations for ethical research, including a favourable risk-benefit ratio, fair selection, social value, informed consent and independent review, and is operationalised through a process of

collaborative partnership (Emanuel et al., 2000; Emanuel et al., 2004; Participants, 2002, 2004). Furthermore, fairness is established via negotiated agreement between researchers and communities. According to the framework if both parties agree that a particular approach to benefits is fair, the interaction is not considered exploitative (Participants, 2004).

The *Fair Benefits Framework* extends the range of possible benefits for research participation beyond the post-study availability of successful interventions (Participants, 2004). Possible benefits might include benefits to the participants and host population during and subsequent to the research, including access to health services essential to the conduct of the research, access to ancillary health services beyond those necessary for the successful conduct of the research, additional public health measures provided to the host population, employment for local people and stimulation of the local economy, capacity development, financial rewards and access to successful interventions (Participants, 2004; Emanuel, 2008; Schulz-Baldes, Vayena & Biller-Adorno, 2007). The *Framework* does not require that all of these benefits be provided, but rather that the level of benefit provided is fair in relation to the burdens and in comparison with those benefits that accrue to other stakeholders, including researchers, sponsors and other communities (Emanuel, 2008; Gbadegesin & Wendler, 2006; Participants, 2004).

Although the benefits of research may not accrue solely to the research participants, since they bear the large proportion of the burden of research, the *Fair Benefits Framework* defines them as the group most at risk of exploitation and therefore as the relevant group to receive the benefits and to determine their fairness (Participants, 2002, 2004). *Fair Benefits* requires consideration of how much even indirect benefits (like capacity building for local people) benefit research participants. The *Framework* acknowledges that the community may also bear some of the burden of research, as local resources may be utilised, and it should benefit accordingly. *Fair Benefits* explicitly argues that those stakeholders who are impacted by the study through burden or risk should be included in discussions to determine what constitutes fair benefits (Gbadegesin & Wendler, 2006; Participants, 2004).

Since there is no internationally agreed upon normative standard of fairness, *Fair Benefits* takes as its baseline the benefits that would accrue to each party in an idealised market interaction that is free of deception, coercion and fraud, and in which a fair level of benefits is determined via comparisons with the benefits received by other people interacting in similar circumstances (Participants, 2004). However, it is acknowledged that reasonable people will disagree on what constitutes fairness and are likely to assign different values to the potential benefits of research participation (Participants, 2004). As such, the population, being targeted for enrolment, should assess whether or not proposed benefits are fair from their perspective (Participants, 2004). "Only the host population can determine the value of the benefits for itself. Outsiders are likely to be poorly informed about the health, social, and

economic context in which the research is being conducted, and they are unlikely to fully appreciate the importance of the proposed benefits to the population" (Participants, 2004, p.23). In order to establish a gauge against which communities might assess the fairness of the benefits to which they agree in return for their participation in research, the *Framework* recommends transparency – that host communities should be made aware of other negotiated research-related benefit arrangements (Participants, 2004). The creation of a publicly accessible database of these agreements is suggested as a means of establishing a sort of 'case law' of fairness (Participants, 2004).

The *Fair Benefits* approach has been criticised primarily for its lack of attention to contextual factors creating the circumstances for the health problems that are the subject of research, and for the assumption that fairness can be achieved through negotiation. It is argued that this neglects power inequities, which might make it difficult for communities to negotiate fairness with researchers (London, 2005). There are concerns that, in light of global inequities, communities might lose out in the bargaining process (London, 2005).

### 1.7.6.5        *The Human Development Approach*

The *Human Development Approach* to ensuring fairness in international collaborative research represents an operationalisation of the oft-cited rationale for conducting research in developing countries, of addressing global health inequities (London, 2005). This approach is rooted in criticisms of minimalist approaches to ensuring fair benefits, which treat the research interaction as separate from the socio-economic and political context in which it takes place, and represent little more than piecemeal efforts at addressing global injustice (London, 2005; Terrell White, 2007).

The *Human Development Approach* (London, 2005) views health not simply as a biomedical issue, but as a function of social capital or the existence of efficient structures in the community through which people can access mechanisms to meet their health needs, protect their basic human rights and be empowered to have control over their lives and circumstances (cf. Campbell, 2000; Campbell & Jovchelovitch, 2000; Wakefield & Poland, 2005). As opposed to a simply process of finding an answer to a question, research is seen as one aspect within the matrix of inter-relationships that can help to improve the social structures within the community (London, 2005). The Human Development Approach, in its focus on benefitting communities by targeting the gap between their health needs and the capacity of existing social structures within the community to address these, represents a shift towards an increasingly endorsed systemic approach to research (cf. IJsselmuiden, Kass, Sewankambo & Lavery, 2010; IJsselmuiden & Matlin, 2006). In order to be beneficial, research should "both directly and indirectly expand the capacity of the host community's basic social structures, either to meet the distinctive health priorities of that community's members or to meet their basic health needs under distinctive social or environmental circumstances"( London, 2005, p.33).

To the extent to which the existing resources and social structures within the community are unable to sustainably translate the results of the research into benefits for the broader community, or to meet the ancillary health needs of the population, the *Human Development Approach* obligates researchers to secure the funding to provide ancillary care or to implement results of the research in community (London, 2005). In situations in which the resources or capacity in host communities to meet these needs is lacking, researchers are obliged either to assist in capacity development, by engaging community structures in partnerships with other organisations that can augment local capacity, or to conduct the research in communities, which already have the structures in place to provide these essential services (London, 2005). Essentially, according to this approach, researchers have a duty to create partnerships with institutions that can provide aid to the host community, and their obligations of partnership development and capacity-building are strongest in communities with the greatest needs (London, 2005).

### 1.7.6.6        Other benefit obligations

Both the *Fair Benefits Framework* and the *Human Development Approach* include the provision of health care beyond that which is required by the protocol, as a potential benefit of health-related research (Participants, 2004; London, 2005). Collateral benefits or ancillary benefits refer to services provided to participants that are beyond those which are essential for ensuring the scientific validity of the study, ensuring the safety of the participants or addressing any injuries to participants resulting from study involvement (Richardson & Belsky, 2004; Belsky & Richardson, 2004). While some perspectives suggest that researchers are under no obligation to provide ancillary benefits (cf. CIOMS, 2002), others advocate that, on the grounds of reciprocity for research participation (cf. Macklin, 2008), addressing global injustice (cf. Shapiro & Benatar, 2005) and fulfilling general beneficence or 'Good Samaritan' obligations (Hawkins, 2006, 2008), ancillary benefits are an important aspect of fair benefits.  Questions are raised, however, about specifically what should be included as within the researchers' scope of responsibility (Belsky & Richardson, 2004; Participants, 2008; Richardson, 2007; Richardson & Belsky, 2004).

How the researcher's role is defined has implications for assessment s of the fairness of what research participants should receive (Hawkins, 2006, 2008). Where a researcher 's role is defined according to the 'medical model' researchers may be expected to address all the health-related conditions of research participants as a personal physician would, even if this compromises the research (Hawkins, 2006, 2008; Richardson & Belsky, 2004). An alternate view is that, the principal purpose of clinical research is the generation of generalisable knowledge, not the provision of healthcare, and thus, researchers should not be required to provide care and treatment beyond that which is required by the protocol (Richardson & Belsky, 2004). Recent commentary on researcher obligations seems to adopt the view that, while research is primarily geared at producing knowledge and is not designed to

promote the health of participants, morally, researchers must engage with participants as people rather than "mere carriers of chemicals or conditions" (Richardson and Belsky, 2004, p.29).

In consenting to research, participants are argued to entrust certain aspects of their health to researchers (Belsky & Richardson, 2004). Thus, researchers do have obligations to provide ancillary care for some conditions affecting participants' health, which might emerge during research. The strength and extent of their responsibility to address these conditions however, varies according to the depth of the researcher-participant relationship, the vulnerability of participants, the number of risks or burdens undertaken by participants that are not otherwise compensated, and how dependent participants are on researchers for care (Belsky & Richardson, 2004; Richardson & Belsky, 2004). In certain circumstances, researchers may be in a unique position to meet the needs of participants, and on the grounds of general beneficence and their relationship with participants, they have a duty to do so (Belsky & Richardson, 2004; Hawkins, 2006, 2008; Richardson & Belsky, 2004).

### 1.7.6.7        *Concerns about the provision of benefits*

In addition to concerns that the benefits of research participation might serve as undue inducements, a frequently raised concern is that even with a full understanding of the risks, socio-economically disadvantaged participants are more likely to accept an unfair risk-benefit ratio and so to be exploited (Bateganya, 2007; Denny & Grady, 2007; Emanuel, 2004, 2005; Grady, 2009). Disadvantaged individuals are argued to have few options for accessing the goods which might be offered as part of research, and unfair benefit in exchange for risk is perceived as better than no benefit (Bateganya, 2007; Denny & Grady, 2007; Emanuel, 2004; 2005; Emanuel et al., 2005; Grady 2009). Concerns have been raised that where the fairness of benefits is determined via community acceptance, researchers may seek out impoverished populations in order to reduce study costs, while maximising research targets, because participants are likely to accept less (Benatar, 2002; London, 2005; Siegel, 2008). In response to concerns about 'undue inducement', researchers might reduce benefits to reduce their decision-impairing potential. However, this could also contribute to increased selection of disadvantaged populations for research, because this would allow researchers to provide participants with less (Grady, 2009).

However, concerns have also been raised that where researchers have enhanced obligations to participants from resource-poor settings, researchers may seek out better-resourced populations, depriving disadvantaged populations of the potential benefits of research (Emanuel, 2008).

Some have argued that research participants should not be provided with more than they would ordinarily receive outside of research because, this would create a double standard, and injustice within the host community (cf. Macklin, 2004). Furthermore, enhanced services may not be sustainable beyond the life of a single study, and this could lead to communities experiencing a sense of

abandonment at the conclusion of a study (cf. Altman, 1995; NBAC, 2001). Obligations to address the various needs of participants and host communities have also been argued to place an excessive burden of researchers, to divert limited resources away from important research efforts and to potentially confound study results (Belsky & Richardson, 2004; Shapiro & Benatar).

Responses to these concerns increasingly endorse community participation and the establishment of collaborative partnerships between researchers and other stakeholders, like service providers and health authorities (Altman, 1995; Shapiro & Benatar, 2005; UNAIDS-AVAC, 2007). These partnerships facilitate resource and expertise sharing, and provide a platform for local capacity-building (Altman, 1995; Shapiro & Benatar, 2005; UNAIDS-WHO, 2007). This is argued to be a mechanism for making progressive improvements to the general standard for care, for delivery of better services to the community as a whole, and for facilitating community ownership of interventions and thereby ensuring sustainability (Altman, 1995; Shapiro & Benatar, 2005).

## 1.8    The Imperative for Community Participation and Collaborative Partnerships in research

Trends and debates in international research saw growing consideration of the ethics of research, not just at the level of individuals, but also at the level of the communities (Emanuel & Grady, 2006; Hawkins & Emanuel, 2008). Alongside worries about exploitation in research with members of resource-limited communities in developing countries, research targeting socially identifiable groups, like Ashkenazi Jews and Aboriginal communities, to examine genetic precursors to disease, raised concerns about the potential impact of research on non-participating members of these communities (Sharp & Foster, 2000, 2007; Weijer, 1999; Weijer & Emanuel, 2000). Ethical protections based on principilism were criticised as leaving communities vulnerable to exploitation, because of their individualist focus (Emanuel & Grady, 2006; Weijer, 1999; Weijer & Emanuel, 2000). Worries about harms to community members, regardless of their actual participation in research, generated calls for increased protection for communities (Sharp & Foster, 2000; 2002; 2007; Wallwork, 2008; Weijer & Emanuel, 2000). Furthermore, increased concern about the ethics of research in developing countries has seen increased focus on the nature of the relationship between researchers and communities (Benatar, 2002).

The notion of community participation in research has gained increasing attention as a mechanism for enhancing ethical protections (cf. Dickert & Sugarman, 2005; Gbadegesin &Wendler, 2006; Weijer, 1999; Weijer & Emanuel, 2000). There has been a shift in the ethics of research to considering not just the individual research participants, but the communities from which they are drawn, as entities worthy of ethical attention (Dickert & Sugarman, 2005; Emanuel & Grady, 2006; Lavery et al., 2010; Weijer, 1999).

### 1.8.1 The notion of community

The notion of 'community' is variously defined, and the term is frequently used without definition (Heitman & McKieran, 2003; Howarth, 2001; Jewkes & Murcott, 1996; Tindana et al., 2008).

Standard definitions of 'community', particularly in the fields of public health and research, have focussed almost exclusively on geographical location (Heitman & McKieran, 2003; MacQueen et al., 2001; Tindana et al., 2008). However, there is increasing agreement that the definition of 'community' is multifaceted and is far broader than 'locality', incorporating relational qualities of social ties and, shared interests, values and activities (Heller, 1989; Hunter & Riger, 1986; MacQueen et al., 2001; Tindana et al, 2008). Communities may house many other communities and individuals may simultaneously be members of many communities (Heller, 1989; Hunter & Riger, 1986).

### 1.8.2 The principle of respect for communities

Communities are conceptualised as consisting of social structures and moral frameworks from which, through socialisation, individuals acquire their values and beliefs (Vygotsky, 1978; Weijer, 1999; Wertsch, 1991). Communities' moral frameworks and social institutions shape individual preferences and influence their decisions (Vygotsky, 1978; Weijer, 1999; Wertsch, 1991). As such, the notion of completely autonomous choices made by completely autonomous individuals is flawed (Wallwork, 2008; Weijer, 1999), and it is only in the context of the social institutions and structures, which have shaped an individual's values and preferences that his behaviour can be fully understood (Gilbert, 1989; Shweder, 1991; Weijer, 1999). Communities are an important source of an individual's values and self-concept and house various social structures which are essential to the well-being of the members of that community (Buchanan, et al.,2008; Gilbert, 1989; Weijer, 1999; Weijer & LeBlanc, 2006). Thus, respecting individual research participants and their decisions, demands respect for the communities that influence individuals and their choices (Weijer, 1999). Researchers are obligated to respect the beliefs, values, traditions and decision-making processes of the community, and to protect its structural and cultural integrity (Weijer, 1999). The *principle of respect for communities* has been proposed as a supplement to the *Belmont* principles (Weijer, 1999).

The *principle of respect for communities* "confers on the researcher an obligation to respect the values and interests of the community in research, and wherever possible, to protect the community from harm" (Weijer, 1999, p. 506). Furthermore, the researcher is obliged to abide by decisions taken by a communal authority (Weijer & LeBlanc, 2006). It is argued that an individual's interests are separable from the community's interests, and the two may differ from one another (Weijer, 1999). For example, in studies in which individuals face minimal risk but the potential for group harm is significant (Buchanan, et al., 2008; Weijer, 1999). The *principle of respect for communities* argues that populations

have a collective right to have a say in research that may have an impact on their collective identity (Buchanan, et al. 2008; Weijer, 1999).

Just as the *principle of respect for persons* affords moral status to individuals, the principle of respect for communities gives moral status to communities as ethical entities, requiring that the interests and needs of the community be seriously considered (Buchanan, et al., 2008; Weijer, 1999). Moreover, analogous to the *principle of respect for individual autonomy*, which acknowledges an individual's right to determine his own interests, according to the *principle of respect for community autonomy*, the community is the best judge of its own interests (Buchanan, et al., 2008). The community itself should determine whether research participation is congruent with its identity and values, and should decide on what would constitute a fair benefit arrangement in exchange participation (Buchanan, et al., 2008; Weijer & LeBlanc, 2006). It is argued that community input into determining research priorities is vital in order to ensure the just allocation of resources (Buchanan et al., 2008).

### 1.8.3   Community participation in research

Community participation in research represents a mechanism for enacting the *principle of respect for communities* (Brugge & Kole, 2003; Buchanan et al., 2008; Schell & Tarbell, 1998; Sharp & Foster, 2000).

Community participation is usually understood as a "process of working collaboratively with relevant partners, who share common goals and interests building authentic partnerships, including mutual respect and active, inclusive participation; power sharing and equity; mutual benefit or finding the 'win-win' possibility" in the collaborative initiative" (Tindana et al., 2007, p.002).

The notion of community participation in research has its roots in diverse disciplines spanning the social sciences, but has become an increasingly popular and respected approach to research in the health sciences (Chung & Lounsbury, 2006; Dickert & Sugarman, 2005; Green & Mercer, 2001; Minkler, 2004, 2005; Trickett & Espino, 2004; Wallerstein & Duran, 2006).  While the specific methods of implementing community participation vary, common to all approaches is an ethic of co-learning, an orientation towards the usefulness of knowledge produced through research, and the goal of achieving shared control of the research process between researchers and communities (Chung & Lounsbury, 2006; Israel et al., 1998; Viswanthan et al., 2004).

### 1.8.4   The rationale for community participation
Community participation in research is argued to have numerous pragmatic and ethical benefits

#### *1.8.4.1        Responsiveness*
In identifying the health needs and priorities of host communities and incorporating community-generated recommendations, community involvement in the planning and conduct of the research,

helps to enhance the local relevance and responsiveness of the research, and to ensure the judicious use of limited resources (Beauvais, 2006; Cornwall & Jewkes, 1995; Dickert & Sugarman, 2005; Edwards, 1989; Emanuel et al., 2004; Israel et al., 1998; Minkler, 2005; Wallwork, 2008).

### *1.8.4.2 Risk Benefit ratio*

Community involvement in research is argued to represent a critical means of minimising risks, increasing protection, and enhancing benefits to participants and communities, in order to ensure a favourable ratio of risks to benefits (Dickert & Sugarman, 2005; Emanuel et al., 2004). The social, cultural, economic and historical context of a community, as well as the social structures in the community, inevitably impact on the assessment of research-related risks and benefits to participants and communities, and are a key consideration in making risk-benefit ratio assessments (Emanuel et al., 2004; Emanuel et al., 2008; Trimble & Fisher, 2006).

### *1.8.4.3 Protection*

As outsiders to a community, researchers may lack the capacity to fully anticipate potential harms to participants and communities, particularly when they are working with groups whose culture is different from their own (Crocker, 1991 in Eichbaum, 2008; Dickert & Sugarman, 2005). Community participation is argued to be central in the identification of contextually defined research-related risks, which might not be apparent to outsiders, and to assist in tailoring appropriate protective measures to address the identified risks (Buchanan, et al., 2008; Dickert & Sugarman, 2005; Emanuel & Grady, 2006; Sharp & Foster, 2002, 2007; Trimble & Fisher, 2006; Wallwork, 2008). Community participation might also help to identify subgroups within a community who may particularly be placed at risk by research involvement, and so would require extra protection. Also, community participation is suggested as a means of identifying and offsetting the risks of research to non-participant members of the community (Dickert & Sugarman, 2005; Wallwork, 2008).

### *1.8.4.4 Fair Benefits*

Community-researcher partnerships are argued to both protect vulnerable communities in research and to ensure that these communities benefit fairly from their involvement in research (Dickert & Sugarman, 2005; Participants, 2004; Wallwork, 2008).  As with identifying and mitigating the risks of research, because outsiders may lack insight into the contextual realities of life in a community and so may under-appreciate the value of certain benefits to a community, community participation represents an important mechanism for operationalising the notion of fair benefits in research (Participants, 2004; Weijer & Leblanc, 2006). Furthermore, as articulated in the fair benefits framework, community participation helps to ensure that the benefits of research are congruent with the preferences and priorities of the host community (Dickert & Sugarman, 2005; Participants, 2004; Weijer & Leblanc, 2006).

Beyond the tangible benefits associated with community participation, like access to resources and increasing employment opportunities, some of the most important benefits, of community participation in research, are argued to reside in the process of participation itself (Zakus & Lysak, 1996).Community participation in research might encourage the development of 'social capital[7]' within a community, which could have benefits beyond an individual research project and is argued to facilitate health improvements (Campbell & Jovchelovitch, 2000; Campbell & MacPhail, 2002; Wakefield & Poland, 2005).

### 1.8.4.5    *Enhances validity*

Collaborative approaches to research are also justified by the epistemological assumption that the relationship between the researcher and the researched has an impact on the validity of the data (Trickett & Espino, 2004). It is argued that traditional approaches to research, in which the researcher assumes control over the goals and conduct of the research, lead to relationships similar to those in hierarchical organisations between employees and senior management, which create certain unintended consequences which might impact on the validity of the data collected (Argyris, 1968 in Trickett & Espino, 2004). For example, people may refuse to participate or drop out of the study; they may respond or behave in ways in which they perceive the researcher to want; they may become covertly hostile and provide only the minimal information required; and there are concerns that they may participate simply for the money (Argyris, 1968 in Trickett & Espino, 2004). Thus, it is argued that enhancing the validity of the data collected requires a reduction in researcher control over the research process (Trickett & Espino, 2004).

Pragmatically, collaboration and active participation by local stakeholders in the research design and process can provide valuable information regarding which members of a community are credible sources of information about a particular issue, which is likely to have implications for the validity of the study (Trickett & Espino, 2004). Furthermore, in developing trust and fostering relationships between researchers and the community, as well as encouraging a sense of community ownership over the research, community-research partnerships help to enhance validity by fostering compliance and ensuring that results are interpreted correctly (Wallwork, 2008).  Community involvement in research is also argued to be a useful means of ensuring that measurement instruments are contextually valid – for example that questions are worded in ways which are likely to produce valid responses (Minkler, 2005)

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[7] Social capital is a complex concept whose definition is a subject of debate (cf. Campbell, 2000; Campbell, Williams & Gilgen, 2002; Schuller, Baron & Field, 2000). Broadly, social capital refers to the social resources of a community, including interpersonal community relationships and networks, which might be used in managing power dynamics and fostering health (Campbell & Jovchelovitch, 2000).

### 1.8.4.6 Demonstrates Respect for Communities

Community involvement seems to be a crucial aspect of enacting respect for participants in research (Brugge & Kole, 2003; Buchanan, et al., 2008; Schell & Tarbell, 1998; Sharp & Foster, 2000).

Researchers are obligated to demonstrate respect for the social, cultural and traditional beliefs, values and practices of participants and communities (Emanuel et al., 2000; Emanuel et al., 2004). A failure on the part of the researchers to learn about and understand a community's culture and traditional values, or to credit indigenous knowledge as a valid and valuable commodity, may be perceived as a lack of interest or respect, which could generate negative feelings towards the researchers and the research, which could in turn negatively impact on the research (Schell & Tarbell, 1998). Furthermore, a failure to consider the social and cultural context of a community could lead to a misinterpretation of the data and a misrepresentation of the community, which could be harmful to a community's integrity (Schell & Tarbell, 1998; Sullivan et al., 2001). Community involvement helps to facilitate a process of co-learning and mutual understanding between communities and researchers (Schell & Tarbell, 1998; Viswanthan et al., 2004). Community involvement in the research process recognises and takes into account the value of local knowledge[8], which, in addition to enhancing the validity of the research, demonstrates respect for participants and host communities (Schell & Tarbell, 1997).

### 1.8.4.7 Procedural Justice & legitimacy

There is increasing recognition of the critical importance of ensuring not only that the outcomes of community-research interactions are fair to stakeholders, but also, that stakeholders regard them as fair (Daniels, 2000, 2004; Innes & Booher, 1999). It is argued that even if the outcomes of a community-research interaction are objectively fair, if the process by which these outcomes are achieved is perceived to be unfair, this could lead to significant unhappiness among stakeholders and might result in claims of unethical conduct or exploitation (Daniels, 2000, 2004; Gutmann & Thompson, 1997; Innes & Booher, 1999; Participants, 2004).

In encouraging deliberation and the sharing of perspectives and concerns about the research process and outcomes among affected stakeholders, meaningful community participation helps to confer legitimacy on the research project and its conduct, because individual stakeholders perceive their voices to have been heard and respected and to have played a role in arriving at decisions affecting them (Dickert & Sugarman, 2005; Daniels, 2004; Gutmann & Thompson, 1997).

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[8] Local knowledge refers to "the integrative framework people in a particular setting use to make sense of their lives. It is a collection of ideas and assumptions that are used to guide, control and explain actions within a specific setting…" (Van Vlaenderen, n.d., p. 2). In accessing local knowledge, a researcher accesses not only information regarding the community's definitions of various issues, but also the social dynamics and power relations surrounding these issues (Van Vlaenderen, n.d.; 2001).

### 1.8.4.8 Informed consent

Active community involvement in discussions of study goals, procedures, risks and benefits, prior to the initiation of a study is noted to create a supportive environment where there is a general understanding of the research study, and thus to enhance individual participant comprehension in IC processes (Fitzgerald et al., 2002; Dickert & Sugarman, 2005; Woodsong & Abdool Karim,2005). Consultation with community members also helps to inform researchers of the most effective ways of communicating information to potential research participants and thus facilitates understanding in IC processes (Strauss, Sengupta, Quinn et al., 2001; MacQueen, Shapiro, Abdool Karim & Sugarman, 2004; Dickert & Sugarman, 2005). Community involvement in research helps to alert researchers to factors relevant to the context, which might influence individual participants' decisions to participate in research, or could threaten the voluntariness of their consent, in order that they might mitigate against these threats (Marshall, 2007).

## 1.8.5 Approaches to implementing community participation

Community participation is often conceptualised as a continuum of varying degrees of community involvement in, and control, over the research process and outcomes (Arnstein, 1969; Cornwall & Jewkes, 1995). In traditional research approaches, community members are relatively passive 'subjects' with little influence over either the process or outcomes of the research. More participatory approaches, however, emphasise empowerment and seek to establish equal partnerships between researchers and community members (Chung & Lounsbury, 2006; Cornwall & Jewkes, 1995; Marsh et al., 2008; Trickett & Espino, 2004). A key differentiating factor between different approaches to community engagement is the alignment of power in the research process (Cornwall & Jewkes, 1995; Marsh et al., 2008). Sharp and Foster (2000) describe a spectrum of increasing community involvement in the research process, ranging from community dialogue, involving information dissemination and informal discussion with community members, to community partnership, whereby community members are included throughout, from inception and design to results dissemination. Weijer and Emanuel (2000) outline various approaches to community involvement, which are determined based on specific community characteristics and are argued to be protective of communities. These include consultation on protocol development and informed consent, community consent to research participation, involvement throughout the research, access to data, and involvement in dissemination and publication of results (Weijer & Emanuel, 2000).

### 1.8.5.1 Community Advisory Boards

The most common method of implementing community participation in research is the use of Community Advisory Boards (CABs) (Marsh et al., 2008; Quinn, 2004; Shubis, et al., 2009; Strauss, Sengupta, Quinn, et al., 2001). CABs generally consists of interested community members and act as liaisons between researchers and the community, communicating community concerns to researchers, reviewing protocols, making inputs into research materials like consent forms, and assisting in the

dissemination of research information and findings (GCM, 2004; Marsh et al., 2008; Quinn, 2004; Strauss, Sengupta, Quinn et al., 2001). CABs are also noted to be critical in managing rumours about research and to ensuring realistic community expectations (GCM, 2004; Quinn, 2004).

The CAB model has its roots in the demands of AIDS activists the U.S., for community input into the research process (Killen, 2008; Morin et al., 2003, 2008; Strauss, Sengupta, Quinn et al., 2001). CABs have come to be a standard in most health-related research around the world (Morin et al., 2003, 2008; Shubis et al., 2009). Concerns have been raised however about relying on the existence of a CAB to constitute meaningful community engagement, particularly in international HIV prevention research (GCM, 2004; Shubis et al., 2009). Unlike the original CAB members in the U.S., CAB membership in developing countries is often drawn from disadvantaged communities, and so CAB members may be disempowered and may not have the requisite skills or education to fulfil their roles (GCM, 2004). Furthermore, ensuring that the CAB is an authentic representative of a community is a challenge (GCM, 2004; Killen, 2008; Marsh ,et al., 2008; Shubis et al., 2009; Strauss, Sengupta, Quinn et al., 2001).

### 1.8.5.2 *Participatory approaches to research*

As the value of community participation in research has gained growing endorsement in health-related research, and the ethical concerns of research in community contexts have been increasingly recognised, values and perspectives from the social sciences have started to be accepted in mainstream clinical research ethics (Quigley, 2008; Wallwork, 2008).

Community-based participatory research (CBPR) is an approach to research that seeks to maximise community participation in all aspects of the research process (Israel et al., 1998; Minkler, 2004, 2005; Trickett & Espino, 2004). Although CBPR is typically associated with qualitative research (cf. Reason, 1994; Reason & Bradbury, 2001), rather than endorsing any specific research method, CBPR represents a particular orientation to research, and could be used with any research design, including randomised controlled trials (RCTs) (Cornwall & Jewkes, 1995; Leung, Yen & Minkler, 2004; Minkler, 2004, 2005; Viswanthan et al., 2004).

Participatory research approaches are grounded in the ideals of democracy, social justice and empowerment, and emphasise the value of the research process as facilitating benefits beyond those produced in the form of research results (Kelly & van der Riet, 2001; Trickett & Espino, 2004). Participatory approaches advocate an equitable partnership between researchers and community members, grounded in collaboration, mutual respect, mutual benefit, mutual understanding, power-sharing and empowerment (Israel et al., 1998; Schell & Tarbell, 1998; Sullivan et al., 2001; Wallwork, 2008). Collaborative approaches to research involve an explicit awareness and exploration of underlying biases and power disparities and adopt a contextual perspective on research (Wallwork, 2008). True partnerships between researchers and communities are seen as involving active

collaboration between the parties, based on the recognition that in order to meet their respective needs they need one another, and so must find a way of compromising and accommodating their perspectives in relation to the other's (Wallwork, 2008). As such, participants and communities are viewed as partners in the research, who should rightfully be involved in from the outset (Wallwork, 2008).

> To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials (UNAIDS-WHO, 2007, GP 2).

UNAIDS-WHO (2007, GP 2, Commentary) argues that the community should "be effectively represented in decision-making early in the design of the study protocol," and that "the nature of community involvement should be one of continuous mutual education and respect, partnership, and consensus-building regarding all aspects of the testing of potential biomedical HIV prevention products."

### 1.8.6   The PrEP trial closures in Cambodia & Cameroon

Community participation was explicitly endorsed in UNAIDS (2000, GP 5) and NCOB (2002, 2005). However, it was the premature closures, in 2004, of two pre-exposure prophylaxis (PrEP) trials of Tenofovir (an ARV) to prevent HIV infection amongst high-risk populations, which were planned to be conducted in Cambodia and Cameroon, that really highlighted the significance of meaningful community engagement in successful research implementation, particularly in HIV prevention clinical trial research (Forbes & Mudliar, 2009; McGrory, Irvin & Heise, 2009; Newman, 2006; Tindana et al., 2007).

Before they had even started, the trials were fraught with negative international media coverage, heated debates about the ethics of the design and implementation of the trials, and accusations of exploitation (Forbes & Mudliar, 2009; McGrory et al., 2009; Mills, Rachlis, Wu, Wong, Wilson, & Singh, 2005). In both trials, community advocates and AIDS activists raised ethical concerns about the selection of 'vulnerable' and marginalized groups from resource-constrained settings for research into a product whose safety had not been established among healthy individuals (Forbes & Mudliar, 2009; McGrory et al., 2009). Concerns were that the researchers had chosen to conduct the trials in Cameroon and Cambodia for reasons of convenience, that they could conduct the trials more inexpensively in these contexts, that the host countries and communities were unlikely to benefit from the research and were thus being treated as 'guinea pigs' (Forbes & Mudliar, 2009; McGrory et al., 2009). Concerns were also raised about inadequate risk-reduction counselling for trial volunteers, the absence of antiretroviral treatment for those who became HIV infected during the trial, and the

introduction of a drug, used for treatment, for the purposes of prevention, in a setting where most HIV-infected individuals had no access to it for treatment (Forbes & Mudliar, 2009; McGrory et al., 2009; Mills et al., 2005).

Inadequate communication and transparency by researchers was interpreted as disrespectful and to indicate deceit, and a lack of basic research literacy among community members is argued to have contributed to misunderstanding and miscommunication between stakeholders (Forbes & Mudliar, 2009; McGrory et al., 2009).

The activities of the media during the controversy surrounding these trials demonstrated its role as a key stakeholder in research (Mills et al., 2005). In addition to drawing public attention to the controversies relating to the trials, the media's involvement amplified misunderstandings, and spread misinformation, exacerbating the controversy and outrage (McGrory et al., 2009).

There were also perceptions of limited and tokenistic community consultation, and objections to what were seen as inadequate informed consent processes (Forbes & Mudliar, 2009; McGrory et al., 2009; Mills et al., 2005). In both Cambodia and Cameroon, there were also significant resource disparities between researchers and trial populations, and there was a legacy of distrust in clinical research as a result of colonial history and prior abuses (Forbes & Mudliar, 2009; McGrory et al., 2009).

The closure of the tenofovir trials demonstrated that even where other ethical issues have ostensibly been addressed, challenges regarding community engagement can still undermine research. In addition, the trial closures provided a platform for considering what would constitute meaningful community involvement in research (Forbes & Mudliar, 2009; McGrory et al, 2009; Tindana et al., 2007). The heated debates and various miscommunications and misunderstandings around the closure of the tenofovir trials highlighted the imperative for researchers to communicate more effectively with local communities, and, the media, and to have plans in place for responding to controversies honestly and to ensure consistent messaging (McGrory et al, 2009).

Following these trial closures, it was argued that "it seems curious that we invest millions of dollars in product development, clinical training, design and building of facilities, etc, but often leave vital processes of community engagement largely to trial and error" and "that it might be prudent to devote as much effort to addressing the complex community challenges of successful trial implementation as we dedicate to the formidable biomedical challenges of developing new forms of HIV chemoprophylaxis" (Newman, 2006, p.302).

Subsequent to the closure of these trials, there has been an increased emphasis of the centrality community participation, particularly in health-related and clinical research (UNAIDS-AVAC, 2007). The notion of community participation as an ethical norm in HIV prevention research is explicitly endorsed in the UNAIDS-WHO (2007) *Ethical considerations in biomedical HIV prevention trials*. The events surrounding the closures of the tenofovir trials also provided the impetus for the development of the UNAIDS-AVAC (2007) *Good Participatory Practice* (GPP) guidelines, which focus on operationalising the notion of meaningful stakeholder engagement and community participation in HIV prevention research (Forbes & Mudliar, 2009; McGrory et al. 2009; UNAIDS-AVAC, 2007).

### 1.8.7   Good Participatory Practice

Consideration of partnerships in HIV prevention research resulted in the development of the UNAIDS-AVAC (2007) *Good Participatory Practice* (GPP) guidelines, which focus on operationalising the notion of meaningful stakeholder engagement and community participation in HIV prevention research (Forbes & Mudliar, 2009; McGrory et al. 2009; UNAIDS-AVAC, 2007). The GPP guidelines (UNAIDS-AVAC, 2007) outline core principles and key activities underpinning the establishment and maintenance of meaningful partnerships between researchers and communities, many of which are drawn directly from participatory research approaches. In addition to ensuring that research has ethical and scientific integrity in accordance with established standards, meaningful community engagement requires mutual respect among all research stakeholders and the upholding of respect for communities (UNAIDS-AVAC, 2007). Furthermore, it is essential that stakeholders are given the opportunity to articulate their expectations, and that the roles and responsibilities of those involved in research are negotiated and clearly established (UNAIDS-AVAC, 2007). There should also be shared responsibility among relevant stakeholders throughout the research process, as this helps to foster capacity development and to facilitate a sense of ownership of the project among community members (UNAIDS-AVAC, 2007). Meaningful community participation involves active engagement of affected stakeholders in meaningful roles, and open, transparent and ongoing communication between researchers and communities (UNAIDS-AVAC, 2007). Moreover, researchers should make all research-related materials including protocols, records of decisions taken and communication plans publicly available (UNAIDS-AVAC, 2007). As an important aspect of empowering communities to make more informed decisions, and to better engage in the research process, researchers have a responsibility to build research literacy among community members (UNAIDS-AVAC, 2007).

Research ethics is increasingly regarded as a living field, growing and evolving in response to scientific developments which produce unique ethical concerns, shifts in approaches to research and political and societal trends (Sieber, 2010). Since the second world war there has been a significant expansion in the field of research ethics which has seen the emergence of concerns about the vulnerability of participants and the need for independent ethical review, emphasis on the autonomy of individuals and concerns about the fair distribution of the benefits of research, and growing concerns about the

globalisation of clinical research, the involvement of communities in research, and concerns about research conducted in developing countries (Emanuel & Grady, 2006). There has also been increasing consideration of communities, in addition to individual participants, as entities worthy of moral consideration, and growing understanding of the meaning and value of collaboration and partnership in research (cf. UNAIDS-AVAC, 2007).

## *2.      Barriers in the researcher-community relationship*

In the community-researcher relationship, communities and researchers approach the research interaction from fundamentally different perspectives. Researchers generally share a scientific world-view and most research participants a lay, non-scientific world-view (cf. Benatar, 2004).

Contextual variables play a critical role in shaping the community-researcher relationship. Public mistrust of science and research, based on misunderstandings, rumours and previous negative experiences with researchers and health authorities, could result in a reluctance to participate in research, and might create barriers to the establishment of meaningful community-researcher partnerships (cf. Freimuth et al., 2001; Green & Mercer, 2001; Gamble, 1997; Schell & Tarbell, 1998; Thomas & Quinn, 1991).

An extensive literature, which is beyond the scope of review here, examines the willingness of communities and individuals to participate in research, particularly biomedical and HIV prevention research and identifies barriers to participation (cf. Buchbinder et al., 2004; Clark, 2008; Lesch, Kafaar, Kagee & Swartz, 2006; Mills et al., 2004; Newman et al.,2006; Newman et al., 2008). Some of the common barriers or reasons for reluctance to participate include safety concerns, mistrust of researchers, concern about social consequences of research participation, and pragmatic or logistical challenges to participation (cf. Lesch et al., 2006; Mills et al., 2004). Although not the subject of extensive discussion, 'research fatigue' or 'over-research' have also been cited as reasons to decline or withdraw from research and as potential barriers to future research (cf. Coy, 2006; Green & Mercer, 2001; Thomlinson et al., 2003).

### 2.1          **Rumours & community perceptions of research**

Community perceptions of research have been highlighted as a significant factor in willingness to participate (Lesch et al., 2006). In contexts, which lack familiarity with science and research, and in many cases have exploitative colonial and complex political histories, community members are likely to fill gaps in understanding about research by forming their own explanations based on what they see and hear and interpreting information within their socio-cultural context (Molyneux, Peshu & Marsh., 2005). Misunderstandings between researchers and communities, particularly where the two parties have significantly different socio-cultural, linguistic and educational backgrounds, are noted to have generated concerns and rumours about research and to have raised questions about the ethics of

research, potentially undermining trust in the research institution (Geissler & Pool, 2006; Marsh et al., 2008; Molyneux, et al., 2005).

Concerns about blood and organ stealing are common as are rumours that research is a mechanism for perpetrating genocide, aimed at spreading disease among certain population groups (IAVI, 2007; ICASO, 2006; Geissler & Pool, 2006; Mfutso-Bengo, 2008; Molyneux et al., 2004).

In many communities negative experiences with researchers and government authorities, in addition to socio-economic and political marginalisation in some, has left a legacy of suspicion and distrust (cf. Freimuth et al., 2001; Gamble, 1997; Hagen, 2005; Schell & Tarbell, 1998; Thomas & Quinn, 1991).

The previous experiences that communities have had with all healthcare providers, not just with researchers, has an impact on the way that they perceive health research – those previous experiences influence the relationships between the communities and researchers, and are a baseline which must be taken into account when engaging in research in community settings (Sullivan et al., 2001; UNAIDS-AVAC, 2007).

## 3. Contextual factors impacting on community-researcher relationships in South Africa

### 3.1 Research in apartheid South Africa

The South African context is characterised by a history of profound oppression and routine undermining of human rights (Baldwin-Ragaven, de Gruchy, & London, 1999). Policies, based on racist agendas, both from the colonial and apartheid past, have had a significant and enduring impact on health and healthcare in South Africa (Baldwin-Ragaven, et al., 1999; Coovadia, Jewkes, Barron, Sanders, McIntyre, 2009). The apartheid system permeated every sector of society and sought to maintain racial domination through the disempowerment and disenfranchisement of black people (Baldwin-Ragaven et al., 1999; Coovadia et al., 2009). Under the apartheid regime, healthcare facilities were segregated, and resources allocated according to racial hierarchies (Coovadia et al., 2009). Consequently, the facilities allocated to the majority of the population were impoverished in comparison to those servicing the white population (Coovadia, et al., 2009). Sixteen years after South Africa's transition to democracy in 1994, the legacy of apartheid persists, and the country continues to struggle with vast socio-economic and health inequities, which in many cases are correlated with race and ethnicity (Coovadia, et al., 2009).

During the Truth and Reconciliation Commission (TRC) hearings on the health sector's complicity in human rights abuses under apartheid, evidence emerged that, in addition to the provision of sub-standard or nonexistent healthcare services to non-white communities, disturbingly reminiscent of Nazism, research and science in South Africa had been used as a mechanism for advancing the racist

agenda of apartheid (Baldwin-Ragaven et al., 1999; Baldwin-Ragaven, London & de Gruchy, 2000; TRC, 1998). Health professionals and scientists were found to have been involved in the military's Chemical and Biology Weapons programme, headed by Dr Wouter Basson (Baldwin-Ragaven et al., 1999; TRC, 1998). The activities of this programme included the development of poisons to be used against anti-Apartheid activists, and the creation of compounds that would be lethal but would make death appear to have occurred naturally (Baldwin-Ragaven et al., 1999). The programme was also involved in contraceptive research programmes to control black fertility through an anti-fertility vaccine, which would be used clandestinely on black people (Baldwin-Ragaven et al., 1999; TRC, 1998). This programme was supported by international collaborators, including the United States (Baldwin-Ragaven et al., 1999).

Much of the government-sanctioned health research during this time was aimed at undermining the health of entire communities. Science and research were also used to justify apartheid and white minority rule, through manipulating research findings to produce scientific 'proof' of white superiority, and through suppressing the results of research, which was not in line with the status quo (Baldwin-Ragaven et al., 1999; TRC, 1998). Scientists hid behind the long-held understanding that science was objective and impartial, and did not engage in debate over how the results of their research were being used to maintain the system of apartheid (Baldwin-Ragaven et al., 1999; Baldwin-Ragaven et al., 2000).

## 3.2    Research in post-apartheid South Africa

In post-Apartheid South Africa, the context of health-related research and science has continued to be one of mistrust and confusion, characterised by debates about AIDS science and policy (Abdool Karim & Abdool Karim, 2010; Baldwin-Ragaven et al., 1999; Cullinan & Thom, 2009; Nattrass, 2008).

With arguably one of the highest HIV prevalences in the world, South Africa is seen as the epicentre of the AIDS epidemic. Central to addressing an epidemic like HIV/AIDS is a coordinated effort, including health-related research, which is supported by government (Abdool Karim & Abdool Karim, 2010). While hopes were initially raised by development of what seemed to be a progressive AIDS plan in 1993, subsequent scandals around AIDS awareness (with Sarafina II) and resistance to the introduction of antiretrovirals for pMTCT swiftly scuppered those hopes (Nattrass, 2008).

While, health-related research targeting vulnerable populations was a characteristic of the apartheid regime's approach to health, in post-apartheid South Africa, related to the government's anti-scientific stance on HIV/AIDS, unethical research continued (Baldwin-Ragaven, et al., 1999). One of the first scandals, involved attempts by the then minister of health, Dr Dlamini-Zuma and Depty President Mbeki to pressure the South African drug regulatory authority, the Medicines Control Council (MCC) to approve human trials of Virodene (Nattrass, 2008; Myburgh, 2009). Virodene, a proposed anti-HIV drug

had been blocked from human use in South Africa and elsewhere because of its dangerous side-effects (Baldwin-Ragaven et al., 1999). Despite political pressure, and the restructuring of the MCC by the Health Minister, the researchers and producers of Virodene failed to obtain approval for their protocol because it lacked scientific merit and the potential risks to participants outweighed the benefits (Myburgh, 2009). However, unapproved, the researchers went ahead with a trial of the drug in otherwise healthy HIV-positive patients (Baldwin-Ragaven et al., 1999; Myburgh, 2009).

Government opposition to scientific methods of HIV prevention and treatment became more entrenched when Mbeki became president in 1999 (Cullinan & Thom, 2009). Surrounding himself with AIDS denialists, Mbeki actively tried to interfere with the scientific bodies involved in regulating research into, and treatment of, HIV/AIDS (Nattrass, 2008; Cullinan, 2009; McGregor, 2009; Thom, 2009). Choosing to accept the views of 'AIDS dissidents', like Anthony Brink an attorney with no scientific training), that HIV was harmless or non-existent and that the symptoms of AIDS were caused by poor nutrition and ARVs themselves, Mbeki adopted an acrimonious and "distrusting stance towards the scientific establishment" (Nattrass, 2008, p.162).

> Despite having nothing to offer other than ideology in place of ARVs for people with weak immune systems, Brink and his allies managed to ingratiate themselves into South Africa's body politic by exploiting divisions etched by apartheid. They used South African's deep – and given the country's aparthied history, understandable – distrust of Western powers and medicine , as well as the new democratic government's immense sensitivity to criticism, to sow seeds of doubt about an epidemic that is largely sexually transmitted and incurable (Cullinan, 2009, p.110-111).

Dr Manto Tshabalala-Msimang, the National Minister of Health from 1999 to 2008, furthered this denialist agenda by her continued support of unproven methods of HIV treatment, her resistance to the introduction of Highly Active Anti-Retroviral Treatment (HAART), and her undermining of HAART once it had been forced through in law (Abdool Karim & Abdool Karim, 2010; Nattrass, 2008; Cullinan, 2009). She described ARVs as 'poisons' and advocated nutritional treatment of HIV/AIDS instead (Nattrass, 2008; Cullinan, 2009; Thom, 2009).

Dr Tshablala-Msimang and President Mbeki also lent their support to German-born entrepreneur, Matthias Rath, who, following various legal interdicts in Europe, for his claims that the vitamins his foundation produced and sold, could cure cancer, established himself in South Africa, peddling a 'cure' for AIDS (Cullinan, 2009; Nattrass, 2008; Thom, 2009). Rath's foundation also conducted an unofficial trial of his vitamins in Kayalitsha, outside Cape Town, without seeking approval from South Africa's regulatory structures, but with tacit support from the Health Minister (Nattrass, 2008). Despite claims to the contrary, this 'trial' proved harmful to HIV-positive individuals who were encouraged to stop taking ART in favour of Rath's micronutrients, exposing themselves to opportunistic infections and the

risk of developing resistant strains of HIV (Nattrass, 2008; Thom, 2009). It is noted that "even more devastating would be the less explicit consequences of Rath's actions and those of his collaborators, which would for years manifest in the confusion sown in the minds of vulnerable communities" (Thom, 2009,p.113).

## 3.3    HIV prevention research in South Africa

Home to an estimated 5.7 million, of the 33.4 million people living with HIV worldwide, South Africa bears the largest burden of the global AIDS epidemic (UNAIDS, 2009). As a country with a significantly high prevalence and incidence of HIV/AIDS, South Africa has hosted a fair number of HIV prevention studies, including studies of behavioural interventions and various clinical trials of HIV vaccines, microbicides, male circumcision and the pMTCT (Ramjee et al., 2010).

Most biomedical HIV prevention methods are tested in randomised-controlled trials[9] (RCTs) in which the candidate products are evaluated against a control group, inactive substance or placebo[10]. All HIV prevention trials enrol HIV-uninfected participants. Phase I trials are safety studies and enrol small numbers of participants at low risk of HIV infection. Phase II trials enrol larger numbers to assess whether or not the intervention produces clinically significant effects, like an immune response in a vaccine trial. Phase IIb trials and Phase III trials are tests of intervention efficacy in preventing HIV transmission. The only way to determine the efficacy of a preventative intervention is whether or not more people on placebo or in the control group acquire HIV infection compared to those given the intervention. As such, HIV prevention efficacy trials are conducted in populations with high HIV incidence rates, as this makes it more likely that even with access to standards of prevention people will be exposed to HIV and it will be easier to detect if the intervention has an effect (Bass & Kahn, 2005; NBAC, 2001). HIV infection risk is correlated with other sources of vulnerability, including poverty, social marginalisation, unemployment, and inadequate access to education and healthcare services (Bass & Kahn, 2005; South African National AIDS Council [SANAC], 2007).

The HIV/AIDS epidemic in South Africa reflects the history of social disruption, racial discrimination and inequitable resource distribution institutionalised under apartheid. Black South Africans are significantly more affected by the epidemic than other population groups, with a prevalence of 33% among young black women and 24 % among young black men (SANAC, 2007; Shisana et al., 2009).

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[9] These trials involve the random assignment of participants to groups either receiving or not receiving the intervention. Because assignment is random, participants have an equal chance of being selected for either group. Random assignment helps to overcome systematic factors that might lead to bias in the outcome of a study.

[10] RCTs involving the use of a placebo are usually double-blinded, meaning that in order to avoid bias neither the researchers nor the participants know whether or not they are receiving the active product or a placebo. While products such as vaccines or microbicides are typically evaluated against a placebo, in some cases this may not be possible, such as trials of male circumcision or behavioural methods for HIV prevention. In these cases, the control group is provided the standard of care received by all volunteers and is followed up.

Of the HIV prevention studies conducted in South Africa, some have determined efficacious methods of prevention and been hailed as successful, for example studies of male circumcision for HIV prevention (Auvert et al., 2005). However, others have not produced positive results, and some have closed prematurely owing to evidence of increased risk of HIV infection in the product arm, for example the Cellulose Sulfate microbicide trial (cf. Ramjee, et al., 2007) and the STEP/Phambili HIV preventive vaccine trial (cf. Cohen, 2007). When trials fail to demonstrate intervention efficacy or show a trend towards harm among participants, they can potentially generate controversy, are often accused of ethical violations and lead to myths, misconceptions and rumours about research (cf. Ramjee et al., 2007, 2010; Stadler, Delaney & Mntambo, 2008; van de Wijgert & Shattock, 2007). Even when trials produce positive results misperceptions can be perpetuated (cf. Mngxitama, 2010)

# C    METHODOLOGY

## 1    *Analysis of Ethical Guidelines*

Accepted international (CIOMS, 2002; Declaration of Helsinki, 2008; UNAIDS-WHO, 2007; UNAIDS-AVAC, 2007) and South African (SA MRC, 2001; 2003; SA DOH, 2004; SA DOH, 2006) ethical guidance documents were thoroughly searched for explicit reference to "over-research" and "over-researched communities". These guidelines were also coded according to the coding framework guiding overall analysis, and were used as a source of comparative data in the analysis of empirical data.

## 2    *Empirical component*

Given the lack of literature and discussion of the concept of 'ORCs', the empirical component of this study, which involved an iterative process of data collection and analysis, became the primary means of exploring the notion of the 'ORC'. Empirical research has been argued to be a critical component of research ethics, helping to debunk widely held but erroneous views about what people think or believe, assessing the relative significance of ethical concerns to stakeholders, and in facilitating research ethics decision-making, which reflects on the ground reality and is responsive to the concerns of stakeholders (Emanuel, 2002).

### 2.1    Qualitative approach

Since there seemed to be no coherent theoretical conception of the notion of the 'ORC', this study's primary goal was exploratory – to explore stakeholder perspectives on the notion of the 'ORC'. As such, a qualitative approach, broadly informed by the interpretive paradigm, was adopted. This allowed for flexibility and for stakeholders to express their conceptions of the notion of 'over-research' in the absence of pre-determined categories.

Face-to-face interviews comprised the primary form of data collection. Face-to-face interviews were chosen in order to facilitate rapport building with respondents. While the study was broadly informed by the interpretive paradigm, in many ways the interviews adopted a participatory approach. Respondents were considered active participants and were engaged in a process of critical reflection, whereby both interviewer and interviewee, through the process of exploring an unknown idea or concept, like 'over-research' come to a shared understanding of the idea, and parties are prompted to reflect critically on their own views – like their perceptions of the 'ORC' (Kelly & van der Riet, 2001). Critical enquiry is argued to promote a critical self-reflection, through which individuals become aware of the limitations of their views of reality and allows for the development of new ways of understanding (Kelly & van der Riet, 2001). Many respondents initially argued that they had no idea of what the notion could mean, but through a process of critical reflection were able to articulate possible meanings. Many also reflected, at the start of the interview, that they would not have thought of the notion in particular ways but through thinking about it more, had gained a new perspective.

Given this approach, the interview situation was viewed as socially-situated and it is important that the data emerging from the interviews be understood as such and be interpreted in relation to the context – both the interview situation itself, as well as the context of HIV prevention research more broadly. All interviews were conducted after the Cellulose Sulfate microbicide trial closure (c.f. Ramjee et al., 2007). The second round of data collection occurred at the time of the closure of the Phambili trial (Researchers 4-6; CABs 1& 2; CLO, 1; RECs 5-8) and the third round of data collection (Researcher, 7; CABs 3-7 & CLO 2) occurred in the context of the closure of a particular clinical trial and the closure of a trial site (ostensibly because of the accusation of 'over-research'). It is possible that these events would have coloured respondents' views regarding the notion of the 'ORC'.

## 2.2 Data Collection

### 2.2.1 Sample

In order to obtain a holistic perspective on the notion of the 'ORC', the sample was selected to include representatives of three major stakeholder groups involved in health-related research in community-settings, namely: researchers, community representatives (CABs)[11] and research ethics committee (RECs) members. For the purposes of clarity, the term 'respondent' is used here to indicate those who participated in interviews for this study, while the term participant is used with reference to individuals who participate in the health-related research which the respondents here discuss. Respondents were selected purposively and via snowball sampling where respondents suggested others who might be willing to participate in this study. Given the exploratory nature of this study, sample size was intentionally traded for richness of data.

The final sample of 24 respondents consisted of seven researchers involved in HIV prevention research (both in rural and urban areas) in South Africa; eight members of two biomedical research ethics committees in South Africa; seven members of community representative groups (CABs) at three HIV prevention trial sites; and two community liaison officers (CLOs) at two sites. These respondents were drawn from RECs and research organisations based in two regions of South Africa. Although the initial intention had not been to include CLOs in the study, these site-staff offered to participate in interviews on two occasions where interviews with CAB members had been organized but these potential respondents failed to arrive.

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[11] While the title Community Advisory Board (CAB) has been criticized as being inappropriate to the South African (and developing country) context, because of the connotations of the terms advisory and board, and many representative groups do not refer to themselves as CABs, for the purposes of standardization and anonymity (sites have their own titles for these bodies) the shorthand CAB is used here.

### 2.2.2 Procedure

Once ethical approval had been obtained, the preliminary interview schedule was piloted and amended.

Emails and letters containing information about the study and requesting permission to approach researchers and community representatives at sites, were sent to the principal investigators or directors of seven research organizations involved in HIV prevention research in South Africa (Appendix 1). Most (n=6) responded favourably, however two of the organisations, connected to Demographic Surveillance Systems (DSS) research, were reluctant to participate. As DSS sites have been linked to some of the hypothesized concerns about 'ORCs', these had been targeted as critical cases. The opportunity to approach community representatives from a community that has been labelled 'over-researched' did however become available later, and was valuable as a critical case.

Similar emails and letters were sent to the chairs of four South African research ethics committees involved in the review of large-scale clinical trials, to request permission to approach committee members (Appendix 2). Most (n=3) of these responded favourably.

While the initial intention was to target researchers and CABs at HIV prevention research sites and RECs country-wide, as well as to explore the notion of the 'ORC' with those from research organisations which had been connected with the term, the scope of this study was limited by funding constraints to two regions of the country (KwaZulu-Natal & the Western Cape), and to where permission was granted to approach organisation staff.

Information sheets and cover-letters were emailed to all potential researcher-respondents at those organisations which had agreed to participate, and to REC members inviting them to indicate via email, whether or not they would be willing to participate in a face-to-face interview exploring the concept of the 'ORC' (Appendix 3). Once individuals had indicated their willingness to participate, arrangements for a face-to-face interview were made. Informed consent documents were emailed to potential respondents for their perusal.

In all but one instance research organisations opted to arrange CAB interviews via internal structures through their CLOs who would inform the CAB about the study at a CAB meeting. In this instance contact was made with the CLO who agreed to inform the CAB members of the study at their next meeting and to request permission to release their contact details. Each CAB member was contacted telephonically, informed of the study and the researcher's affiliations and invited to participate in an interview. This is arguably a far better approach because the researcher was able to contact more CAB members and to re-iterate the purpose of the study as well as her independence from the research organisation.

Data were collected between August 2007 and October 2008 in three rounds of data collection.

All interviews were conducted at locations of the respondent's choosing.

At the start of each interview informed consent was re-iterated and permission for audio-recording of the interview was obtained. All respondents agreed to audio-recording (see Declaration Appendix 3).

All interviews, apart from the CAB interviews in KZN were conducted in English. Recruitment for these interviews was also conducted in isiZulu and all information sheets and IC forms were translated into isiZulu. At the commencement of these interviews, these respondents were given the option of speaking either in isiZulu or in English depending on their preference. Most spoke predominantly in isiZulu and codeswitched with English. One of the five KZN CAB interviewees chose to speak only in English.

All interviews were transcribed verbatim and transcripts were checked for accuracy.

Interviews were coded in hard copy and then electronically in NVivo 8 qualitative data management software. Coding was broadly informed by the Emanuel, Wendler, Killen and Grady (2004) framework for ethical research, which also constituted the theoretical framework for this study.

Interviews were analysed thematically using the constant comparative method (Silverman, 2005).

### 2.2.3 Instruments

An interview schedule, containing minor variations for each stakeholder group, was developed moving from questions relating to research generally, to those specifically targeting the notion of the 'ORC' (see Appendix 4).

Following ethical approval this schedule was piloted and amended accordingly. During the first round of data collection, several interviews were transcribed and preliminarily reviewed by a team. While it was decided not to amend the interview schedule, recommendations for improved interview technique and as to where prompts would be useful, were made.

Between the first two rounds of data collection, further transcription and reflection on the interviews led to the decision to remove questions which seemed to break the flow of the interview and did not appear to be producing useful information – it had been intended to explore the idea that perhaps

'ORC' could be defined by some sort of epidemiological calculus.[12] Accordingly, respondents were asked to quantify proportions of the populations to which they were connected which were involved in research and had been involved in research on more than one occasion. The responses to this question revealed it to be challenging to answer and that the answers in many cases seemed to be fairly arbitrary. Therefore this question was not asked in subsequent interviews.

Experience and reflection in the second round of data collection led to more targeted prompting in later interviews.

## 2.3    Coding and Analysis

Although interpretive and exploratory approaches often make use of primarily inductive coding and analysis methods, because this study sought to explore whether 'ORC' concerns reflected new or existing ethical issues, coding and analysis were necessarily approached using a flexible deductive approach. The Emanuel et al. (2004) framework for ethical research, as a comprehensive model of ethical behaviour, was used to guide coding and analysis, and formed the basic structure of the analytic framework ( Appendix 6). Each of the practical principles formed a broad theme under which codes or sub-themes identified in the data were organised. This framework was however, not rigidly applied, and where novel themes were identified in the data, which did not appear to fit into the framework, adaptations and additions to the framework were made.

Data were analysed thematically, using the constant comparative method. Participatory Research theory and other models of researcher-community interaction and other relationships in research, as well as models of exploitation and its avoidance (see section A) were used to make sense of the patterns and tensions identified in the data.

Thematic analysis is a flexible method for encoding qualitative data and for identifying, analysing and reporting themes or patterns within the data (Boyatizis, 1998; Braun & Clarke, 2006). Given that thematic analysis is the analytic approach underlying many more complex methods of qualitative analysis (like discourse analysis and grounded theory), and the fact that it is compatible with a range of theoretical and epistemological stances (Braun & Clarke, 2006), it is entirely appropriate for use in exploratory studies such as this (it does not preclude further analysis and may in fact form the basis for further exploration). Furthermore, thematic analysis is argued to be a useful means of ensuring that

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[12] What proportion/percentage of the population of your community would you say have, at some stage, been involved in research?
In each of the communities in which you've worked, could you estimate the proportion of the community population involved in your research?
Would you be able to estimate the proportion of the participants in your research who had been involved in research previously (if any)?
What proportion, if any, of the participants in your research were simultaneously involved in other research?

the findings of a qualitative study such as this are accessible to others working in different fields, and who are not necessarily versed in qualitative research (Boyatzis, 1998). Given the applied focus of this study, and that the intended audience comprises people working in clinical research as well as lay people, the use of thematic analysis is further justified.

Thematic analysis relies on the constant comparative approach to "develop ways of understanding human phenomena within the context in which they are experienced" (Thorne, 2000, p.69). The constant comparative method was originally developed by Glaser and Strauss (1967) for use in grounded theory, and involves constantly comparing sections of data with other pieces of data, both within and across interviews and groups and data sources (Silverman, 2005; Thorne, 2000). The constant comparative method also helps to enhance the quality and credibility of the data by ensuring comprehensive data treatment and comparison (Silverman, 2005).

### 2.3.1   Analytic Procedure

The initial phase of data analysis involved immersion in the data. Audio-recordings of each interview were replayed while the researcher simultaneously followed the transcript of the interview. This was a useful means of ensuring the accuracy of the verbatim transcripts, of enhancing the consistency of the data and of becoming familiar with the data.

Marginal remarks containing initial observations about, and descriptions of the data, were made on hard copies of the transcripts.  Initial ideas regarding the thematic code appropriate to the segment of text were also noted. These initial themes were then organised according the Emanuel et al. (2004) framework. Themes were defined as coherent ideas in the interviews which could be categorised according to know ethical concepts.

Once two researchers had read five of the interview transcripts and made initial observations, a more detailed coding framework, using the Emanuel et al. (2004) framework as a guide was developed. Each of the benchmarks specifying the broad principles was used as a sub-code. Where there were discrepancies in how themes were assigned, these were debated until consensus was reached. Debate and discussion of coding and analysis was ongoing throughout the process of analysis.

Each thematic area was assigned a colour, and, using a coloured pen, each section of text in the hard copies of the transcribed interviews was coded according to the theme it dealt with.

Annotations paraphrasing the text, linking the ideas raised to theory and other data, were made throughout.

Where themes or ideas were raised which did not seem to fit into the coding framework, these were added as separate themes to be incorporated into the framework later, if appropriate. Thus, coding allowed inductively generated codes to emerge from the data.

Once all interviews had been coded in hard-copy, and it was possible to have an overview of the themes in the data, the coding framework was amended accordingly.

Each interview was then coded electronically using NVivo qualitative data management software. Throughout, annotations, in addition to those already made, were made, and patterns emerging in the data were identified. A specific focus was on tensions and differences in how each respondent and stakeholder group made sense of the notion of the 'ORC'.

Once all interviews had been coded and annotated electronically, the coding framework was again amended, and coding was checked.

The focus of analysis was on stakeholders' understandings of the notion of the ORC. Respondents' general discussions about the ethics of research in community settings were used as a source of comparison and as a means of further examining perspectives of the 'ORC'.

The concerns raised by respondents directly in relation to the notion of the ORC were explored in relation to the eight principles of the Emanuel et al. (2004) framework. Respondents' perspectives on the notion of the 'ORC' were constantly compared, within interviews, with their discussions of the ethics of research in community settings. Where respondents discussed the idea of the 'ORC' as a concern about a specific principle, this was compared to their discussions of how these concerns should be addressed more generally. Where feasible, perspectives on the 'ORC' were also compared across interviews, within, and between stakeholder groups.

Each of the concerns and perspectives raised in relation to the notion of the 'ORC' was also compared to existing ethical guidance on that particular issue, where such guidance existed. Similarly, where possible, links and comparisons between respondents' perspectives on the concept of the 'ORC', and existing discussions in the literature, were made.

## 2.4    Quality measures

The standards of 'validity', and 'reliability', against which the quality of quantitative research is measured, cannot be dismissed with regard to qualitative research (although certain qualitative researchers might argue that they are inappropriate for qualitative research). However, given that the goals of qualitative research are different to those of quantitative research, the application of the qualitative criteria is different (Gergen & Gergen, 2000; Kvale, 1996; Mays & Pope, 2000; Reason &

Rowan, 1981; Silverman, 2005). As such, where possible, measures to ensure rigour, credibility, consistency and dependability, and transferability, were adopted.

### 2.4.1  Validity - Credibility

It is argued that all research, even apparently 'hard' quantitative approaches, ultimately involves subjectivity and that different methods are likely to produce different perspectives on the issue under study (Mays & Pope, 2000; Silverman, 2005). Some 'extreme' qualitative researchers would reject the concept of validity as a measure against which the quality of research is to be assessed, arguing that it assumes a belief in an unequivocal social reality or truth which is independent of the researcher, participant and context of the research process (Mays & Pope, 2000). However, the approach adopted in this study was 'subtle realism'. The existence of an external truth which could be accessed was not assumed, but rather that there was some form of reality which could be variously represented (Mays & Pope, 2000).

It is acknowledged that there is no infallible approach to ensuring the validity of a qualitative study. However, several strategies for enhancing the credibility of the findings have been suggested (cf. Gergen & Gergen, 2000; Kvale, 1996; Mays & Pope, 2000; Reason & Rowan, 1981; Silverman, 2005)

Silverman (2005) observes that a common critique of qualitative studies is the tendency towards anecdotalism, or the use of only a few examples from a large body of data to support a particular contention. Overcoming this pitfall involves attending to contradictions and deviant cases in the data and ensuring comprehensive data treatment (Mays & Pope, 2000; Silverman, 2005). As described above, the use of the constant comparative method, as in this study, helps to ensure comprehensive data treatment and to enhance the credibility of the findings.  It also ensures that, where there are contradictions and deviant cases in the data, these are explored (Silverman, 2005). Furthermore, explicitly linking data from different sources, including existing theory and literature was employed as a means of validating the data and of enhancing the credibility and comprehensiveness of the study.

Some commentators recommend respondent validation, whereby researchers return tentative results to respondents and then refine them in light of their reactions, as a mechanism for enhancing validity (Reason & Rowan, 1981). However, while reflection and checking of respondent accounts during an interview may be appropriate, respondents may not have the capacity to validate analysed qualitative data , since they may not be familiar with a researcher's theoretical orientation (Silverman, 2005). Furthermore, since interviews are understood to occur within a social context, and respondents are neither static nor isolated from socio-historical events, their responses to certain questions likely vary on different occasions (Silverman, 2005). Thus, in this study, respondent validation (beyond reflection during the interview) was not employed, and explicit effort was made to adopt a stance of reflexivity

(Kelly & van der Riet, 2001) and to be sensitive to the potential impact of the research and the research process, as well as broader contextual factors (like trial closures) on the data collected.

## 2.4.2  Reliability – Consistency and dependability

Efforts to enhance the reliability of the findings rest on ensuring consistency throughout the research process. While an interview schedule was used to guide the topics of discussion in the semi-structured interviews with respondents, the way in which questions were asked, the prompts used and reflections made, by the very nature of face-to-face interviews varied from one interview to another. In some cases interviews were shortened because respondents expressed strict time constraints. In other cases respondent fatigue necessitated leaving out certain questions in the interviews.

At the level of transcription, all interviews were transcribed verbatim, using transcription conventions (Appendix 5) to help ensure consistency. All transcripts were double-checked for accuracy. All transcripts were stored in hard copy and electronically and will be stored for five years should further analysis be required.

In terms of coding, the coding framework was developed following consensus on preliminary coding of five transcripts by two researchers independently.

Boyatzis (1998) suggests that consistent coding involves assigning the same code to the same piece of data on two separate occasions. Measures to enhance such consistency involved coding of hard copy transcripts preliminarily (in pencil), then coding them according the analytic framework in coloured pens, and then coding them electronically. At each stage of the coding process, codes assigned to sections of data were discussed and debated between at least two researchers.

Silverman (2005) argues that in order to ensure reliability of analysis, verbatim data, as opposed to researcher inferences and summaries of parts of data, should be presented in the final analysis. This is argued to enable readers to make their own judgements regarding the appropriateness of the analysis. For this reason, wherever possible, verbatim exerts of respondents' accounts from the 30 hours of recorded interviews, are included. While this contributes substantially to the length of the final analysis this was seen as necessary in order to ensure consistent interpretation and preserve the integrity of the data.

## 2.5   Ethical Considerations

### 2.5.1  Consultation & Collaboration:

 Prior to approaching the members of any REC or staff or CABs affiliated to a research organisation, the REC chair or Principal Investigator or CAB chair were contacted and permission for the study requested. Each organisation's processes and procedures for approaching staff and CABs were

respected and followed.

To the extent possible given time and resource limitations, and institutional constraints, respondents were engaged as colleagues in the research process, not 'subjects'. It was not assumed that the respondents would automatically know what the meaning and ethical dimensions of the 'ORC' were. Instead respondents were engaged in a process of shared critical reflection on the notion of the 'ORC'.

### 2.5.2   Social Value:
As outlined in the rationale for this study, its value lies in critically addressing a vague issue in order, perhaps to more appropriately understand and address the ethical issues involved in research with communities. Furthermore, critically exploring this notion and assessing its relevance in research ethics discourse, has potential implications for policy and research ethics guideline development.

### 2.5.3   Scientific Validity:
This study was reviewed for scientific validity. Aside from some limitations regarding representativity of the sample, the methods adopted are appropriate to exploratory research of this nature.

### 2.5.4   Informed Consent
Informed consent was obtained from all respondents both for participation in the study and for the voice recording of the interview. Respondents were informed of the purposes of the study and were provided with the opportunity not to participate or not to answer certain questions should they choose not to.

### 2.5.5   Ethical review
 Prior to any data collection this study was ethically reviewed and approved by the Human and Social Sciences Ethics Committee of the University of KwaZulu-Natal (Approval No: HSS/0283/07M). All respondents were informed of the ethical review process and were provided with the contact details of the REC should they have any queries or concerns about the study.

### 2.5.6   Potential risks and risk minimization:
It was expected that some respondents might experience anxiety about perceived shortcomings in knowledge and may be uncomfortable about presenting a perspective as a representative of a particular group. Furthermore, it was anticipated that respondents may feel anxious that their responses might lead to an organisation's or site's practices being judged as unethical, which could lead to negative consequences for them or their institution (like the removal of research benefits from a community). As such, the research was presented as a collaborative problem-solving endeavour around a shared concern. Respondents were reassured that the purpose of the research was not an evaluation of their or their institution's capabilities but rather an exploration of the notion of the 'ORC', and were encouraged to present their own viewpoints. Participants were informed of confidentiality measures in place (see below) to help minimise these risks, as well as of their right to withdraw or refuse to answer any of the questions asked.

### 2.5.7 Expected benefits and benefit-maximization:
Few, if any direct benefits were expected from this research, although, some of the respondents reported that the process of critical reflection on perspectives on the 'ORC' as well as on the ethical conduct of research in community-settings, was beneficial in terms of their own thinking. It is hoped that increased clarity on the notion of the 'ORC' will be of benefit to stakeholders involved in research and that from this research recommendations regarding the use of the term 'ORC' can be made to the NHREC.

### 2.5.8 Payment:
CAB members who had to travel to central locations to participate in interviews were re-imbursed for their expenses. No payment was made to respondents from other stakeholder groups because interviews were usually conducted at respondents' places of work and so they did not incur any expenses to participate. Although it is ethical to compensate participants for research for time and inconvenience (Koen et al., 2008), budgetary constraints made this difficult.

### 2.5.9 Confidentiality:
Each *interview* respondent was assigned a code that was recorded on his/her interview transcript. Records of participant and organisational identifiers were stored separately from the data. Furthermore, efforts were made to disguise information, which could be linked to certain individuals or organisations, in the data. However, owing to the limited sample size, it is conceivable that individual participants' responses may be "identifiable" in a summary report, such as through rich text quotes (cf. Tolich, 2009). This limit of confidentiality was outlined to participants and every effort was made to reduce this risk.

### 2.5.10 Results dissemination:
On finalisation of this study, efforts will be made to ensure that all respondents receive feedback. Furthermore, it is hoped that the results of this study will lead to a peer-reviewed publication of some sort, in order to contribute constructively to debates about research and the involvement of communities in research. Furthermore, it is hoped that a memo will be submitted to the NHREC and to various other REC to enhance their awareness of and critical thinking regarding decisions about research involving communities.

# D    FINDINGS

This section presents the respondent perspectives on the notion of the 'ORC'. The views expressed have been broadly clustered according to the ethical principles, outlined in Emanuel et al.'s (2004) framework for ethical research in developing countries.

## *Theoretical framework*

Incorporating basic moral values (including those expounded in the Belmont Report, 1979), Emanuel et al.'s framework synthesizes ethical guidance found in existing codes and guidelines into eight broad, universally applicable, ethical principles: (1) collaborative partnership; (2) social value; (3) scientific validity; (4) fair participant selection; (5) favourable risk-benefit ratio; (6) independent review; (7) informed consent; (8) ongoing respect for participants and communities.

While none of the traditional guidelines on the ethics of clinical research explicitly addresses all of the eight principles in Emanuel et al.'s framework, these principles are conceptually included in most existing normative guidance.  Each of the eight principles in this framework is justified by widely accepted ethical values (Emanuel et al., 2000; 2008) and is specified by benchmarks which provide elaboration on the principle and guidance for what is practically required to meet the principle (Emanuel et  al., 2004; Emanuel et al., 2008). According to this framework, in order for research to be considered ethical, each of the eight principles must be fulfilled (Emanuel et al., 2000; 2008).

The framework has been shown to be useful in organizing stakeholder perceptions of the ethics of HIV vaccine trials in developing countries (Essack et al., 2009); in assessing the ethics of vaccine research (Grady, 2004); with regard to the ethical issues in complementary and alternative medicine (Miller, Emanuel, Rosenstein & Strauss, 2004); and in discussing the ethics of research conducted in conflict settings (Ford, Mills, Zachariah & Upshur, 2009). It has also been applied to the ethical review process of Participatory Action Research (PAR) protocols (Khanlou & Peter, 2005) and to the ethics of environmental health research (Lavery, Upshur, Sharp , & Hoffman, 2003). The framework has been adapted for use in considering the ethics of community-based participatory research (Chen, Jones & Gelberg, 2006; Flicker et al., 2007) and has also been used in considering ethical issues in social science research (cf. Wassenaar, 2006). It has been incorporated into national ethical guidelines, including the Kenyan guidelines for the ethical conduct of biomedical research involving human subjects in Kenya (2004), and has been used to conceptually  organize Emanuel, Grady, Crouch, Lie, Miller and Wendler's (2008) textbook on Clinical Research Ethics, as well as Lavery, Grady, Wahl and Emanuel (2007).

Although Emanuel et al.'s (2004) framework includes benchmarks which provide elaboration on each principle and guidance for what is practically required to meet the principle, respondents did not necessarily raise issues relating to the 'ORC' in relation to each of the benchmarks, these are thus not

always included as sub-issues in the findings, because doing so would have required artificially forcing perspectives to fit inappropriately into these benchmarks.

Each section of the findings begins with an over-view of the ethical principle underpinning the category. This is followed by a presentation of respondent perspectives on the notion of the 'ORC'. Each section concludes with a summative overview of the main issues in the section. In some cases descriptive links to relevant literature are made.

Given that the principles in the framework are not mutually exclusive and are highly inter-related, it was sometimes difficult to assign respondent perspectives to one category only, as many of the issues raised in relation to the 'ORC', seemed to be appropriately represented by a number of principles simultaneously. While attempts were made to categorise perspectives according to which principle best represented the issue raised, there was sometimes overlap between categories. Wherever possible, where the issues seem interrelated, links and cross-references between principles have been made. Most respondents' discussions of the notion of the 'ORC', implicated several principles.

While Emanuel et al. (2004) list 'collaborative partnership' as the first principle in their framework perspectives, bearing on this principle, are presented as the last category here. Collaborative Partnership was the last principle to be added to the original framework for ethical research (cf. Emanuel et al, 2000). Furthermore, issues relating to the principle of 'collaborative partnership' emerged as underpinning many respondents' interpretations of the notion of the 'ORC', collaborative partnership issues linked together many of the other concerns represented by the 'ORC ', and provided a broader framework for interpreting the notion.

This chapter begins with some of the respondents' initial interpretations of the notion of 'over-research'. The sections, which follow and are organised according to the theoretical framework, represent respondent views of the notion, which emerged on probing. The chapter concludes with respondent assessments of the legitimacy of the notion of the 'ORC'.

### (i) Various perspectives on the 'ORC' – General interpretations of the notion

### "I don't know what it means"

One of the most striking features of the notion of the 'ORC' was the range of possible interpretations offered by respondents. Most respondents, particularly researcher and REC respondents, were reluctant to position themselves as fully understanding the term, many arguing that: *"I don't know what that means"*(Researcher 1), *"I've heard the term 'over-researched' community, but I don't know what it means"* (Researcher 3), *"I don't think I've got a very clear picture in my mind of exactly what it what it should mean"* (Researcher 4) and *"I haven't really thought about it, or read a lot about 'over-researched' communities… I haven't really thought about it"* (Researcher 6).

### "There are many different interpretations"

Furthermore, it was argued that the concept of the 'ORC' *"is this very amorphous diffuse thing"* (Researcher 1), *"It's a term that's just used far too loosely* (Researcher 2). *"I think people talk a lot about 'over-researched communities' but they don't know what they are talking about [laughter]…"* (Researcher 4). 'Over-research' was noted to be difficult to define because there are multiple possible interpretations of it, and different people are likely to interpret it differently: *"I tried to get opinions from people …who are saying using that terminology. I went to them to get them to explain to me what is 'over-researched' and for them 'over-researched' meant a whole lot of things"*(Researcher 1); *"there are a number of potential interpretations you could put on it. I didn't use the word. I didn't define it"* (Researcher 3); *"I don't think there is a single term which captures what it means"* (REC 1); and:

*As I said to you, you walk out the door, you know, somebody else is going to tell you something different… There are many different interpretations, it can have… depending what is convenient to the individual, who's being asked* (REC 7).

### "The first thing that comes to mind, of course, is exploitation"

Many respondents spontaneously suggested that 'over-research' might reflect concerns about 'exploitation' or research with vulnerable populations: *"The first thing that comes to mind of course is exploitation. The second thing that comes to mind is that one is targeting… a disadvantaged group"* (REC 7). Respondents argued that when the concept of the ORC was raised, this could reflect, *"that there's exploitation of a community. Maybe it's abuse of one community,"* (Researcher 2) or *"when they're using the term, the 'ORC', what's they're saying is that this community's exploited. That's what I think they're trying to say. I think people are trying to say it's exploited"* (Researcher 3). *"When people say that a community is 'over-researched', they think that… people are exploiting [the community members] because they don't have money and things like that"* (CLO 3). *"I think that what that person might have meant when he said site A is 'over-researched', is that the people of Site A are being*

*exploited"* (CAB 3). In many instances the concepts of 'over-research' and 'exploitation' were used interchangeably, suggesting a perceived relationship between the two ideas.

## *"It's sort of, a relatively hypothetical concept"*

The notion of the 'ORC' was noted to be *"a relatively hypothetical concept, rather than any definition of it. You know, people bandying the term around without, I think fully having thought about it, or really appreciating what it is"* (REC 1).

Although a few respondents suggested that certain specific communities were 'over-researched', many argued that there were no concrete examples of ORCs: "*I haven't heard of a single one*" (Researcher 4). "*I wouldn't consider any communities to be 'over-researched'*" (REC 1). Respondents also contended that while they were not aware of any specific communities which they would consider to be 'over-researched', it might be applicable to very distant communities and 'over-research' was a theoretical possibility: *"It's purely hypothetical. I am not aware of communities in this area being 'over-researched' so I cannot state that categorically. I am aware that potentially it's a problem though"* (REC 5)*.* Furthermore:

> To be honest, we've never sort of discussed a community and thought 'Well, shew. I mean that's' … I've never heard anyone say, 'I think that community is over researched'. I think it's a concept at this point, to me. I'm not aware of communities where I'd say they were 'over-researched.' So for me it's still a concept (Researcher 5).

## *"There is no 'over-research' here"*

Community-representative respondents seemed to have a relatively 'clear' idea of the notion of 'over-research'. While community representatives did not seem to question the legitimacy of the notion of 'over-research', all were quick to point out that the particular community in which they resided was far from 'over-researched' and in fact required more research, and thus questioned the legitimacy of the concern being applied to their own community: *"It would be lies. It would be lies because there is no Over-Research in Site A"* (CAB 4)*.* The reluctance to be called 'over-researched' could reflect the perception that the notion has no ethical relevance. Furthermore, community-representatives' interpretations of the idea seemed to be quite descriptive – too many projects. This could reflect language barriers and perhaps different educational levels and understandings of research.

## 1. (a) Social Value: Overview of the principle

Biomedical research is not an end in itself. Its primary purpose is the advancement of knowledge, which can contribute to improvements in health and wellbeing (Levine, 2008). As such, a fundamental ethical justification for conducting research lies in its capacity for contributing to the greater good, to generate benefit at a societal level – in other words, its social value (Emanuel et al., 2004; Emanuel et al., 2008; Lairumbi et al., 2008; Levine, 2008). Research may benefit society directly through informing improvements to policy and practice, or indirectly through contributing to knowledge, which might lead to further research, which could ultimately lead to improvements in health and wellbeing (Emanuel et al., 2004; Levine, 2008). The principle of *social value* is justified by the ethical values of non-exploitation and the responsible use of finite resources (Emanuel et al., 2000). It is argued that research which lacks social value, "exposes participants to risks for no good reason, and wastes resources" (Emanuel et al., 2004, p. 932).

*Social value* is largely concerned with the potential for the practical implementation of research findings (Emanuel et al., 2004; Grady, 2004). There is broad agreement that research should generate social value in the context in which it is conducted, and that the value of the research for the participants is an important consideration (Emanuel et al., 2008; Grady, 2004; Lairumbi et al., 2008). Although the *social value* of research is frequently used to justify the conduct of health-related research, it is acknowledged that the translation of research into actual health improvements is not straight-forward, and much research is never translated into practice (Graham et al., 2006 in Lairumbi et al., 2008). In developing countries where infrastructure to support the translation of research findings into actual improvements in health and wellbeing is frequently lacking, the situation is exacerbated (Black, 2001 in Lairumbi et al., 2008). It is argued that, where research findings are not translated into healthcare improvements, participants and host communities bear the burden of research for little benefit, while the benefits accrue primarily to the researchers and sponsors (Benatar, Daar, & Singer, 2005; Emanuel et al., 2004; Lairumbi et al., 2008).

Research should be valuable in that it is responsive to the health needs and priorities of the prospective beneficiaries. While research may not have immediate practical ramifications, in order for it to be socially valuable, it must generate or contribute to important knowledge (Emanuel et al., 2000). Moreover, a research project should not undermine a community's existing healthcare services. Social value can also be enhanced if improvements are made to existing facilities (Emanuel et al., 2004).

Mechanisms to enhance the social value of research include the development of collaborative partnerships with local stakeholders through which the needs and priorities for research might be determined and the findings can impact on policy and practice (Emanuel et al., 2004). Emanuel et al. (2004, p. 933) argue that "when research is integrated into a long-term collaborative strategy, so that

the research project forms part of a more comprehensive research and healthcare delivery strategy to address significant health problems" *social value* can be enhanced.

## 1.(b) 'ORC' as a concern about Social Value: Respondent perspectives on the 'ORC'

From the perspectives of most of the respondents, the notion of ORC reflected concerns, which could broadly be classified as concerns about social value.

### 1.1 Concern about the responsiveness of research

Respondents discussed the notion of the 'ORC' as a concern about meeting the 'responsiveness requirement' of research, that is, whether or not the research is responsive or relevant to the health needs and priorities of a community:

> *What it would be is that, is it relevant to the community? … If you're looking at research that is relevant to that particular environment, to that community and then to the greater community, then the answer is, it's not over-researched* (REC 4).

While there was general agreement that "*the research that you want to do must be applicable in that community*" (REC 4), there was some disagreement regarding determining the health needs and priorities of the participants and host communities in order to ensure that research is responsive to these.

The notion of the 'ORC' seemed to reflect a disparity between how communities define their health needs and priorities versus what researchers, and possibly RECs, consider important to address via research. This discordance is evident in terms of what community members may expect of researchers, and what researchers see as within the scope of their obligations (see section D-7, Ongoing Respect). The social priorities of the community are often largely development focussed compared to those defined by researchers. Therefore, 'over-research' could be argued to be rooted in different definitions of what might be considered socially valuable research, which could lead to perceptions that research lacking social value, is being, or has been, conducted.

Concerns about 'ORCs' may arise as a consequence of many simultaneous health issues in a community, which could be addressed via research, and that there may be difficulty in making a subjective determination that one study is more important than another:

> *Well, I think that sometimes you have communities where there are lots of different important health problems and all of them actually deserve to be looked at. You know, how do you determine what is a more important research question than something else? So, I think that's actually quite a complex issue* (REC 8).

However, having projects to address all the identified health needs within a community might also give rise to perceptions of 'over-research' because of the number of studies being conducted.

The notion of the 'ORC' might also be raised as a concern, where there is a perception that research is only focusing on one issue, while other socially important needs are being neglected:

> *'Why is there so much money for HIV versus something else?' ...And a lot of that is [determined by] foreign funding coming in. So, people are saying, 'You know, is this why? Why is only HIV research going on?'* (Researcher 1).

### 1.1.1 Concern about local ownership of the research agenda

Furthermore, there was a sense among respondents that a lack of local ownership of the research agenda was a concern (see also section D-8, Collaborative Partnership).

For some, 'over-research' reflected a concern about how the research agenda was determined. The notion of the 'ORC' was linked to a concern about an unequal balance of power in the community-researcher relationship and in setting the research agenda, and that this may lead to inequities in the potential for benefit between the researchers and the community:

> *To say they both benefit equally is naïve. I mean, research is a long process. Ultimately it's determined by research agendas. The questions are not framed by the community, they're framed by the researchers. So right up front it skews it in the favour of research benefits researchers* (Researcher 6).

Because research questions were seen as framed by the researchers, it was argued that social value was determined by researchers.

The notion of the 'ORC' also seemed to reflect concerns about a failure to address the needs and priorities of the host community in establishing research priorities, suggesting a lack of responsiveness:

> *The ideal way would be to come to the community with questions, and to start asking the community, 'What are your questions?' and, 'How can we help research those?' ... The questions they're wanting to answer are ones that are important ones for that community and are relevant and are going to make a difference in some way or the other* (Researcher 6).

However, it was recognised that: *"...that's not always how it happens because researchers...may have particular questions they're interested in and get funded for those ...and then come to a community"*(Researcher 6). As opposed to the 'actual' needs and priorities of the host community, it was noted that the way in which research is funded plays a significant role in determining what issues are given research attention.

Therefore, the notion of the 'ORC' might reflect worries about the influence of funding agencies on the research agenda. Accessing funding for topics which do not fit with funder agendas were also noted to be a challenge for researchers who may wish to conduct research which responds to an issue of importance to a local community, but which does not comply with funders' priorities.

*In a horribly practical, very mercenary, political sort of level, I guess it's also about what funders are prepared to fund… that will also drive what happens in the research field. You slog hard to get something that's a little less mainstream funded… It shouldn't be the final decision but it might explain why more research goes one way rather than another* (Researcher 5).

In addition to concerns about inequities in the research agenda-setting process, the notion of 'over-research' was discussed as a concern about a failure of the research to generate and contribute to knowledge, which could lead to improvements in health and well-being.

## 1.2 Concern about research contribution to knowledge

Respondents argued that repeated or apparently similar studies in a community might lead to concerns about 'over-research' because they would waste resources and would not contribute to progress in useful knowledge.

Some argued that 'over-research' would be a worry *"if you keep on doing the same thing in a community that you already have the answer to, but you keep on doing  the same thing"* (Researcher 4). 'Over-research' was linked to a sense of futility regarding the conduct of duplicate research, because it was seen as unlikely to generate new and important results: "*To me 'over-research' would mean doing research over and over again, in one place,… that will give you nearly the same result"* (CAB 7).

> *You're not really learning anything new; you're not moving things forward; you're just re-inventing the wheel, and you're not gaining anything new that's informative. Then I think you might have killed that horse* (Researcher 5).

Of particular concern was that repeat research, which was perceived as lacking the potential to contribute to knowledge progress, was a waste of limited resources:

> *One would have to look at what is the research, and if there's already similar ones going on, one should say, 'No,' because what are you going to achieve? …Why go in on information that's already there? Because you're wasting money. You're wasting time. You're wasting energy… If it's going over the same territory all the time [it would be a problem] because what is the aim? … Now I would say to the researcher, 'And your point is?'* (REC 7).

It was also suggested that repeat research represented a concern about researchers failing to adequately consider the context in which the research was proposed. In some cases it might appear that the findings of, and the community's experiences with, previous research had been ignored.  A concern underlying the notion of the 'ORC' would be:

> *Whether it's really something new, or is it just repeating something that has already been done? How does it add to, and does it actually use previous research as a base? So is it building on something that's already been completed?* (REC 8).

Concerns about research not responding to what has already been done in a community, could also reflect concerns about researchers failing to collaborate with one another, and to share resources and experiences.

> *Well, I think then, whether that research adds to and builds upon as opposed to simply repeating… there are studies recently that we have certainly turned down, which have simply been… repeating the same research question… Where we have now said, 'You need to go and speak to these other researchers, because this work has just been completed, and you don't need to ask this…. in order to inform your study go and speak to the other investigator, and find out the results'* (REC 1).

Respondents proposed that the notion of the 'ORC' might have some legitimacy where the same questions were repeatedly being asked of the same populations.

On the other hand, while 'over-research' seemed to reflect a concern about repeating the same or similar research in a community, it was also acknowledged that in some cases, repeat research could have social and scientific value if it validated or expanded existing findings.

> *Is it ethical to repeat studies that have already been done? Some might argue not only is it ethical, it's scientifically appropriate, because you have to look at whether it's repeatable or not. So I'm sure an argument could be made both ways, why studies should or shouldn't be done* (REC 5).

Furthermore, it was argued that, while repeat research for the confirmation of findings is acceptable for the purposes of enhancing the scientific validity, and therefore social and scientific value of the study, there must be a legitimate justification to repeat research, otherwise it may well constitute 'over-research'. It was suggested that 'over-research' might be a concern where the purpose of the research appeared unclear, and where participants perceived the research as repetitive.

### 1.2.1 Nature of the research strategy: Multiple studies in one site

On the one hand, in situations where there are multiple ongoing studies seeking to address many of the identified health needs in a community, there could be perceptions that social value is undermined and that the community is 'over-researched'. On the other hand, where research is part of a long-term collaborative effort, comprehensive research strategies could actually be socially valuable and 'over-research' would not be a concern.

Multiple ongoing studies could be socially valuable because they might enhance the scientific validity of a particular study or its potential contribution to knowledge. Having multiple ongoing studies would arguably enable numerous aspects of a topic to be explored simultaneously, and could enable a situated and holistic understanding of study results: "*you could have a number of studies that are going on at the same time that together help you understand what is going on*" (Researcher 1). Furthermore, multiple studies addressing a core problem in different ways could enhance the knowledge contribution that each study might make, in addition to improving means of addressing the core issue.

While, (see Section D- 3, Fair Selection) focussing research efforts on one site was noted to be a concern, some respondents suggested that there could also be potential value in focussing research on one community only:

> *I think there are some benefits about concentrating the research in a particular area of a community. So for example… we have our community-based study; we have the clinic-based study; we have a schools-based intervention. I think all of them approach the problem of HIV/AIDS from very different…questions and very different points of view. So there's a real benefit about doing it her*e (Researcher 6).

> *So, as I said … we have… positive prevention, we have voluntary counselling and testing; we have treatment; we now have a microbicide; we have stigma and discrimination reduction … Is this community 'over-researched'? My answer to that would have to be, 'No', because they're all answering different questions, in trying to understand how're we gonna make a difference, in this epidemic for this community?* (Researcher 2).

It was proposed that having numerous studies concentrated in one area may be beneficial to the community, if the different studies ask different research questions, and are co-ordinated so that they enhance the social value of the research overall, and contribute to addressing a larger problem facing the community, e.g. HIV/AIDS. Because HIV/AIDS is such a multidimensional problem, affecting so many different layers of society and aspects of life, it was argued that addressing these various aspects in the conduct of research was necessary for the scientific validity and the social value of HIV/AIDS-related studies.

Furthermore, where different studies were co-ordinated in such a way that they contributed to an overall enhancement of healthcare delivery for a community, the community was suggested to be unlikely to be perceived as 'over-researched'. The implication was that where this is not the case, there could be concerns about 'over-research'.

How multiple studies are conducted and co-ordinated was perceived to have an impact on the capacity of the research to generate social value and on whether or not 'over-research' was a concern:

> *There are times when there really is an advantage in having an additional study coming in, like if you have a prevention study and you then have an early treatment study. Well, then there's advantage to co-ordinating those two so that anybody who becomes infected in spite of the prevention work can rapidly access treatment. But then you may have other studies that which fundamentally don't add value one to the other and where you are overburdening an individual or group of individuals  by being subjected to just too much* (REC 1).

If there is collaboration and co-ordination between studies and between researchers, social value can be enhanced. Poor collaborative partnership formation was argued to detract from the social value of the studies:

> *I think it depends on the way in which the research has been done… You know that  I'm sure it's possible for a community to be … saturated but I think the time to that saturation point is*

*probably very much dependant on the way in which the relationship that the researchers have built with that community, the nature of the social responsibility,  the nature of the prior research… where there's a natural building on from one to the other, or whether this is just a set of, clumsy sort of, disorganised and slightly chaotic studies then I'm sure a community could get very fed up* (REC 1).

Concern about the 'ORC' may thus reflect a concern about a lack of co-ordination between studies and research groups. Having many different uncoordinated research groups working simultaneously in a community could be confusing to the participants or the community and could undermine *social* value (see also section D-5, IC). It was suggested that having only a single research organisation in a site could enable better co-ordination between the studies.

With regard to multiple studies in one site, given the argument for co-ordination of efforts to ensure social value and avoid 'over-research', the suggestion seemed to be in favour of a need for large research centres to assist with long-term research agenda setting and planning in specific settings.

### *1.2.2 Concern about the publication and dissemination of findings*

The publication of research findings is often considered a benefit, in terms of career advancement, for researchers. However, publication was noted to be an important aspect of ensuring the social value of research through contributing to knowledge:

*So publication is not a benefit, it's an ethical responsibility you have; that you have subjected a whole lot of people to procedures and umpteen visits and you've collected all this data, and unless you want to be a data repository, to be a scientist you have to share that. I feel very strongly about publishing data that's been collected and interpreting it … it should be a requirement that you do that; otherwise what's the point in subjecting all these people whether it's to an interview, or whether it's to blood draws… and never make that available?* (Researcher 1).

Publication of research findings in an academic context alone, however, was noted to be insufficient to ensuring that research results would have pragmatic significance for host communities.

### 1.3 Concern about research contribution to policy and practice

In addition to identifying, and conducting research which is responsive to the needs and priorities of host communities, most respondents noted that, out of respect for participants and in order to be truly responsive, research must generate social value locally, through the application of knowledge generated, and the implementation of evidence-based policies. It was argued to be imperative that research findings were translated into constructive benefits for local contexts and host communities.

In this regard, the notion of 'over-research' was also linked to concerns about international collaborative research, where the value of the research was perceived as unlikely to accrue locally.

From the perspectives of many respondents, concerns about 'over-research' seemed to reflect worries about a failure to act on the findings of a study, or to take actions, which would enhance the likelihood that the research results would be, translated into policy or practice. "*If the research doesn't get interpreted into policy you could say, 'Yes, the researchers benefit more'*"(Researcher 2).

Meeting the principle of social value was seen to require that mechanisms be developed to disseminate results to key stakeholders like policy-makers, as a means of increasing the likelihood that research would have an impact on policy and hopefully practice:

> *If you learn stuff that can impact things, then it must impact things. So taking that information to policy makers - We have a good relationship with the local health authorities, and so, we feedback the information and say, 'This is what we're finding out. This is what we would recommend', you know. So, to find ways of that information becoming something practical, for communities, rather than just accumulating knowledge* (Researcher 5).

Beyond simply studying an issue, which is of relevance to the host country or community, it was argued that social value required action on findings. The suggestion was that studies, which collect data but do not act on the findings, are not respecting the community and are not being responsive to the needs of the host community (see also section D-7, Ongoing respect).

In this regard, questions were raised about the ethics of observational, non-intervention studies, like Demographic Surveillance Systems (DSS). There seemed to be a suggestion that research methods, which do not deliver direct benefits or interventions to the host community, might incur accusations such as 'over-research' (see also section D-4, Risk-Benefit):

> *The danger of course with observational studies is that they can be resistant to allowing intervention studies, [in the population under observation], right ? But you can't simply go on observing endlessly and not intervening … Any observational study has to account for the fact that there will be interventions coming along … they have to account for that they shouldn't try and restrict them* (Researcher 3).

It was argued that observational studies could only be considered socially valuable if they were used to inform pragmatic interventions. However, they were not justified in themselves.

> *I do think it is dangerous to do research that is entirely observation and never amounts to any practical applications for the community…You know, there's a difference between you come in and you do a survey, and if it's a once off survey - they want to find out the HIV prevalence in South Africa … even then you hope that that would generate some kind of - you know, HIV is a problem… let's get treatment programmes out there …or whatever… we did a survey on knowledge and attitudes and we used it to inform our education campaign* (Researcher 5).

On the other hand, it was noted that "*when you're doing public health research, there's immediately a social justice component to it that's driving it … by definition you're asking questions that are of benefit… that have a contribution to make to society*" (Researcher 1).

In addition: "*This is what we're doing for the greater good*" (Researcher 3) and it is this greater good, or incremental social value which justifies the research. However, this can be very difficult for communities, particularly those that are resource poor, to accept and understand (See section D-7, Ongoing Respect).

## 1.4 Concern about impact of research on existing healthcare services

The notion of the 'ORC' was presented as a concern about research undermining the existing healthcare infrastructure in a community. It was suggested that competition for resources and referral sites, which could arise in situations where there were multiple ongoing studies, might burden existing services.

The 'ORC' also reflected a concern that multiple studies in a community could result in a community becoming dependent on a research organisation for service delivery, and failing to take the initiative to access healthcare services independently. "*Well for one thing, you could develop a dependence on that particular research team, for medical care, and you might not make any efforts to, [access care] yourself*" (REC 6). This in turn could create a situation in which the community might feel 'abandoned' when the research organisation completes its work there.

Furthermore, it was argued that having multiple studies in a community could lead to public healthcare services becoming dependent on the research organisation to provide, or support services. This could result in shirking of responsibility by government, and might create problems of sustainability when the project ends.

> *A lot of times funding that comes from research is used to sort of boost existing health structures with the Department of Health Services which are actually the government or the Department of Health's responsibility, but which end up being driven and supported by research funding. And then to remove research from those communities because they viewed as overfunded or 'over researched' but then could have an impact on the health delivery that they have become used to, so you could get a deterioration* (REC 8)*.*

Furthermore, through providing high-standard services, research may highlight inadequacies in existing services and thereby undermine them. The effect may be enhanced with increased research. However, in highlighting the inadequacies these could possibly be addressed, so ultimately it could have a positive effect.

## 1.5    Summary:  ORC as a concern about social value

Respondents suggested that 'over-research' reflected worries about research without social value.

'Over-research' reflects concerns that, owing to power asymmetries between researchers and communities in the research agenda-setting process, research is not responsive to the needs and priorities of the host community. However, research stakeholders may have disparate understandings

of what would constitute socially valuable research (cf. London, 2005; London, 2008), which could create the potential for perceptions of 'over-research' to arise. Over-research' implies that, from the points of view of certain stakeholders, in making subjective determinations of priority issues, other socially important concerns were being neglected (cf. Jentsch, 2003).

The notion of the 'ORC' also represents concerns about unjustified repetitious research, which wastes resources and fails to generate new and useful knowledge through integrating with other research and building on existing knowledge. Repeating research could serve socially valuable goals if its purpose is to validate findings, and multiple studies could enhance social value if they are part of a co-ordinated effort addressing a multifaceted issue.

'Over-research' also represents concerns about a failure to act on the findings of research and thus to generate social value locally (cf. Lairumbi et al., 2008). Allegations of 'over-research' seem to be more likely, where there is a failure to appropriately disseminate findings to relevant stakeholders in order to facilitate the translation of research results into policy and practice.

Multiple ongoing studies in a single community might compromise the existing healthcare services, by burdening limited resources or allowing the community and service providers to become dependent on the research organisation for resources and service provision, which may not be sustainable beyond the conclusion of a study, and which could create a sense of abandonment at study conclusion.

## 2. (a) Scientific Validity: Overview of the principle

*Scientific validity* is a requirement of ethical research (Emanuel et al., 2000, 2008; Emanuel et al., 2004). Unless research is designed and conducted in such a way that it produces valid and reliable data, it cannot generate results that will be useful to the intended beneficiaries of the research, will not produce any benefits, and so cannot justify exposing participants to risks or burdens (Emanuel et al., 2000; 2008; Emanuel et al., 2004; Levine, 1988). As Levine (1988) argues, participants are entitled to assume that their participation in research will lead to something of value, which is unlikely without attention to scientific rigour.

In order to meet criteria for scientific validity, the study must be practically feasible, must have sufficient power to test hypotheses definitively, and must allow plausible conclusions to be drawn (Emanuel et al., 2000). The study should be designed in such a way that the results are interpretable in, and applicable to, the local context, or that they provide a reliable base for future research and can be generalised to similar contexts (Emanuel et al., 2004). Furthermore, the study should not require interventions which cannot practically and sustainably be introduced into the local context (Emanuel et al., 2004). Ultimately, the study must be determined to be feasible given the political, social and cultural context of the community (Emanuel et al., 2004). Where there is bias in the sampling, data collection or analysis or achieving an adequate sample size is unlikely within the given timeframe, the study will not generate results that can validly answer the study questions (Emanuel et al., 2000). The validity of the design notwithstanding, research must also be implemented and conducted with methodological rigour in order for it to produce meaningful results.

## 2. (b) ORC as a concern about scientific validity: Respondent perspectives on the 'ORC'

'Over-research' as a concern about *scientific validity* was primarily an issue for researcher and REC respondents. Community representative respondents on the other hand, made little mention of *scientific validity* as a concern relating to 'over-research', other than in relation to the issue of co-enrolment, or individuals participating in more than one study at a time.

It was suggested that the 'ORC' might be an unconsidered remark, "*it's another, sort of, shoot from the hip comment*", indicating a concern about the scientific integrity of research in a particular community: "*that, just on scientific grounds, you will make mess of the scientific question you're trying to understand*" (Researcher 1).

The notion of the 'ORC' represented a concern about the potentially negative impact that multiple ongoing or subsequent studies in a single, geographically-defined, community or population group might have on the scientific integrity of the research:

> *I think then you'd want to look at whether the research is overlapping in the same population, whether you're likely to get contamination. So, whether, from a scientific perspective, whether one study's going to be compromised by, the arrival of another study* (REC 1).

## 2.1 Concern about contamination between studies

"*Having multiple ongoing projects [in a community]*" was argued to have "*the potential to confuse both the researchers and the participants*"(REC 2) (see also section D-5, IC). Of particular concern were the challenges of multiple extraneous or nuisance variables which might be introduced by having multiple studies conducted in a single community, which were difficult to control for in individual studies, and which could create "*a scientific stew there*" (Researcher 1). Given the potential for contamination of data between studies, there would be difficulty determining what, in the range of things to which the participants may have been exposed, created the observed effect: *It doesn't work, because how do you tease out what works?*" (Researcher 1). "*When there is an impact, how do you know that whether it's your intervention or theirs, that's made the difference?*" (REC 4).

### *2.1.1 ORC as a concern about co-enrolment*

It was argued that having multiple ongoing studies in a single community increased the potential for these studies to compromise the scientific integrity of one another, for example through the repeated selection of the same population, or co-enrolments between studies, which could would raise questions about the validity of the findings of the individual studies:

> *If in one's recruitment to participate...you recruited a certain population to participate in your study and they're already participating in another study; and the activity which they were doing, or the drug they were taking, or the intervention that was being planned in some way, had an impact on the other study, that could call into doubt the validity of the findings... I think we will have to question whether that it's a good idea or not, having multiple studies* (REC 5).

In a context in which there were multiple ongoing studies, particularly where these were similar types of studies: "*if you've got three or four different STI studies happening, all within a very closely defined geographical area ... that creates a complexity; that's what could start leading to co-enrolments*" (Researcher 2).

Several interviews were conducted shortly after a serious issue with co-enrolments was uncovered between two clinical research sites, testing similar but different products in two different trials (cf. CAPRISA, 2008; Ramjee et al., 2010). It is thus unsurprising that co-enrolment was a frequently raised source of inter-study contamination, potentially creating bias or allowing uncontrolled interaction effects to occur between studies. 'Over-research' seemed to represent a concern about the scientific validity of research taking place in a community in which multiple studies were conducted. That, as a

result of co-enrolments and contamination between studies,: *"you'd have so much bias by having people participating in multiple studies that you can't understand anything at all"* (Researcher 1).

However, it was noted that while:

> *a lot of work is complementary it's only when you're doing similar but different things...so, if you're doing microbicides and we're doing a behavioural intervention then you've got to be careful that you're not enrolling the same people. Whereas, if I'm doing a prevalence survey, and you're doing a microbicide study, me taking a sample for HIV prevalence on a patient who's enrolled in your study is not a problem. So it just depends* (Researcher 5).

On the other hand:

> *When we do the HIV prevalence and incidence study, we always ask them, 'Are you taking part in something else?' Because if you look at something like HIV incidence, it does have an impact if they're already taking part in something else where they're also doing risk reduction counselling...Also, with HIV vaccines, if they get vaccinated they may develop antibodies which would test false positive on a normal anti-body rapid test. So, in a study where HIV tests will be done, like a prevalence study, they might test false positive and even though they're not infected* (Researcher 4).

Therefore, co-enrolment, as a concern represented by the notion of 'over-research', could only be considered a legitimate issue with regard to certain types of research, like clinical trial research, which might introduce confounding variables when run alongside one another.

### *2.1.2 ORC as a concern about serial enrolment*

While co-enrolment was raised as one specific mechanism via which contamination between studies could occur, other sources of contamination, for example as a result of serial enrolment in research, including drug interactions and priming, were also noted, although not as extensively discussed.

'Over-research' was suggested to be a concern that multiple studies, whether run concurrently with, or subsequent to one another, targeting the same population, could comprise the scientific integrity of the individual studies, through repeat or concurrent enrolment. Several respondents noted, though, that epidemiological, longitudinal health surveillance research studies, like Framingham and the Matlab (cf. Durrant & Menken, 2004) in Bangladesh, *"where the community has been studied to the nth degree over decades, but is valid as far as I'm aware"* (REC 2), *"continue to provide good results, which are helpful to researchers"* (Researcher 3).

Whether or not 'over-research', in the context of multiple studies, was linked to a concern about compromised scientific validity, as a result of co-enrolments and contamination, seemed, in part, to be dependent on the types of studies that were ongoing, particularly whether the studies involved interventions (like clinical trials) or were observational (like Demographic Surveillance Systems). Where studies were purely observational, co-enrolment in multiple studies did not raise concerns regarding validity, nor did there seem to be worries about contamination between observational studies. The

scientific integrity of studies involving interventions however, could be compromised by other intervention studies, particularly where there was a potential for co-enrolment. Furthermore, while observational studies might not compromise the integrity of intervention studies, intervention studies could affect the validity of observational studies – and for this reason it was observed that they might resist interventions (see section D-1 Social Value). So, while 'over-research' may refer to compromised scientific validity as a result of contamination or co-enrolment, it did not seem to refer to this concern with regard to observational studies – despite the fact that many of the respondents linked the notion of 'over-research' to particular communities where a significant amount of observational research was known to be conducted (e.g. Site A) (cf. Durant & Menken,2002; Pison, 2005).

### 2.1.3 ORC as a concern about study co-ordination and synergy

While having multiple studies conducted in one community could certainly compromise the scientific validity of the results if there was contamination between them, "*you could have a number of studies that are going on, at the same time, that together help you understand what is going on*" (Researcher 1). It was argued that, in a single community, different studies addressing different aspects of a complex problem, like HIV/AIDS, could be entirely appropriate (see also section D-1, Social Value) and could help to obtain a more holistic understanding of the issues, and might enhance the scientific validity of the findings of each study by contextualizing them.

Therefore, rather than a concern about the number of studies conducted in a community, 'over-research' was suggested to represent a concern about the interaction of the various studies with one another – whether they contributed value to each other or detracted from one another and compromised scientific integrity. "*So to me it's not how many studies but, how do these studies interact with each other? So not conflicting...Is it synergistic? Is it antagonistic?*" (Researcher 1).

### 2.1.4 ORC as a concern about researchers as community gatekeepers on the grounds of maintaining scientific integrity

From a scientific point of view, researchers may be tempted to eliminate, or at least control, all potential extraneous or confounding variables that could affect the validity of study findings, by controlling access to a community by other researchers or preventing study participants from accessing other interventions (see also section D-8, Collaborative Partnership). While there is the very real potential for other studies to impact on one another, in some way,

> *to be realistic, you can only control that so far... You can't kind of say, 'Don't do research here because we want to have a pure effect.'...that's silly ... because you're denying the community the right to have those studies* (Researcher 6).

### 2.1.5 ORC as a concern about study feasibility: Enrolment problems

Furthermore, 'over-research' suggested concerns that if multiple studies were conducted in one community, the feasibility of conducting and successfully completing some of these studies could be compromised. Because investigators "*would fight for eligible participants and would be competing for*

*resources"* (Researcher 7), there may be difficulty meeting enrolment targets and completing the studies with scientific integrity:

> *So ['over-research' is] similar types of studies competing for participants. For example if you have a very small community, where you need to get the same participants for ten different studies, then I think that's where you run into problems; where you don't have enough participants to actually recruit for the studies that you want to do in there* (Researcher 4).

### *2.1.6 Gatekeeping on the grounds of scientific integrity is not fair or ethical*

While *"there's always competition for access and control of the community"* (Researcher 3) because of concerns that *"somebody else coming in may steal their idea, or may undermine their study"* (Researcher 1) and that *"from a scientific point of view we always want to try and keep things controlled"* (Researcher 6), there seemed to be agreement that it was not *"fair or ethical [for researchers] to try to control access to a community"* (Researcher 6) by other researchers, or to control what other interventions a community could access. It was argued that, while putting measures in place to avoid contamination between studies was fair,

> *You can't deny people information about things that they could access, that might benefit them... We conduct research in a real world context... and so... people will look for things that work for them; people will try and get as much as they possibly can, and I think, that's the way it should be* (Researcher 6).

A criticism was raised that researchers might use 'scientific integrity' to justify not providing participants and communities with benefits, or to prevent other researchers from conducting research in the same community and potentially contaminating their results. It was noted that it was the researcher's responsibility to address the potential scientific complexity which could arise if there were multiple studies conducted in a community, and this should not be used to justify preventing participants and communities from accessing the potential benefits of participation in other research:

> *You need to then deal with your own scientific problems around how you make sense of what you've found given that somebody may have accessed this, or this or that other kind of thing that was happening* (Researcher 6).

Also, it was noted that

> *...rigorously designed studies all have potential bias, and you've got to figure out how to deal with the bias. You can't make a blanket statement 'I'm here first so I should be the only one doing the work here' or something like that* (Researcher 1).

Rather than proposing that if one research organisation was working in a particular community, that others be prevented from accessing the same community for research, there seemed to be consensus that the appropriate response to having multiple studies conducted in a community, and addressing the concerns about contamination would be, *"to build it into your design in such a way that you can pick it up and evaluate it"* (REC 4).

### 2.1.7 Collaboration as key to overcoming internal validity concerns of 'over-research'

One of the recognised ways of ensuring the scientific validity of a study, where it is not possible to eliminate confounding variables by controlling them, is to be aware of their potential impact and to factor them into the final analysis:

> *We'll document what else is happening and then when we're at the point of analysing our results we can then offer some explanation if we have an effect or don't have an effect as to what else is happening* (Researcher 6).

As such, it was seen as important to recognise that research does not occur in a vacuum and so "*knowing what else is going on in the community*", is an essential aspect "*of informing, the work we're doing*" (Researcher 5). "*We're a randomised trial, so we want to, as much as possible have some sense of who's doing what*" (Researcher 6). "*They all communicate with each other to see what's going on where... Because they know...if they're not going to take that into account their studies are going to fail*" (Researcher 4).

Ensuring that studies do not confound one another through the introduction of nuisance variables, and implementing mechanisms for avoiding contamination (via co-enrolment), was argued to require collaborative effort (see also section D-8, Collaborative Partnership). "*We had one incident of co-enrolment where our study co-ordinators had to get together and talk about what was going on, and come up with a strategy for how we are going to move ahead*" (Researcher 5); and researchers "*understanding and dialoguing with each other*" (Researcher 7) and engaging in "*discussion about where they're wanting to work and how they're wanting to work, so that we don't have contamination of issues*" (Researcher 6).

In the interests of scientific integrity, it was argued to be critical for researchers to develop collegial relationships with other investigators working in a community, and to ensure collaborative communication between trial sites:

> *If you're interested in coming and doing similar kind of work, it's collegial to discuss it, and make sure that you're not undermining each other's work by doing two different things, or two similar things, that might confound each other...So it's a case of saying, 'We're both here. What are you doing? What are we doing? How do we make sure that our work doesn't overlap or impact?'* (Researcher 5)

It was argued that the position that: "'*We're not a service organisation. We're just here to do science*'" (Researcher 6) and that other research or interventions could compromise this scientific mission, was untenable, particularly in the context of public health research where one of the purported aims is to make a difference in the lives of the participants and communities. It was argued that it was possible to maintain scientific integrity at the same time as not denying participants and communities access to potential benefits. This may simply require reframing the research question or altering the research

design: *"I think if you ask the question in a different way, you can still do good science and at the same time make a small difference"* (Researcher 6).

The notion of 'over-research' also seemed to reflect a concern about the way in which these concerns are managed, particularly that "*there's a danger also of sort of a colonial approach to research. Groups say, 'Listen I own this community. Don't cross my boundaries"* (Researcher 3) (see also section D-8, Collaborative Partnerships).

## 2.2 ORC as a concern about generalisability

Another potential interpretation of the notion of the 'ORC' was that *"the research in the community makes the community no longer typical"* or representative of the population to which the findings of the study are to be applied, and therefore that *"conclusions based on research in the community are no longer generalisable, because too much has been done in that community"* (Researcher 3) (see also section D-3, Fair Selection). The view of 'over-research' as a concern about compromised generalisability was linked to concerns that "*you could probably have Hawthorne-type effects"* (REC 6) - the notion that simply the act of research *"might alter the community. Sort of, the social Heisenberg effect – the Hawthorne effect - by researching it you change it*" (Researcher 3).

Concerns that communities in which many studies had been conducted would be altered in some way, effectively compromising their representativity and thus the potential for drawing generalisable conclusions from further research in them, were also expressed as worries about *"professional participants"* (REC 4) who *"probably know exactly what to do when they join the trial"* (Researcher 4). It was suggested that data collected *"in the over-researched community… would be not valid"* because the participants are no longer representative of the broader community "*because they've been involved in so many research and they know what happens; because they know maybe the tricks and what of the research"* (CLO 1).

## 2.3. ORC as a concern about 'research fatigue' creating distorted/invalid results

Respondents frequently linked the notion of 'over-research' to that of 'research fatigue', or used these ideas synonymously (see section also section D-4, Risk-Benefit). 'Research fatigue' was described as *"an exhaustion"* (Researcher 3), being fed up, lacking interest, boredom, "being *sick of people asking them questions all the time"* (REC 2). "*You know how you feel when telemarketers phone you at home [laughter]…another person knocking on your door to ask you to be part of this survey. I'd imagine that could be annoying, an irritation"* (Researcher 5).

"*Research fatigue and boredom, which would potentially affect the information gained and which would therefore affect the validity of the results"* (REC 2) were specifically raised as concerns underlying the notion of 'over-research'. It was argued that *"grind[ing] away at the same community*

*all the time might give distorted information out of that particular group of people"* (REC 2). 'Over-research' therefore seemed to represent a concern that, as a result of the sense of 'fatigue' induced by frequent or ongoing research being conducted in a single community, *"participants may perhaps not be as co-operative…and also not give enough information …so then you are actually missing the point and you're not getting valid data"* (REC 7); or *"for example with a questionnaire where you just tick, tick, tick, without reading the question, so it's a joke isn't it? So that kind of malaise can set in"* (REC 4); or *"people will just tell you all sorts of things to get rid of you [laughter] and I would in that position, if people were asking me all sorts of intrusive questions"* (REC 3).

## 2.4. Summary: ORC as a concern about scientific validity

'Over-research' was suggested to reflect a concern about the negative impact of multiple studies conducted concurrently or subsequent to one another in the same community, on the scientific integrity of the individual studies. Of particular concern was that confounding variables, which would compromise the internal validity of each individual study and create difficulties in drawing accurate conclusions from research data produced in the context, would be introduced (cf. Baiden, Hodgson & Binka, 2006).

Co-enrolment and serial enrolment of participants, in multiple studies, were raised as possible sources of inter-study contamination and confounding variables. Co-enrolment or serial enrolment in multiple studies, however, did not raise worries about scientific integrity when the studies were observational, and only represented a threat to scientific validity when intervention studies, like clinical trials, were involved.

As opposed to the number of studies conducted, 'over-research' was suggested to be a concern about collaboration between researchers and the co-ordination of multiple studies with one another, in order to ensure scientific integrity and maximum benefit. 'Over-research' might also represent concerns about researchers taking ownership of a community on the basis of maintaining scientific validity, and preventing other researchers from accessing the community.

Furthermore, 'over-research' was argued to represent a concern that extensive research involvement results in the  community is no being longer representative of other communities, such that the data produced in this community can no longer be generalised to other communities.

'Over-research' was also suggested to be synonymous with 'research fatigue', which could potentially create distorted, invalid results because either the participants respond in a learned way, or in ways which misrepresent reality because they no longer take the study seriously (cf. Argyris, 1969 in Trickett & Espino, 2004; Clark, 2008).

# 3. (a) Fair Selection of participants and communities: Overview of the principle

The principle of distributive justice, which requires an equitable distribution of the burdens and benefits of research, gives rise to obligations to ensure fair selection (Beauchamp & Childress, 2001; Belmont Report, 1979; Levine, 1988). There is general agreement that the selection of study participants and target communities should be fair or equitable (Emanuel et al., 2000; Emanuel et al., 2004). Participant selection refers to decisions about which populations will be targeted for the recruitment of participants into a study, where study sites will be located and on what basis participants will either be included into or excluded from a particular study (Emanuel et al., 2000; Levine, 1988).

Given their relative lack of power, resources or education, or their general inability to protect their own interests, in addition to their availability and the perception that they were somewhat expendable, it is contended that historically, research has placed an excessive burden on the most vulnerable members of society (Emanuel et al., 2000, 2008; Meltzer & Childress, 2008). Furthermore, such research was rarely beneficial to these vulnerable groups (Emanuel et al., 2000, 2008). Initially, in order to protect vulnerable groups from the burdens of research, vulnerable groups were largely excluded from research, and some remain so, for example pregnant women. However, a shift in perspective to a focus on research as potentially beneficial, as opposed to burdensome, particularly to the groups identified as vulnerable, led to demands for access to research by these so-called vulnerable groups (Emanuel & Grady, 2006; Mastroianni & Khan, 2001; Meltzer & Childress, 2008; Weijer, 1996). Equity requires that no group bear an excessive quantity of the burdens of research participation, but equally, that no group be deprived of its share of research-related benefits. Fair selection requires the equitable, morally and scientifically justifiable, distribution of the burdens and benefits of research participation (Emanuel et al., 2000; CIOMS, 2002, Guideline 12).

In order to be fair, the selection of participants and communities for research should, at minimum, be based on ensuring scientific integrity and not reasons of convenience, vulnerability or factors which are unrelated to the scientific purposes of the study (Emanuel et al., 2000, 2008; Emanuel et al., 2004; SA DOH, 2004, 2.8; UNAIDS-WHO, 2007, GP7). The exclusion of any participant or community from a study must be explicitly justified (Emanuel et al., 2000; CIOMS, 2002, Guideline 12; SA DOH, 2004, 2.8; UNAIDS-WHO, 2007, GP 7).

Furthermore, the selection of participants and communities for research should minimise risk to both participants and communities (Emanuel et al., 2000, 2008; Emanuel et al., 2004). This is consistent with the recommendation that research target less vulnerable groups ahead of those that are at greater risk

of experiencing harm (Emanuel et al., 2000, 2008; Emanuel et al., 2004; Jonas, 1969 in Meltzer & Childress, 2008; Weijer, 1996). Where target populations or potential participants meet the scientific criteria for inclusion in a study, but are for social or scientific reasons at risk of experiencing significant harm as a result of research participation, they, justifiably, should be excluded (Emanuel et al., 2000, 2008; Emanuel et al., 2004). While selection decisions should not be based on the vulnerability of potential participants, where populations meet the scientific criteria for study inclusion and are likely to benefit from research, fair selection requires that researchers identify and introduce measures to mitigate the source of these populations' vulnerabilities (Emanuel et al., 2004; UNAIDS-WHO, 2007, GP 8).

Fair selection also requires that participants and communities are selected for research in such a way that the potential benefits to individuals and communities are maximised, that the social value of the research is enhanced, and that the development of a collaborative partnership is likely (Emanuel et al., 2000; Emanuel et al., 2004). This means that those who are among the intended beneficiaries of the research, and communities where the likelihood of benefit is greatest, should be included in the study.

## 3. (b) ORC as a concern about Fair Selection: Respondent perspectives on the 'ORC'

Most respondents, in discussing their views regarding the notion of the 'ORC', raised concerns about unfair selection.

Concern about the fair selection of communities for research seems one of the most obvious ways of interpreting 'over-research,' as the term 'over-research' implies being repeatedly selected for research: "*…to me when it is said the community is over-researched, [it's]… when two researchers are researching the same people*" (CAB 6). Most respondents described 'ORCs' as "*communities that have been the recipients of a lot of research*" (Researcher 6). Furthermore, several communities were consistently linked to the notion of the 'ORC'. The site A community, from which most of the community representative respondents originated, was mentioned on numerous occasions by many of the respondents as being perceived to be 'over-researched'.

### 3. 1 Concerns about how selection decisions are made: *Why here? Why this community?*

In reflecting on the notion of the 'ORC', respondents noted that they often encountered concerns from communities about how selection decisions were made: "*We've certainly never been accused of exploiting the community or anything like that, but I guess there's a sense of, 'why?' You know, some people do ask, 'Why here? Why this community? Why us?'*" (Researcher 5).

Respondents suggested that, from the perspective of communities, 'over-research' reflected a sense of being 'singled out' as the targets of research, and that their selection was not necessarily based on good reasons, or, that the basis for their selection was unclear:*"Some they even verbalize that, 'Hey, we don't trust this thing why you want to test your product on us?' So they keep on asking, 'Why, you are targeting us?'* (CLO 1).

Furthermore, the notion of the 'ORC' could reflect a perception that selection decisions have perpetuated the subjugation of certain groups: *"It could be that ... something might have gone wrong; Or people has got the perception that 'we are guinea pigs'. You know, they say, 'Why, only us?"* (CAB 1).

### 3.1.1 Selection decisions that perpetuate racial prejudice: Why are they only doing it with black people?

Unsurprisingly, given South Africa's apartheid history, several respondents noted that suspicions regarding how selection decisions were made were often linked to perceptions about research perpetuating the racial injustices of the past.

It was argued that the history of exploitation on racial grounds in research conducted in South Africa has left a legacy of the perception of researchers as exploitative of communities:

> *The old understanding of research especially in South Africa is, you know, researchers are here as abusive people - the apartheid days, that thinking exists strongly, the use of people. The guinea pig scenario - that still exists in our communities* (Researcher 7).

Also because of South Africa's history of racial discrimination and subjugation of black people, there is a perception that black communities are the primary targets of research, simply because they are black:

> *In South Africa in particular, for a long time, black people have felt very exploited as the subjects of research. So, very often, when the subject, the community, is a black one, the community itself will say: 'Why aren't you studying whites? Why is it now that these bloody researchers are continually studying us, black people?'* (REC 3).

> *Yes, I've come across of that term [ORC], but not here... I was once in this CAB meeting and then people said in Site A... the people say, 'Ja, they've been doing all those things here, we're sick and tired of these things,' that, 'Why are they only doing it here? Why are they only doing it with black people? all this. Then, 'They've really over-done it here. They should go to white people. Go to the suburbs, you know* (CAB 2).

In addition, while there may be legitimate scientific reasons for the targeting of certain communities for research, it was noted that the reality of South Africa's history of racial oppression, frequently leads to a 'knee-jerk' response to 'white' researchers conducting research in 'black' or previously disadvantaged communities (cf. Barsdorf & Wassenaar, 2005). Prior to the examination of the scientific

reasons for the selection of this community, the automatic assumption is that it is racist and exploitative:

> *One never wants to talk about the segregation that there was, or the apartheid era. Unfortunately that is part and parcel of the whole thing. And so one becomes quite suspicious, when you find that , 'Why is the white researcher just going to the coloured people? Or to the black people?' That goes in your mind … initially until you realise … it is because there is no other material…[that is where you have to go to answer your question and that it has little if anything to do with race]* (REC 7).

Moreover, since race and racism are sensitive political issues, several respondents seemed to suggest that the notion of the 'ORC' was an alternative means of expressing concerns about racism and the ongoing structural inequities, which are a legacy of apartheid.

> *... and that's a serious question. You know, you happen to be studying the illnesses of poverty. Well that's where the poverty lies. But … for the people concerned they feel as if the spotlight's always on them because they're black* (REC 3).

### 3.1.2 Selection on the basis of convenience- 'everything happens around what's convenient'

Most respondents cited convenience, in terms of geographic accessibility and ease of set up and conduct of studies, both critically and uncritically, as a usual consideration in making decisions about the selection of communities for research. There was general agreement among all respondents that those communities with access to transport links, and which are geographically accessible, are more likely to be researched: "*I mean, you know, everything happens, or tends to happen around what's convenient and what's accessible in a community*" (Researcher 6). It was argued that while less accessible communities could be neglected for research, those that are easy to access could be 'over-researched'. Furthermore, engaging with communities that are less resourced and difficult to access is far more burdensome and demanding on researchers.

For many of the respondents, 'over-research' reflected a concern that convenience rather than science, at the expense of fair selection, was the primary factor underlying selection decisions: "*the danger for the ethics comes with the fact that it looks more and more convenient and easier to go do research in one particular community*" (REC 6).

Existing infrastructure in a community, including a research site, community structure like a CAB, previous experience with research, and the potential for the formation of collaborative partnerships, could increase the likelihood that a community might become 'over-researched':

> *There might be other communities that are not targeted for those projects because they lack the infrastructure … and also they lack the buy-in. They don't have the exposure to research, to have that community participation attitude… And therefore they're not chosen because it actually takes a lot of work to develop those relationships with communities, so once they're established, people like to maintain them… and when they do one study and then they do a*

*long term follow-up study, then all the infrastructure's in place. So, that was a successful study, we must go back and do our next study then our next study, so I think it does tend to happen, and that is how communities get 'over-researched'* (REC 8)*.*

The concern about repeated selection on the basis of existing infrastructure, seemed to be a worry about researcher 'laziness' or reliance on the hard work of others, as opposed to investing time and resources into creating infrastructure in a community which might benefit from research, but in which there was no existing infrastructure: *"the danger is once you've got a tangible research site you will find a lot of people who want to come and 'piggy-back' … and that's where it can become 'over-researched'* (Researcher 2).

However, it is worth noting that while some may have concerns about 'over-research' as a result of the use of existing research infrastructure by multiple researchers, other respondents argued that they would actively encourage other researchers to use the infrastructure that they have developed in a community, in the spirit of fostering collaborative partnerships between researchers (See Section D-8, Collaborative Partnerships).

Certain convenience factors, like accessibility, existing infrastructure or community relationship, were also argued to be both necessary and legitimate considerations in making decisions about the selection of communities for research, although not at the expense of fair selection:

> *And there's also an issue of convenience - whether that community is sufficiently accessible to the researcher to be able to complete the research within a given time and at a reasonable cost....I think those are legitimate considerations* (REC 1).

### 3.1.2.1 Selection on the basis of Community compliance – 'the community is seen as a good bet'

In terms of the perception that researchers simply choose the easiest route to completing their studies, and make selection decisions on this basis rather than on the appropriateness of the community to answering the research question, 'over-research' also reflected concern that communities are selected because "*the community is seen as a good bet… and so is targeted for a lot of different research projects, or it's easy to utilise that community*" (REC 8).

It was suggested that researchers might interpret the success of another's research project in a particular community as an indicator of the likelihood of the success of their own projects. A community may be frequently selected for research on this basis: "*You just see someone's project's successful there and you also want to go there*" (CAB 2).

The notion of 'over-research' reflected a concern that selection decisions are based on the assumption of community compliance or agreement to the research, without researchers having to undertake

intense, and often lengthy, community education and engagement processes prior to research implementation.

> That they will get what they want, and the response from the community will be positive. I think maybe the researchers are just afraid of this waiting period, because if they give them that waiting period just to work on the issue maybe the community at the end will say "no we don't need you'.  Maybe it's this disappointment of when the people say, 'No, we don't need researchers here'. So maybe that's the reason they use the same people that have been involved, and understand everything about research (CLO 1).

### 3.1.2.2 Selection of 'captive' populations: 'They are a captive audience' 'Just rats in a cage'

Certain community characteristics, were noted to increase the likelihood they would be unfairly selected, and that they might become 'over-researched'. It was argued that 'over-research' could be a concern about "*the over-use of a particular community because it happens to be conveniently circumscribed and has a definable population which can be followed up*" (REC 2). Furthermore, a particular community, Site B, which has been labelled 'over-researched' was defined as:

> ... beautifully confined [with] a relatively stable population because it is physically isolated from the others. Whereas [Another specific community] Site K, is a vast extended area and you couldn't ring fence a similar group of people. So, these investigators have gone to that area [Site B], which is confined (REC 6).

A highlighted concern was the use of 'captive' communities, simply for convenience factors rather than because they are specifically suited to addressing the research question:

> People begin to feel that … this is abuse. That they are now just guinea pigs. And that the only reason these people are coming to our town is not because they really like us, or they want to help us … but because we're convenient, and we are the rats in this particular cage and they're just testing us (REC 6).

### 3.1.3 Selection on the basis of vulnerability

In addition to 'over-research' being a concern about selection solely on the basis of convenience, it was also discussed as a concern about selection solely on the basis of vulnerability: *"What comes to mind is that [an investigator] is targeting … a disadvantaged group who don't have the clout, or the finances, to challenge [the research]"* (REC 7).

On the one hand it was suggested that, because "*the chances of getting participation from poor and neglected communities, is someway higher, than it is from … getting busy, middle-class people to participate*" (Researcher 3),

> … poor people tend to be researched more than non-poor people. You know the business of researching up and researching down? It seems to me that by and large most researching is done down. There are very few of the case of 'up'. It's harder etcetera, because 'ups' can protect themselves. 'Downs' can't protect themselves, and the undue incentives and the few packets of beans that are strewn around make a difference to their lives (REC 3).

### 3.1.3.1 'Under-research' as a consequence of 'over-research'

On the other hand, it was argued that vulnerability and marginalisation could in fact lead to the non-selection or 'neglect' of certain groups for research, and to these groups becoming 'under-researched'. It was suggested that groups, which lacked financial power were unlikely to have the political power to ensure that their interests were represented on the research agenda.

It was argued that 'vulnerable' groups might be 'under-researched' because they are unlikely to have the financial power to purchase drugs developed in research, or because of "*a paternalistic attitude*" towards these groups (REC 6) (see also section D-6, Independent Review).

Furthermore, stigmatised, marginalised, and other vulnerable groups were argued to often be difficult to access and so less likely to be selected for research participation.

## 3.2 Concern about distributive justice: Fairness in the distribution of the burdens and benefits of research

The concern about unfair selection (or non-selection) underlying the notion of 'over-research', seemed to also be located in a concern about fairness in the distribution of the burdens and benefits of research.

It was argued that 'over-research' was *"also about justice, that research actually should be distributed in such a way that it is equitable"* (REC 8), and that *"there's also a perception that: why do all the research in one community. Why? There're lots of communities out there"* (Researcher 1). Respondents noted that concerns about 'over-research' were likely to be raised in relation to the number of studies being done in particular communities and that *"there may be some obligation for an ethics committee to sit and say, you know, why is everybody going to this place? Why don't they go to another place?* (REC 3).

It was argued that in making selection decisions researchers "*must be careful we don't marginalize communities*" (Researcher 2). It was reported that "*we've also... not concentrated in one area ... I think we are aware of trying not to saturate a particular sector of the community with research*" (Researcher 6)*.*

Furthermore,

> *there is a sense sometimes that there are some communities that are over-studied and there are other communities that are ignored. And that might be a reason to say, 'Well, gee, we keep on going into this particular area in Site K, why are we not looking at this area in Site L as a potential platform?'* (REC 5).

It was also suggested that if a community was perceived to be 'over-researched' this might be a reason for an REC to deny approval for a study proposed there: "*So I think that would be another reason potentially why a place might be denied, is that it was over-studied*" (REC 5).

Respondents linked 'over-research' to concerns regarding the distribution of burdens between communities, suggesting that communities should be protected from being excessively included in research because this would result in their bearing an excessive degree of burden: *"Getting a single group of individuals to always participate in studies that carry with them risk, doesn't spread the risk; is not equity in society"* (Researcher 3).

> *Are we over-burdening the potential pool of informants?... If you have too many projects coming in, the same bunch of people … will be continually asked bloody questions and will be continually badgered. So you've got to protect from over-exploitation. And that I think an ethics committee has a responsibility to look for, but equally so does the researcher* (REC 3).

In addition to concerns about selection decisions which result in an unfair distribution of the burdens of research between communities, respondents also linked 'over-research' to concerns regarding the fair distribution of benefits between communities.

 *"If people aren't looking at what your needs are as a group then you're going to miss out on the benefits that accrue from research"* (Researcher 5). It was therefore argued that

> *…populations should have the opportunity to participate in research because research should be a conduit to improvement and change, and if there are groups that are being ignored … maybe they aren't seen as an economically good investment for drug companies or whatever, then [they] lose out* (REC 1).

Alongside concerns about 'under-research' (above), it was noted that, because research arguably provides resources to the communities involved, *"if you get into a situation where you just have the same people taking part, you know, nobody else is benefiting anyway"* (Researcher 4). There seemed to be a suggestion that a concern about 'over-research' might be raised as an expression of this perceived unfairness in the distribution of research-related benefits, because:

> *…there are communities which may actually have valid needs or valid questions that require research and require input in terms of research to answer those questions or address those health issues, and there, they are being neglected for whatever reason, for lack of infrastructure or that they are difficult to access or that there're language issues; or cultural issues make it very difficult to establish research in those communities* (REC 8).

The notion of the 'ORC' also reflected a concern that some communities, feel, or are, neglected, or 'under-researched': *"Maybe because other communities, the surrounding communities, won't understand why we chose those communities …They feel like we are giving those people more. What about what  they need? But we are just neglecting them"* (CLO 1).

Some community-representative respondents suggested that, emerging from the perception of research as providing communities with resources, 'over-research' could reflect jealousy of people who are not being researched, and might be raised for political gain:

> *This is to me politically motivated… Sometimes politicians know that in area A how much support do I have, because the results tell you during election time, and in area B, in area C. And then, if I see people always servicing the constituency that is not mine, I will start raising questions, 'You are over-researching people', so that I can sound very rational, reasonable for the people. Yet, I want them to spread to other areas as well as also to where it's my constituency* (CAB 7).

## 3.3 Research literacy - A lack of appreciation of how much it costs to set up research infrastructure

While arguments for the equitable distribution of the burdens and benefits of research in the way in which selection decisions are made, are valid, it was also argued that equity is an aspirational goal. Realistically, it is not be possible for investigators to invest in research and community development everywhere. It was argued that investigators must be strategic about what is most possible and where they can have the most impact given the available resources. This requires making selection decisions:

> *Well here's the interesting thing… If you really want to do good research, and you want to do it in a community, you need to put in place the infrastructure, that might mean putting up a building, staffing it and so on. You can't do that everywhere. You put it in a certain limited number of places. You pick what you think is the most appropriate one, and you don't just do your research there, you make sure that that facility can be used for other things, community outreach and so on* (REC 5).

It was suggested that when the notion of 'over-research' was raised in relation to subsequent research in a particular community, this reflected a lack of appreciation of "*how much it costs to set up research infrastructure; hire people and do that; if we could; if research was like that, we could have research at every corner like a common tearoom or something like that*" (Researcher 1).

Furthermore, owing to resource constraints, it was argued that investing in research and its associated benefits equally in all communities was impossible, and accusations about 'over-research', particularly when motivated out of a perception that some communities are losing out, reflected a lack of appreciation of that reality: "*One has to be realistic, sometimes people have difficulty accepting this,… you… cannot treat every single… disadvantaged community equally when it comes down to doing research. It's just not physically possible*" (REC 5).

## 3.4 Concern about selection decisions which undermine scientific validity

The concern that certain communities are 'over-researched' was also linked to worries about selection decisions which undermine the scientific integrity of research (through introducing bias, exacerbating the potential for contamination and co-enrolment between studies, or decreasing the representativity of the sample and thereby impacting on generalisability) (see also section D-2, Scientific Validity).

Maintaining the scientific integrity of research and avoiding 'over-research' were argued to be important reasons for ensuring a fair distribution of research between and within communities:

> *I think that's why it's important for us that we don't recruit just from one area. We make sure that we recruit from all the areas in our community, because… [otherwise] you're going to introduce bias into your studies* (Researcher 4).

It was suggested that where selection decisions led to multiple studies being conducted in one community

> *There's a problem … that's an 'over-researched community'…[because]…then you're worrying about whether [there are] contamination effects; but if you're spreading that out, then I think you do limit some of those [concerns]* (Researcher 6).

On the other hand, there was also a suggestion that repeat selection of the same community for research could actually enhance the scientific integrity of a study, in that coherent information would be collected, and so repeated selection was not necessarily 'over-research' (see also section D-2, Scientific Validity).

## 3.5 Concern about selection decisions which lack social value

Respondents also linked worries about 'ORCs' to concerns about selection decisions which compromised the social value of research (see also section D-1, Social Value). While 'over-research' was clearly linked to multiple projects being conducted in one geographical community, a major worry for some respondents seemed to be a lack of social value to the various studies being conducted there: *"if we're talking about 'over-research' we are talking about an abundance of research here in Site A where there is no need for it"* (CAB 5).

Where selection of a community for research was on the basis of an identified need or the potential for the research to benefit that community (socially valuable and responsive research), regardless of the number of projects being conducted in the area, it was argued that the community could not be considered 'over-researched': *"but there is a lot of research which is occurring around [this community], but it's related to HIV and AIDS, which is a problem in our area. So… to us it's not 'over-research'"* (CAB 6). By implication therefore, 'over-research' reflected a concern about selection decisions, which are not responsive to the needs of the community.

## 3.6 Concern about selection decisions which compromise collaborative partnerships

There was also a suggestion that 'over-research' reflected a concern about selection decisions which would lead to researchers *"competing for participants, that's not good, because [they]'re all working together and [they]'re all, at the end of the day, going for the same goal"* (Researcher 4) – in other words, that would compromise collaborative partnerships, or strain the relationships between

researchers. It was suggested that selection decisions, especially for similar trials, could raise concerns about ORC and unfairness if they undermined relationships between researchers (see also section D-8, Collaborative Partnership).

## 3.7. Summary: ORC as a concern about fair selection of participants and communities

One of the most commonly raised interpretations of 'over-research' was the fair selection of participants and communities for research.

'Over-research' indicated that the grounds on which selection decisions were made were unclear or unjustified. In some cases 'over-research' seemed to be an automatic concern about research conducted in South African communities given the history of apartheid and consequent heightened sensitivity to possible racial injustice. 'Over-research' may reflect an interpretation of research dynamics in light of enduring segregation, structural inequities and other artefacts of apartheid.

'Over-research' also represented concerns that convenience factors, at the expense of fairness, were weighted more in selection decisions than science. Although not at the expense of justice, certain convenience factors were noted to be legitimate considerations in making selection decisions to ensure the timely and cost-effective completion of research.

Concerns were also raised about selection decisions that were based entirely on vulnerability. On the one hand, 'over-research' represented concerns that 'vulnerable', economically disadvantaged communities would bear an unfair proportion of research burden because they were more likely to be targeted for research than better-resourced communities were. On the other hand, however, disadvantaged communities might be 'under-researched', neglected for, or protected from, research, and thus deprived of potential research benefits (cf. Emanuel & Grady, 2006; Mastroianni & Khan, 2001).

Concerns about 'ORCs' were also argued to be reflective of a lack of understanding of the costs involved in implementing research in a community, and the complexity of factors usually considered in making selection decisions.

Furthermore, 'over-research' was also suggested to reflect concerns about selection decisions which undermine scientific validity, social value and collaborative partnerships.

## 4. (a) Risks, benefits and a favourable risk-benefit ratio: Overview of the principle

Ensuring that participants benefit fairly from research involvement is central to avoiding exploitation (Wertheimer, 2008). Given that research is investigation into areas and testing of interventions about which there is limited existing knowledge, it involves uncertainty and inevitably some degree of risk. However, in order to be justified, the risks to which participants in research are exposed must be minimised, the potential benefits must be maximised, and the potential benefits to individual participants and to society must be at least proportional to, or outweigh the risks (Emanuel et al, 2000; Emanuel et al., 2004).

For participants and participating communities, research participation might include physical, psychological, social or economic risks and benefits (Levine, 1988). Direct benefits accrue to only to participants as *direct* result of receiving the study intervention, while collateral or indirect benefits, like capacity building, are received by participants and communities simply as part of the study, and are not tied to the specific intervention (King, 2000; Participants, 2004). In addition to benefits associated with study participation, the potential benefits of research to participants and host communities might be derived from the social value of the study, the engagement between researchers and the community, and the demonstration by the researchers of respect for study participants and communities (Emanuel et al., 2004).

In order to be ethical, the risks of research must be outweighed by the potential benefits. While participants and host communities may benefit from the contribution of research to society (social value), improvements to local infrastructure (indirect benefit), the services necessary for maintaining the welfare of  participants (ongoing respect), and capacity building and empowerment activities (collaborative partnership), only those benefits directly associated with the intervention (direct benefits) should factor in determining whether or not the risk-benefit ratio is acceptable. Otherwise the addition of unrelated benefits could be used to justify risky research (Emanuel et al., 2004; Emanuel et al., 2008). Some recent approaches to making risk-benefit assessments, however, blur the distinction between direct and indirect benefits, and include both in the assessment (King, 2000). In many respects, the prospect of direct benefit is not under the control of the investigators and is largely theoretical. Furthermore, in research with healthy volunteers the prospect of direct benefit is somewhat limited, and so risk must be weighed against the benefits to society (Jonsen & Miller, 2008).

The risk-benefit ratio must be favourable firstly to individual participants, secondly to the community, and thirdly to society at large (Emanuel et al., 2004). Given that the severity of risk and the value of benefit vary depending on biological, social and environmental context, the risk-benefit ratio

assessment must take into account contextual factors (Emanuel et al., 2004). For example, in contexts where, for various social, biological or environmental reasons the risks of a particular disease, faced by community members, are higher, the value of a potential intervention is enhanced, and so riskier research in pursuit of that intervention may be justified because the risk-benefit ratio is favourable. Similarly, in contexts where the social value of a study is high the risk-benefit ratio may be favourable, but in contexts where the research has low social value, the risk-benefit ratio may be unfavourable and the research unjustified there (Emanuel et al., 2004).

Although not part of the risk-benefit ratio assessment, it is argued that as a matter of general beneficence, benefits to individual participants and their communities should be enhanced wherever possible, particularly where these can be easily provided, and do not compromise the scientific integrity of the study (Beauchamp & Childress, 2001; Emanuel et al., 2008; Emanuel et al., 2004). A fundamental ethical challenge is that, while participants and host communities assume the burdens and risks of research, the knowledge gained may benefit others, beyond the trial participants, who have not been exposed to these risks and burdens. As such, of particular ethical concern, is ensuring that those who bear the burdens of the research also enjoy the benefits (Emanuel, 2008).

## 4. (b) 'ORC' as a concern about Risks, Benefits and the favourability of the risk-benefit ratio: Respondent perspectives on the 'ORC'

Most respondents explicitly linked the notion of the 'ORC' to ethical concerns regarding risks, benefits and the favourability of the risk-benefit ratio for research participants and host communities.

Research was frequently framed by respondents as being primarily beneficial to participants and communities. The notion of 'over-research' however, seemed to emerge out of a concern that the benefits are not without risks, and raises a cautionary flag about over-emphasis on the often uncertain benefits of research.

### 4.1 'ORC' as a concern about risks

It was suggested that the notion of the 'ORC' reflected a concern about the potential for research to harm participants and communities in some way: *"For me 'over-research' is if there's harm to the participants [and] if there's harm to the community"* (Researcher 7).

Given that any study carries both potential risks and benefits, it was argued that being exposed to multiple studies increases not only the number of potential benefits but also the amount of risk that communities and participants are exposed to: *"you're exposing yourself to multiple risks for the greater good"* (Researcher 3).

'Over-research' was contended to reflect a concern that multiple projects being run in a community, either concurrently or subsequent to one another, could result in the exposure of the community and its members to excessive risks, and that repeated exposure to research could be detrimental to the community.

## 4.1.1 Concern about physical harms –"co-enrolments might put a person into a hazardous area"

Several respondents suggested that the 'ORC' might reflect a concern about the enhanced risk of physical harms to participants in contexts exposed to multiple studies, because of increased opportunities for co-enrolments. *"I've heard concerns about co-enrolment …if they do this, it's causing harm to themselves"* (Researcher 1); and, *"there might be people who might participate in more than one study, which might… put that person in a hazardous area"* (CLO 2).

> *I am conscious of that there are studies where there've been co-enrolments, where you would find a participant being enrolled in two different studies… I think that would happen …where there's access to multiple different studies happening… if you're using two different products … you can get drug interactions"* (Researcher 2).

(See also section D-6, IC and section D-2, Scientific Validity for links to co-enrolment)

## 4.1.2 Concern about social harms – "*communities can be labelled*"

In addition to the risks of physical harm, a concern underlying the notion of the 'ORC' was the potential social harms associated with research participation (see also Section D-7 Ongoing Respect. While any study was noted to have the potential for social harms, in the context of multiple studies in the same community, the risk of harm was argued to be increased.

The notion of the 'ORC' seemed to reflect a concern about the potential for a research presence to generate assumptions, leading to stigma and discrimination of communities or groups. It was observed that "*communities where there's a lot of research happening … can be labelled*" (Researcher 2). It was suggested that the attention drawn to a particular community, even by potentially beneficial research, could harm the community: "*but whether it could do some harm… whether it's bringing too much attention to the area… that's something we'd have to think about*" (Researcher 6).

### *4.1.2.1 Concern about media notoriety- "media coverage as an indicator for 'ORC'"*

It was noted that "*too much media coverage*" and the degree of celebrity and international attention drawn to a particular area, as a result of the research being conducted there, had been explicitly linked to the notion of 'over-research': "*Somebody actually said, 'media coverage is an indicator for over-researched community"* (Researcher 1). Although there was disagreement about whether or not media coverage could indicate 'over-research', it was suggested that "*the more research that's done, the more possibility there is that it will be translated into headlines… if the name of the community is made known, they get known*" (REC 3). Extensive media coverage of research being conducted in a particular

area could also increase the potential for communities to be labelled, and could create a public perception of the community as being 'over-researched': *"The idea that ...in Site A we have too many research projects ['over-research'] comes from being talked about and from being in the media"* (CAB 3).

'Over-research' reflected a concern that research would draw negative attention to participants and host communities:

> *Front page news: 'Site A has a continuously high HIV rate'. No – that's wrong. That's not the way to do things. ...if you want to make public that the rate of HIV and AIDS among the people is increasing, there should be consultation with the people in a meeting – not in the media. Because now if a person arrives from elsewhere, they will say,'They have got a lot of HIV in Site A'. So now it ends up that the people of Site A have this stigma, for all the world to see* (CAB 3).

### 4.1.2.2 Concern about HIV/AIDS-related stigma and discrimination – "people just automatically think you're infected if you're involved"

Concerns about the potential social harms of research were noted to be more likely when the research conducted is *"around sensitive issues and possibly political issues"* (REC 3) like *"HIV/AIDS,[which] brings in a whole area of ethical issues... because it's not curable, there's no treatment and because it becomes more political than an ordinary infectious disease"* (Researcher 7).  In addition to this, because of its association with largely taboo subjects of sex and death, *"the stigma associated with HIV is intense"* (REC 3). As such, the risk of social harms to participants and host communities involved in HIV/AIDS-related research was noted to be more likely.

Several REC-respondents observed that, in their experience , when 'over-research' was raised as a concern about community-based research in the context of ethical review, it was largely in connection with HIV/AIDS research.

Of particular concern *"...is that  [these communities] can be identified with problematic social behaviours; they get inappropriate notoriety"* (Researcher 3).

> *There is this one community called Site B, where a group of HIV investigators are doing a lot of research. If I was a participant and said I was from Site B and the stigma that it is has to be about HIV. That might be an issue... [So some of my concern] might be about labelling the community as having a high prevalence of HIV... Do I really want my township to be known as this?* (REC6).

It was noted that communities being labelled in this way could have implications for how individual members of the community are perceived by outsiders:

> *There's the potential for people saying 'Oh you live in that community. Well, we know that the HIV prevalence is so high in that community because the research that comes out [[which shows that]] the TB rates are so high in that community, so you must be HIV positive'* (Researcher 5).

It was noted that simply by being associated with HIV/ AIDS research, people and communities risk stigma and discrimination, and thus the risks associated with participation in HIV/AIDS-related research are intensified for individuals and communities: *"If for instance you are involved in HIV and AIDS issues or stay in whatever community where there is research, people just automatically think that you're infected"* (CAB 2); and *"as soon as you're studying people, there'll be the implication that they must be HIV positive"* (REC 3).

The notion of the 'ORC' seemed to suggest a concern about these potential social harms and that the more research attention, particularly associated with HIV/AIDS, given to a particular community, the greater the likelihood of these harms:

> When many HIV studies are done on that area you'll find that the outside people see that differently. They might think that in that community, a lot of people in that community has HIV, which might not go down well with the community where the research is situated (CLO 2).

In combination with low levels of research literacy in the broader community (see also section D-5, IC), HIV/AIDS-related stigma exacerbates the potential social harms associated with participation in HIV/AIDS-related research. *"If people misunderstand the study they're involved in …and think that it means they're HIV positive if they're part of a research project and they get stigmatized because of that"* (Researcher 5). Particularly in populations, which are not familiar with research, the risks of these misperceptions and consequent discrimination are more likely:

> They will have that perception that these are people who deal with research with HIV/AIDS. When they come to you, it means, somewhere somehow …there is HIV and AIDS related with you… Because sometimes, when they see the vehicle from research getting into your house, then a person who is seeing it, might say, 'The car is going there every-time because maybe, so-and-so is HIV-positive'. Because you know, research is associated with HIV. To ordinary people, it will not matter whether these people are researching on HIV, but they will say 'Oh, the HIV car'. Because research and HIV were just taken as one thing. It's like a football player and a human being who is a football player. When you see him … what comes to your mind is football. (CAB 7).

It was suggested that increased frequency of contact of participants with research might be perceived to confirm others' negative perceptions, which could lead to social harms, thus increasing the risks of research involvement for participants and communities. Concerns about 'over-research' seemed to be linked to these worries about increased risk because of increased research involvement.

Furthermore, an intense or exclusive focus on a particular community or group, especially in relation to HIV/AIDS, was argued to fuel stigma:

> Because our focus has been mainly on women, you have the men saying, 'Why aren't men in research?' So, you can also then fuel a stigma that it's the women who are responsible for the HIV epidemic (Researcher 2).

A generally held perception among respondents was that the involvement of the media in clinical research exacerbated the potential social harms to participants and communities. *"Negative media*

*hype [that the] community may not need"* (Researcher 7), was explicitly cited as a potentially negative effect of research on a community, and as already noted, increased media exposure was suggested both, to be a result of increased research conducted in a community, and, to create perceptions that a community is 'over-researched'.

### 4.1.2.3 Concern about being at the fore-front of the media messages

There was a suggestion of general animosity towards the media (see section D-8, Collaborative Partnerships) and a perception that in order to sell a story the media would misrepresent research. This would, in turn, feed into the general lack of research literacy, and intensify misrepresentations and therefore, the potential for social harms:

> *Research issues were taken badly and misquoted by the media. They changed the truth of the matter... You know how the media work. They change something that's written here and then they won't do anything to take it back* (CAB 4).

> *Journalists will get hold of your [research reports] and you'll see it blown out of all proportions...You know, newspaper headlines. You have to be nightmarishly careful with reporters ... reporters are like hell.... I mean they can twist things and get the wrong end of the stick and once it gets into the newspapers that's truth as far as the whole world's concerned* (REC 3).

The notion of the 'ORC' was linked to concerns that, particularly given the potential for studies (like HIV prevention trials) to close prematurely or produce results which are not favourable, in addition to the risks undertaken by individual research participants, clinical research generates further risks for communities, because of how they might be represented in the media.

> *Without the clinical trial you wouldn't be the community that put yourself at risk for a study to stop, pause, halt or to have those negative results, because if your community took part in those studies then you also at the fore-front of the media messages and all of that* (Researcher 7).

## 4.1.3 Burdens to already burdened populations

The notion of the 'ORC' also implicated a concern that research would place further burdens on participants and communities that were already severely burdened in some way, for example by health or socio-economic difficulties.

## 4.2 Concern about benefits

'Over-research' was also argued to imply that the level of benefits to participants and their communities was unfair compared to those received by other stakeholders in the research relationship, or that the benefits of research participation failed to outweigh the risks assumed by participants and their communities: *"that there is more harm than good, or that there is something wrong with the risk-benefit balance in that community"* (REC 8)*.*

In addition to research failing to produce "*benefit because you already know what the answer is*" (Researcher 4) and thus to contribute to 'the greater good' (see section D-1, Social Value); and assertions that "*the burden of research should be borne by a larger community and that beneficence should be more widely spread around society*" (Researcher 3) (see section D-3 Fair selection);  a prominent concern underlying the idea of 'over-research' was a concern that benefits to participants and communities were, in some way, unfair.

## 4.2.1 Concern about a lack of benefit

Many respondents suggested that 'over-research' reflected a concern about a failure (real or perceived) of host communities and participants to benefit from research participation:

> *I think 'over-research' is if people are using an area repeatedly, and conducting data collection in the community, whether that's behavioural or clinical, or any form of research and … there's no benefit for the community … Community members continually participate and get nothing out of it, that would be 'over-researched'* (Researcher 7).

Ensuring that, if there are direct benefits from a trial intervention, participants and their communities are recipients is a crucial concern regarding the fairness of the risk-benefit ratio. "*If there's benefit gained from the study then the community should see that. So if interventions are developed then they should benefit from that intervention*" (Researcher 5). "*Because we would like to see if the research is done, that at least our community benefits to a portion… if they find a licensed [able] product*" (CAB 1). "*If people participate in the development of a new drug or a new product and it benefits them personally, they should actually be able to have access to that benefit for as long as it's going to benefit them*" (REC 8).

A lack of "*post trial access to the successful results of a study*" by those who participate in the research was noted to be the result of investigators failing to fulfil their responsibility  to consider "*before study activation,  what is going to be the outcome? What is the access going to be of those communities [that participate]?*" (Researcher 2), and was suggested to be likely to raise concerns about 'over-research.'

Several respondents presented 'over-research' as a concern about research placing burdens on the community without returning any kind of benefit: "*it's taking a long time and, it's really just sort of sapping the community; it's taking too much away from the community, without them seeing any results or benefits*" (CAB 3). 'Over-research' seemed to describe a situation in which the research "*has induced research fatigue*" (Researcher 3), where "*the community's… fed up and saying, 'We've had enough'*" (Researcher 5), "*After a while [they] get studied to death and [they] get fed up with it*" (REC 5), "*KZN people said we're sick and tired of all this*" (CAB 2), "*we've had enough; we don't get anything back from this lot*" (REC 3). While the sense of 'research fatigue' was linked to ongoing research participation for little if any benefit, there was also a suggestion that it was contingent on issues relating to the community-researcher relationship (see also section D-8, Collaborative Partnership).

'Over-research' *"means things happening and no solutions coming up; and only problems… and then they say …you're over-doing us, you know you're exhausting us"* (CAB 2). When research seems to fail to produce tangible benefits or solutions to challenges facing communities, there may be perceptions that research not only fails to produce benefits but burdens participants and communities.

An exclusive focus on the health-related benefits derived from the research intervention (excluding all adjunct therapies and collateral benefits) to individual participants, was noted to create significant complexities. In the face of negative trial results for example, there could be the perception that there are no benefits to balance the burdens participants and communities undertake in participating. This might give rise to the perception that they have been exploited or 'over-researched'.

> *There also can be false expectations … unreasonable expectations [of a successful trial result]… expectations [are] raised; it fails; it takes then twenty years before you get enough community support to go back and do another trial* (Researcher 3).

It was suggested that where expectations were unreasonably raised and trial results were negative, there could be disappointment among host communities, and accusations of unethical behaviour or 'over-research' were likely.

## 4.2.2 ORC as a concern that research primarily benefits researchers

Respondents' views of 'over-research' also touched on concerns that, research conducted in developing contexts by developed world investigators, was for the benefit of those in developed contexts, and thus that the research-related benefits of research do not accrue to those who bear the burden.

Beyond the participants and host communities not benefitting from their participation in research, 'over-research' was linked to concerns that research might be conducted solely for the researcher's benefit, *"without giving anything back to the community"* (REC 4). *"They think that when you're going to investigate your product with them, they won't benefit. The only person who's going to benefit it's you as a researcher"* (CLO 1).  'Over-research' was described as a situation *"where people feel exploited; where they feel the researcher's getting everything, and nothing is going back into the community"* (REC 3).

Many respondents framed this perceived unfairness as 'exploitation'. Perceptions that researchers *"take advantage of participants and host communities for their own benefit"* (REC 7) were likely to be magnified when researchers were perceived to have the trappings of wealth, and the socio-economic gap between researchers and the community was significant:

> *I think that exploitation is what happens when the area of the trial site itself is wealthy and people live there in comfort and with money, while the community outside the immediate trial site zone don't get anything…The community is being exploited if the trial has five million rand*

*but here in the community there is nothing continually day after day. And sure, with this money it's one thing to give salaries to the people who work at the trial site – but they drive around in luxury cars with all the other trimmings, and they take the community and bring the research, but nothing else is done with that* (CAB 3).

Furthermore, it was suggested that a failure to balance the risks and burdens associated with research participation with some form of tangible benefit to individuals and host communities, while researchers apparently enjoyed career advancement, was likely to raise concerns such as 'over-research':

> *I do think that if we just gathered this information, and we were publishing it, and we were going to conferences to present it, and we weren't ever doing anything constructive back for the community, then... I would be anxious* (Researcher 5).

Concerns about a lack of tangible benefit to participants and communities, were noted to have an enhanced likelihood of being raised with regard to observational research, where the direct benefits of the research may be minimal: "*I do think it is dangerous to do research that is entirely observational and never amounts to any practical applications for the community... I think then they have every right to feel like guinea pigs*" (Researcher 5) (see also Section D-2 Social Value; Section D-7 Ongoing Respect).

It was suggested that 'over-research' might be linked to concerns about a failure to provide tangible benefits in purely observational research like epidemiological studies and population surveillance studies (DSS), given that these studies usually monitor the health of unhealthy and impoverished communities for significant lengths of time and might actively resist beneficial interventions because of their possible impact on the validity of the study:

> *If you're working in a very poor community - very impoverished; high unemployment; high mortality rate from HIV - you have to be engaging in interventions that can lead to direct [tangible] benefit. You can't just be engaged in counting the deaths* (Researcher 3).

### 4.2.3 ORC as a concern about a failure to demonstrate reciprocity to communities

In addition to balancing the risks of research participation, it was suggested that the provision of some form of benefit was an important aspect of enacting reciprocal justice obligations to communities and participants: "*They should certainly, gain from having contributed to the science*" (Researcher 5). Accusations of 'over-research' could represent a concern about a failure to demonstrate reciprocity through some form of benefit to participants and their communities.

> *I don't think that researchers should just take communities' [information]. We'll be here… seven years. It's a long time to be immersed in the life of a community. And you can't just, go in there, take your data and move out … So, I just think that …it's not ethical to just come into a community to take stuff and leave. That your responsibilities are what do you give back?  And what you give back is a tricky question, but it is about, in little ways, can we make a difference?*

> *... and I think that that's a responsibility of researchers doing this kind of work. You just have to* (Researcher 6).

While it was acknowledged that, "*there might not always be a direct benefit*", from research in terms of benefits from the intervention specifically, "*but ...there can* [and should] *be indirect benefits... I would like to think that there's some kind of positive effect, spill over, to the community*" (Researcher 1). Most respondents seemed to broaden the definition of potential benefits: "*Research provides employment opportunities, certainly provides capacity building within the communities and hopefully provides some level of empowerment through all those things*" (Researcher 5), among others. "*You've given something back to the community and not just taken their participation to get your information*" (Researcher 4). "*I think that obviously what you want to avoid is the exploitation of communities where information and biological samples and data is taken from them in exchange for nothing*" (REC 8). Furthermore, in some cases indirect benefits were argued to be significantly valuable, and to make research participation worthwhile, even in the absence of direct benefits:

> *Even if there is nothing that remains with people, that can be touched by hand; that out of the study, this is a vaccine, and we became the first recipients of the vaccine as the people who had been researched; even if that is not the case; even if it could not be said 'this is a product you can use it, we've found it's good', the education in the process ...has been a positive effect on the community ...If you can compare two communities the community that has been researched, and a community that has not been researched, Site A is better off* (CAB 7).

Many community representative respondents explicitly argued for access to indirect benefits as obligatory, and seemed to pay less attention to the question of access to the product under study (see also section D-7, Ongoing Respect). Community respondents argued for economic upliftment of communities, education and employment opportunities as benefits that communities should receive as a matter of course, in exchange for their participation in research.

### 4.2.4 'ORC' as a concern about what constitutes fair and appropriate benefits

Several respondents argued that communities should have a say in what would constitute fair benefits for their participation: "*I think it depends on the community, what they might want to gain from research*" (REC 8), and "*what is provided has to be negotiated with the communities*" (Researcher 3). Thus, the perception that there has been a lack of benefit, leading to accusations of 'over-research', could reflect disagreement in the benefit negotiation with communities, or that there is a mismatch between stakeholder perceptions of what would constitute fair benefits, and what is in fact provided.

The relative value that communities and researchers respectively assign to potential research-related benefits may differ. For example, it was noted that, while researchers might consider capacity building, and the education of communities about HIV/AIDS, to be fair benefits in HIV prevention research, communities might consider development focussed interventions to be more appropriate and fairer, and may not view HIV education as a fair benefit:

*Perhaps what may have been negative or bad, is that people had a view that good things weren't really happening, and that perhaps there wasn't sufficient focus given to development. People thought that they weren't being helped by the research. So, although they were being capacitated regarding HIV and AIDS, with regard to development they felt neglected* (CAB 3).

It seems possible that, in addition to a disparity in the way in which different stakeholders define researcher obligations to address participant and community needs (see also section D-2, Social Value; Section D -7 Ongoing Respect), the notion of 'over-research' emerges in the context of broadly divergent opinions on how participants and communities should benefit from research participation.

*[What should researchers and sponsors be required to provide to the communities in which the research is conducted?] ...How much? And it's a fine line between buying over a community and fulfilling a reasonable social responsibility to that community. I think that it's commensurate on the amount of research; the scale of research; the long term presence of the researchers. It can't be too much it shouldn't be too little. That there's got to be social responsibility and yet not buying over the community.* (REC 1).

In addition to concerns that research has failed to benefit communities in some way, 'over-research' was also argued to represent concerns that while, there may be benefits provided to communities, these benefits are, in some way, inappropriate. For example, they are not commensurate with the burdens borne by participants and communities, or the level of benefits received by communities is unfair in comparison to the benefits that accrue to researchers and sponsors.

*For me, if I were to examine the idea [of 'over-research'], it would perhaps mean that research is conducted, and that one finishes, and another starts, and it is conducted, and it finishes, and another starts. So, these people then become like slaves that do different types of research – this would be a good description of the term 'over-researched.' Or possibly too if one research project is conducted and finishes and no 'thank you' is said, and instead they say "we have conducted this one and we are starting another one, and we don't give any feedback, and then we start another one, we finish it and we send it to ourselves – we send off the good outcomes back to where we came from – and finally at the end we say 'thank you.' But not in a sustainable way either – maybe they just give everyone a present like a watch or something* (CAB 5).

Although a few respondents suggested that "*sometimes it's better to do something in kind for a community, put up a football field*" (REC 3), most seemed to suggest that benefits which were unrelated to health and community development might be inappropriate: "*being given more blinking playing fields, wasn't the intention. They're getting playing fields as opposed to things which can uplift them*" (REC 7). It was argued that, not only could such benefits increase concerns about 'undue inducement', but they also did not fulfil social responsibilities:

*That there's got to be social responsibility and yet not buying over the community...if you simply go in and start building swimming pools and football pitches and leisure centres, then it'd be very hard for a more vulnerable individual within that community to actually say no, to that research* (REC 1).

There were several suggestions that communities might benefit from the donation of research infrastructure or the building of schools and clinics, however, there also seemed to be some discomfort

regarding these as benefits because of concerns about sustainability (see also section D-7, Ongoing Respect):

> *I'm not a big one for having to put up clinics and having to provide all sorts of infrastructure, because, you know, it isn't the infrastructure that counts it's, actually the care delivery. None of the companies [sponsors] are ever going to be able to afford salaries to [support] the… healthcare workers and [delivery of services] outside of a research project* (REC 6).

Furthermore, while there was broad agreement that "*the research structures must remain with the community, so that the community will continue making use of it*" (CAB 6), community representative respondents expressed concern about the value of concrete infrastructure as a benefit without financial and human resource support:

> *I don't see how well this will work with the researchers gone. Even if they have left behind their park-homes and their computers, even so there will continue to be the problem of maintenance and electricity and things like that. These park-homes are good, but what will we do with them?* (CAB 5).

Some argued that concrete benefits like buildings did not constitute fair benefits. Fair benefits rather, included increased knowledge and understanding, enhanced health literacy and increased research literacy, which would benefit the entire community, rather than just the trial participants:

> *One of the things that can be done if the researchers are coming to introduce their research here if they can come with the donors, who are sponsoring the research and then maybe look at the infrastructure within the area … and then maybe try and upgrade those towards the benefit of the community, or the education and information that they are getting, I think that can be great* (CLO 2).

## 4.2.5 'ORC' as a concern about broader beneficence and social justice obligations

Beyond balancing the risks of research and providing tangible benefits to participants and communities, respondents noted that researchers have general beneficence responsibilities to participants and their communities. It was argued that researchers should be cognisant of the context in which they work, and should fulfil certain social justice obligations. Several respondents suggested that fair benefits to host communities would include some sort of 'collateral' or ancillary benefit (see also section D-7, Ongoing Respect).

There seemed to be a suggestion that 'over-research' was a concern about a failure to acknowledge and address these broader beneficence and social justice responsibilities. Defining the specifics of these obligations is rather subjective and a potential source of conflict. While some positions might argue that these are essential components to ensuring fair benefits, others worry that addressing these issues could be seen as 'undue inducement':

> *You see, we used to differ with the researchers when it comes to that …We differentiate very well bribing people. We understand the concept of ethics very well. But, the research must have a social responsibility. To come to do a research to a person who is dying of hunger, and all you*

*are interested in is to research about the person, and you have nothing to do with the hunger problem a person is experiencing, to me, [then] research does not have a human face. There is this thing humanity. Humanity has nothing to do with a bribe; humanity is not against ethics. Humanity is being human… Now that is where we used to differ with the researchers…When they have come into the area they must be able to identify, problems [and consider] how can we address these problems…because these are people you are researching* (CAB 7).

'Over-research' seemed to reflect a concern about benefits of research that were inappropriate, in that they failed to contribute to community upliftment and were not sustainable.

## 4.2.6 ORC as a concern about benefits to vulnerable populations as 'undue incentives'

At a more fundamental level, 'over-research' seemed to suggest a concern that researchers might take advantage of the poor socio-economic conditions of certain communities. In resource-limited contexts researchers might offer benefits which were unfair in relation to the burdens of the study, but which participants would nevertheless accept because they do not recognise the unfairness of the offer; perceive meagre benefits to be better than nothing; or feel that they have no option but to accept. 'Over-research' therefore implicated a concern about benefits compromising the voluntariness of informed consent in vulnerable populations (see also section D-5, IC).

> *Let's take an example of the multi-national drug company…the reason they coming to do research here is not for altruistic reasons, they're coming here because they've got a captive audience, they can do the research cheaply, and if that succeeds they are going to make billions and that community will be forgotten* (REC 4).

It was argued that researchers might be able to conduct research less expensively with impoverished populations because they would be more likely to accept less for their participation. Research was noted to be a source of benefits, like health literacy and education, medical care, employment and capacity building, to which the participants and communities would otherwise have been unlikely to have access. As such, there were concerns that these communities would have little choice but to participate, and might lack the bargaining power to negotiate for fairer benefits, than the little that researchers might offer in exchange for participation.

There were also concerns that in the face of inappropriate benefits 'vulnerable' participants and communities might have difficulty fully comprehending, or might pay less attention to, the risks involved. *"Possibly communities could be exploited if they're 'over-researched' because the researchers could use the …the reimbursement to make communities accept the research"* (Researcher 7) because *"poor people need money… So they'll do anything for money, and have more difficulty really understanding the risk that's involved"* (Researcher 3). *"It is the group who will be dependent on that little handout that they get"* (REC 7). 'Over-research' also seemed to reflect worries that researchers might use their position of power, of being able to provide incentives or resources that would

otherwise be unavailable, to manipulate communities into accepting and participating in their research.

> *You don't want to have perverse incentives, that people are being bribed, the communities are being inappropriately incentivised, where - you are trying to convince a community or individuals in a community to take an unnecessary risk without comprehension in exchange for something inappropriate that effectively would be a bribe. I think anything where the balance of power is inappropriate or where the risk benefit is not balanced could raise concerns* (REC 8).

Navigating the distinction between appropriate benefit for time and effort, and inappropriate benefit or 'undue inducement', was noted to be a challenge:

> *Benefits in a poor community pose numerous problems. People get quite grasping about money …you're getting on that nasty slippery slope to undue incentives…Listen these are two edged swords because they could be seen as undue incentives if you're giving people money and you're giving them cool-drinks and you're giving them parties and all that sort of thing, you could see it as reciprocity for time and effort and all that; but you can also see it as bribery* (REC 3).

However, the paternalistic response to concerns about 'undue inducement', particularly with regard to communities that are considered to be vulnerable, of decreasing the benefits to participants, could in fact deprive communities of benefits, which in turn could lead to accusations like 'over-research' (see section D 4.2.1, above).

## 4.3. Being labelled 'over-researched' in itself is perceived as a social harm

The mere fact of being labelled as 'guinea pigs' or 'over-researched' was argued to be stigmatising, and thus to represent a risk to participants and communities. Being identified in this way, "*that they will always be the target group"* (REC 7), suggested a subjugation and dehumanization of the group labelled as such (see also section D-7, Ongoing Respect). Being labelled as 'guinea pigs' was noted to carry a certain stigma, which could colour the interactions between the researched community and others:

> *Like it's being like a traumatising issue ... people talk to other people as like you guinea pigs and you all those things... And the people from other communities knowing that this is happening there, then they will start having problems with you and they will start influencing the people there* (CAB 2).

There was the suggestion that being labelled as 'guinea pigs' or 'over-researched', like many of the other potential social harms associated with research participation, had its roots in a lack of research literacy and conveyed a stigma about the competence  and understanding of  research participants:

> *The participants are very, very upset that they were being treated and reported in this derogatory manner by community members who didn't even understand their role and participation in this study. Some even said to us, 'How dare community members even say and call us guinea pigs. Because they're assuming that we know less; they're assuming that we didn't know better. Come talk to us as participants, because we know what we engaged in, we know this information'* (Researcher 7).

Community-representative respondents, many of whom were from Site A, which has been openly labelled as 'over-researched' (cf. Ndebele, 2003), adamantly argued against the notion of 'ORC' being applied to their community. *"It would be lies. It would be lies because there is no 'over-research' in Site A"* (CAB 4)*.* It was argued that the accusation that site A was 'over-researched' reflected "*misperceptions that too much research has happened"* and that the "*community, [were] totally against those misstatements"* (Researcher 7)*.* In fact, all the community-representative respondents were quick to point out that the particular community in which they resided was far from 'over-researched', and in fact required more research: *"We really want to welcome research again. We will welcome further research. We really want it"* (CAB 5).

## 4.4 'Over-research' is a risk that communities will not benefit from future research

Broadly, there seemed to be a worry that researchers may be disallowed from conducting research in communities which are deemed to be 'over-researched'  or that, as a result of being 'over-researched', there would be a general reluctance to participate in research. As such, participants and communities may be harmed, or at least may fail to benefit, because they do not access potentially beneficial research and interventions.

*"The ultimate consequence will be that the community will just say by whatever means to the researcher, 'Go away'"*(REC 1). "*People will just say, 'Nooit. Go away. We've had enough of you researchers"* (REC 3); "*People don't want to participate … you'll find very few participants"* (CAB 1). *They might become cynical about research, they might become disenchanted with research, they might they might start to believe that it's something that they shouldn't be participating in, that it has a negative in that studies can't be conducted* (REC 5).

It was noted that not only would it be difficult to conduct research, but a sense of having been 'over-researched', owing to a failure to benefit, could result in future lack of benefits because participants and communities would distrust researchers and would be unlikely to engage with them:

> *The effects on people in an ORC may be very extensive…You will see it because the people will say, 'Let's lock our doors when the research is coming back and wanting to do more. We'll never participate – what do we get from it? Because they are conducting the research; they say that we will be helped but then they scarper and they give us nothing and we remain just as we are'. Because they will not welcome research again they will not be helped by anything whatsoever that comes afterwards* (CAB 5).

A researcher-respondent reported that even perceptions that a community is 'over-researched' could result in the non-selection of that community for future research, and this could lead to the community forgoing potential benefits:

> *We've also been told that Site A is 'over researched', I've heard this many times. We've just ended our first ever clinical trial there and it's sad that that's the perception, because we will not be doing any other future clinical trials in Site A. It's a combination of factors, but one of the*

*driving factors is the perception of 'over-research'. The community members were very upset about it - they said they don't understand where people have made this perception that Site A is 'over-researched' because they would encourage more research to take place there, because it's through the research that they've developed a good understanding of HIV the disease AIDS, treatment, care, and they were quite sad that our last meeting with them was the last meeting ever* (Researcher 7).

Ironically, while the notion of the 'ORC' seems to be a concern about communities and participants failing to benefit from research, the use of the term could ensure that they do not benefit from future research.


There seemed to be general concordance among respondents that communities should determine whether or not they participate in research (see section D-5 IC; section D-8 Collaborative Partnerships), that concerns such as 'over-research' are only of concern when raised by the community in question, and, that as long as the community believe that they are benefiting from research participation, there is no problem. However, concerns were raised that, particularly in resource-limited settings and in the context of limited choices outside of research, research-related benefits could blind participants and communities to risks, such as 'over-research'.

*I can think of reasons why a community might not say they were 'over- researched', even if they were - because of the benefits. I think there's a balance that needs to be had there: 'We take part; we get money to reimburse us for our time and our effort and inconvenience. And we get all this training, people get trained. So people like the idea of research and they may not identify the 'over-researched' problem and so to some extent I imagine a lot of responsibility lies with researchers to be aware of what's going on. I think [over-research is] the community's being fed up and saying, 'We've had enough," but, I can also see that there would be people who say, 'But wait a minute, if this group leaves I lose my job' …That's a fine line that would have to be walked and again the responsibility would lie with the researchers, to make sure that it's still appropriate for them to be in a community* (Researcher 5).

Because there may be stigma attached to the label, 'ORC', and because of the benefits that they receive from research participation, communities might not wish to be identified as 'over-researched'. Furthermore, they may not have the breadth of perspective to attend to or may chose to ignore possible ethical concerns about excessive research. Researchers therefore, have a responsibility to be aware of the potential problems of extensive research involvement in a community, and to ensure that studies are still appropriate in a community and are not placing communities or participants at undue risk when making selection decisions (see also section D-3, Fair Selection).

## 4.5    Summary: ORC as a concern about risks & benefits

Most respondents explicitly argued that 'over-research' represented concerns about the risks, benefits and the risk benefit ratio of research for participants and host communities.

'Over-research' represented concerns about the potential for research to harm participants and communities physically or socially, and that multiple studies could increase the amount of risk, to which participants and host communities were exposed. Low levels of public understanding of research, high levels of stigma about HIV/AIDS, and the possibility of being negatively portrayed in the media redoubled the risks of extensive research involvement (cf. Milford, Barsdorf & Kafaar, 2007).

'Over-research' also reflected concerns that research failed to benefit participants and communities, that the benefits to participants and communities were minimal and unfair in relation to benefits to other stakeholders, or that the benefits failed to adequately balance the risks of research participation.

Perceptions of 'over-research' seemed to emerge from discordances among stakeholders in defining fair and appropriate benefits for research participation. There were a wide variety of opinions on what would constitute fair benefits and it was noted that different stakeholders might value the potential benefits differently. Perceptions of 'over-research' could arise as a consequence of a failure of research to produce direct benefits, or because of a lack of attention to ancillary benefits and social justice issues. Assessment of the fairness of research-related benefits seemed highly variable and subjective.

'Over-research' also suggested a worry about an inequitable distribution of benefits between researchers and communities. Concerns about researchers benefiting from research at the expense of communities seemed to be exacerbated when the socio-economic gap between them was larger.

Most respondents were concerned about a failure to provide benefits to communities, but were equally worried about the impact of benefits on the motivations of people to participate, and the potential for benefits to act as 'undue inducements' or coercive offers, particularly with regard to research with impoverished or vulnerable groups. However, reducing benefits to research participants was also noted to potentially raise concerns about 'over-research'.

Being labelled 'over-researched', was itself noted to be a potential social harm, which could deprive participants and communities of future access to potentially beneficial research interventions, because they refuse to participate (cf. Hawkins, 2008), or are prevented from participating. For this reason, it seemed that communities may not want to be identified as 'over-researched' even if, the vagueness of the notion notwithstanding, they really were.

## 5. (a) Informed Consent: Overview of the principle

Informed consent (IC) is recognized as a fundamental aspect of the ethical conduct of research and is critical to the protection of research participants from exploitation (Emanuel, et al., 2000; Emanuel et al., 2004; Hawkins & Emanuel, 2008; Lindegger & Richter, 2000; Marshall, 2007; Macklin, 2004). IC embodies the principle of respect for persons, and is grounded on the notion of upholding autonomy (Brock, 2008; Emanuel et al., 2000; Levine, 1988). Voluntary consent to research participation by competent individuals, based on relevant information, is a cornerstone of ethical research (Emanuel et al., 2000, 2008; Levine, 1988). Enrolling individuals into research without their consent, constitutes treating them as 'mere means' to an end [instrumentalisation], and could lead to charges of exploitation (Emanuel et al., 2000, 2008).

The purpose of IC is to ensure that individuals are able to voluntarily decide whether or not they enrol in research, based on relevant information about the research and its alternatives (Emanuel et al., 2000, 2008). Valid consent requires that potential participants: receive accurate, complete, relevant and understandable information about the research, including the purposes, methods, risks and benefits of, and alternatives to, the research; fully comprehend this information; consent voluntarily without coercion; and are competent and able to make independent decisions (Emanuel et al., 2000, 2008; Levine, 1988; Lindegger & Richter, 2000; Marshall, 2007).

There is consensus about the importance of obtaining IC for research participation, and IC features in most recognized local and international ethical guidance and policy documents (cf. CIOMS, 2002; Declaration of Helsinki, 2008; SA DoH, 2004; 2006; SA MRC, 2001; 2003; UNAIDS-WHO, 2007). However, its practical implementation is complex (Kass, Maman & Atkinson, 2005; Lindegger & Richter, 2000; Marshall, 2006; 2007), even among educated populations in well-resourced settings (cf. Elbourne, Snowdon & Garcia, 1997; Featherstone & Donavan, 1998; 2002). Various social, cultural and linguistic disparities between researchers and target populations in developing contexts can make IC more challenging (Emanuel et al., 2004; Marshall, 2006; 2007) (cf. Barsdorf & Wassenaar, 2005; Gikonyo, et al. 2008; Kass & Hyder, 2001; Kass, et al., 2005; Leach et al., 1999; Mfutso-Bengo, et al., 2008; Molyneux, Peshu & Marsh, 2004; Molyneux, Wassenaar, Peshu & Marsh, 2005; Pace & Emanuel, 2005; Woodsong & Abdool Karim, 2005). In these settings, it is suggested that valid consent requires consent procedures, including: information disclosure, recruitment methods and the use of incentives for participation, to be culturally and linguistically appropriate to the context (Emanuel et al., 2004).

## 5. (b) 'ORC' as a concern about IC: Respondent perspectives on the 'ORC'

Although not a dominant theme in respondents' discussions of the notion of the 'ORC', the principle of IC seemed, nevertheless, to be an aspect of understanding it. Firstly, 'over-research' seemed to represent a concern about the potential for impaired decision-making, particularly in resource-poor communities, because of challenges in understanding research or susceptibility to 'undue inducement'. Of particular concern was that researchers would take advantage of this impaired decision-making capacity to further their own interests. Secondly, respondents suggested that claims of 'over-research' were based on misunderstandings and misperceptions about research, which might be rooted in problems in the IC process.

### 5.1. IC as an important protective factor against 'over-research'

Respondents generally perceived meaningful IC processes, or the failure thereof, to be a defining feature of an 'ORC'. Community representatives argued that if there was meaningful IC for research involvement, then there could not be any concern about 'over-research'. By implication, 'over-research' was viewed as a concern about improper IC:

> *I don't think there's too much research. Because what is being done by the [research organisations] is something that is accepted by the community – they haven't got a problem with it... We didn't see any sign that the people of Site A have been 'over-researched'. We arranged a meeting and the people said that they are happy to come to this centre voluntarily, and so that's why I say no. All was fine in the community. In my opinion, it is not an over-researched [community] here in Site A* (CAB 3).

In contrast, an 'ORC' was described as a situation in which there was a failure to ensure that sound IC processes were followed: *"They come to do the research but they don't explain exactly why it's being conducted, and what results are expected, and there is no signing of the consent form"* (CAB 6).

Generally, concerns about 'over-research', relating to IC, seemed to implicate the standard components of valid IC, including concerns regarding information provision, understanding, and voluntariness.

### 5.2 Concern about the potential for impaired decision-making

Respondents connected the notion of the 'ORC' to concerns about a lack of capacity to provide valid IC in certain communities. It was argued that researchers may take advantage of this lack of capacity, and that these communities may thus be vulnerable to repeated selection for participation in risky research. It was argued that, particularly in resource-limited communities, there might be low levels of education, limited access to healthcare and a lack of familiarity with research. As such, ensuring that potential participants and their communities fully comprehend all relevant aspects of the research in order to provide meaningful IC, was highlighted as a significant challenge. Moreover, 'ORC' seemed to

represent a concern that the benefits provided as part of research might result in participants failing to pay adequate attention to the risks of a study (see also section D-4, Risk-Benefit).

## 5.2.1 Concern about misinformation & misunderstanding

It was noted that obtaining meaningful IC and avoiding misinformation is a challenge in the South African research context, as there are frequently social, cultural, and educational disparities between researchers and participants. Furthermore, there may be a need for translation and basic education about what research is.

Ensuring that communities, who may be unfamiliar with scientific concepts and ideas about research, are able to fully understand and make informed decisions about research participation, was noted to be a challenge and to require significant efforts by the research team in order to avoid misunderstandings. There was general agreement that these efforts required engagement with and education of communities about issues, which were broader than the specific study and included health issues as well as basic scientific and research concepts. Without this basic education, it was unlikely that communities would understand study specific information.

It was also observed that in addition to difficulties in ensuring accurate translation of research instruments and informed consent documents, capturing culturally and contextually defined connotations of language might present significant challenges and could create the potential for misinformation and misunderstanding.

Where translation is inaccurate or carries the wrong connotations, misinformation might be transmitted to communities, leading decisions to be made based on an incomplete understanding of the research.

### 5.2.1.1 'ORC' as a concern about exacerbating challenges in understanding: "the more studies you do the greater that problem is"

It was suggested that 'over-research' reflected concerns that the difficulties in, and worries about, ensuring valid and meaningful IC, which are inherent in any research interaction and are accentuated in resource-limited settings, might be exacerbated in a situation in which there are multiple studies:

> *If you take it that one study, a single study carries with it risks of miscommunication… inadequate transfer of information… Then I guess arithmetically the more studies you do the greater that problem is. [Over-research] could actually be a worry about that after a while* (REC 6).

### 5.2.1.2 'ORC' as a concern about confusion leading to impaired IC processes: "that's when they are over-researched, when they have become confused"

Several respondents linked concerns about 'over-research' to potential confusion, which might result from multiple studies giving different information to participants from the same community:

> If there are many research [projects] around the community, sometimes that can cause some problems... I think there would be confusion...the community can be confused...because this research is doing this and another organisation is doing something else... This has the potential to confuse people, and that's when they are over-researched, when they have become confused about what is happening amongst them, in my opinion, that's a case for saying that it is 'over' now, let's stop it (CAB 3).

### 5.2.1.3 'ORC as a concern about confusion leading to compromised science

In a context where there are multiple ongoing projects, the potential for misunderstandings, misinformation and confusion among study participants was argued to be enhanced. This might be especially likely where different studies draw participants from the same community, and people participating in different trials are likely to be engaged in informal discussions with one another. This could create difficulties in ensuring clear differentiation between information about different studies, and poses challenges for the IC processes of each individual study.

Of particular concern, was that the confusion generated as a result of several different organisations simultaneously disseminating different information to a community could lead to protocol violations, and that these in turn, could compromise the scientific integrity of the studies (see also section D-2, Scientific Validity). "*People could be talking about different protocols and confusing one another... imagine the crossed lines and the incorrect messages and the misunderstandings that get conveyed. I imagine that within the community there'd be the possibility of confusion*" (REC 6).

It was argued that 'over-research' reflected concern that confusion between study messages and misunderstanding of information could enhance the potential for co-enrolment between studies. *We've had situations where participants have participated in two trials simultaneously because they may have gotten a mixed message that it's ok to take part in two trials at the same time, testing different products* (Researcher 7).

## 5.2.2 Concern about limited voluntariness & 'undue inducements'

In addition to exacerbated difficulties in ensuring complete understanding of study information and the accurate transmission of information, respondents raised concerns about compromised voluntariness and limited autonomy in decision-making among potential participants and host communities in resource-limited settings: "*'Over-research' implies that the some of the ethical principles are being breached in that community so that the community is not able to be fully autonomous*" (REC 8).

Respondents linked concerns about 'over-research' to concerns about 'undue inducements'. Of concern was that any incentive to participate would be so attractive to people with limited resources that it would lead them to agree to participate without adequate consideration of the potential risks. It was argued that poorer populations would be more likely to accept fewer benefits in exchange for greater risks, than better-resourced populations, and might be more easily 'blinded' to research-related risks. As such, researchers might take advantage of the resource-poor circumstances of these populations and target them excessively with high-risk research because they could do more risky research while having to provide fewer benefits:

> Well there's always an argument, you know, people die from clinical experiments right. So,… how much is free will? How much was that incentive, an undue incentive? … Which is the issue that you deal with. For poor persons who, you know, bend down and pick up two rand off the street with their teeth if they have to, any cash incentive can be an undue incentive. I mean, poor people need money, right? So they'll do anything for money, and have more difficulty really understanding the risk that's involved. I think you have to be very cautious about that when you do it (Researcher 3).

### 5.2.2.1 'ORC' as a concern about perceptions of 'obligation' to participate and 'coercion'

'Over-research' also implied worries about voluntary consent and a perception by community members that they could not refuse to participate in research:

> There is also the question of abusing people; of taking advantage of their disadvantaged state or their poverty, and giving them a feeling of being obligated to participate when in fact they needn't. A sort of coercion, although they are told that this is voluntary (REC 2).

'Over-research' was also a concern that rather than acceptance, agreement to participate in research without question reflected a lack of voluntariness, and a perception by participants that they might be negatively affected if they refuse to participate in a study:

> Are you over-exploiting the patients who can't say no? There's an example of this worry about informed consent and voluntary participation…there were a whole lot of women in one of those big studies and they all got told, you know, the informed consent thing and told what the study was about, they could withdraw and their treatment wouldn't be affected  etcetera… Because a lot of them actually believed that. And, by-and-large they all signed on and they thought that they would lose their access to treatment if they didn't. All the rules had been gone through religiously, but they still thought that (REC 3).

### 5.2.2.2 Power and social inequities

The notion of 'over-research' also implied concerns about the impact of power disparities in the relationship between researchers and communities, especially resource-limited communities, on the IC process: "*What one has to look for is the power relationships [in communities and between community members and researchers] Can people say no? Can they refuse? Can they withdraw?*" (REC 3).

 In addition to disadvantaged populations feeling that they have no option to refuse participation, it was argued that background vulnerabilities, emerging from educational differences, a history of deprivation and degradation (lack of a sense of entitlement), and pre-existing social and power

inequities (doctor-patient relationships), might undermine voluntariness, resulting in compliance with researcher wishes and populations being seen as convenient for research (see also section D-3, Fair Selection). *"Is the approach by a doctor or scientist itself a danger, in making people feel obligated to participate?"* (REC 2).

> *Your power relationship is subservient. I mean, you know, middle-class people …have more agency … So the more empowered you are, the more likely you are to stand up for your rights.  I mean, poor and oppressed communities were historically exploited. They're always in a weak position.  And rural black communities here have been exploited … They're in a weak position. The greater the social gap, the greater the possibility of exploitation* (Researcher 3).

It was noted that refusals to participate are an important indicator of voluntariness and validity of the IC process: *"We've gone to communities where communities didn't accept us which is a… marker to say that communities have had a choice not to have research in their area"* (Researcher 7). 'Over-research', therefore, was a concern about compromised voluntariness in research situations involving historically disadvantaged communities, where there are low rates of refusal to participate:

> *We have very low rates of refusal to participate, people are compliant… because our communities are vulnerable and they and don't have the sense of entitlement and… you know, 'the doctor knows best … he went to university and I didn't', all those gradients, let alone the political history"* (REC 6).

## 5.3 Concern about complacency and impaired IC

It was also suggested that 'over-research' reflected a concern that in communities in which there was ongoing and repeated exposure to research, the IC process could be compromised, by complacency and inadequate consideration of the risks of study participation, by the potential participants.

> *After a while it could be that community's response to a new study would 'oh ja that's fine', because 'we do studies'. So there would be almost less communication, because people would switch off early in the process because the ambient culture might be that, 'We are people upon whom studies are done, and so it doesn't actually matter what you come with, we will say yes. And we will say yes also, because we know you guys are a source of medical care, and we've seen what happens to our friends and neighbours and, generally speaking, what you do is ok so, don't worry about the details.'  The difficulty with that, is that should things not go so beautifully well you get this meltdown like with the [PrEP studies], where there was huge outrage and conflict between the researchers and participating communities. So I suppose it could mean that, there's familiarity, and … you become less vigilant when it comes to your own rights, especially your right to be informed* (REC 6).

It was noted that a failure to engage adequately in the IC process, while 'convenient' in the short-term, could have serious long term consequences for both researchers and communities, particularly if the studies do not go according to plan.

With multiple projects, in addition to the concern about participant complacency and acquiescence in the IC process, 'over-research' was also a concern that researchers would allow ethical standards to drop, and would devote inadequate attention to IC processes, because the assumption is that people

already know. "*I think maybe the researchers benefit because they think that the people know everything about the research*" (CLO 1).

## 5.4 'ORC' itself emerges from miscommunication & misunderstanding

The notion of the 'ORC' was regarded with suspicion by several of the REC respondents, who questioned its existence as a formal idea in research ethics discourse. As such, it was suggested that concerns about a community being 'over-researched' could have their roots in rumour and were likely to arise out of misunderstandings and miscommunication between researchers and communities:

> *It [over-research] might be partially misinformation and that's why... the informed consent process is so critically important because if you just get a little bit of misinformation that spreads throughout the community then maybe that is how that idea emerges* (REC 8).

### 5.4.1 Unrealistic expectations and perceptions of a failure to meet obligations

It was noted that worries about 'over-research' could reflect perceptions that researchers have failed to deliver on obligations to participants and communities (see also sections D-4, Risk-Benefit; D-7, Ongoing respect). These obligations, however, may be defined differently by various research stakeholders or may be based on unrealistic expectations and misunderstanding, possibly arising from the IC process, of the difference between research and healthcare.

> *They don't understand the difference between service delivery sometimes and health research, and that researchers are here to do research, and to answer some of those different questions. They're not here to address service delivery issues* (Researcher 7).

It was therefore suggested, that perceptions of 'over-research' might emerge from a failure in the IC process, in that 'unrealistic expectations' imply that, the research purposes, and the type and scope of the potential research-related benefits, were not fully understood by participants and host communities at the outset.

### 5.4.2 'ORC' as emerging from mistrust, confusion and rumour

Trust (cf. Molyneux et al., 2005) or a lack thereof, was identified as contributing to IC challenges and misunderstandings, and as another factor underlying concerns about 'over-research' (see also section D-8, Collaborative Partnership).

In the context of standard difficulties like translation of complex scientific concepts, ensuring valid and meaningful IC was noted to be further complicated by confusion about, and suspicion of, research, particularly HIV/AIDS related research, which has generated political debate. As such, *"When you talk about HIV/AIDS people are suspicious about anything ...if you bring out something new, the community will ask, 'Is this thing not gonna give me AIDS?"* (CAB 1) (see also sectionD-4, Risk-Benefit).

Furthermore, South Africa's history of racial oppression and abuse, is a significant contributor to a climate of suspicion of research. It was argued that the general sense of mistrust, rooted in South

Africa's apartheid history, held by many communities towards research and researchers, further complicated the context for obtaining valid and meaningful IC, and created the space for misunderstanding and the emergence of rumours about research, including perceptions of 'over-research' (cf. Barsdorf & Wassenaar, 2005).

As opposed to identifying an objective or concrete situation, the emergence of the notion of the 'ORC' was suggested to be emblematic this context of misunderstanding, suspicion and rumour:

> "*It's a perception it's not the actual reality… Over-research is like, you know, long ago some people will would say, 'This disease is spread by a white person because he wants to terminate black people' …which is not a true story* (CAB 7).

## 5.5    Summary: ORC as a concern about IC

Although concerns about IC did not receive significant attention as directly underpinning the notion of the 'ORC', it was argued that if there was meaningful consent and community consultation, there should be no concern about 'over-research'.

'Over-research' indicated concerns that, socio-economic, educational and power disparities between researchers and communities generated increased potential for miscommunication and misunderstanding of critical aspects of research and enhanced the susceptibility of communities to 'undue inducements', meaning that consent was based on impaired decision-making. In the context of multiple studies conducted in a community, these difficulties were argued to be exacerbated, creating confusion which could undermine the scientific integrity of the individual studies through protocol violations and co-enrolment.

The notion of the 'ORC' itself might emerge because of miscommunication and misunderstanding of critical aspects of the research process. Perceptions of 'over-research' might arise from a misunderstanding of researcher obligations, research purposes and the potential benefits of research, suggesting a failure in the IC process. As opposed to an objective, concrete situation, the notion of the 'ORC' was suggested to be reflective of the suspicion and mistrust surrounding HIV/AIDS and research in South Africa.

## 6. (a) Independent Review: Overview of the principle

Ethical research requires balancing the goals of advancing scientific knowledge and contributing to the greater good, with obligations to uphold the rights and protect the interests of participating parties (Levine, 1988). At the same time as seeking to contribute to science and society, and protecting research participants from harm, researchers are also legitimately interested in conducting high quality research as efficiently as possible, and in advancing their careers (Emanuel et al., 2000, 2008; Emanuel et al., 2004). As such, there is the potential for these diverse interests to generate conflicts of interest, which could lead researchers to make decisions, even unwittingly, about research, which could compromise the science of the study, or might place participants at risk (Emanuel et al., 2000, 2008; Emanuel et al., 2004; Levine, 1988). Review of all proposed research by a body of individuals, like a Research Ethics Committee (REC) or an Institutional Review Board (IRB), which is unaffiliated with the research, should incorporate a broad range of expertise, and is able to make an independent assessment of the scientific integrity and ethical acceptability of the research, is a mechanism for minimising concerns about these conflicts of interest and ensuring that studies meet ethical standards (CIOMS, 2002; Emanuel et al., 2000, 2008; Emanuel et al., 2004; Garrard & Dawson, 2005). Furthermore, independent review of research promotes social accountability, in that members of society, who are the likely beneficiaries of the research, are assured that those who participate in the studies are treated ethically, and so they are not benefitting from the mistreatment of others (Emanuel et al., 2000, 2008).

In South Africa, ethical review of all health research by an REC accredited with the National Health Research Ethics Council (NHREC), is legally mandated by the National Health Act ( Act no. 61, 2003). Furthermore, ethical approval must be granted prior to the commencement of research (SA DOH, 2004; SA DOH, 2006). All health research in South Africa is also subject to review according to national guidelines as outlined in *Ethics in Health Research: Principles, Structures and Processes* (SA DOH, 2004), and the *South African Guidelines for Good Clinical Practice* (2006). Compliance with the requirement for review and national guidelines is important in fulfilling the principle of *Independent Review* (Emanuel et al., 2008; Emanuel et al., 2004).

Depending on the study, supplementary review by a community council, like a Community Advisory Board (CAB), may be required (Emanuel et al., 2004).

## 6. (b) ORC as a concern about Independent Review: Respondent perspectives on the 'ORC'

While none of the respondents explicitly argued that 'over-research' was a concern about problematic independent review, there was a general suggestion that, assuming 'ORC' to be a legitimate ethical concern, proper independent scientific and ethical review, would minimise the problem.

> *Can [communities] become over-researched? I don't think so… No, because the RECs, when they approve, they are advocating for the people; as well as the CAB members they are advocating for the people. So when these structures are in place, they would never approve if it was 'over-researched'* (CAB 6).

### 6.1 'ORC' as an issue worthy of REC attention

Several researchers implied that the responsibility for preventing communities from becoming 'ORCs' resided primarily with independent ethical review bodies:

> *Ethics Review Committees do have some kind of ethical responsibility … to manage what research and how much research gets conducted in one clearly defined geographical area… Like here, you know things need to go through [one particular REC]… So I do think, there is some kind of need for control once you've got a tangible research site"* (Researcher 2).

It was argued that the notion of the 'ORC' was an issue worthy of REC concern and that they have a responsibility to keep the idea of 'over-research' *"on their radar"* (Researcher 5), *"it's something that ethics committees should always look out for"* (Researcher 4).

### 6.2 'Over-research' as grounds for 'gatekeeping' by a single oversight body

It was suggested that, where there was a single oversight body that was aware of all activities taking place in a community, 'over-research' could be avoided. RECs were presented as the appropriate body for assuming this role. RECs were construed as important gatekeepers, managing what and how much research is conducted in a particular community. It was contended that if all the research in an area is approved by a single oversight body, then it would be less likely that a community would be 'over-researched' because *"every protocol we do in a community goes through that research ethics committee. So, they have a sense of the work we're doing"* (Researcher 5).

Furthermore, where all protocols to be implemented in a particular community are submitted through the same REC, it was argued that concerns which could lead to 'over-research', or which might be interpreted as 'over-research', including repeat selection of the same participants, co-enrolment, contamination between studies, or redundancy of studies (see sections D-1, Social Value; D-2, Scientific Validity), would be more likely to be identified so that they might be addressed, and 'over-research avoided:

> *It's also important that we have a single ethics committee that basically reviews all protocols that's done in that community. Because … if somebody else comes in and they submit a certain research protocol, the ethics committee would be able to know what's already going on in the community …and they would be able to say 'but you know, this is not feasible for this*

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*community' and they can turn it down…Because they would easily pick up … suddenly there's
ten studies, of the same nature in one community… or if there're studies that's competing for
participants* (Researcher 4).

Several researchers implied that the REC responsible for reviewing the majority of research conducted
in a community could legitimately make gatekeeping decisions about further research in that
community, on the basis of assessments of 'over-research'. It was argued that these RECs would be
aware of all projects going on in a community and so would be able to avoid issues, which might be
understood as, or could lead to, 'over-research'. This REC could also ensure that researchers take
appropriate actions to prevent 'over-research'. A process of systematically charting what activities
were being conducted in which areas was alluded to as a mechanism for enabling RECs to manage the
issue of 'over-research':

> *We actually are trying to initiate a process in our ethics committee where we register the sites
> where research is happening so that we can actually see where multiple projects are running,
> and we can actually identify areas which may be too 'over-researched or where there's too
> much going on. So we're trying to establish a system where we can map the, the actual sites in
> the communities where projects have been approved or where they are already running* (REC
> 8).

## 6.3 'ORC' assessments are beyond existing REC capacity: *"it's very hard for us to keep tabs on it"*

However, such mechanisms were noted to not be readily available, making the task of overseeing all
activities ongoing in a community challenging for RECs. "*At the moment we don't have that role, I think
that we rely on what is reported to us by the researcher*" (REC 8). Several REC members contended that
maintaining an accurate perspective on every project being conducted in an area, or monitoring each
researched community, was beyond their existing capacity. While an REC might make some effort to
ensure, when research is proposed in a context where there is other ongoing research, that the
researchers are aware of other ongoing studies and that the studies do not compromise one another
scientifically (see section D-2, Scientific Validity), they generally lack the capacity to oversee this.

> *Whenever we become aware of people working in the same areas then we would say, 'Have
> you definitely discussed this with the other researcher?' But it's also very hard for us to know
> exactly who's doing what, to keep tabs on it, even though they all come through the
> committee. …I mean aside from that there's just not the capacity to even monitor exactly what
> they're doing* (REC 1).

## 6.4 Who decides? 'ORC' assessments should be made by communities themselves

While on the one hand it was contended that the REC's role is to control what and how much research
is conducted in a community; on the other, in many cases from the same researcher-respondents'
perspectives, it was argued that RECs are too removed from the community to make absolute
decisions about research entry into a community, or accurate assessments of 'over-research'.
Therefore, communities themselves were suggested to be better placed to make such decisions:

*I don't know if the Research Ethics Committees have enough knowledge of the particular community and so … on what grounds would they be making a decision? And, who has the right to speak for any community? Other than the community themselves?* (Researcher 2).

*I'm not sure that they [the REC] always know everything… they'd be a group of people that are outside of the context… they would be objectively standing out and trying to evaluate… and say 'Could this work? Is this what this community needs?' But they're not from that community. So, I would say … it would need to come… from somewhere in the community* (Researcher 6).

This argument for accessing the perspective of the community in making assessments regarding issues like 'over-research', was also raised in relation to regulatory authorities making judgements about a community from the perspective of outsiders:

*Because the Minister [of Health] didn't come to the people of Site A and ask about that. She didn't come. Instead, she's busy there saying that 'they are over-researched over there in Site A'. How can she say that when she didn't even go the people of Site A and ask them about over-research… 'How do you know about Site A? What do you know about Site A? Because we live in Site A and we don't have a problem with research"* (CAB 3).

Similarly, while some REC members positioned themselves as having additional protective duties when research is proposed in so-called 'vulnerable' communities: *"My concern is that if there is a vulnerable community, they are not protected. We have to be their protection"* (REC 4), most REC respondents argued that 'gatekeeping' was not part of their role. As a matter of respect for the autonomy of the communities who would bear the burden of the research, it is the community's responsibility to make decisions regarding whether or not research should be allowed to take place: *"[The community members] have to make up their minds, I suppose that would be the authority. Not the ethics committee"* (REC 6).

Community-representatives also seemed to agree that 'gatekeeping' power should rest with the host community, or at minimum, the community leaders. However, advocacy for community empowerment and autonomy notwithstanding, from another community-representative perspective, it was argued that, *"the one who should make the decision about whether research is conducted in the community, is the Research Ethics Committee"* (CAB 6).

### 6.4.1. Collaborative partnership for competent review

Given the apparent disparities in perspectives regarding 'who decides', the emerging conclusion was *"I don't think that there is somebody that, you can say … 'That's the person that can say yes or no'* (Researcher 4). There seemed to be the suggestion that competent independent ethics review required some sort of collaborative partnership between stakeholders in order to access various viewpoints in making assessments of the appropriateness of conducting a study in a community, and making judgements about 'over-research.'

Some respondents suggested that community input into the review process would ensure that concerns raised by research ethics committees (like 'over-research), were reflective of the sentiments of the community and that review decisions were fair and valid:

> *When it goes to ethics they do get input from the community. … I know there's ethics committees now trying to get CAB members onto the ethics committee… So, they always, before they make a decision on a protocol, they do get community input, on how does the community feel about something like this* (Researcher 4).

## 6.4.2 Concerns about validity of community input into review process

While agreeing that, in theory, 'gatekeeping' decisions should be taken by the host community, as opposed to the REC, respondents noted that this also raises complexities, in terms of how a community is defined and what constitutes legitimate community representation:

> *I mean ultimately the community needs to say, but then the question is who is the community? And, you know, can you actually identify the community? And can you authentically identify people who can speak for that community, and genuinely represent the ideas and preferences of that community? … How do you ascertain a community's perspective? I mean can you really rely on one single group of people to speak for an entire community? So I mean is a community advisory board really representative? And do they really speak legitimately for a community? … So I think that would be one of the problems. I think then monitoring and tracking that over time and getting honest and genuine feedback… the disaffected individuals often make themselves heard most, you know. So, if you get some message coming back to the ethics committee is it a true voice? Or is it … a disaffected few? Or a community advisory board that isn't in touch with the people in its community?* (REC 1).

In discussing concerns about the quality and representativity of community input into the review process worries about community representation (see Section D-8 Collaborative partnership), were raised. There were concerns that assessments of issues like 'over-research' might be based on biased information.

## 6.5 ORC reflects REC paternalism

Furthermore, the use of the term 'over-researched community', particularly as a criterion for research entry into a community, was criticised as 'over-protectionist' and paternalistic: *"Just the very sort of notion [of the 'ORC'] implies a fair amount of patriarchy and paternalism … and is it, you know, part of this evolving over-protectionist approach of ethics committees?"* (Researcher 1).

> *'Over-research' may be an adjective that we may use, but then what are we doing? We're being unduly protective. I mean there may be some communities that love being part of research; they're getting lots of resources; they like being part of it"* (REC 3).

It was however acknowledged that in certain circumstances communities may not be sufficiently empowered or have a distanciated enough perspective to exercise appropriate judgement about whether or not they were 'over-researched'. It was in these situations in which an REC would be a more appropriate decision-making body (see also section D-4, Risk-Benefit).

## 6.6    'ORC' notion is incongruous with REC role

There was a sense, particularly from REC-members, that, RECs have an important role to play in ensuring that research does not exploit participants. However, the use of notions, like the 'ORC', for the purposes of determining research entry into a community, was argued to be contradictory to their role. Some REC-respondents, who were members of an REC where the notion of the 'ORC' had reportedly been used as a reason for disapproving research, seemed more open to the idea of RECs as gatekeepers of communities.  Most REC members though, agreed that, "*we have to protect the participants and prevent this exploitation, but at the same time we must not block research*" (REC 4).

The role of RECs was noted to be to facilitate the ethical and scientifically valid conduct of research, as part of a collaborative partnership with researchers and communities, and not to be the "*long arm of big brother sitting there. One of my jobs is to facilitate research not to be a policeman blocking research*"(REC 5). It was argued that the role of the REC was not to raise obstacles to the conduct of important and potentially beneficial research but to *"sensitise people to the potential ethical issues"* (REC 5; REC 6) and to engage with researchers to overcome challenges. Importantly, sensitising people to the issues was noted to involve raising specific concerns regarding proposed research, rather than vague issues like 'over-research', which were difficult to define, let alone address.

As opposed to making judgements such as 'over-research' and preventing research from taking place, most REC-member respondents, particularly from one REC (which seemed more sceptical of adopting the notion of the 'ORC' in research ethics discourse), noted that:

> "*I can't think that we've actually disapproved a study, we always try to go back to the researcher and say 'These are our concerns, can you address these?' So that we try to give him a chance to develop whatever is missing*"(REC 8);

> "*We don't turn down a protocol completely. We say please pay attention to this, this, and this come back and tell us what you've done ... more collaborative...one definitely doesn't want people to think of it as them and us ..so you're not trying to turn things down, you're trying to make sure that, it's done properly*" (REC 6).

It was suggested that where there was a relationship based on trust and collaboration between the REC and researchers, where the REC *"actually expects that the researcher just behaves in some kind of ethical way,"* (REC 8) as opposed to viewing researchers as *"people who flout ethics rules just for their own purposes"* (REC 3), concerns such as 'over-research' were less likely to be raised during ethical review.

## 6.7. Summary: ORC as a concern about Independent Review

Although 'over-research' was not explicitly argued to be a concern about problematic independent review, the notion of 'over-research' was linked by a few comments, to concerns about independent review,

Some respondents contended that RECs were responsible for gatekeeping what research was conducted in a community and for preventing communities from becoming 'over-researched'. However, monitoring all ongoing activities in a community was argued to be beyond REC capacity, and RECs were suggested to be too removed from the community to make accurate assessments of over-research, and legitimate gatekeeping decisions.

While it was suggested that it was more appropriate and respectful of community autonomy to allow communities to make these decisions independently, it was also argued that certain 'vulnerable' communities might benefit from REC protection.

Competent ethical review and assessment of complex issues like 'over-research', which was argued to lack legitimacy when not raised by the community itself, were argued to require collaboration between various stakeholder perspectives in the deliberative process. Community input into the process of ethical review was proposed as a mechanism for improving the validity of REC decisions. Concerns were however raised regarding how a community was defined and what would constitute legitimate community representation.

The use of the notion of 'over-research' as a criterion for gatekeeping was criticised as 'over-protectionist', paternalistic, incongruous to the role of the REC as a facilitator of ethical research and incompatible with a collaborative approach to the review process (cf. Dowdy, 2006; London, 2002; SA MRC, 2001).

## 7. (a) Ongoing respect for recruited participants and study communities: Overview of the principle

The principle of *ongoing respect for recruited participants and study communities* embodies the idea that researchers have ongoing obligations to their participants and host communities from prior to study initiation to beyond the conclusion of the study (Emanuel et al., 2004; Wassenaar, 2006). The principle incorporates protections for participants and host communities as well as aspects of what might be considered forms of benefit. The principle is rooted in the ethical values of respect for persons (Emanuel et al., 2000) and respect for communities (Weijer, 1999) but also draws on certain aspects of distributive justice.

Research involves the collection of potentially sensitive information from participants and communities. Respect for the privacy and integrity of those involved requires that the confidentiality of information collected as part of research be ensured (Emanuel et al., 2000, 2008; Emanuel et al., 2004). Respect also requires that the rights of participants and host communities to autonomy be respected, and that they are aware of their right to withdraw from the study without penalty (Emanuel et al., 2000, 2008; Emanuel et al., 2004). Respect also obligates investigators to establish and maintain mechanisms for communicating new information emerging from the study or in a related study, as it emerges, to participants and host communities (Emanuel et al., 2000, 2008; Emanuel et al., 2004). As a matter of respect, researchers have obligations to maintain the well-being of participants, throughout and following the study (Emanuel et al., 2000, 2008). During the course of a study, the well-being of participants and communities must be monitored on an ongoing basis for any changes in health status, including adverse reactions to the intervention, and where appropriate should be provided with care or removed from the study (Emanuel et al., 2000; Emanuel et al., 2004). In some instances, research may identify conditions or problems which are 'ancillary' to the study; that is, these conditions do not require researcher attention to ensure the scientific validity or the safety of the study, nor to fulfil promises or address research induced injuries (Richardson & Belsky, 2004). There is some debate about researcher obligations in circumstances where there is a lack of available means for addressing these ancillary conditions (cf. Belsky & Richardson, 2004; Dickert et al., 2007; Dickert & Wendler, 2009; Participants, 2006; Richardson, 2007; Richardson & Belsky, 2004). *Ongoing* respect (cf. Wassenaar, 2006), also considers the question of what happens at, and after, the end of a study. While there has been a fair amount of debate about researchers' obligations to make successful research interventions available, to provide ongoing care to participants, and to ensure the sustainability of interventions, it is agreed that, at a minimum, participants and host communities should be informed of the research results and their implications (Emanuel et al., 2000, 2008; Emanuel et al., 2004).

## *7. (b) ORC as a concern about Ongoing Respect for Study Participants and Communities: Respondent perspectives on the 'ORC'*

Most respondents linked the notion of the 'ORC' to concerns about respect for participants and host communities. Broadly, respondents' perspectives on the notion of 'over-research' suggested concerns about a failure by researchers to meet certain obligations, established by the principle of respect, regarding behaviour towards participants and communities throughout the research process and after.

### 7.1 'ORC' as a concern about a failure to respect participants & communities

 It was suggested that concerns about 'over-research' might be raised *"whenever researchers are simply being opportunist, and not adequately respecting the various elements of the community and their future"* (REC 1); *"If they disrespect the community"* (CAB 3). Furthermore, "*it is the concept of respect for my participants that means that I won't abuse them, I won't over-use them"* (REC 4). Some respondents suggested that 'ORC' might be raised as a concern to indicate unhappiness regarding how communities or participants were being or had been treated.

### 7.1.1 Concerns about instrumentalisation & being treated guinea pigs

As an intensified expression of 'not being treated [in the sense of behaviour towards] well', it was argued that the notion of the 'ORC' might be used to convey the sense that people are being 'instrumentalised' or used as instruments or tools to further the ends of the researchers. That "*the research is abusing the people and using them in a way which isn't right… So, these people then become like slaves that do different types of research*" (CAB 5); and that people are being "*treated as a means to an end… and they're not treating you as a human"* (REC 6) and that *"they feel like guinea pigs; that they just feel that people are coming in and just using them for research"* (REC 8). It was argued that, *"it's always a scientific investigator responsibility to shift away from doing research on subjects to doing research with people"* (Researcher 2).

### 7.2 Concern about confidentiality obligations

Because of the potential for stigma and social harms to communities (see also section D-4, Risk-benefit), through them becoming *"labelled"* (Researcher 2; Researcher 3; REC 7), there was general agreement among respondents that researchers have obligations to maintain confidentiality and to be cautious about how results of studies, particularly on sensitive issues like HIV/AIDS, are published or otherwise disseminated. 'Over-research' represented a concern that there was a failure to maintain confidentiality leading to communities and participants becoming the targets of stigma and discrimination.

### 7.3 Concern about ongoing communication and feedback obligations

It was agreed that researchers have obligations to engage in an ongoing process of communication with, and feedback to, communities regarding research progress:

> *[Communities] could at the minimum expect some kind of communication forum, which, be it your CAB or something else, there should be some kind of to-and-fro that is accessible and regular, between researchers and community* (Researcher 5).

Ongoing feedback and communication to communities throughout the research process regarding emerging information, was noted to be crucial to "*prevent[ing] that sense of, 'you're just coming in here and doing things to us and just leaving'* (Researcher 5), and avoiding feelings of 'instrumentalisation' and being treated as 'guinea pigs'.

It was suggested that a lack of ongoing feedback or communication could lead to a community perception that too much research has been done, or that they have been 'over-researched':

> *I would also reach that point if there is no feedback given to me. So, I think if people are not made aware, or if you're only going to the people when there's a problem and you need their help, then I'll be really like, you know, sucked up and not wanting to know anything [laughter] … If someone comes only when it doesn't work or people wait for you to go and ask… and then they say, 'You've continuously done this on your own, you're over doing us, you know. You're exhausting us.'* (CAB 2).

Therefore, rather than being about the amount of research conducted, it seemed that 'over-research' reflected a concern about a lack of ongoing inclusion of the community in the research process via feedback and communication.

### 7.3.1 Concern about ongoing relationship maintenance

It was suggested that worries about 'ORCs' might be raised in relation to a failure to meet ongoing respect obligations of "*taking that relationship [between communities and researchers] really seriously, and maintaining it; not just setting it up, but maintaining it throughout the lifespan of the study*" (Researcher 6); and a failure to see these obligations of maintaining relationships, respecting, and communicating with the community "*as an ongoing thing; it's not like informed consent you sign and that's the end of it … it's beyond*"(Researcher 1). Failure to meet these obligations could lead to: "*misinformation, misperception, misunderstanding…[and a sense that] a group of researchers have not entered that community or completed their research ethically…or that certain sites are 'over-researched'*" (Researcher 7). Ongoing feedback and open communication between researchers and communities was therefore argued to be a critical aspect of respecting the participants and community, and so of maintaining a good relationship between these parties. The fulfilment of ongoing respect obligations, was presented as a precursor to good collaborative partnership between researchers and the community (see also section D-8, Collaborative Partnerships).

## 7.3.2 Concern about feedback of study outcomes

As a matter of ongoing respect for the communities that they work with, respondents generally agreed that, at the conclusion of a study, at minimum, participants and communities should be made aware of the outcomes of the research:

> *I think for all studies it's important that the participants know the results, you know, the outcome of the studies... They should always be kept up to date with what the results were, because you go in to say, 'this is the research; this is what we're going to do; this is what we're going to look at;' so at least, at the end of the study you should tell them: 'well this is what we found'* (Researcher 4).

'Over-research' was noted to represent a failure by researchers to provide this minimum of feedback to participants and communities at study conclusion:

> *What they were complaining about [when they said 'over-research] is the feedback ... they just know that researchers won't take the feedback back to them.. when the study is finished or the trial...no-one is coming back to them [to say]: 'That's ok we are finished now.'* (CLO 1).

## 7.4. Concern about a failure to acknowledge participant contribution: *No thank-you is said*

A critical aspect of meeting ongoing respect obligations was argued to be acknowledging the contributions that the participants have made to research, through feedback of results at least:

> *...and give them the results, because they will want to know, 'I've cooked this food, I've been part of bringing like wood you know to make fire, and then what is my wood doing? Where is the food that my wood has like cooked?'* (CAB 2).

In addition to arguments that "*at the end of the study, feedback with full information must be given*"(CAB 7), it was noted that there should be some kind of plan for moving forward and an indication of what will happen with the results: "*and what next, out of this study?*" (CAB 7). Appropriately analyzing, disseminating and putting the findings of the research to use "*so that it can impact policies or... guide education campaigns or intervention ideas*" (Researcher 5), was proposed as an important aspect of demonstrating respect for communities and participants and of acknowledging their contributions to the research: *"I do think that there needs to be an acknowledgement of the communities who have given up their time and effort and their blood [laughter], and their arms for ...research"* (Researcher 5) (see also section D-1, Social Value).

Failure to meet the obligation of acknowledging the contributions of the participants and host communities to the research, through feedback and putting the data to use (ensuring the social value of the research), could also result in concerns about 'over-research'. *"Over-researched would mean ...if one research project is conducted and finishes and no 'thank you' is said"* (CAB 5).

## 7.5 ORC as concern about a failure to meet obligations of maintaining the well-being of participants

Respondents observed that during the course of research, it was likely that issues would be uncovered, which may or may not be directly related to the subject of the particular study, but which would impact on the well-being of participants and communities. In accordance with the principle of respect, researchers have duties to monitor, maintain, and in some cases, promote, the welfare of participants and host communities. A failure to take steps to address incidental conditions which were discovered during the research process was argued to be unacceptable, leading to a sense of being treated as a 'means to an end' and creating the potential for concerns like 'over-research' to emerge. There were however disparities in how different respondents defined what conditions fell within the researchers' scope of obligation to address, and in what were perceived to be the appropriate measures that should be taken to address these conditions.

### 7.5.1 Disparate perceptions of the scope and depth of researcher obligations

The  disjuncture between researcher and community perceptions of researcher obligations, which creates the potential for concerns like 'over-research' to be raised, is evident in differences in how respondents from these two groups discussed what researchers and their organisations should provide to the communities in which they work.

There seemed to be general agreement among respondents from all stakeholder groups that researchers have  obligations to address adverse events and to ensure access to care and treatment for the condition under study (in this study, usually referred to in relation to HIV/AIDS prevention trials), and a failure to meet this obligation would raise concerns.

Concerns and debates seemed to emerge around obligations to address ancillary health needs or to address development needs.

#### 7.5.1.1 Scope of ancillary care obligations: healthcare

Researcher respondents generally defined the scope of their obligations to participants and host communities in terms of responding to emergent healthcare needs, whether through direct provision of services or assisted referrals to other service providers.

It was suggested that research participants legitimately : *"expect to have access to healthcare…I think so for the health side,  you know, I do think so and I think that that's our responsibility to make sure that they do get access to the standard of care"* (Researcher 4).

Because health-related research is usually conducted by healthcare providers, it was suggested that this could create an obligation to address healthcare needs, which may not be directly related to the research:

> *The reality is also that we do our best. I mean most of the teams are healthcare providers… And so, if there is a need we try and address it if we can. We refer when we can't. But, if someone comes to us with an STI we'll treat it you know …But we're healthcare providers at the end of the day.  We can't see a need and not address it in some way, whether that's providing medication ourselves, or whether that's referring, for care, but, at the end of the day that's still who we are, so we can't really just ignore it* (Researcher 5).

### *7.5.1.2 Scope of ancillary care obligations: development needs*

From a community perspective, there seemed to be a perception that researchers' responsibilities include addressing the development needs of the community. It was argued that development problems could undermine the well-being of participants and communities and could contribute to illness, and, as such, fell within the scope of researcher responsibility:

> *When they have come into the area they must be able to identify problems that are not necessarily illness, but problems that might eventually make people even suffer from illness, that how can we address these problems?* (CAB 7).

Researchers were argued to have obligations to address the needs of the community, which emerge during the research:

> *The research must have a social responsibility.  You see, to come to do a research to a person who is dying of hunger – If all you are interested in is to research about the person and you have nothing to do with the hunger problem, a person is experiencing, to me, research does not have a human face…Now that is where we used to differ - for the entire period - with the researchers; that …the researchers must carry a social responsibility.  …So I think, in short, the research must carry social responsibility. Then you can think of a variety of ways…. Because, these are people you are researching.  You know social responsibility* (CAB 7).

and:

> *It should happen like this, that as they interact with the community and conduct their research, they maybe become aware that there are many orphans in need of help, and that there are child-headed families, and they then make sure that all of these children receive help and are cared for, that they get education* (CAB 5).

Significantly, from a community perspective, the argument was raised that researchers' responsibilities extended beyond the conduct of valid research. The scope of obligations of researchers to the communities in which they work was expanded to include not only healthcare specific needs but also areas contributing more broadly to well-being. Furthermore, community development seemed to be proposed as a mandatory parallel focus of research in resource-poor settings. *"…with regard to the support that the people receive from the research, we should require it of the researchers, when they arrive, that they should develop the community while conducting their research"* (CAB 5).

Furthermore, because: *"there's also the poverty factor in our area, any people coming in to do something people tend to see as a way of earning more. Getting some resources; money; jobs; that's on people's minds"* (CAB 1); *"there're expectations around employment"* (Researcher 6) and *"jobs, jobs, jobs, in a society where unemployment is high, the expectation is jobs"*(Researcher 3).

From a community perspective, given high levels of unemployment, employment opportunities for the local community as part of the study were framed as obligatory, and as an important mechanism for addressing development and poverty concerns:

> *They should benefit from employment too. It shouldn't be the case that, when research is conducted here, they bring people from [elsewhere] to work here. Community members must get employment within the research* (CAB 6).

It was also argued that researchers had obligations to contribute to the long-term economic upliftment of resource-poor communities:

> *There should perhaps be some sort of income-generating projects, so that even though the research is only here for a certain time, like one to five years, there are still people benefiting alongside and after it"* (CAB 3).

and

> I*n my opinion, people should get gardens, so that they may get vegetables. People should get a place for projects that will be made by them – they can sell hand-made crafts, so that they can live and not rely on the money from the grant* (CAB 4).

Additionally, because education is a core component of research, the educational needs of the community were argued to be within the researchers' scope of obligations: *"There should [also] be bursaries that will help these children to get further education"* (CAB 3);

> *They should get education… Because I know that research is conducted to find something out, so people must know what is happening and they must get education – they should learn. Also, it shouldn't be the case that they should only learn about research – there should be capacity-building for the people"* (CAB 6).

It was noted that, especially in disadvantaged communities, research projects could be perceived as being highly resourced, and communities often expect research to respond to all or many of their needs, and to directly improve their daily lives. While research could have social value, in that it might address issues which may contribute to an improvement in the lives of community members, but also of the public, in general, it was argued that it is often difficult for potential participants to have this distanciated perspective, and there is a perception that research should directly benefit them. Communities were argued to see researchers as having access to money and other resources, and thus expected them to be able to meet more of the community's needs. It was suggested that it might be difficult for community members to understand the idea that research benefits are sometimes indirect, especially given their immediate desperate situations:

> *Well, I think communities see you as coming in with vehicles, and with lots of staff, and resources, and  hence, lots of money, and communities in this particular area are poor.*

*Unemployment is high. HIV/AIDS is high so people... don't have a whole lot to start off with, and so there are expectations about, what you can do to improve their daily lives; and research, sometimes feels like it's a far way away from that. It might answer questions that might ultimately improve the life of this community and other communities like it, but that's a very hard thing sometimes for people to get [understand](R: Ja), when you're faced with a whole lot of other...daily challenges* (Researcher 6).

From a community-representative perspective, research, which failed to meet community expectations or to respond to the immediate needs of the community, could be criticized:

*Ja, that's what my opinion of the situation is. The community is being exploited .... It should be the case that when research is conducted, there should be someone who comes with the research who is in charge of development and in charge of sorting out the problems that the people are facing, and in charge of what sort of things need to be addressed quickly ... This whole idea of the research being conducted and then ending after five years, once five million rand has been ploughed into the research site only, is wrong – there should be something to help to lessen the problems here* (CAB 3).

The criticisms raised in this perspective highlight the potential for concerns such as 'over-research' to be raised where there is a *perception* of injustice and unfulfilled obligations.

### 7.5.1.3 Scope of ancillary care obligations: misunderstanding & misperceptions

It was suggested, mainly by researcher respondents, that a lack of research literacy, and a lack of clarity about what investigators are responsible for and can deliver, and what is beyond their capacity, could lead to a misunderstanding of the distinction between research and service delivery. This might lead to communities having unrealistic expectations of health researchers, and could create the potential for concerns, like 'over-research' to be raised (see also section D-5, IC):

*Communities have huge expectations, they expect researchers to deal with their social issues, their development issues, their poverty issues, their water and sanitation issues, that's just an expectation communities have; and if you say you're a health researcher they expect everything from a health researcher* (Researcher 7).

and:

*We've had to do a lot of education around what is research; what can you expect; what can't you expect; what's reasonable and what isn't reasonable; what is the difference between research and health care provision* (Researcher 5)

### 7.5.1.4 Ancillary care: seeking a balance in defining researcher obligations

It was noted that while: *"there're those in the extreme that would say you should do nothing and you should just go in and get your data, and move out"* (Researcher 6); and *"it's not your responsibility [as a researcher] to do community development"* (Researcher 2), and *"...if you're a purist you'd say: '...there's role confusion. Are you a development group? Are you?' So, there's role confusion'"* (Researcher 3); *"You cannot work out of the context of development"* (Researcher 2); and *"I don't think that's a sustainable position anymore"* (Researcher 3), and:

*I'm not of that opinion. I think that, we do have some responsibility, and that you navigate a kind of grey line, boundary all the time... I don't think it's as black and white as that. I think that you do have some responsibility* (Researcher 6).

Researcher respondents therefore, generally appeared to adopt the position that while many of the community's expectations may seem unrealistic or reflect a lack of research understanding, and that development was not their primary role, they did have obligations to ensure the well-being of participants and communities beyond those that were necessary purely for safety or for the science of the study.

Furthermore, there was some agreement that while it may not be possible for researchers to address all of the needs facing the communities in which they work, they cannot ignore the background conditions either. Even  researcher respondents, who explicitly argued that development and the provision of ancillary care services was beyond their scope of responsibility, acknowledged that "*you cannot work out of the context of development*" (Researcher 2).

It was argued that, while defining the scope of responsibility is a complex challenge facing researchers working in resource-limited settings; and technically researchers may simply not have the capacity to address all of the challenges facing a community, researchers do have an obligation to do what they can to maintain and enhance the well-being of participants in host communities. Because researchers have access to information and, perhaps, contacts, it was argued that, they have the ability and the obligation to link communities and participants with service providers who could better address their particular challenges:

> *I mean, staff… who are in the field really struggle with that… "I'm just here to collect data about HIV and AIDS. I can't help with your poverty, with your illness, with … the situation of your household". And technically they can't.  They can't give money; they can't do all those things, but there are a number of things they can do. They can make sure that [community] members know where to go; that there are places that they can be referred to* (Researcher 6).

Researcher respondents reflected that balancing their roles as scientists and their obligations to respond in some way to the immediate needs of the participants and host communities, which may emerge during the course of the research, was an ongoing challenge. It was noted that : *"it's very hard for us [as researchers] to disengage from the healthcare needs of a community where we work"* (Researcher 5).

It was argued that if information, which could have significant implications for the health and well-being of the members of the community comes to light during the course of a study, even where this information is ancillary to the focus of the research, researchers have an obligation to act on that information: "*you can't just discover that and go, 'Oh well that's how it is'. Especially as healthcare providers ourselves … You can't just turn a blind eye to that"* (Researcher 5).

The degree of responsibility that researchers have to respond to the ancillary needs of the communities in which they work was argued to be dependent, to some extent, on the level of

engagement between the researchers and the community, in addition to the nature of the research (as more or less demanding of participant and community time and resources): *"I think that, you know, it's commensurate on the amount of research, the scale of research, the long term, presence of the researchers"* (REC 1).

It seemed that 'ORC' might be raised as a concern where there is a sense that researchers are not fulfilling their obligations regarding the provision of services, and this might in turn be based on conflicting understandings of how the researcher-community relationship has been defined.

### 7.5.2 Concerns about sustainability – *"research has moved in and moved out"*

Another worry that was linked to the idea of the ORC, was a failure to consider what should happen at the conclusion of a study, particularly in terms of sustainability of care and service delivery. It was observed that:

> *….research tends to have a bad reputation about coming in; getting data from people… and then moving out; and there's no sense of accountability; of follow-up on how's the data gonna help this community in any way? …I think often the problem is people come in and go out, and there's no real consideration given to how that impacts on the community* (Researcher 6).

In reflecting on the notion of the 'ORC', respondents suggested that there could be a sense that communities are simply abandoned once researchers have what they want: *"The researchers came, and they just toyed with us, and then they picked up what they could carry and left once we had helped them"* (CAB 5).

Some respondents raised concerns about the provision of care by researchers on the grounds of equity and sustainability: *"I mean obviously you can't ensure that they'll get ten times better care because you can't sustain it after a study"* (Researcher 4). It was suggested that the provision of a higher standard of care to trial participants compared to what was generally available in the community, would lead to the creation of dual standards, which could in turn be perceived as unfair and might constitute a situation where discontent could lead to concerns such as 'over-research' being raised:

> *…the other issue is that creating a group of privileged community members because they taking part in your trial, and I personally disagree with creating a privileged group of people as part of your trial. Because they then may have access and then their family will not have access to care, because they didn't take part in my trial. Then that's another form of discrimination* (Researcher 7).

> *I mean, ancillary care should be what is available to everybody. And what we should be advocating is if it's not available how do we make that available? And if we create an artificial standard for trial participants …and it's only as long as the trial is running. So it kind of - you know during the abortion legislation debates… you have a group of people who only are concerned about the foetus at the time of conception and at birth. And then, after that what happens to this child post-delivery is not their business. So in a way, some of the standards that are being set in trials are a bit like that. It's: we're only interested while you're participating in the trial* (Researcher 1).

A failure to ensure sustainable access to care could also result in a sense of abandonment on the part of communities: *"you have led people down a one way road and that's a dead end…"*(REC 6) and: *"at the end of a study participants might be left with maybe less than they had before."*(REC 8) Such a situation might be argued to give rise to concerns about 'over-research'. Furthermore: *"A problem with research is if it does not establish people for sustainable living, and it ends up doing things which confuse people"*(CAB 3).

Some respondents argued that, in addition to feedback on the results of the study, at the conclusion of a study, ongoing access to beneficial interventions that might have been part of the research process was a critical obligation, so that there is not a sense of deterioration in standards.

Given the concerns regarding the sustainability of the research-related improvements experienced by communities, a common and prominent position from various respondents was that researchers have an obligation to act as advocates for the community and to ensure that through the community engagement process, communities are empowered to advocate for their own needs independent of the researchers, and so are able to sustain improved standards (see also Section D-8, Collaborative Partnership).

It was argued that research should assist the community to gain a critical understanding of the issues that they face and their potential solutions. Researchers have an obligation to enable communities to be equal partners with other stakeholders, and should improve their capacity for networking and advocacy around service delivery. Research should also be targeted at skills development or capacity development and skills transfer, in order to enable this networking and advocacy process. Communities should also be empowered to take control of their situations.

> *I think by the end of a research project if the community has not been able to understand its community better … so that they can network; so they can then follow through with government; so they can then follow through with service delivery;  it's a problem. That means simple skills development… to begin to say, 'I'm confident enough to dialogue with government, with service delivery people through my interaction with the research,'. Everything that we do is part of skills development skills transfer, it's about making the community understand that you know you are being empowered, to know this information so that it helps you in future… it just depends how you want to see this help* (Researcher 7).

> *I believe that, if you do research, irrespective of what, research you do, when you finish that study, you have to be able to say that you left something behind in that community. Whether it's knowledge that you gave them, or whether it's a better understanding of health, or you empowered them in some way that they can take better care of themselves, or that they understand their circumstances better - then you've given something back to the community. And not just taken their participation to get your information* (Researcher 4).

## 7.6. Collaborative Partnerships for addressing obligations

Given the position that, as a matter of meeting the requirements of ongoing respect, researchers have some obligation for the maintenance of the well-being of the participants and community, and the argument that they cannot ignore the context in which they work, together with the counter-position that researchers are not development workers and community development is not their primary focus, it was suggested that the establishment of collaborative partnerships with other stakeholders and organisations was a means of navigating this complexity and meeting this obligation (see also Section D-8, Collaborative Partnership).

> I think from an ethical perspective … researchers have a responsibility to network communities because researchers have access to information. You know, versus a community out there who may not have access to all the information. So I mean the researchers' responsibility, if there are development issues, is to say, 'You know what, the best we could do is network you with the water and sanitation department.' You know, 'We can help you write a letter to the water and sanitation department or to the nutrition department.' (Researcher 7).

Furthermore, given concerns regarding equity or fairness in terms of service provision, it was suggested that establishing partnerships with service-providers, might help to ensure that the broader community also accesses the same standard of care, which could be improved through contact with the research organisation. Such partnerships could also help to negotiate the issue of researchers' responsibilities to provide ancillary care: *So we have a relationship with all the healthcare providers within our community, and if we have a participant in our trial and there's a problem, we know where to refer them to get treated"* (Researcher 4); and to address issues of sustainability of care provision and research-related benefits: "*those sort of things are responsibilities of researchers to address but not to do it on their own, because sustainability is an issue"*(Researcher 7).

Regarding concerns that communities might feel abandoned at the conclusion of a study if sustainability is not considered, a best practice for what should happen at the conclusion of a research project was proposed. Prior to research initiation, there should be a view as to how to ensure the sustainability of a project intervention beyond the life cycle of the research. This would involve developing collaborative partnerships between stakeholders during the formative stages of research, and maintaining these relationships throughout the study:

> Ensuring some sustainability is important. But …I'm not sure that it's a model that everyone follows, that everybody can afford to follow. We were lucky because we motivated for the funds [for skills transfer] and we got it… It was a key principle by which we started to do this work. It's like, we really wanted to set up some sustainability mechanism up front … We started right at the beginning in our formative stage kind of looking for partners, local community and other stakeholders, [like the] department of health, to partner us in this research… the view for us always at the beginning was about how to ensure sustainability. So that when we leave there isn't this huge hole but that there is a continuity of some of those services… And I'm not sure if other groups always think about that [or] always feel as though that's their responsibility to do that… But for us it was an important consideration (Researcher 6).

## 7.7. Summary ORC as a concern about ongoing respect

The notion of the 'ORC' seemed to be an articulation of unhappiness at the treatment of participants and host communities, throughout, and subsequent to, the research process. Failing to maintain confidentiality or neglecting to engage communities in ongoing meaningful relationships, together with a lack of communication, feedback or acknowledgement of participant and community contributions, could give rise to perceptions that communities are being treated as the 'mere means' to furthering researchers' ends (cf. Buchanan et al., 2007; Buchanan et al., 2008; Emanuel et al., 2004).

Perceptions of mistreatment seemed especially likely to arise in relation to researchers' obligations to monitor, maintain, and in some cases, promote the welfare of participants and communities during the course of research. While there was general agreement that researchers were obliged to ensure the safety of participants and to address side effects of interventions, there were significant disparities between respondents regarding what other conditions and issues were within a researcher's scope of responsibility to address. While researcher respondents focussed on healthcare concerns, community-representatives seemed to define researcher obligations far more broadly, and, in addition to healthcare needs, included socio-economic and development concerns. The disparities in how various stakeholders define researcher obligations seems to create the space in which concerns like 'over-research' might be raised. Disparate perceptions regarding researcher obligations were noted to be especially likely where research is seen as highly resourced and in a position to address all or many of a community's needs.  Furthermore, a lack of research literacy and a misunderstanding of researchers' roles and responsibilities could also contribute to the discordance.

'Over-research' also reflected concerns about the sustainability of research-related care and service delivery, beyond the life of a single study, and the sense of abandonment frequently experienced by communities at the conclusion of a study. Moreover, concerns were raised about introducing a double standard into a community context by providing participants with better care than what is normally available to them.

Collaboration between researchers, service providers and communities was noted to be a mechanism for navigating the complexity of sustainability and more broadly defined researcher obligations (cf. London; Shapiro & Benatar, 2005).

## 8. (a) Collaborative Partnerships: Overview of the principle

The principle of collaborative partnership requires the development of partnerships with researchers, communities and other stakeholders like policy makers (Emanuel et al., 2004). Furthermore, all partners should share in the decision-making, conduct, oversight and implementation of the research (Emanuel et al., 2004). The establishment of collaborative partnerships between stakeholders is argued to help to ensure that research is socially valuable, in that it is responsive to the needs and priorities of the local context, to enhance the likely benefits of the research locally, and to help to ensure ongoing respect, through the sustainability of interventions (Emanuel et al., 2004). The establishment of collaborative partnerships also demonstrates respect (Emanuel et al., 2004).

Meaningful engagement and collaboration between stakeholders involves acknowledging and seeking to overcome existing disparities between stakeholders in terms of power, access to resources and existing capacity, in order that stakeholders might engage as equal partners and that the relationship is not dominated by one party (Emanuel et al., 2004; UNAIDS-AVAC, 2007; UNAIDS-WHO, 2007). Meaningful collaborative partnerships between researchers and communities require ongoing community participation, mutual trust and respect (UNAIDS-AVAC, 2007; UNAIDS-WHO, 2007).

While, the call for collaborative partnership between researchers seems to have emerged largely in relation to international collaborative work (cf. Costello & Zumla, 2000), the notion that there should be collaborative partnerships of mutual respect in the relationship between researchers seems equally applicable to the context of different researchers working on different projects in the same community.

Although cited first in the framework, the principle of collaborative partnerships is the eighth principle added to Emanuel et al.'s (2000) initial framework of seven principles for the ethical conduct of research (Emanuel et al., 2004). This appears linked toall of the other principles in the framework(cf. Emanuel et al., 2004).

## 8. (b) 'ORC' as a concern about Collaborative Partnerships: Respondent perspectives on the 'ORC'

In discussing the notion of the 'ORC', one of the central issues raised by almost all respondents as underpinning both the notion itself, and the various ethical concepts which either describe, lead to, or result from 'over-research' (see section D1 – D7), was a concern about the relationships between the various stakeholders in the research endeavour.

The establishment of collaborative partnerships between stakeholders in research has come to be a principle of research ethics (Emanuel et al., 2004), and among respondents, concern about collaborative partnerships was the most frequently raised, and arguably, most heavily emphasised interpretation of the notion of the 'ORC'.

Assuming 'over-research' to be a legitimate ethical concern, respondents argued that either a failure to establish, or a breakdown in, collaborative relationships between stakeholders in research, could result in 'over-research'. Furthermore, the legitimacy of the notion of the 'ORC' as an ethical concern notwithstanding, respondents noted that if 'over-research' was raised as an ethical concern, this, in itself indicated a failure in the relationships between stakeholders.

## 8.1. Community-researcher relationships

Given the centrality of the researcher-community relationship in research, especially in clinical trials, it is unsurprising that this was a relationship of particular concern. It was suggested that: "*... if a community said, 'We're tired of research' that would be a good indicator, that your relationship's broken down*" (Reseacher 5). Furthermore, rather than being a concern about the actual research or about the number of studies that have been conducted, it was argued that: *I strongly think ['over-research'] is about the relationship*" (CAB 2);

> *It's really a product of the relationship between researchers and the community and whether that relationship is managed well or not ... rather than calling it saturation [where too much research has been done]... I think it's probably more of an issue of having strained that relationship* (REC 1).

### 8.1.1. ORC is a concern about a breakdown in the community-researcher relationship: "*when the relationship gets strained*"

It was argued that, as in any relationship, there was the potential for things to go wrong in the community-researcher relationship. When there is a breakdown in the relationship between researchers and the community, the potential for misunderstandings and miscommunication, and for perceptions about 'over-research' to emerge, is enhanced, and the likelihood for a 'meeting of the minds' between community and researcher is diminished (cf. Gilbert, 1997): "*What you're dealing with is a very complicated relationship that you're always managing*" (Researcher 6).

It was therefore argued that the 'ORC' referred to a situation in which the community-researcher relationship was poorly managed:

> *You know with friends... when you take each other for granted, when there's no reciprocation, when you don't talk to each other, when you don't communicate well, when you just are clumsy and stupid...that's when the relationship gets strained and I think that's probably what I would see 'over-research' as being, when things just haven't been managed well...in relationships between a research group and a research community, whenever people have over-stepped the mark in terms of just taking [each other] for granted, not communicating well, not having*

*carefully chosen the studies so that one is building on the next, and whenever researchers are simply being opportunist and not adequately respecting the various elements of the community and their future* (REC 1).

## 8.1.2 ORC is a concern about poor community engagement

The notion of the 'ORC' was suggested to represent a concern about inappropriate or inadequate approaches to community engagement or participation. It was argued that good community engagement would mean that concerns about 'over-research' were unlikely to arise because *"researchers themselves should be sensitive enough to know when the community they going back in again to do the nth study are getting ...research protocol fatigued"* (REC 5). *"'Over-research' means that the entry hasn't been done properly ... when people just come in here and do things and then after a while they leave there is no partnership, proper partnership"* (CAB 1).

Many respondents linked the notion of the 'ORC' to the idea of people being treated as 'guinea pigs' in research, suggesting the two ideas to be synonymous with one another (See also section D-7, Ongoing Respect). Complaints about being a 'guinea pig' or an 'ORC' were argued to represent reactions to dissatisfaction with being a part of research, resulting rather from a failure to ensure adequate engagement and meaningful participation from the outset of the research interaction, than from misconduct of the research. It was suggested that 'over-research' was a way of articulating a concern about poor community engagement:

> *I think the difficulty would be that maybe that people begin to feel that ...this is abuse, that they are now just guinea pigs... I think if I felt myself to be 'over-researched'...one of the ways I might verbalise my unhappiness would be, 'Oh, they're just using me as a guinea pig'... That is one of the earliest complaints that you will hear if people are in any way dissatisfied with any kind of research, ... is 'I'm a guinea pig' and it's almost as though it's a knee-jerk reaction to being unhappy when you have been a participant in research, regardless of ... whether it was a bad intervention or whether the study went skew, it's your generic response and it probably isn't because you were a participant, but it is more likely because you were not properly engaged with when you were enrolled...I think you can avoid a great deal of that confrontation ...if you pay people the respect of engaging them, but really engaging them... So it goes all the way back to that original idea that when you are going to research a particular community go and sit down with those people [and engage with them]... So it all goes back to community engagement* (REC 6).

### 8.1.2.1 Meaningful versus tokenistic community engagement

In relation to the notion of the 'ORC', several respondents also highlighted distinctions between meaningful and tokenistic community engagement. Given that community engagement has become a matter of principle in conducting community-based research within certain sponsor networks (both HPTN & HVTN; cf. UNAIDS-WHO, 2007), for the purposes of funding, it was argued that researchers were obligated to make efforts regarding community involvement in the research. However, respondents observed that this was not always geared towards establishing truly collaborative relationships between researchers and communities. It was argued that *"there are some kinds of structures which are more lip-service and tokenistic, than actually with an emphasis on establishing*

*true partnerships"* (Researcher 2). The suggestion seemed to be that 'over-research' was not simply a concern about a lack of community engagement, but that this engagement was not meaningful but rather tokenistic. *"There has got to be much greater and much more substantial and authentic community engagement as opposed to a nominal, saying that, 'We have discussed with the community'"* (REC 1).

It was noted that *"If you do not have full community participation, I'm not talking consultation, I'm talking participation, you will struggle"* (CAB 1). Meaningful community engagement efforts were noted to be invaluable to the success of a study.

While meaningful community engagement was noted to involve an orientation towards the formation of truly collaborative relationships between researchers and communities, based on participation and partnership, it was suggested that tokenistic engagement was undertaken as a pacifier to ensure that, from the perspective of the researchers, research could be completed with minimal obstacles.

### 8.1.2.2 Communication & dialogue as central to meaningful engagement

It was noted that an important aspect of establishing meaningful partnerships was an *"appreciat[ion] that community engagement is not like a linear thing; it's much more complex"* (Researcher 1), requiring transparent, ongoing and iterative communication and dialogue (Researcher 5; REC 3) . *"I think it's an ethical obligation that you establish a dialogue"* (Researcher 2) and ensure that *"people [in the community] have to be given time to go back [and think] and come back and ask questions of the researchers"* (CAB 1). Furthermore, it was noted as critical that communities felt that their questions and concerns were heard, and that measures were taken to address these issues: *"in the community itself I think we've always kept it open, when we go in, having community meetings, talking with all the stakeholders having focus-group discussions, listening to what people's concerns are"* (Researcher 1).

*"The more you're open about what you are doing, and the more you listen to what people are saying, the better for your research, and the better for your relationships"* (REC 3). Where communities feel that they have not been listened to, or that their concerns have not been adequately addressed, it was suggested that they might resist research and perceptions about 'over-research' might emerge (Researcher 1). Furthermore, it was contended that 'over-research' represented a situation where there was a failure to establish effective communication mechanisms, and *"people are not made aware or if like you're only going to the people when there's a problem and you need their help"*(CAB 2). It was noted that engaging communities in dialogue at the outset of a study was:

> *a good idea, and the reason it's a good idea is because if you don't do it you could have certain unpleasant consequences, or you might not be able to do more research, the research that you want to do. If there are unexpected outcomes of the study or a study is discontinued early, you have to be able to explain it, and you really can't explain unless you've had the conversations*

*beforehand. Because you would have had the engagement, there would be a good way of wrapping it up and a good result* (REC 6).

### 8.1.2.3 Meaningful community engagement as collaborative partnership

There was general agreement among respondents that meaningful community engagement involved a partnership between researchers and communities:

> *To me, working in a community, it's a partnership, and, in a partnership each people add value to the process... It has to be a joint effort. So for me it's... how do we work together to leave this community better off? ...And that starts from the time I enter the community. It's not something I think about right at the end* (Researcher 1).

In addition, it was agreed that in order to establish a collaborative partnership between researchers and communities, communities needed to be engaged early in the research process and throughout the life of the study. Ongoing community engagement was argued to be critical to avoiding perceptions that the community is only of interest to researchers when there are problems or the researchers need something (see also section D-7, Ongoing Respect):

> *I don't believe once we've gained community entry acceptance that we then just leave the research to happen and then they don't see the faces [of the researchers]. So the community needs to feel you're not just there for the approvals but for the issues, you know* (Researcher 7).

*"The community engagement process is an ongoing one"* (Researcher 1; Researcher 4); and *"there're lots of real benefits from taking that relationship really seriously and maintaining it. Not just setting it up, but maintaining it throughout the lifespan"* (Researcher 6).

### 8.1.2.4 Meaningful community engagement as power-sharing in research-related decision-making

The concept of a collaborative partnership between researchers and communities suggested an ideal of equitable power-sharing and decision-making responsibilities between the two parties. "*So if we talk full participation let us be equal partners*" (CAB 1). Ideally, this would involve shifting the power dynamic to a situation in which communities initiate the relationship with researchers, rather than the traditional dynamic of researchers approaching communities (Researcher 1). There were also calls for increased community involvement in establishing research priorities and planning research implementation as means of creating a more equitable sharing of power in the community-researcher relationship (see also section D-1, Social Value): "*Go and sit down with those people ask them, 'Do you think this is something that you want?'Do you see this as a problem?'Is this really what your problem is or do you have other priorities?' and 'if you do can we discuss them?'"* (REC 6). "*When we talk about planning, especially with research... that is what we would like to be part of ... So that we can give input there's a lot of community members who's not scientists, that can make a positive contribution towards the research*" (CAB 1).

However,

*that's not always how it happens because researchers... may have particular questions they're interested in; get funded for those and then ... come to a community, and now start the process. Ideally it should happen the other way. In the real world it often doesn't happen. And so the key issue is ... How do you involve the community? Given that you haven't in that first critical stage. How do you now build a much more collaborative relationship with them where, in some way what they think and what they feel, and their issues do impact and influence?* (Researcher 6).

Ideally, research priorities should evolve through community engagement processes, but, researchers usually approach communities with a question, a protocol and funding for that specific issue, and so already a power differential exists which could create complexities around building collaborative partnership.

### 8.1.2.5 Power inequities as a broader concern than the research interaction

Unequal power dynamics between researchers and the community, was argued to be rooted in access to resources and perceived level of expertise, and was suggested to result in community deferral to researcher opinions. The suggestion was that disempowerment of communities to play an active role in decision-making, was a structural artefact and was broader than simply the research interaction:

*I think that the type of research conducted should be controlled by the researchers and by the government. They say, 'let's go in there'. They can decide that, 'we want this research to be conducted' because they have the resources... and as for the community, it doesn't get involved much. No, the community's part in the process is only to check that the research to be conducted will not injure the community...It's not right, but the community is not empowered... It's supposed to be the case that the community has a say. There are many things which are supposed to be researched in our areas, and which we know are supposed to be researched, but because we haven't got any say at all, they don't ask the community first. The community does also not know how to stand firm and to say "no, we don't want this* (CAB 3).

*I think that it is the researchers who should decide what and how research is done in the community. It's not easy for the community or community representatives to know what type of research should be done because they often know nothing. And even in instances where they do know something, they can't verbalize it properly. So even if they are addressed at a gathering and consulted saying, 'What sort of research would you like us to do?' they may simply wait or respond with, 'I don't know, it's up to you' – or perhaps they will wait for someone who may have a viewpoint on the issue. I certainly can't say which type should be conducted* (CAB 5).

Community-representatives reported a sense of lacking both the capacity and the power to contribute meaningfully to research-related decisions which affected them. It was also noted that communities often lacked the broader, more distanciated perspective of researchers to comprehend the significance of studying particular issues and how this contributed to global health efforts. They were thus unlikely to question researchers' decisions. Meaningful community engagement therefore required significant education, capacity-building and empowerment efforts to overcome these obstacles to the establishment of truly collaborative partnerships.

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### 8.1.2.6 'ORC' as a concern about community support for research

Community engagement and participation were noted to be critical to the establishment of a meaningful collaborative partnership between researchers and the community, and for ensuring community support of the research. Ensuring community acceptance of the research was argued not only to be a matter of ethical principle, demonstrating respect for the community, but also represents a pragmatic necessity "*because if they're not on board, then you're wasting your time*" (Researcher 5);

> *You want to know that you've got the community buy-in at the outset. It's not ...only an issue of right ...it's probably the wise thing on the part of the researcher to know that they are starting on a on a platform of community acceptance* (REC 1).

Without community acceptance, research is unlikely to be successfully conducted: "*If the community don't accept me, how will I do my research? ... the fact that research can be implemented is a very good indicator ... of community engagement, community working relationships*"(Researcher 7) .

Therefore, it was suggested that the notion of the 'ORC' represented a situation in which there was a failure to achieve community buy-in or acceptance of the study.

### 8.1.2.7 'ORC' as a concern about community entry

The way in which the researchers negotiate entry into a community sets the stage for the process of community engagement and of developing collaborative relationships. Most respondents noted that appropriate entry into a community involved ensuring that all relevant stakeholders and existing community leadership structures were consulted in the process of negotiating access to the community for research. Failure to acknowledge and appropriately negotiate access via, community gatekeepers was likely to be interpreted as a lack of respect and to result in study failure because community members would be reluctant to be involved in something which was not supported by the leadership: "*They will say 'we cannot be part of this'*" (CAB 4). Appropriate community entry was noted to be:

> *...probably one of the most important things... You cannot in any community just go in. You need to know who the stakeholders are who the political leaders are because if you don't have their support you can forget to go into any community* (Researcher 4).

*In our communities we've got systems of relaying information to the community. You cannot just go into a community and call a meeting. That's the dynamics... of a community. You have to go to the leadership* (CAB 1). It was thus suggested that the 'ORC' represented a concern about inappropriate entry into a community.

### 8.1.2.8 'ORC' as a concern about community representation

Community representation was also raised as an important aspect of meaningful community engagement and of making sense of the notion of the 'ORC'. It was argued that ensuring that community representative structures like a Community Advisory Board (CAB), which consisted of

capacitated local people, were in place, was key to effective community engagement and entry activities:

> *We live with the people. We can relate to them. We know how to approach them. And that makes it easier for the trials to be conducted... How to enter; how to relay the correct messages; where to and who to target first..."* (CAB 1).

It was noted that these community representative structures *"act as a kind of liaison between... the scientists or researchers and the community, in terms of alerting us to issues; alerting us to how the community is responding and are there problems?"* (Researcher 6). The role of CABs in alerting researchers to potential problems, like possible 'over-research', in order that they could be addressed, was foregrounded: "*I think this is what CABs are about, you know... Saying, 'People are tired'... that's the sort of feedback you expect to hear from your CAB"* (Researcher 5). The suggestion seemed to be that 'over-research' was a concern that the appropriate community representative structures had not been put in place and were not adequately fulfilling their roles, because *"if you have all of those structures in place there should be enough checks and balances to insure against exploitation or 'over-researching'"* (Researcher 1). Thus 'over-research' was argued to be an absence or breakdown of the representation of the community's interests.

Furthermore, questions of whether the ostensible community representatives are truly representative of the community were raised. Even in situations in which appropriate community representative structures seem to be in place

> *I guess the difficulty there is that you don't know if they are representative of [the community], and you don't really know whether the issues they bring to the table are the things that your participants are going to be worried about* (REC 6).

> *How do you ascertain a community's perspective? I mean can you really rely on one single group of people to speak for an entire community? So I mean is a community advisory board really representative and do they really speak legitimately for a community?* (REC 1).

It was noted that although efforts were made to ensure that different sectors of the community were represented on the CAB (CAB 4), conflicting priorities limited sustained commitment, leading some sectors to lose their representatives on the CAB (CAB 2). Furthermore, there was the suggestion that individuals joined the CAB because of the opportunities for personal capacity-building and that there was minimal interest in truly representing the community. Furthermore, there was also the suggestion that the CAB agenda might be driven by the views of the existing leadership in the community, who often make up part of the CAB (CAB 4). 'Over-research' was thus suggested to indicate a concern about a failure of the representativity of the existing community representative structures. "*The question is, 'Are those representatives?' It's always easy to find a representative. The question is, 'Is that representative, truly, a representative of that community?"* (REC 1).

In light of concerns about the representativity of the CAB, questions regarding whether or not feedback from a CAB that a community was 'over-researched' was genuine were raised. It was argued that "*any squeaky wheel out there can stop the process*"(Researcher 3) and

> *…the disaffected individuals often make themselves heard most. If you get some message coming back to the ethics committee is it a true voice? Or is it a disaffected few or a community advisory board that isn't in touch with the people in its community?* (REC 1).

It was thus suggested that where the CAB was not necessarily representative of the community, inappropriate concerns about 'over-research' were likely to be raised.

Moreover, if there was a failure in communication between the CAB and community, a sense of being 'over-researched' could arise.

> *So we have CABs in all our communities and they are very interested individuals and committed people but I'm not always sure how good the feedback is back to communities… Everything goes through our CAB and they get feedback at the end. But, how well that's fed back to participants I'm not sure* (Researcher 5).

'ORC' thus represented a concern that the CAB was not fulfilling their role of feeding information from the researchers back to the community. In addition to this, were concerns about researchers instituting and working through a CAB only, or approaching only the leadership of a community, and assuming this to constitute community engagement. "*There has to be complete, broad consultation. And, not only at the CAB level …So you can't just access the CAB and think you've done consultation*"(CAB 1); and "*it's not only the leader that the research will be done on or will be participating in the research … but the actual community people will take part in the research. So everybody needs to be engaged*" (CAB 2). Thus 'ORC' might suggest that researchers have considered consultation with community leaders or CAB members to be sufficient community engagement activities, when this is not the case. *"Leadership is one level, but what do people think?"* (Researcher 1).

Beyond simply engaging with community representatives or leaders and research participants, it was noted that meaningful community engagement involved engaging with the community more broadly in order to foster the support critical to the successful completion of studies and to avoiding perceptions of 'over-research'. "*The whole community has to be supportive of the idea, because otherwise, it would be very hard for those individuals to be part of that programme of research*" (Researcher 5).

### 8.1.3 Perception of 'ORC' as emerging from low research literacy

It was also noted that true community engagement in research was limited by low research literacy: "*it's difficult for communities to fully grasp the nature of research*" (Researcher 3). In order for people to be fully engaged with research "*a lot of training has to go into it*" which is complex when people have competing needs and priorities "*It's not like they have the luxury of a good paying job and extra time to really be able to participate*" (Researcher 3). Low levels of research literacy present a challenge

to the development of truly collaborative partnerships between researchers and communities, and enhance the potential for concerns about 'over-research' to arise (see also Section D-5, IC).

## 8.1.4. ORC as a failure in community literacy

Just as communities require research literacy, researchers require community literacy in order to engage meaningfully with communities (cf. UNAIDS-AVAC, 2007). It was noted that different approaches to community engagement might be appropriate in different contexts "*because I think that all communities are not the same and some communities understand research and some are completely naïve to research*" (REC 8), "*you don't have a cookie-cutter approach to community engagement*" (Researcher 1)."*So you really need to understand the population that you're dealing with well before you can actually go in*" (Researcher 4).

## 8.1.5 ORC as rooted in community history and prior experiences of research

"*If a community are saying, 'We don't want any more research', it may not be that they are 'over-researched' it might be they've had bad experiences of research*" (Researcher 5)*.* A community's prior experience of research was noted to colour the relationship between researchers and the community, to possibly impact on the establishment of collaborative partnership and to create potential perceptions of 'over-research':

> *There're concerns depending on what happened and what's been done. What are the expectations? Were there frustrations?  Did people feel that they were let down? Did people feel that they were used? But you have to be aware of the environment that you work in* (Researcher 3).

An important aspect of achieving 'community literacy' was noted to be considering a community's prior experience of research:

> *You've always the potential of different research groups [that] function in different ways, and you may have one group that have behaved very well and another group comes in, in a less good way … you can have either trust increased or diminished by that type of dynamic* (REC 1).

Trust was noted to be a key foundational component of meaningful collaborative partnerships between researchers and communities: "*if you are doing something you need to develop trust and you need to build that trust with the people*" (CAB 2); and represented a highly valued aspect of successful community-research relationships:

> *I do think the work is in trust, and that's for any community, developing trust... I mean we've worked hard and we've developed a good relationship of trust and we protect that very jealously in our communities*" (Researcher 5).

Maintaining trust in the complexity of the community-researcher relationship, was noted to be a challenge, *"a tightrope that you walk"* (Researcher 6), particularly because the relationship frequently consists of parties with differing interests, agendas, backgrounds and socio-economic status.  Trust was argued to be difficult to gain, but easy to lose.

Previous negative experiences with research, which has failed to uphold ethical standards, or is perceived to have been detrimental to the community, could undermine trust between researchers and communities. This could impede the establishment of meaningful collaborative partnerships in future research. *"There have been incidents in the past …you did have disasters and horrific things or unethical research happening in communities and those things linger you know the effect of it, the aftertaste"* (REC 8).

Where communities have experienced unethical research, establishing trust in future interactions between researchers and communities to build collaborative partnerships and conduct research, was noted to require significant effort on the part of the researchers.

In the South African context, several respondents suggested that distrust and perceptions of 'over-research' were related more to the socio-economic inequities and legacy of apartheid, which permeate the researcher-community relationship, than negative experiences related to specific research interactions. (See also section D-3 Fair Selection).

> *I mean this community where I'm working,… I think we were the first sort of serious researchers who've done prolonged [work there]; who've stuck around and done the work, any sort of work we had to do around the ideas of research are …old issues rather than something that a group came in and we had to undo or we had to re-explain how we were different or whatever it is …we haven't had that. …And it is hard because the townships we work in are obviously were obviously very struggle affected- [affected] by apartheid and so they've got a lot of trust issues, which are completely understandable …and I think it's that more generally"* (Researcher 5).

In many cases, it was noted that the communities in which HIV prevention research was generally conducted lacked familiarity with, or understanding of, research, and thus the challenges to the researcher-community relationship, which were suggested to underpin the notion of the 'ORC', were linked to more general social issues as opposed to research specific issues. Racial tensions and general mistrust of the healthcare sector on the basis of its apartheid involvement *"Some people would say 'this disease [HIV/AIDS] is spread by a white person because he wants to terminate black people'"* (CAB 7); and perceptions regarding the socio-economic status and motivations of the researchers *"for example a person would say 'if you participate in the research', and this was the belief, 'they will make you die and they will benefit from it and get money from it'"* (CAB 5); were seen as obstacles to meaningful partnerships between researchers and the community, and as underlying the concern about 'ORCs'.

## 8.1.6 Extensive community engagement as 'over-research'

While respondents generally proposed that the notion of the 'ORC' indicated a worry about a lack of meaningful community engagement in research and a failure to establish truly collaborative partnerships between the researchers and the community, it was observed that, at the same time,

extensive community engagement and the establishment of strong community-researcher relationships, might be interpreted as 'over-research':

> *I think … it can get raised when, a group of researchers or investigators have established a rapport with a community and they've got a tangible presence in a community  that then it can come up that that community is being 'over-researched', just because there the presence of researchers there. But then it raises for me the ethical question of what is better? To be well established in a community, have that community support, community buy-in, or is it better just to do, as I say parachutist research? That you parachute in collect your data bye-bye thank you very much, and sometimes there isn't a thank you very much and you're never seen again? I think with a presence in the community you have greater accountability (Researcher 2).*

The notion of the 'ORC' thus highlighted the tension between the requirement to invest in community relationship-building and the worry that significant researcher involvement in communities could raise concerns about 'over-research'.

## 8.2 Researcher-researcher relationships and co-ordination of multiple studies

Concerns about the relationships between different researchers working within the same community, and between researchers and other research stakeholders, were also key to the way in which 'over-research' might be understood, and to many of the other ethical concerns underpinning the notion of the 'ORC'.

### 8.2.1 ORC as a failure in the co-ordination of multiples studies

Of particular concern was whether the relationship between researchers working in the same community was "*synergistic or antagonistic*" (Researcher 1). This had implications for whether or not the different studies they conducted *"impinged on one another"* (REC 3) and could be successfully conducted. It was argued that in a context in which there were multiple ongoing studies, whether or not a community was considered 'over-researched', had little to do with the number of studies being conducted but rather with how they were conducted and whether or not they were co-ordinated with one another.

> *When there's multiple research activities going on it is best if you can be co-ordinated… I mean the analogy always made is that research in a community, it's like a single lab. So you have to try and co-ordinate what goes on (Researcher 3).*

It was noted that:

> *you can have two or three studies happening within one community, very well co-ordinated, very well managed, and everybody comes off better for it. And you can have the exact same protocols being implemented, and poorly managed, and poorly co-ordinated, and it just actually being a bad thing (REC 1).*

Proper co-ordination of studies was noted to be critical to ensuring that the studies overall were beneficial rather than burdensome, and that they had scientific integrity. ORC represented a failure in the co-ordination of multiple simultaneously conducted studies

The co-ordination of studies conducted in the same community by different researchers was noted to rest on the relationship between these researchers. It was noted that:

> *researchers can be highly competitive. They can be highly suspicious. They can be naturally antagonistic [and] selfish. So there can be real competition for access to participants if several different researchers want to do similar research in the same area"* (Researcher 3).

Given that health researchers are ostensibly all aiming for the same goal of improving the health of the populations they work with, it makes sense to ensure that it's "*complementary research not competitive research"* (Researcher 7).

Communication between different researchers was argued to be critical to research success, and that 'over-research' reflected a concern about a lack of such communication:

> *There hasn't been, in my view, any major conflict but then that's because we've worked as a big group with understanding and dialoguing with each other... but I'm aware of issues, other scientists and researchers would have faced if they had both entered the same community, you know, without talking to each other prior* (Researcher 7).

In order to ensure that studies are co-ordinated in such a way that they can be successfully completed and are beneficial to the community, the establishment of collaborative partnerships between the researchers was noted to be necessary. It was noted to be important for "*the researchers to make sure that they haven't complicated life for each other"* (REC 1).

> "*I think it's about being collegial certainly if you've got a number of prevention programmes running you need to make sure you're not enrolling participants on both studies. So it's a case of saying 'We're both here. What are you doing? What are we doing? How do we make sure that our work doesn't overlap or impact? That we're not just redoing the same thing? So it's about developing relationships with the people and working out those sorts of things."* (Researcher 5).

### 8.2.2. ORC as concerns about researcher gatekeeping of communities: "*Groups say, I own this community"*

It was noted that

> *if there's an established group working in the community and you're interested in coming and doing similar kind of work, it's collegial to discuss it, and make sure that you're not undermining each other's work things that might confound each other* (Researcher 5).

However, the notion of the 'ORC' was linked to concerns about researchers setting themselves up as the gatekeepers of a particular community, and preventing other researchers from accessing that

community: *"There's always competition for access, and control of the community...there's a danger also of, sort of a colonial approach to research. Groups say listen I own this community. Don't cross my boundaries"* (Researcher 3). In situations in which research is proposed in a setting in which there is already ongoing research:

> *I think maybe because of competition, you know, from the actual investigator's point of view, that if you got in then do you feel you now have monopoly on that community... I think that especially where you have, using your own research funds, built up a site and put staffing in and done a lot of training and you sort of developed a site as a particular sort of you know in the HIV site or TB site or a site that does women's health or whatever then I think that there is, to an extent a bit of ownership that people feel"* (REC 8).

> *Because a lot of the time I'm going in where nobody else has gone and have tried to figure things out and set things up... and [the thinking is], you put in all this time and effort and went through all of this, now how can somebody waltz in and do his research?* (Researcher 1)

There was some suggestion that in order to avoid 'over-research', the gatekeeping role was legitimate in the relationship between researchers:

> *The researchers who have the established centre have an ethical responsibility to manage it... [because]... what starts happening, and the danger is, once you've got a tangible research site, you will find a lot of people who want to come and 'piggy-back'. Then you get phone calls and [they] say, 'Oh, I've got this research project. Can we come and speak to you?" and there I think you have an ethical responsibility. And that's where it can become 'over-researched'*
> (Researcher 2)

The concern raised was that others might use a researcher's hard work in establishing a relationship with a community to facilitate their entry into the community. However many more respondents argued that in the context of limited resources and significant need, collaboration between researchers was necessary to ensure that as many pressing issues as possible could be addressed. The relationship between researchers and among research stakeholders *"should really be collaborative from all sides"* (REC 8). Collaborative efforts between researchers to address multi-faceted issues, were suggested as enhancing the social value and benefit potential of the research (see also sections D-1, Social Value; D-4, Risk-Benefit).

Furthermore, when studies are proposed in contexts in which there is already ongoing research, it was noted, that in order to maintain scientific integrity, it might be in the interests of the researchers to have *"some discussion about where they're wanting to work and how they're wanting to work, so that we don't have contamination of issues"* (Researcher 6) (see also Section D-2, Scientific Validity). However, it was also argued that *"to be realistic , you can only control that so far. You can't say 'don't do research here because we want to have a pure effect'"* (Researcher 6). *"You can't make a blanket statement 'I'm here first so I should be the only one doing the work here', or something like that"* (Researcher 1). Preventing other researchers from working in the community, not only demonstrates a failure to engage in collaborative partnerships with other research stakeholders, it also effectively

denies the community access to potentially beneficial research *"I mean that's silly, because you're denying the community the right to have those studies"* (Researcher 6). *"Most of the time gate-keeping is for personal interest. It's not in the interest of the community. It's that they want to display that they have power, and they have control"* (Researcher 1).

It was also suggested that competition between researchers could undermine the relationship between the community and the opposing research organisation. Reportedly, in order to maintain their hold on a community, researchers from a competing organisation might manipulate community leadership structures enforce their gatekeeping capacity and prevent a competing research organisation from accessing or successfully conducting research in the community: "It*'s a typical sort of old-line British way to deal with communities, which is, divide and rule"* (Researcher 3). Furthermore, given the potential for prior research to impact on the community's perceptions of research and their willingness to engage in future research, out of an obligation to maintain collaborative relationships between researchers, researchers have an obligation to, at minimum, not create a negative relationship with the community thereby sabotaging future researchers' prospects of community engagement.

### 8.2.3 Collaboration to foster community literacy

Acquiring community literacy not only requires collaboration between researchers and the community, but also between researchers working on different projects within the same community. *"it's just important for everybody to be aware that other stuff can be going on, and that before you set out doing something... you should get that information and make sure that you understand what everybody else is doing"* (Researcher 4). Furthermore, engaging collaboratively with other researchers who have previously conducted research within a particular community in order to establish challenges and best practices, might help to obviate some of the concerns about 'over-research' within that community:

> *One of the important things would be to see whether that went well or whether it left a bad taste. I mean any decent researcher reads all the stuff that's been done beforehand, speaks to previous researchers and uses it as part of the sort of situational analysis* (REC 3).

## *8.3 Researcher-other stakeholder relationships*

In addition to concerns about the nature of relationships between researchers and the community, and between different researchers working within a community, concerns about the nature of the relationships between researchers and other stakeholders also had bearing on the notion of the 'ORC'.

Concerns about 'over-research' were frequently attributed to media misrepresentation of research (see Section D-4, Risks-Benefits). Respondents generally portrayed the media as an unhelpful

stakeholder in clinical research *"reporters are like hell"* (REC 3); "*This media dispersal of information is something we won't accept*" (CAB 3) that would sensationalise research, either because they lack research literacy or because they are generally unscrupulous *"they can twist things and get the wrong end of the stick"* (REC 3) *"media people can do what they want because its journalism"* (Researcher 7). Furthermore the relationship between researchers and the media generally seemed to be described as antagonistic. While the role of the media in transmitting information and in shaping public perceptions of research "*once it gets into the newspapers that's truth as far as the whole world's concerned*" (REC 3), and potentially as a tool for enhancing research literacy (Researcher 7; REC 5) was acknowledged, little, if any effort, to engage the media in a collaborative partnership with the researchers was reported. Just as a failure to ensure collaborative partnerships between researchers and communities leads to misperceptions, animosity, a lack of 'meeting of the minds' and the emergence of worries about 'over-research', a failure to establish a collaborative relationship with the media contributes to the concern about 'over-research'.

## 8.3.1 Collaborative partnerships in order to meet obligations to communities

A critical aspect of the relationship between researchers and the community was the obligations of researchers to communities, which emerged from this relationship. In order to meet these obligations of sustainability beyond the life of a study, especially clinical trials, and meeting ancillary care requirements researchers need to establish collaborative partnerships with organisations already working in the community or to partner with organisations who can come into the community to assist with addressing these issues:

> You cannot work out of the context of development but it's not your responsibility to do community development; but then how do you then play the role of connector?  So, that for me is the ethics of partnerships in research (Researcher 2).

It was suggested that, while researchers may not be able to address all of the needs and issues in a community, there is an obligation for researchers to link communities with structures that may assist with provision of services, and in addressing the issues. Therefore, researchers should take on an advocacy role, because they have access to information and contacts:

> When the researchers arrive here, they should call in other NGO's, to say, 'We have this that we are looking after, so please, can you help us with the other aspects?'  But those other people will be under an 'umbrella' of the researchers (CAB 4).

Furthermore, given concerns regarding equity in terms of standards of service provision, it was suggested that researchers have an obligation to establish partnerships with service providers, because these ensure that the broader community also accesses the same standard of care, which could potentially have been improved through contact with the research organisation. Such partnerships could also help to negotiate the issue of researchers' responsibilities to provide ancillary care: "*So we*

*have a relationship with all the healthcare providers within our community, and if we have a participant in our trial and there's a problem, we know where to refer them to get treated"* (Researcher 4).

## 8.4. Summary: 'ORC' as a concern about collaborative partnerships

Concern about the relationships between various research stakeholders was central in discussions of the 'ORC'. 'Over-research' was argued to represent a concern about a failure to establish collaborative partnerships between stakeholders, or to reflect a breakdown in relationships. This seemed to be a critical interpretation of the 'ORC', the preceding sections notwithstanding.

Rather than a function of the number of studies conducted in a particular community, 'over-research' reflected a sense of the community-researcher relationship having been strained. A failure to meaningfully engage with communities through ongoing dialogue, communication and genuine efforts to foster collaborative partnership and power-sharing, could result in perceptions of 'over-research', in which community participation is seen as tokenistic and merely undertaken to satisfy funders or to gain community agreement to the study.

Achieving truly collaborative partnerships, however, was noted to be a challenge given broader structural power-inequities, which limit opportunities for community involvement in research-related decision-making and result in community deference to researchers in decision-making processes. Perceptions of 'over-research' were also argued to reflect a community's history and prior experiences of research, which could create mistrust and might hamper the establishment of truly collaborative partnerships.

Where community representative structures fail to communicate with the community they represent, are not truly representative of the community, or do not alert researchers to unhappiness and rumours about research in the community, concerns about 'over-research' were argued to be likely to emerge. Concerns about the 'ORC' also highlighted that meaningful community engagement involved engaging with the broader community and not just the ostensible representatives.

While on the one hand, there was agreement that the notion of the 'ORC' represented concerns about a lack of meaningful community engagement, on the other it was suggested that extensive community engagement with research could also be perceived as 'over-research'.

'Over-research' also represented a concern about a lack of collaboration between different researchers conducting studies in a single community, which could result in poor co-ordination of the studies in order to ensure scientific integrity, overcome confusion and to enhance the value of the research. The 'ORC' also represented concerns that researchers might take 'colonial' control of a community and

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attempt to regulate what other research projects or interventions are introduced into a community, in order to maintain scientific validity and to avoid other researchers benefitting from their investment of hard work and resources in establishing a research site.

The media were frequently portrayed as an unhelpful stakeholder in research, and were argued to fuel misperceptions about research. Concerns about 'over-research' seemed likely to arise publicly as a consequence of a poor relationship between researchers and the media.

Perceptions of 'over-research' might arise as a result of researchers failing to meet their obligations to communities because of poor relationships with service providers, who are critical to supporting researchers addressing the needs of communities and of ensuring sustainability of interventions.

## *Assessment of legitimacy*

It was argued that given its definitional variability the notion of the ORC lacked ethical relevance in that it failed to specify specific ethical violations which could be addressed.

Respondents, although generally suspicious of the notion of the 'ORC', and critical of the term's ambiguity and lack of clarity, were reluctant to wholly dismiss it as ethically irrelevant. A few adopted the position that the concept of the 'ORC' lacked ethical relevance and did not contribute substantively to ethical debates about research in developing country contexts: *"I don't think it's got much content frankly"* (REC 6) and

> *I don't know that it's necessarily a helpful term. I don't know what it means. This one seems like a not very useful, catch-all non-specific term.  I think it's because it's so ambiguous a term. I think any term which is full of ambiguity is not helpful* (Researcher 3).

Some suggested that, the notion of the ORC had ethical relevance, but that its use required qualification:  *"It's not the term to use without qualification"* (REC 4), and supporting evidence:

> *I'd have no difficulty with somebody raising that issue as an ethical issue. I think it's a legitimate concern. And I think if uh, if somebody on the committee was to make the case, 'I think this particular area or this particular community is over researched', then I think the onus would be on them to prove it. Just to use anecdote or whim or personal opinion, I mean we base medicine on methods of treatment on evidence, and science on evidence. I think there must be evidence that it's, it's an 'over-researched community'* (REC 5).

Most respondents however vacillated between arguing that 'over-research' was an idea that they would never use, that lacked ethical relevance because it was so vague, that they could not understand or define, and that was at most hypothetical and applicable only to distant hypothetical communities, and the position that *"It's ethically relevant because it conveys a certain idea, but it's a vague idea. And, it's one that is in my mind a bit hard to define"* (REC 1), and that although, *"I think it probably requires definition, but I think it is ethically relevant"* (REC 8).

> *"I'm not crazy about the terms 'under-research' and 'over-research'… I think you need to deal with the specifics, to know what we're doing. In general I think discourse should move away from slogans into substance, right. It's a slogan…So sloganeering … and I don't think it adds to our discourse at this point in time"* (Researcher 3)

Most respondents agreed that if the term were to be used it would require further exploration and definition in order that the issues underlying it might be addressed.

# E    DISCUSSION

This section discusses the major cross-cutting themes and issues which emerged in respondents' perspectives on the 'ORC' in relation to research ethics and good community practice literature. Throughout, the focus is on the ideas and observations emerging from respondent perspectives, and where these mirror ideas in the literature, it is suggested that readers 'confer' (cf.) with the relevant papers. Unless otherwise specified, all references to, and interpretations of 'over-research' or the 'ORC' refer to respondent perspectives in this study.

'Over-research' is increasingly raised as an ethical concern and as a challenge to engaging participants and communities in research (cf. GFBR, 2005; IRENSA, 2007; Ndebele, 2003). Various studies have examined the reasons potential research participants refuse to participate in research, and several others have explored the nature of the relationship between researchers and communities. However, there is an apparent lack of both empirical and conceptual literature directly addressing the notion of 'over-research'.  Apart from a single study, exploring how 13 researchers understand research fatigue and 'over-research' as reasons for refusal to participate in qualitative research, to the researcher's knowledge, this is the only study directly examining the concept of 'over-research' in health-related research from an ethical perspective. Importantly, in most cases, when communities are referred to as 'over-researched' or when 'over-research' is cited as a barrier to research engagement, the notion itself is treated as self-evident and is not defined. Clark's (2008) appraisal of 'over-research', while identifying some of the practical precursors to, and providing limited critical analysis of, the issue, seems to accept the 'ORC' as a legitimate and distinct concern about research in community settings. Where definitions of 'over-research' are offered, these are usually descriptive and provide little insight into the real concerns underlying the allegation. Clark (2008) proposes that

> "research fatigue can be said to occur when individuals and groups become tired of engaging with research and it can be identified by a demonstration of reluctance toward continuing engagement with an existing project, or a refusal to engage with any further research... research fatigue may also lead to the suggestion that particular groups of interest are being 'over-researched'. Indeed, such claims are an overt expression from communities that they are tired of participating and no longer value the experience or any of the associated outcomes" (p.955-956).

This study sought to critically analyse the concept of the 'ORC' as an ethical concern, to explore whether or not it reflected a new issue for which provision was not made in existing ethical frameworks for research, and to assess the ethical relevance and legitimacy of the notion.

In most cases, the perspectives on the notion of the 'ORC' offered by researchers and RECs were fairly similar, given the academic orientation of these respondents and the fact that many members of RECs reported that they were researchers themselves. Differences in perspective were noted between these

academic respondents and community representatives. These differences might reflect disparate stakes in research, but could also be a function of varying levels of education as well as language barriers.

As opposed to a distinct, specific ethical concern, this study found 'over-research' to be an 'umbrella' concern, which might refer to any of a whole range of ethical issues. In suggesting that 'over-research' represents concerns about any or all of Emanuel et al.'s (2004) eight principles, respondent perspectives on the 'ORC' confirmed the practical and ethical vagueness of the notion. Furthermore, most respondents offered multiple possible interpretations of the notion of the 'ORC', suggesting that it refers to various discrete ethical concerns simultaneously, reinforcing the view of the notion as non-specific.

The notion of the 'ORC' seems to be a vehicle for simultaneously capturing various existing ethical concerns about research conducted with vulnerable populations, research conducted with communities and research conducted in developing or resource-limited settings.

There are various levels of interpretation of the notion of the 'ORC'. One interpretation is 'over-research' as a concrete description of a research situation. 'Over-research' might also reflect a perception, which might result from another specific ethical violation, for example, a failure to ensure meaningful consent. Furthermore, 'over-research' might reflect a perception of an ethical violation, even when none has occurred. For example, there may be a perception, based on confusion about the role of researchers, that researchers have failed to meet their obligations by not securing employment for community members.

Along these lines there seemed to be three major meta-thematic trends emerging from respondent perspectives on the 'ORC': (1) 'Over-research' is synonymous with exploitation (2) 'Over-research' is a perception emerging from disparities in perspectives on what constitutes fair benefits, discordance about researcher roles and obligations, and different levels of understanding and research literacy (3) 'Over-research' is fundamentally a concern about the relationships between stakeholders involved in research.  Each of these is discussed in turn.

## 1     *ORC and exploitation*

In this study, exploitation was the concern most directly and concretely linked with the notion of 'over-research'. In many respects, the notion of the 'ORC' seems to mirror that of 'exploitation', and several respondents used the terms synonymously. Furthermore, the over-arching concept framing the eight principles of ethical research in developing countries is non-exploitation. The violation of any of the principles might arguably constitute exploitation (Emanuel et al., 2004; Emanuel et al., 2008). Since the

notion of the 'ORC' was linked to all eight principles in various ways, it seems plausible that 'over-research' is also connected to exploitation, and might commonly signify concerns about exploitation.

As with exploitation, 'over-research' was implicated both in concerns about procedural unfairness and outcome unfairness, and was noted to represent a knee-jerk response to research conducted with so-called 'vulnerable' populations (cf. UNAIDS-WHO, 2007, GP 8, Commentary; Wertheimer, 2008 a, 2008b).

## 1.1    Procedural unfairness

Like exploitation, from the perspectives in this study 'over-research' seems to reflect concerns about the process of the interaction between researchers and communities and about how participants and communities are treated prior to, during and subsequent to a study (cf. Carse & Little, 2008; Emanuel et al., 2004; Wertheimer 2008a, 2008b).

### 1.1.1   Concerns about informed consent

In addition to a concern about a lack of consent altogether, respondents argued that 'over-research' also might represent concerns that the consent process, while in place, is in some way faulty, for example because of inadequate information provision, a failure to understand relevant aspects of the research, susceptibility to the decision-impairing effects of 'undue inducements', and other threats to the voluntariness of decisions (cf. Denny & Grady, 2007; Grady, 2009; Siegel, 2008). In line with the Kantian conception of exploitation as unfair process (cf. Buchanan, 1985 in Macklin, 2004; Siegel, 2008; Wertheimer, 2008a), 'over-research' seems to be a concern that participants are involved in research without their voluntary informed consent, or consent to participate in risky or unfairly compensated research because of impaired decision-making (cf. Denny & Grady, 2007; Grady, 2009; Siegel, 2008).

### 1.1.2   Concerns about a lack of respect for communities

Furthermore, as articulated by respondents, 'over-research' as a failure to maintain community confidentiality, resulting in social harms, or a failure to achieve community agreement to research prior to community entry, arguably demonstrates a lack of respect for the autonomy and integrity of communities as distinct ethical entities (cf. Buchanan et al., 2007,2008; Weijer, 1999; Weijer & Emanuel, 2000). Similarly, exploitation refers to such failures to acknowledge autonomy and to uphold the principle of respect for persons and communities (cf. Siegel, 2008).

Also, in accordance with the Kantian perspective on exploitation, this study suggested that 'over-research' was likely to be raised to indicate unhappiness at how participants and communities are being, or have been, treated (cf. Clark, 2008), and might emerge when there are concerns about participants and communities being used as the 'mere means' to furthering researchers' ends. Like exploitation, 'over-research' also seems to be associated with claims of instrumentalisation and being

treated as a 'guinea pig' (cf. Siegel, 2008). A sense of instrumentalisation is likely when researchers fail to meet their obligations of treating participants and communities with respect and dignity, and as ends in themselves (cf. Carse & Little, 2008; Hawkins, 2008; Siegel, 2008).

The ongoing respectful treatment of participants and communities is a critical aspect of avoiding exploitation, and similarly, seems to be a central aspect of not just preventing 'over-research', but preventing perceptions of 'over-research' (cf. Carse & Little, 2008; Emanuel et al., 2000, 2008; Emanuel et al., 2004). Where developed-world funded research, conducted in resource-limited contexts, is not responsive to the needs and priorities of host communities, perceptions are likely to arise of participants and communities being used as 'mere means' and "of the developed world raping the resources of the developing world for the benefit of those already unjustly privileged" (Carse & Little, 2008 p.218). Likewise, respondent perspectives suggested that externally funded research which did not appear congruent with local priorities was likely to incur accusations of 'over-research'.

From respondent perspectives, a failure to engage in, and maintain, ongoing respectful community-researcher relationships, as well as poor communication and a lack of feedback to study participants and host communities regarding research progress and outcomes (cf. Buchanan et al., 2007; Buchanan et al., 2008; Emanuel et al., 2004), could result in perceptions of 'over-research'. Literature suggests that researchers seldom provide feedback on study findings to participants or host communities (Reynolds Whyte, 2001), and a lack of feedback to study participants and host communities regarding the outcomes of research is a frequently cited source of frustration and is noted to be a precursor to research fatigue and charges of 'over-research' (cf. Clark, 2008; Reynolds Whyte, 2001). Respondent perspectives on the lack of feedback to participants and communities echoed sentiments articulated by community representatives in other studies examining the community-researcher relationship. A lack of feedback of study results to host populations, leads to feelings that, "we've been researched, we've been surveyed, up to our noses" (community advisor, in Sullivan et al., 2001, p.145) or "we've been researched to death" (Singer, 1993, p.19).

## 1.2    Outcome unfairness

Exploitation also represents concerns about unfair outcomes of research (Wertheimer, 2008a, 2008b). In respondent views, 'over-research' also reflected concerns about unfairness in study outcomes. Like exploitation, 'over-research' seemed to be a concern about the potential for research to harm participants and communities in some way. This study suggests that 'over-research' implies that researchers are benefitting from an interaction which is harmful to participants and communities, who are rendered worse off than they would have been had they not participated in the study (cf. Hawkins, 2008; Wertheimer, 2008a, 2008b).

### 1.2.1 Concern about harm

In addition to the risk of physical harm, 'over-research' implies concern about increased risk of social harms to participants and communities, which have been noted to be particularly likely with regard to research conducted on sensitive, stigmatised issues like HIV/AIDS (cf. Milford et al., 2007). Hosting HIV-related research might exacerbate a community's reputation as an area of high HIV prevalence, thus increasing the potential for social harms to participating communities, especially if their involvement in this research becomes publicly known (GCM, 2004; Essack et al., 2009; Milford et al., 2007; Taylor & Johnson, 2007). In the same way, concerns that communities are 'over-researched' were noted by respondents to be more likely to be raised in relation to sensitive issues like HIV/AIDS, where communities might be associated with socially stigmatised behaviours (cf. GCM, 2004; Milford et al., 2007). Furthermore, respondents argued that multiple studies increase the amount of risk to which participants and host communities are exposed. While a single HIV/AIDS related study could result in perceptions that a community has a high incidence of infection, the risk of these negative perceptions and consequent stigma was argued to increase relative to the number of studies conducted in that community (cf. Shapiro & Benatar, 2005).

### 1.2.2 Concerns about unfair benefits

Like exploitation, it seems that, even if both researchers and communities benefit from research, and there is no harm done to either party, it is still possible that the outcomes are unfair, and, 'over-research' might still be alleged (cf. Hawkins, 2008; Wertheimer, 2008a, 2008b). Although both researchers and communities benefit from a research interaction, 'over-research' seemed to suggest that the level and distribution of these benefits is unfair, or that the burdens of study participation are perceived as too high and not adequately compensated for by the benefits. Clark (2008) notes this to be a precursor to 'research fatigue' or 'over-research'.

A commonly raised concern in relation to exploitation is that, while resource-limited communities bear the burdens of research, the benefits accrue primarily to the researchers and sponsoring countries (cf. Annas & Grodin, 1998; Carse & Little, 2008; Sullivan et al., 2001). Similarly, from the perspectives in this study, 'over-research' seems to reflect concerns that sponsors and researchers benefit to excess while communities receive little in return for their participation in the research. The notion of the 'ORC' suggests concerns that researchers and sponsors "perceive the desperate conditions of the third world opportunistically" (cf. Siegel, 2008, p.176), as allowing them to provide communities with mere 'trinkets for ivory', and thus to conduct research more cheaply (cf. Benatar, 2002, p.1137). Likewise, in the literature, claims of the exploitation of participants from resource-limited communities are often associated with concerns that sponsors and researchers "view the union of illness and impoverishment as an ideal opportunity for efficiently and inexpensively testing pharmaceuticals they wish to market" (Siegel, 2008, p.176). Against the background of significant socio-economic disadvantage, respondents

noted that even objectively unfair offers may be perceived as 'better than nothing', and so communities and participants may accept minimal value benefits in exchange for their participation (cf. Annas & Grodin, 1998; Benatar, 2002; Carse & Little, 2008). Since they are able to provide less to participants and communities in exchange for research participation, the margin of profits that investigators stand to gain from the interventions developed is increased (cf. Benatar, 2002; Carse & Little, 2008; Siegel, 2008), and impoverished communities might become favoured for repeated research selection, raising concerns about 'over-research'.

In order to be fair, it is generally agreed that the benefits of research should be equitably distributed between stakeholders and should not accrue solely to one stakeholder group (cf. Benatar, 2002; Macklin, 2004). Most respondents concurred that allegations of 'over-research' might be made when certain communities bear the burdens, the benefits of research accrue to sponsors, investigators and wealthy populations, and the researched communities receive an inadequate share.

## 1.3   Does 'over-research' refer to exploitation?

While it may seem clear to suggest that the notion of 'over-research' is synonymous with 'exploitation', 'exploitation' has also been argued to be a deceptively complex concept (cf. Hawkins & Emanuel, 2008).  "Although commentators advance accusations of exploitation with relative ease, they rarely provide an account of exploitation on which their accusation rests" (Wertheimer, 2008a, p.64). Exploitation is frequently conflated with other ethical concerns like 'coercion' and 'undue inducement' (Emanuel, 2004, 2005; Emanuel, Currie, & Herman, 2005; Hawkins & Emanuel, 2005; Pace & Emanuel, 2005). Some interpretations of 'over-research' in this study also refer to these terms. However, although several coherent and convincing suggestions have been advanced, the precise and agreed upon definitions of both 'undue inducement' and coercion are lacking, and there remains disagreement regarding whether coercion and exploitation are separate concepts which can occur simultaneously, whether they are separate and contrasting concepts, and whether coercion is a variety of exploitation (cf. Carse & Little, 2008; Emanuel, 2004, 2005; Hawkins & Emanuel, 2005; Grady, 2001, 2005).

While exploitation may represent a legitimate term in research ethics discourse, it is also argued to be vague, simultaneously capturing a range of ethical concerns and requiring substantial interrogation of its ethical dimensions to ensure that appropriate action can be implemented to address the issue to which it refers (cf. Hawkins & Emanuel, 2008). Thus, interpreting 'over-research' as 'exploitation', might be argued to do little to enhance clarity on the notion of 'over-research', and may simply represent substituting one vague concept for another.

What seemed to emerge quite strongly was that while 'over-research' might be a literal concern about the number and type of studies conducted in a community relative to the population size, the same

studies could be conducted in the same context without any problems emerging. 'Over-research' therefore seems to be a far more complex concern located in the intricacies, tensions and different perspectives in research stakeholder relationships.

## 2    *Disparate perspectives*

'Over-research' might emerge because of a particular perception, regardless of the number of studies conducted in a community. 'Over-research', at a more conceptual, meta-thematic level, as opposed to a mechanism for articulating an actual ethical violation, seemed to represent a perception of an ethical violation whether one had occurred or not. The perception of 'over-research' might also reflect the perspective of certain stakeholders but not others.

As illustrated in the perspectives in this study, different stakeholders arguably have different interests and agendas to advance in research (cf. Altman, 1995; Gilbert, 1997; Sullivan et al., 2001), which in some cases might conflict with one another. For example, as argued by respondents, while researchers might be primarily interested in ensuring the scientific integrity of study outcomes, community members, who are faced with the challenges of everyday living, are more likely to focus on the tangible rewards of research and achieving solutions to their immediate concerns (cf. Altman, 1995; Benatar, 2004; Wallerstein & Duran, 2003). These divergent positions result in different understandings of what constitutes socially valuable research, contrasting definitions of fair and appropriate benefits of research, and disagreement regarding researcher obligations to communities. These disparities in viewpoint evident among respondents seem to create the potential for misunderstandings and miscommunication (cf. Gilbert, 1997). Furthermore, like allegations of exploitation, allegations of 'over-research' seemed to emerge in response to different understandings and experiences of background injustices (cf. Participants, 2004).

### 2.1    Divergent interpretations of responsiveness

As with exploitation, the way in which fair benefit for research participation is defined seems to have implications for whether or not claims of 'over-research' are likely to be advanced.

Concerns that research is not responsive to the needs and priorities of the host community might reflect a failure to adequately engage with communities (Cornwall & Jewkes, 1995). However, this concern might also emerge as a result of divergent notions of what constitutes relevant and responsive research (cf. Sewankambo & IJsselmuiden, 2008; London & Kimmelman, 2008). Respondent perspectives support the view that communities might have multiple needs worthy of research attention and different communities might allocate different priorities to various needs depending on their respective social concerns (cf. London, 2005, 2008). 'Over-research' might therefore imply that, from the points of view of certain stakeholders, in making subjective determinations of priority issues, other socially important concerns are being neglected (cf. Jentsch, 2003).

## 2.2 Different perspectives on fair benefits

The notion of 'over-research' seems also to reflect broadly divergent opinions on how participants and communities should benefit from research participation. There was broad agreement among respondents that communities and participants should benefit fairly from research participation. However, determining what constitutes fair and appropriate benefit is complex and remains the subject of debate (cf. Lie, 2010; London, 2005; London & Zollman, 2010; Participants, 2004). The variety of views illustrated in the responses of the small sample of stakeholders represented by the respondents here, gives an impression of the potential for disputes and misunderstanding regarding what constitutes fair benefits. While some respondents suggested that ensuring access to beneficial interventions was a researcher's responsibility, others argued that researchers were not responsible for access, and others suggested that other indirect benefits were as, if not more, important than this. Some argued that benefits in kind, and unrelated benefits were what should be provided, others countered that these were inappropriate. Most respondents were concerned about a failure to provide benefits to communities but were equally concerned about the impact that benefits have on the motivations of people to participate and the potential for benefits to act as undue inducements or coercive offers, particularly with regard to research with 'impoverished' groups, illustrating a tension between fair benefit and undue, or decision-impairing incentive.

Respondent opinions on the 'ORC' and the question of fair benefits, mirror inconsistencies in existing research ethics discourse about benefits of research participation, referring to that which is provided only to participants receiving the intervention under study; that which is provided to all participants; or, that which is provided to the broader community (cf. Heise & Wood, 2005).

### 2.2.1 Direct benefits

If research benefit is narrowly defined as only that which results directly from the intervention under study, concerns about exploitation might be advanced when investigators fail to ensure that participants and host populations have reasonable access to successful interventions (cf. Annas & Grodin, 1998; Crouch & Arras, 1998; Glantz et al., 1998). Similarly, 'over-research' was suggested by these respondents to reflect concerns that communities and participants fail to benefit because arrangement has not been made for providing host communities with access to successful interventions post-trial.

Respondent perspectives, however, also support the view that an exclusive focus on interventions derived from the study as the only possible benefit, is excessively restrictive (cf. Emanuel, 2008; Participants, 2004). Direct benefits are noted to be, for the most part theoretical and contingent on the demonstration of the efficacy of an intervention (cf. Emanuel 2008; Participants, 2004). Furthermore, they are unlikely to be a feature of research with healthy volunteers, and are only a possibility in studies of interventions, usually clinical trials (Emanuel, 2008; Participants, 2004). When trials have

negative results or are prematurely stopped, as has been commonplace in HIV/AIDS prevention research recently (cf. Cohen, 2007; Forbes & Mudaliar, 2009; McGrory et al., 2009; Ramjee et al., 2007), a perception of a lack of benefit, and thus 'over-research' may be fuelled (cf. London, 2005; Participants, 2004; Schulz-Baldes et al., 2007; Terrell White, 2007).

### 2.2.2 Tangible benefits

Tangible, clearly identifiable benefits, whether resulting directly from the study intervention or from the supplementary or ancillary procedures in a study, were highlighted in discussions of the 'ORC' in this study, as ethically important in order to demonstrate reciprocity for community contributions to research, and to avoid exploitation (cf. Clark, 2008; Sullivan et al., 2001). It was argued that a lack of tangible benefits could lead to feelings among participants and host communities that they have not been fairly compensated for their participation in research or have been 'over-researched' (cf. Clark, 2008; Sullivan et al., 2001). Concerns to this effect were suggested to be particularly likely to emerge with respect to longitudinal, observational or surveillance research. South African guidelines note that a lack of tangible benefit to research participants is a possible concern in observational or health surveillance research, like demographic surveillance systems (DSS), which can generate valuable information about patterns of disease and health behaviour that can provide the basis for interventions or further studies (Baiden, et al., 2006; Durant & Menken, 2002). However, researchers must negotiate the tension between providing health benefits to communities, and maintaining the scientific integrity of a study (cf. Carrel & Rennie, 2006), a challenge, which respondents suggested might be articulated as concerns about 'over-research'.

### 2.2.3 Ancillary benefits

'Over-research' was linked to concerns about researchers flouting their obligations to participants and host communities (cf. Hawkins, 2008). However, these obligations were defined vaguely and subjectively by respondents.

There was consensus that when research is conducted in a community, something must be given back (cf. Grady,et al., 2008; Sullivan et al. 2001). Respondent perspectives generally supported arguments that researchers are obligated to provide the services necessary to ensure the safety and scientific validity, and that they should ensure access to care and treatment for the condition under study (cf. Emanuel et al., 2004; Heise & Wood, 2005). Debates about benefits emerge regarding the provision of other 'ancillary' benefits (cf. Emanuel et al., 2004; Heise & Wood, 2005), or health and social services which are not strictly necessary to ensure the safety or the validity of a study, or to address harms or fulfil promises (Richardson & Belsky, 2004). What some respondents seemed to suggest were researcher obligations, others argued were supererogatory.

Recent work suggests that communities expect, and that investigators should provide, more in terms of benefit than what is necessary for the safe and valid conduct of research (cf. Barsdorf et al., 2009; Grady et al., 2008; MacQueen et al., 2007). Congruently, respondent perspectives advocated that, on the grounds of general beneficence (cf. Beauchamp & Childress, 2001), if researchers can do something to assist communities at minimal cost to studies or themselves, then they have a positive obligation to do so (cf. Barsdorf, Maman, Kass & Slack, 2010; Hawkins, 2008). As such, researchers were noted to have 'duties of rescue' or 'Good Samaritan' obligations to participants and host communities (cf. Hawkins, 2006, 2008; Richardson & Belsky, 2004).

'Over-research' was suggested to represent concerns about a failure to attend to needs that researchers were perceived as being able to easily address, and was suggested to refer particularly to inadequate attention to the social and economic development needs of communities. This failure might potentially be interpreted as treating participants and communities disrespectfully and as the 'mere means' to an end, and leading to accusations of exploitation (cf. Hawkins, 2008).

Respondent perspectives support the view that in the context of severely limited health and social resources, researchers are sometimes perceived as the only ones who can help. Thus, while problems that are unrelated to a particular study might not strictly be within researchers' scope of responsibility, researchers may nevertheless have an obligation to do something to assist participants and communities, for example, by providing assistance to the community to contact relevant parties who may be better able to help (cf. Hawkins, 2008; London, 2005).

Because the nature of the relationship between researchers and participants allows researchers access to aspects of participants' and communities' lives, respondents in this study argued that researchers have an obligation to respond to community needs outside of the study (cf. Belsky & Richardson, 2004; Richardson, 2007; Richardson & Belsky, 2004). As articulated in the 'partial entrustment model', the extent to which researchers would be expected to go to address problems that emerge during the course of research, depends on the burden generated by the research and the scope, intensity and duration of the researcher-community relationship (cf. Belsky & Richardson, 2004; Richardson, 2007; Richardson & Belsky, 2004).

There were disparities in stakeholder perspectives on the obligation to address ancillary community concerns, which may be far broader than the focus of a single study and which may not fit within the scope of researcher-defined issues of importance (cf. Grady et al., 2008). However, it was generally emphasised that research occurs within a context that cannot be ignored if research is to be conducted both ethically and validly (cf. Benatar, 2002; Carse & Little, 2008; London, 2005). Furthermore, it was argued that, since research in developing or resource-limited contexts is frequently justified on the grounds of its contribution to the improvement of conditions within such contexts, it follows that

research should be conducted in such a way that it impacts positively on conditions in the community (cf. Benatar, 2002; London, 2005; Shapiro & Benatar, 2005). This view is congruent with increasing support for a more systemic approach to health-related research (cf. Ali, et al., 2006) and recommendations for integration of research efforts into local and national healthcare systems (cf. UNAIDS-WHO, 2007). There is increasing recognition that, in developing countries, research is a fundamental aspect of supporting, and 'ratcheting up' standards, in healthcare systems (cf. Shapiro & Benatar, 2005; Volmink & Dare, 2005). Where researchers fail to take context into account, and do not consider the integration of health research efforts into general health systems, concerns about exploitation, or 'over-research' might emerge (cf. Benatar, 2002; Costello & Zumla, 2000).

Discussion of the 'ORC' by respondents in this study highlight shifts in conceptions of research-related benefits from what has been termed the 'minimalist perspective', which only takes into consideration fairness, or perceived fairness, at the micro-level of the researcher-community interaction, to broader, increasingly holistic, development focussed perspectives which views the social and political influences on health as relevant to determining researcher obligations (cf. Abdool Karim & Abdool Karim, 2010; London, 2005; IJsselmuiden et al., 2010). Despite arguments that researchers are not responsible for addressing the social development needs of communities, most respondents acknowledged that, given the degree of contact that researchers involved in lengthy community-based studies have with communities, and that in many developing country contexts health researchers are the among the few parties who have the capacity to assist, researchers cannot dismiss needs which might emerge during the course of a study.

## 2.3   Disparities in definitions of researcher roles

In this study, community respondents defined the scope of researcher obligations much more broadly than academic respondents did, explicitly arguing for attention to development needs. The disparities in perceptions of researchers' obligations seem to be rooted in different definitions of the role of the researcher. For example, where health researchers, are understood to be doctors, their obligations are defined according to a medical model, and the relationship between researchers and participants is viewed as that between physician and patient, and the researchers' obligations to participants are those doctors would have to their patients (Belsky & Richardson, 2004; Hawkins, 2008; Richardson & Belsky, 2004). In this case, a researcher failing to respond to participants' medical needs might be perceived to constitute an ethical violation.

Similarly, where researchers are understood to be development agents, or service providers, the failure to deliver services or to respond to development needs, might be perceived to be an ethical violation and could lead to allegations of 'over-research'. It is this role confusion, which seems to be behind what might be perceived to be unrealistic expectations of community members (e.g. that researchers should provide funding for the tertiary education of community members; that

researchers should be responsible for implementing income generating projects) (cf. Horng & Grady, 2003; Kimmelman, 2007; NCOB, 2002).

It was noted in this study that researchers experience a tension between their role as scientists and thus their obligation to generate reliable, generalisable and valid data, and their duty to aid, given the, often desperate, conditions faced by the members of the communities in which they work. While there have been suggestions in the literature regarding how to determine the scope and depth of researcher obligations to respond to the needs of participants and communities (cf. Belsky & Richardson, 2004; Hawkins, 2006, 2008; Richardson & Belsky, 2004), it seems that on the ground, particularly in resource-limited contexts, there is a lack of clarity regarding roles and attendant obligations.

While some researcher-respondents argued that their obligation to address the healthcare concerns of participants is grounded in the their role as healthcare providers, others argued that researchers should not be obliged to provide more than was necessary for safety and validity, as they are not service providers and the conflation of healthcare provision with researcher roles undermines the purpose of research through possibly compromising the quality of data (cf. Hawkins, 2008; Richardson & Belsky, 2004).

Researchers occupying various roles simultaneously might make it difficult for communities to have a clear idea of what they can legitimately expect from them. The sense that people have been exploited or 'over-researched' or that there has been a failure to fulfil obligations, might be located in the complexities regarding the role of researchers in resource-limited settings.

Furthermore, ostensibly informed community-representatives argued for benefits that several researcher respondents contended to be unreasonable. Even after reportedly extensive engagement and education, and having been informed of, and having agreed to, what the researchers would and would not provide to participants and the community, there were still significant divergences in perspective between researchers and community respondents. This suggests either that information regarding the scope and limitations of researchers' responsibility was either not clearly communicated at the outset, or not fully understood. Regardless, this divergence in perspective reveals a fundamental disconnect and a lack or 'meeting of the minds' between researchers and communities.

## 2.4    Concerns about vulnerability & tensions in the conception of justice

The socio-economic inequalities between researchers and communities create significant power disparities in their relationship (cf. van der Riet & Boettiger, 2009), which in turn foster community vulnerabilities to exploitation (cf. Carse & Little, 2008; SA MRC, 2003, Guideline 5.1). While ethical guidelines and research ethics literature identify numerous groups as vulnerable in research (cf. CIOMS, 2002, Guideline 13; Iltis, 2009; Levine et al., 2004; SA MRC, 2001), in relation to the notion of

the 'ORC', vulnerability seems primarily to refer to socio-economic disadvantage. Many of the concerns raised in respondents' perspectives on the 'ORC' mirror existing concerns about the vulnerability of those with limited resources in research, including that they are more susceptible to 'undue inducement' to participate in risky research, or that they may accept an unfair level of benefit relative to the risks they bear because of their limited options (cf. Denny & Grady, 2007; Grady, 2009).

Power and vulnerability are central in the dynamics of research stakeholder relationships, are key to various conceptions of exploitation (cf. Hawkins & Emanuel, 2008; Macklin, 1998, 2003, 2004a), and are features of various interpretations of the notion of the 'ORC' articulated in this study. Analogous to concerns about the exploitation of developing country communities in international health research, 'over-research' arguably represents concerns that impoverished communities are more likely to be unfairly targeted for research than better-resourced communities, for reasons of convenience rather than science (cf. Belmont Report, 1979; Wallerstein, 1999).

However, there are no data to suggest that socio-economically disadvantaged individuals are more likely to enrol in risky research because of impaired decision-making as a result of benefits (Emanuel, 2004, 2005; Grady, 2009). Furthermore, offering fewer benefits to avoid decision-impairment represents an inappropriate response, research which is inherently unethical, or requires participants to endure unreasonable risks, should not be conducted at all, for any reward, or with any group of participants (Emanuel, 2004, 2005). There has also been some suggestion that economically disadvantaged groups are actually less likely to be blinded to the risks of a study than their more advantaged counterparts, because they are especially experienced at making difficult decisions in the context of limited resources (cf. Denny & Grady, 2007; Emanuel, 2004, 2005). Higher enrolment figures among poor populations in some studies do not necessarily indicate 'undue inducement', or 'over-research' and in many instances the decision to enrol in research may be entirely logical and appropriate in the context – research participation may be the best means of accessing certain kinds of care in resource-limited circumstances (cf. Denny & Grady, 2007).

Moreover, although taking advantage of unfair conditions to manipulate an individual's decision, or to offer an unfair level of benefits, is exploitative, if the level of benefits offered is fair, and participants and communities are treated with due respect, regardless of the involvement of economically-disadvantaged participants, the claim of exploitation does not stand (Denny & Grady, 2007; Grady, 2009; Wertheimer, 2008a, 2008b). Just as under different socio-economic circumstances some individuals might choose to be employed in a different job (e.g. doctor versus a miner), in another situation, where other options are available, some individuals might choose not to participate in research.

Although vulnerability in itself does not make exploitative research inevitable, where researchers take unfair advantage of background vulnerabilities to offer unfair compensation or to manipulate participants into agreeing to research enrolment on the basis of inadequate understanding, exploitation is more likely (cf. Grady, 2009; Participants, 2004; Wertheimer, 2008a, 2008b). Similarly, while not all 'vulnerable' communities which host research are 'over-researched', where researchers take advantage of community compliance or misunderstanding in order to avoid challenges in the conduct of research, allegations of 'over-research' are more likely.

The notion of 'over-research' also  seems to represent concern that owing to a lack of power in the research relationship, communities might fail to object to, or raise concerns about, unethical treatment in research and so might be excessively targeted for risky research for these very reasons leading to their becoming 'over-researched'.

Many of the reasons advanced as potentially leading to the excessive targeting of communities for research, might also result in 'vulnerable' and disadvantaged communities being 'neglected' for research, or 'under-researched', because they do not have the political power to draw attention to their needs, or the financial power to attract the attention of researchers and research organisations, or because they do not share the researchers' language (cf. Wallerstein, 1999) or are geographically difficult to access (cf. Thiessen et al., 2007). Furthermore, cautious protectionist approaches to research ethics, might effectively result in the exclusion of vulnerable groups from research (cf. Belmont Report, 1979; Stone, 2003). The exclusion of groups from research on the grounds of vulnerability has been criticised as rendering findings needlessly less generalisable (cf. Macklin, 2003), and depriving these groups of the potential benefits of research (cf. Mastroianni & Kahn, 2001). Discussions of the 'ORC' highlight a tension between 'under' and 'over' research.

Recent perspectives on vulnerability adopt the position that, although factors contributing to vulnerability of certain groups must be considered when making decisions about the selection of participants for research, the categorical exclusion of these groups from research, might constitute unjustified paternalism and could deprive already disadvantaged groups of needed benefits (cf. Denny & Grady, 2007; Emanuel et al., 2004; UNAIDS-WHO, 2007, GP 8).

Respondent perspectives suggesting that vulnerability might result in either 'over-research' or 'under-research', thus highlighting tensions in conceptions of justice as either protection from possible burden or access to potential benefit, evident in the varying paradigmatic approaches to research oversight , and emphasised during the AIDS movement in the U.S., are clearly highlighted (cf. Emanuel & Grady, 2006; Mastroianni & Kahn, 2001).

Discussions of the legitimate gatekeeping authority for 'vulnerable' communities in relation to the notion of the 'ORC', also draw attention to tensions between protecting communities through justified paternalism[13] by RECs (cf. Beauchamp & Childress, 2001), and respecting community autonomy. While it was argued that 'over-research' could only be considered a legitimate concern if raised by communities themselves, and that on the grounds of respect for community autonomy that communities should make gatekeeping decisions regarding what happens in their community (cf. Edwards, Kirchin & Huxtable, 2004). It was simultaneously argued that, especially vulnerable, communities might fail to identify problems like 'over-research' because they may have an over-optimistic view of the potential benefits of research, and may have an inadequate understanding of the long-term implications of their involvement in certain kinds of research, and so may not be the best judges of their interests (cf. Garrard & Dawson, 2005).

## 2.5    'Over-research' as a misunderstanding or rumour

Several commentators have argued that concerns about exploitation might be inappropriately advanced when research is conducted in impoverished contexts, even when research is fundamentally ethical, because of confusion between background injustices and unfair processes or benefits in the research interaction  itself (Denny & Grady, 2007; Grady, 2009; Wertheimer, 2008a, 2008b). This study found that 'over-research' might represent a similar confusion.  In light of perspectives articulated by respondents in this study, it seems possible that concerns about 'over-research' represent concerns about socio-economic and historical injustices that, although they are highlighted by the research, have little to do with the conduct of research itself.

Vulnerability and structural and social inequities, in addition to a community's history, might give rise to perceptions of exploitation (cf. Participants, 2004), or as evident in this study, perceptions of 'over-research'. In many ways, community and public perceptions of unethical treatment in a particular study are as insidious as actual cases of exploitation (cf. Participants, 2004) and can have as powerful an effect as negative scientific results on researcher-community relationships, on whether or not a study can successfully run to completion, and on public perceptions of research in general (cf. Freimuth et al., 2001; McGrory et al., 2009; Ramjee et al., 2007).

Allegations about unethical research conduct, for example, perceptions that research participants have been 'instrumentalised' or treated as 'guinea pigs', are frequently argued to represent misunderstandings and misconceptions about research, arising from a lack of research literacy among stakeholders (cf. Forbes & Mudaliar, 2009; IAVI, 2007; McGrory et al., 2009; Ramjee et al., 2007). Similarly, concerns about 'ORCs' were argued by respondents to reflect a lack of research understanding by those raising the concerns. It was also suggested that communities may struggle to

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[13] Justified paternalism refers to over-riding an individual's autonomy for his or her own good

understand subtle theoretical differences between studies and one study is likely to look very much like another (cf. Clark, 2008). Establishing the value of a study and ensuring that the purpose of its conduct is clear, were argued to be mechanisms for averting concerns about 'over-research' (cf. Peterson 1999 in Clark, 2008).

In contexts where familiarity with, and understanding of, science and research is limited, communities may lack the context and tools for making sense of information provided to them by researchers, and this could create the potential for misunderstandings and misinterpretations (cf. Forbes & Mudaliar, 2009). In combination with low levels of research literacy, widespread mistrust of science and health researchers and a lack of understanding of medicine, generally, could give rise to rumours about research, for example that researchers are exploiting or 'over-researching' certain communities (cf. IAVI, 2007; ICASO, 2006; Shah, 2006; Thiessen et al., 2007). Rumours about biomedical research are common in most developing country contexts (Geissler & Pool, 2006; Gikonyo et al., 2008). The notion of the 'ORC' in relation to HIV prevention research was noted by respondents to arise in the context of significant mistrust of research in South Africa (cf. Cullinan & Thom, 2009; Nattrass, 2008) and was thus suggested to have some of the qualities of a rumour.

While frequently dismissed as misunderstandings of science and medicine, rumours about research have been shown to flourish even in communities with high levels of scientific understanding (cf. Geissler & Pool, 2006; Gikonyo et al., 2008). The concerns underlying rumours about research developing countries are frequently rooted in the history of colonialism and exploitation (Geissler & Pool, 2006). Similarly, perceptions of 'over-research' were also argued in this study to reflect a community's history and prior experiences of research. It was suggested that previous negative experiences with research could create mistrust and might hamper the establishment of truly collaborative partnerships.

It has been suggested in the literature that in some cases concerns about the ethics of research raised by communities may not be literal concerns, but rather are rational attempts to fill gaps in understanding (Geissler & Pool, 2006; Gikonyo et al., 2008; Marsh et al., 2008). For example, 'over-research', in the South African context, in suggesting concerns that selection decisions perpetuate the racial injustices of South Africa's apartheid history (cf. Essack et al., 2009), might represent a platform for expressing worries about enduring segregation, structural inequities and other artefacts of apartheid, which are often sensitive and difficult to talk about outright. Some respondents suggested that the notion of 'over-research' might be an automatic response in a context which is highly sensitised to potential racial injustice (cf. Barsdorf & Wassenaar, 2005). Given the significance of race in the South African context, concerns about racial injustice are likely to be at the forefront of people's minds and people are arguably highly sensitised to the potential for such injustice to occur. Thus, it is

predictable that concerns might be raised about racism when there is a sense of injustice occurring, to the extent that other concerns might be inappropriately labelled as such.

## 3      *Relationships between research stakeholders as a central concern*

Understanding the relationships between various stakeholders in a research interaction emerged as key to interpreting the notion of the 'ORC'. Furthermore, overcoming the complexities created by the disparate perspectives from which different stakeholders approach research is dependent largely on the relationships between stakeholders. Respondent perspectives on the 'ORC' strongly suggest that problems with collaborative partnerships between stakeholders result in ethical concerns which describe or result in allegations of 'over-research', and this suggestion is supported by literature outlining the value and rationale for collaboration between stakeholders in research.

### 3.1      Community-researcher relationships

In addition to facilitating meaningful informed consent (cf. Dickert & Sugarman, 2005 Marshall, 2006,2007; Trickett & Espino, 2004; Wallwork, 2008), to facilitating research literacy (cf. ICASO, 2006 ; UNAIDS, 2006; UNAIDS-AVAC, 2007) and ensuring that research is responsive to the needs and priorities of the host community (cf. Cornwall & Jewkes, 1995). Respondents highlighted  good community-researcher relationships as critical to minimising and addressing rumours about research, which commentators have suggested are symptomatic of problematic relationships between researchers and communities, and might represent a failure by researchers to consider the contextual factors, which might impact on community engagement in research (Geissler & Pool, 2006; Molyneux et al., 2005). In fostering community literacy, respondents noted that active community-researcher engagement would assist researchers to anticipate context specific research-related risks and to implement appropriate protective measures (cf. Dickert & Sugarman, 2005; Emanuel et al., 2004; Emanuel et al., 2008; Wallwork, 2008). Respondents also highlighted community-researcher collaboration as central in operationalising fair benefits (cf. Buchanan, 2008; Dickert & Sugarman, 2005; Emanuel & Grady, 2006; Sharp & Foster, 2002, 2007; Trimble & Fisher, 2006; UNAIDS, 2006; Wallwork, 2008),that are perceived as fair (cf. Gutmann & Thompson, 1997). In addition to mediating negotiations of benefits which are perceived as fair, allowing communities to articulate their concerns about the research process and outcomes, meaningful community-researcher relationships demonstrate respect for community perspectives and this helps to confer legitimacy on the research project and its conduct, because individual stakeholders perceive their voices to have been heard in relation to decisions affecting them (Brugge & Kole, 2003; Buchanan, 2008; Dickert & Sugarman, 2005; Daniels, 2004; Gutmann & Thompson, 1997; Schell & Tarbell, 1998; Sharp & Foster, 2000).

The notion of the 'ORC' in respondent perspectives, also indicated concerns about a failure by researchers to consider broader beneficence and social justice obligations. Social justice concerns were complex issues for researchers as they are frequently more extensive than the single research

interaction. Researchers may lack the resources for dealing with them. However, community-researcher collaboration was argued to serve as an empowering process, strengthening the capacities of participants to address the conditions affecting their health, and encouraging the development of 'social capital' within a community, which is arguably critical in addressing more of the social justice issues, which form the backdrop to a research interaction (cf. Buchanan et al., 2007; Campbell & Jovchelovitch, 2000; Campbell & MacPhail, 2002; Innes & Booher, 1999; Wakefield & Poland, 2005). Thus, good community-researcher relationships, in helping to foster community empowerment and the development of social resources which enable communities to take control of and address their own problems independently, are critical to meeting social justice obligations(Campbell & Jovchelovitch, 2000; Zakus & Lysak, 1996), and to avoiding 'over-research'.

Furthermore, community-researcher collaboration, in fostering community ownership of research interventions and contributing to community capacity-building was argued to be a key mechanism for addressing the health inequities in developing countries and for fostering health improvements, and for delivering health benefits to the broader community (cf. Clouse et al., 2010; Shapiro & Benatar, 2005). Such collaboration also helps to overcome the reputation of research as collecting data and leaving, without any consideration of the impact of this on the community (cf. Costello & Zumla, 2000; Edejer, 1999; Macklin 2003, 2004), and to ensure sustainability of research-related interventions beyond the life of a single study (cf. Altman, 1995).

### 3.1.1   Tokenism versus meaningful collaborative partnership

Respondent perspectives on the notion of the 'ORC' underlined concerns about meaningful versus tokenistic community participation (cf. UNAIDS-AVAC, 2007). The value of community engagement in research as a tool for achieving community empowerment was acknowledged. However, concerns were raised about the potential use of the superficial language of collaboration simply to portray an outwardly collaborative partnership and thus legitimise the conduct of studies, even when they do not include substantive community involvement (cf. Cooke & Khotari, 2001; Flicker et al., 2007; Khassay & Oakley, 1999; Morgan, 2001).

Allegations of 'over-research' seem likely to arise when communities are perceived to be involved in research tokenistically and that engagement reflects a utilitarian effort to facilitate the efficient implementation and cost-effective conduct of research using community resources (cf. Morgan, 2001), or serves merely to fulfil funding, or ethical, requirements and has no real orientation towards the establishment of true collaborative partnerships (cf. Koné et al., 2000).

For the most part, despite the laudable goals and somewhat lofty theoretical ideals articulated by respondents, the degree of community participation in research reported appears primarily to involve CAB review of consent documents and input into recruitment methods. These activities are largely

researcher-driven and are geared towards obtaining community buy-in and support (cf. Arnstein, 1969).

What emerged clearly in this study was the impact of broader structural power dynamics within society, on the relationships in the research context (cf. London, 2005; van der Riet & Boettiger, 2009; Wallerstein, 1999; Wallerstein & Duran, 2003). At one level, the tendency for communities to defer to researchers in decision-making processes evident in this study suggests a low level of participation and an inadequate power sharing between stakeholders (cf. Arnstein, 1969; Cornwall & Jewkes, 1995). However, the tendency for community representative respondents to defer to both researchers and RECs regarding gatekeeping and research priority setting decisions, suggests that this disempowerment is the result of structural power dynamics that are broader than the individual research situation. While lack of community objection to research might be taken to indicate community acceptance (cf. Ramjee et al., 2007), some respondents noted concerns about disempowerment. It was suggested that this might rather be indicative of compromised voluntariness in socially marginalised communities, which may promote acquiescence to requests for research participation, regardless of actual willingness to participate (cf. CIOMS, 2002, Guideline 13, Commentary; Gaventa, 1980, 2006; UNAIDS-WHO, 2007, GP 7, Commentary; van der Riet & Boettiger, 2009). Furthermore, frequently lacking even basic resources, impoverished communities are in a disempowered position, relative to researchers (cf. Gaventa, 2006; van der Riet & Boettiger, 2009)and thus lack the bargaining power to advance claims for fairer benefit offers or to challenge researchers regarding the fairness of study procedures (cf. Carse & Little, 2008; London, 2005).

While most respondents agreed that research should be responsive to the needs and priorities of the host community, there was also acknowledgement that communities usually had little or no influence on research priority setting. Ideally, communities should share power in the research agenda-setting process, but research funding might preclude this (cf. NCOB, 2002; Trickett & Espino, 2004). It was noted that the priorities for research are shaped by global economic and political forces and are often set by external sponsors (cf. Benatar & Vaughn, 2008; London & Kimmelman, 2008; Macklin, 2004; NCOB, 2002). As such, in most externally funded research (as is usually the case with HIV prevention research), researchers approach communities only after a significant portion of the research planning has been completed, which immediately skews power in favour of the researchers (cf. Trickett & Espino, 2004). It was noted in this study, that since the researcher-community relationship is initiated with a power imbalance at the outset, this creates a challenge for establishing a collaborative partnership with the community (cf. GCM, 2004).

### 3.1.2 Community representation

The model of community representation via a CAB has incurred criticism as tokenistic, serving merely to placate communities by giving them the impression that their perspectives have been considered

(cf. GCM, 2004; Koné et al., 2001). However, CABs seemed to be the primary mode of community engagement. Concerns were raised about how representative of the community the CAB really is particularly given challenges regarding definitions of the notion of 'community' (cf. Jewkes & Murcott, 1998; Marsh et al., 2008;Trickett & Espino, 2004; Viswanthan, 2004). Furthermore, respondents raised concerns that, as opposed to community opinion, the views articulated by the CAB are merely the perspectives of a few powerful individuals, who share little with the majority of the community (cf. GCM, 2004; van der Riet & Boetigger, 2009; Wallerstein, 1999), and expressed uncertainty about whether or not CABs were fulfilling their role as intermediaries between the researchers and the community (cf. GCM, 2004; ICASO, 2006), which could give rise to concerns about 'over-research'.

Discussions about the 'ORC' in this study also uncovered concerns regarding the capacity of CABs to provide a critical community perspective on research in resource-limited and developing country settings. This resonated with worries about the translation of the CAB model, which emerged among educated, resourced and empowered communities, to impoverished, disempowered communities, with low levels of formal education (cf. GCM, 2004). Respondents agreed with recent perspectives advanced in the literature and ethical guidance that community engagement efforts should extend beyond the CAB model (cf. GCM, 2004; UNAIDS-AVAC, 2007). However, suggestions of concrete alternative approaches that have been, or could be, taken were limited. This suggested that despite the rhetoric, the practice of community engagement remains focussed on the CAB model.

Some respondents questioned the independence of CABs and raised concerns about their capacity to provide critical input into research, since most are initiated, funded, trained and supported by the research organisation conducting the study. In a context where research involvement provides CAB members with capacity-building and travel opportunities, the likelihood that they would criticise a study, even when justified, was questioned.

## 3.2    Researcher–researcher relationships

The relationship between researchers seems to have received less attention in the literature than the community-researcher relationship. However, it appears to have significant bearing on the interpretation of the notion of the 'ORC'.

Research is recognised as highly competitive, politicised and hierarchical (cf. IJsselmuiden et al., 2010; Martin, 1998). Funding for research is usually allocated through competitive, often politically influenced, grant-awarding processes, and since prestige and career advancement for researchers is based on innovative and progressive ideas. Thus, it is perhaps unsurprising that respondents characterised the relationships between researchers as frequently competitive and somewhat antagonistic. In the context of multiple studies being conducted in the same community, a failure to establish a collaborative relationship with other researchers working in the same area could result in

the conduct of repetitious and unnecessary research, thus compromising the potential contribution of the research to knowledge progress, wasting limited resources, and undermining social value (cf. Lairumbi et al., 2008; Whitworth et al., 2008).

In the context of multiple ongoing studies, concerns about the nature of the relationship between different researchers working in the same community were highlighted as central to the scientific validity of each individual study. Whether or not co-enrolment or contamination between studies (both of which were linked to the notion of the 'ORC') were concerns, depended to a large degree on how well these studies were coordinated with one another (cf. Ramjee et al., 2010). Good coordination was, in turn argued to be dependent on a collaborative relationship between researchers. To address the potential for co-enrolment in multiple studies, some researchers have implemented systems for checking whether or not potential participants are enrolled in other studies for example by using a confidential database of participants linked to identity numbers, or a database of participant fingerprints (cf. Ramjee et al., 2010). Ensuring no overlap or co-enrolment between trials might be easier when all trials are co-ordinated by a single research institution. However, as illustrated by the discovery in 2008 of the co-enrolment of 192 participants in two different microbicide trials run by two different research organisations at two separate sites (cf. CAPRISA, 2008; Ramjee et al., 2010), inter-organisational collaboration is arguably critical to maintaining the scientific integrity of studies.

Furthermore, 'over-research' was characterised in respondent perspectives as a concern about confusion which might arise different projects providing different information to the community. This misunderstanding was suggested to potentially compromise the scientific integrity of studies through increasing the possibility for protocol violations and co-enrolments. Collaboration between researchers would help to deliver co-ordinated messages to the community so as to avoid confusion and to facilitate a more cohesive approach to community engagement, but ensuring that everyone understands who is doing what in a community.

Relationships between researchers, usually involving researchers from developed countries and those from developing countries, have been described as 'scientific colonialism', wherein exploitative relationships between colonies and colonists, are replicated in research contexts with the use of developing country resources to meet developed world priorities . While relationships between researchers discussed by respondents in this study were not typically 'north-south' researcher relationships (cf. Costello & Zumla, 2000; Edejer, 1999), there were gestures of concern regarding the analysis of local data by foreign investigators and about the activities of externally funded and controlled research sites.  What emerged quite strongly however, was the notion of researchers taking 'ownership' of, or 'colonising' the communities in which they conduct research (cf. Costello & Zumla, 2000). A perhaps insignificant observation is that in discussing their research experiences, researchers

consistently refer to "our community", suggesting a sense of possession. Although it may be a linguistic feature, community representative rarely if at all refer to "our researchers".

The 'ORC' seemed to reflect a concern about researchers taking 'colonial' control of a community in which they are working, and attempting to regulate what other research projects or interventions are introduced into a community. Furthermore, respondents contended that, the notion of 'over-research' might be used as a mechanism for exercising this control, and preventing others from entering into the community (cf. Nattrass, 2006). There was some suggestion in respondent perspectives  that researchers would exert this gatekeeping power in response to concerns about maintaining scientific integrity or concerns about the best interests of the community. However, it was also contended that, plausibly, in line with the idea of community ownership, the notion of 'over-research' might be used to justify preventing other researchers from entering the community and exploiting their hard work at establishing infrastructure and community relationships.

There has been limited exploration of the relationship dynamics between different researchers working on different studies within the same geographical community (cf. Hoeyer, et al., 2005; Nattrass, 2006). Nattrass (2006), suggests that researchers may deny other researchers access to "'their' patients, not because they are worried about the adverse implications of the ...research for the patients, but because they do not want any other research (besides their own) being conducted on the patients" (p. 18).

Respondent perspectives also advanced the viewpoint that 'gatekeeping' of a community, was not a fair or ethical position for researchers to occupy because it undermines the principle of respect for individual and community autonomy (cf. Nattrass, 2006). Respondents argued that researchers making decisions regarding what other research or interventions are allowed to be conducted in a community is paternalistic and implies that community members do not have the capacity to make these decisions independently (cf. Nattrass, 2006). Furthermore, this approach might deny communities access to other potential benefits. It was suggested that as opposed to preventing other interventions or research from taking place in a community, researchers should build other interventions into their design. Furthermore, collaboration between researchers could help manage some of the complexities of maintaining scientific integrity in the context of multiple ongoing studies, if this is a concern.

Gatekeeping of communities by researchers in order to prevent others from accessing the community, represents a violation of, and unwillingness to fulfil ethical principles, which call for collaborative partnerships between stakeholders (cf. Emanuel et al., 2004; UNAIDS-AVAC, 2007; UNAIDS-WHO, 2007, GP 2). It also indicates a particular attitude towards the community – as an object to be owned. 'Over-research' was observed to be a concern that researchers might use communities as collateral in

their disputes with other researchers. In effect, displaying an attitude of ownership and domination towards community.

## 3.3 Relationships between researchers and other stakeholders

This study found that relationships between researchers and other stakeholders in HIV prevention research, including RECs, the media, and governments, could have a significant bearing on allegations of 'over-research'.

### 3.3.1 Research Ethics Committees

Respondent discussions of the 'ORC" highlighted tensions in defining the role of the REC - as either an authoritarian gatekeeper or a partner in the process of ethical review. Perspectives from most respondents lent support the view that particularly in developing countries, in order to maximise limited resources and capacity, a collaborative approach to ethical review involving inputs from researchers and community members, was necessary (cf. Dowdy, 2006; London, 2002; SA MRC 2001).

### 3.3.2 Government

Since the potential benefits of research to the population of a host country are often advanced as justification for research conducted in resource-limited settings, the translation of research findings at a national policy level is central to delivering on this promise, and establishing partnerships with policy-makers and implementers at the outset of research is essential for this to occur (cf. Lairumbi et al., 2008). Respondents argued that a failure by researchers to establish collaborative relationships with government, policy-makers, and those responsible for implementing policies would compromise the likelihood that research findings will be implemented into policy and practice (cf. Lairumbi et al., 2008; WHO, 2004), which could, in turn, lead to worries about 'over-research'.

In the South African context, perceptions of 'over-research', particularly with regard to HIV/AIDS-related research, may have been fuelled by a failure to translate research findings into policy and practice (cf. Abdool Karim & Abdool Karim, 2010). Despite producing world-class HIV prevention and AIDS treatment research, South Africa is observed to be missing a vital link between research, policy and programme implementation, and as such, the population rarely benefits from this locally-generated scientific progress (Abdool Karim & Abdool Karim, 2010). In addition to having to follow global funding agenda, a critical obstacle has been the often acrimonious relationship between researchers and the South African government, particularly during the Mbeki-Tshabalala-Msimang era (Abdool Karim & Abdool Karim, 2010; Cullinan & Thom, 2009). As such, until the change in government in 2009, researchers had little, if any relationship with the government and no influence on policy, meaning that, beyond individual research studies and non-governmental service delivery, HIV/AIDS research could have little practical impact in South Africa (Abdool Karim & Abdool Karim, 2010; Cullinan & Thom, 2009).

Dissemination of findings was emphasised to be critical to ensuring their contribution to scientific knowledge progress and their translation into policy and practice (cf. Emanuel et al., 2004; WHO, 2004). However, traditional methods of disseminating research results to decision-makers, like presenting findings at academic conferences or publication of research reports in academic journals, are criticised as relatively 'passive' and inaccessible to stakeholders outside of academia (cf. Lairumbi et al., 2008; WHO, 2004). Perspectives in this study suggested that these methods of disseminating research findings, while contributing to the career development of researchers, might have limited practical application, and compromised social value (cf. Lairumbi et al., 2008), which could result in perceptions of 'over-research'. In line with recommendations in the literature (cf. Lairumbi et al., 2008; WHO, 2004), respondents suggested that partnerships need to be established and results disseminated in an action-oriented, implementable format, to key stakeholders. Thus, in many ways 'over-research' seems to imply concerns about the purpose of research and the generation of knowledge for use (cf. Singer, 1993).

### 3.3.3   Local service delivery

'Over-research' was also suggested to refer to concerns about research undermining local health care infrastructure by placing excessive burden on limited resources. However, collaborative relationships between researchers and those responsible for health service delivery, in creating the space for the negotiation of mutual benefit , might help to avoid this situation and could actually facilitate the improvement of these services through resource-sharing, additional training and capacity building. As highlighted by several commentators and empirical studies, a lack of sustainability of research interventions from which communities benefit, beyond the life of a single study is a common complaint by communities, and a possible source of perceptions of exploitation, abandonment or 'over-research' (cf. Altman, 1995; NBAC, 2001; Reback et al., 2002; Sullivan et al., 2001; Trickett & Espino, 2004). The active involvement of service-delivery agencies in research collaborations is noted to be important for facilitating a sense of local ownership of research-related interventions, and for fostering the capacity to manage these interventions independently (Altman, 1995; Reback et al., 2002). Therefore, meaningful collaboration is essential to ensuring sustainability, and avoiding concerns about communities becoming dependent on research organisations for service delivery (Altman, 1995).

While some suggested that, as reciprocity for their participation, research participants should receive benefits and a higher standard of healthcare than that which would otherwise be available, many academic respondents supported the perspective that introducing higher standards of health care for research participants in creating a dual standard locally, would be unfair to those who were excluded from research participation, and might be interpreted as 'over-research'. Furthermore, higher standards of healthcare and ancillary benefits could constitute 'undue inducement' to participate. However, in accordance with trends which link research efforts to perspectives on advancing global justice, and, advocate a holistic, systemic approach to research (cf. Benatar, 2002; IJsselmuiden et al.,

2010; London, 2005; Shapiro & Benatar, 2005) it was contended, particularly strongly by community respondents, that researchers should respond, not just to the needs of those participating in a particular study, but to those of the broader community. As articulated by Shapiro and Benatar (2005), the provision of benefits and health care improvements to the broader community helps to overcome concerns about double standards, unfairness and undue inducement.

Furthermore, on the grounds of beneficence, there was strong advocacy for researchers to provide a range of ancillary benefits to participants and communities (cf. London, 2005; Shapiro & Benatar, 2005). Given the potential scope of ancillary benefits and worries that delivering them might be burdensome to researchers, as commentators suggest, it was proposed that researchers should collaborate with agencies responsible for local service delivery (cf. London, 2005; Shapiro & Benatar, 2005). In addition to assisting researchers to meet their ancillary care obligations, partnerships are critical for linking research to programmes, and to the provision of support for progressively 'ratcheting up' the standards of health care in resource-constrained settings through resource-sharing and improved capacity (cf. Clouse et al., 2010; London 2005; Shapiro & Benatar, 2005; UNAIDS-WHO, 2007, GP 14).

While a failure to address the development needs of participants and communities might result in disagreement which gives rise to allegations of 'over-research', respondent perspectives on researcher-service provider partnerships, resonate with suggestions that the research enterprise should be conceptualised and implemented as "a kind of anchor point around which aid can be coordinated" (London, 2005, p.33).

### 3.3.4   Media

A relationship of particular concern with regard to the notion of the 'ORC' was between researchers and the media. The media have been identified as a key research stakeholder with the power to educate the public about and facilitate support for research, but also to create confusion and controversy and to fuel misperceptions about research (cf. Forbes & Mudaliar, 2009; McGrory et al., 2009; Mills., 2005; Ngilangwa, 2007).

This study linked many of the perceptions of 'over-research' to irresponsible and inaccurate media reporting of research, to a largely research illiterate public, who tend to trust information in the media (cf. IAVI, 2007; ICASO, 2006). The media were frequently portrayed as an unhelpful stakeholder in research and were argued to fuel misperceptions about research, and to create concerns about 'over-research', where there was no cause for this. Media involvement in research was noted to increase the possibility of social harms to participants and communities. The more research conducted in a community the more media attention is likely, and in addition to the risks inherent in research

participation, media involvement raises additional risks for participants and communities because of how they might be publicly portrayed.

Journalists were noted to lack scientific research literacy and thus to be more likely to misunderstand research and to misrepresent studies when reporting on them (cf. Essack et al., 2009; Ngilangwa, 2007). The relationship between researchers and the media, which gives rise to perceptions of 'over-research' has been described as somewhat acrimonious (cf. Essack et al., 2009; Ngilangwa, 2007). While researcher responses may be to dismiss the media, as reported in this study, and refuse to engage with them, it is suggested that this might further perpetuate the acrimony and that it would perhaps be prudent rather to make active attempts to forge good relationships with the media (cf. Ngilangwa, 2007; UNAIDS-AVAC, 2007). This engagement might help not only to foster research literacy among media personnel, but might also help to ensure more accurate dissemination of research information and better general research literacy and better public perceptions of research (cf. Ramjee et al., 2007).

'Over-research' might be understood to mean exploitation. However, exploitation itself could mean a range of different things. 'Over-research' seems fundamentally linked to disparate positions and perspectives between stakeholders in the research interaction arising from challenges in inter-stakeholder relationships.

# 4 Limitations

## 4.1 Generalisability – Transferability

Given the limited sample size, the fact that respondents were drawn from only two regions of South Africa, and that CAB respondents were primarily representative of a single site at a particular point in a study, the generalisability of the findings of this study may be limited. However, 'generalisation', in the quantitative sense, may not be an appropriate aim for this kind of research, which aims to collect and interrogate rich data. It might be suggested that extrapolation (Silverman, 2005), the notion that if some, or all, respondents in a group mention an issue as important then it demonstrates that their perspective is feasible within their contexts, is more fitting.  This does not mean that the full spectrum of possible perspectives have been covered within a stakeholder group, nor does it provide information regarding the probability with which these perspectives will occur in the broader population. However, it does allow exploration of the range of positions and arguments that are possible and acceptable within each stakeholder group and the differences of position that are possible between groups. Rather than reaching conclusions regarding the percentage of members of a stakeholder group supporting a particular perspective of the 'ORC', the analysis aimed to explore the range of opinion, highlighting dilemmas, debates and diversity of opinion both within and between groups.

Any future exploration of 'over-research' should specifically aim to access the perspectives of CAB members from a broader number of sites.

The selection of the CAB members dependent of who the researcher was 'allowed' to contact by the research sites is problematic, because the CAB members who were selected might be those who supported the philosophy of the organisation. Furthermore, this may have created the impression that the researcher was not independent of the research organization and so CAB members may have been reluctant to voice negative sentiments that they may have towards research or the organisation to which they were affiliated. It is thus possible that the views of these CAB members might have been skewed or biased in some way. The approach of allowing the researcher to contact the members of the CAB independently, was arguably much less prone to concerns about bias. CAB respondents seemed more willing to raise critical concerns in this case. This observation also links to some of the general concerns in the literature about the independence of CABs (cf. GCM, 2004), who are often initiated by, and financially supported by the research organisation.

While the perspective of community representatives from a community that has been labelled 'over-researched', added substantial value to exploring the connotations of the notion, not having the opportunity to include the perspectives of researchers and community representatives at Demographic Surveillance Sites, which have explicitly been linked to 'over-research', was a significant limitation of this study. Future research should once again attempt to explore the notion with stakeholders at these sites, or to at least explore the concept with researchers involved in observational research.

## 4.2    Language barriers

While a translator was available for some of the CAB interviews, which allowed non-English first language speakers to express their ideas in their mother tongue, a lack of capacity to communicate in the local language did however limit the potential sample of CAB members at some sites. While it may be easier for respondents to express their ideas in their own language, translation does alter the dynamic of the research situation, creating distance between the researcher and the respondent and making it difficult for the researcher to follow up on nuanced ideas raised by respondents (Squires, 2008; Temple & Young, 2004). Furthermore, because, in qualitative research such as this, the research interaction is a dynamic process of active knowledge production, to which all involved contribute, the translator cannot be considered a neutral transmitter of messages (Temple, 2002; Temple & Edwards, 2002). As such, it may be challenging for a translator to refrain from adding his or her own interpretations of the issues to the interview, and to maintain the connotations of words and ideas across different languages (Squires, 2008; Temple, 2002; Temple & Edwards, 2002). This raises concerns about the quality of the translation, which might compromise the conceptual equivalence of

respondent perspectives and this might affect the credibility of the findings (Squires, 2008; Temple, 2002).

Another difficulty noted in this study, and perhaps explaining the less nuanced and more concrete perspectives of CAB members on the notion of the 'ORC', was that the notion of the 'ORC' is an idea 'languaged' in English, which did not appear to have a direct equivalent in many of the local languages spoken by the CAB members. It may be challenging to articulate ideas related to the concept in English, because of a lack of fluency, and in their own languages, because the vocabulary of the concept may not exist.

## 4.3    Validity

Qualitative research is frequently criticised on the grounds of validity. However as described in section C (Methodology) this study did not seek to uncover an external truth, nor did it assume the existence of some objective reality. Rather it sought to explore perspectives of stakeholders interacting with the researcher at a particular point in time and in a particular context.

## 4.4    Theoretical limitations

The framework for ethical research in developing countries proposed by Emanuel et al. (2004) provided a useful mechanism for making sense of the data because it incorporates principles from most existing ethical frameworks, and provides a fairly balanced approach to ethical analysis because is not a reaction to a specific ethical scandal. However, it was found that the ethical principles suggested in this framework were far more interrelated than and not as discrete as suggested in Emanuel et al.'s (2004) original presentation of the principles. While this is not necessarily problematic, it did make assigning issues identified in this study to single categories challenging, and it was sometimes unclear which principle best represented concerns in this study. While efforts were made to cross-reference between principles wherever possible in the presentation of the findings, it is acknowledged that there may be instances where this was not done and where others may interpret the perspectives differently to how they are interpreted here.  The challenges associated with classifying concerns about 'over-research' into discrete categories may also be a function of the complexity of the notion itself.

Limitations regarding the philosophical expertise of the researcher are also acknowledged. A moral philosophical analysis of the notion of the 'ORC' might have provided different insights into the notion.

## 5    *Future research*

This study has provided a useful examination of the variety of possible interpretations of the notion of the 'ORC'.  However, there might be value in future research examining these interpretations in more detail.  There might also be value and interest in exploring the discourses and power dynamics at play between stakeholders in discussions and descriptions of 'over-research'.  Furthermore, now that there

has been an examination of the content of the notion, a survey among stakeholders to examine how widely held these interpretations are, might be worthwhile.

# F    CONCLUSION

The concept of the 'ORC' has arguably evolved in the context of increasing emphasis on the ethical issues regarding community involvement in research. However, in mirroring the range of ethical concerns and existing tensions in research ethics, the notion of the 'ORC' appears to be little more than a recycling of existing research ethics discourse, with a community emphasis.

In incorporating the variety of ethical concerns that respondent perspectives suggest 'over-research' to represent, the concept appears excessively broad and nebulous, meaning everything and nothing at the same time. The notion also appears to accommodate conflicting ethical concerns, for example 'over-research' as a concern that any offer in research is an undue inducement, and 'over-research' is a concern about a lack of benefit to participants and communities. Furthermore, 'over-research' seems to be a highly subjective and variable assessment of a community's involvement in research, which may be advanced to achieve various ends.

Although most respondents argued that they did not have a clear understanding of what the notion meant, many were unwilling to dismiss it wholesale, suggesting that 'over-research' implies a sense of some kind of ethical discomfort.

The usefulness of the term 'over-research' is arguably limited because it serves little more than to substitute a complex range of ethical concerns for a single but vague term. Since it lacks a standard definition or objective epidemiological calculus, and seems to create redundancy and confusion, 'over-research' should have no formal place in official research ethics discourse, where the goal should be to use terminology that indicates the source of concern, such that it may be addressed (cf. Emanuel, 2004, 2005; Hawkins & Emanuel, 2008).

However, the notion cannot be dismissed without examination. Even if it turns out to be a rumour or to be the result of a misunderstanding or failure in research literacy, it demands attention because these issues in themselves demonstrate some concerns about the relationship between communities and researchers. When 'over-research' is raised as a concern, this should prompt further investigation.

# G    RECOMMENDATIONS

Stakeholders should avoid using the term as it creates confusion.

Although vague the notion of 'over-research' appears to be a proxy for other legitimate ethical concerns and is arguably an indication of a perceived ethical violation. Given that allegations of 'over-

research' can be damaging to stakeholder relationships, its being raised should prompt further interrogation. Some suggestions of prompts for this interrogation include:

- What community engagement activities have been undertaken? Are these adequate and appropriate?
- Who are the legitimate and interested stakeholders? Who is raising the concern?
- What do various stakeholders expect from the research?
- Is the purpose of the research clear? How were research priorities established? What are the community's needs and priorities? How do locally defined needs and priorities correspond with the topic of research?
- How will the research contribute to knowledge, policy and practice? And what measures have been taken to this effect?
- How does the research impact on existing healthcare services?
- What activities are ongoing in the concerned community? How might they impact on one another? Is there evidence of collaboration between organisations working in a geographical community?
- What is the community's prior experience with research?
- What is the socio-historical context of the community? Have researchers undertaken formative research to understand the community context? How familiar are they with the community?
- How might the research harm or benefit the community? Have efforts been made to address the ancillary needs of the community?
- What factors might contribute to misunderstandings and miscommunications between stakeholders?
- What factors might be perceived to limit voluntariness?
- How might the community involved be considered vulnerable?
- Why has this community been selected for research?
- Is the concern really about research, or does it implicate broader structural inequities?

Recommendations to avoid allegations of 'over-research':

- Prioritise stakeholder engagement
- Researchers should initiate sound relationships with communities, based on mutual respect, understanding and transparency.
- Ensure that expectations are not unrealistically raised. Researchers should ensure a clear definition and understanding of roles and what they can and cannot do for the community.
- Prior to research initiation there should be efforts to achieve a meeting of the minds – there should be a mutual negotiation, understanding of what various stakeholders perceive to be research priorities, community needs, researcher obligations and fair benefits. This negotiation should also involve the clarification of misunderstandings.

- Prior to research initiation researchers should establish working relationships with research stakeholders beyond the community of participants. Partnering with service providers and NGOs could assist researchers to meet the 'ancillary' needs of the community. Ensuring partnership with policy-makers and implementers will help to ensure sustainability and pragmatic impact of the research.
- Ensuring a collaborative relationship with the media may facilitate more accurate and balanced reporting of research. Researchers should consider the long-term effects of including identifying details of a community in research reports or media interviews.
- Researchers should initiate a broader research literacy campaign in order to educate the general public about research and thus mitigate concerns about stigma and rumours about research.
- Researchers should be clear about the purpose of community involvement in their projects. They should also be cautious about making claims about community participation for its cosmetic value as this might lead to accusations of tokenism and 'over-research'.
- The CAB model of community engagement and representation should be reconsidered – a broader community representative body which has an understanding of the entire geographical area and which is independent of the research organisation might be more legitimate.
- Researchers should engage with one another as partners, sharing resources and contributing to each other's projects collegially.
- RECs should not block vital research by using ill-defined terms, but should encourage and facilitate the conduct of ethical research in partnership with researchers, communities and other stakeholders.

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# APPENDICES

APPENDIX 1:   Letter to clinical research site directors

10 July 2007

Dear XXX

I am a research intern at the HIV/AIDS Vaccine Ethics Group (HAVEG) under the direction of Prof. Graham Lindegger and Cathy Slack - funded by SAAVI to research ethical-legal concerns in HIV vaccine trials (see http://www.saavi.org.za/haveg.htm ).

For my Masters degree I am conducting a qualitative study exploring *stakeholder perceptions* of the notion of the "over-researched community" under the supervision of Prof. Doug Wassenaar. Although the term appears to be in increasing use, it is not always clear what this term means to various stakeholders in the research process.

We believe that exploration and analysis of the meaning and use of the concept could be useful to researchers, communities and research ethics committees.

I write to ask if you would permit me to approach various stakeholders (e.g. researchers, CAB members) at [your site] to invite them to take part in this research. Of course, all prospective volunteers will be informed of the study's purpose, methods (individual interviews), potential risks/ burdens, confidentiality requirements and other relevant information, and will be free to refuse to take part or to withdraw at an time. Personal details of informants and their institutional affiliations will remain confidential in any reports or publications arising from the study. Interviews should take between 30 and 60 minutes each.

This study has been approved by Research Ethics Committee of the Faculty of Human and Social Sciences at the University of KwaZulu-Natal, approval No.: HSS/0283/07M

Please do not hesitate to advise me on any organisational issues or requirements that might apply.

I would appreciate it if you would be so kind as to notify me by email at koenj@ukzn.ac.za by July 30th whether you are able to allow me access to individual members of your centre.

Your assistance would be greatly appreciated.
Yours sincerely,

Jenny Koen (BA Hons)
Supervised by
Prof D R Wassenaar

# APPENDIX 2: Letter to REC Chairs

10 July 2007

Dear XXX

I am a research intern at the HIV/AIDS Vaccines Ethics Group (HAVEG) under the direction of Prof. Graham Lindegger and Cathy Slack - funded by SAAVI to research ethical-legal concerns in HIV vaccine trials (see http://www.saavi.org.za/haveg.htm).

For my Masters degree I am conducting a qualitative study exploring *stakeholder perceptions* of the notion of the "over-researched community" under the supervision of Prof. Doug Wassenaar. Although the term appears to be in increasing use, it is not always clear what this term means to various stakeholders in the research process.

We believe that exploration and analysis of the meaning and use of the concept could be useful to researchers, communities and research ethics committees.

I write to ask if you would permit me to approach various staff in the XXX Ethics Committee to invite them to take part in this research. Of course, all prospective volunteers will be informed of the study's purpose, methods (individual interviews), potential risks/ burdens, confidentiality requirements and other relevant information, and will be free to refuse to take part or to withdraw at an time. Personal details of informants and their institutional affiliations will remain confidential in any reports or publications arising from the study. Interviews should take between 30 and 60 minutes each.

This study has been approved by Research Ethics Committee of the Faculty of Human and Social Sciences at the University of KwaZulu-Natal, approval No.: HSS/0283/07M

Please do not hesitate to advise me on any organisational issues or requirements that might apply.

I would appreciate it if you would be so kind as to notify me by email at koenj@ukzn.ac.za by July 30th whether you are able to allow me access to individual members of your research ethics committee.


Your assistance would be greatly appreciated.
Yours sincerely,

Jenny Koen (BA Hons)


Supervised by
Prof D R Wassenaar

# APPENDIX 3: Information & invitation letter

Dear Colleague,

I am a Research Psychology Masters student at the University of KwaZulu–Natal in Pietermaritzburg. I am also working at the university for the HIV/AIDS Vaccine Ethics Group (HAVEG), under the direction of Prof. Graham Lindegger and Cathy Slack who are supporting this research. HAVEG is funded by SAAVI to research ethical-legal concerns in HIV vaccine trials.

For HAVEG and for my Masters degree I am conducting a qualitative study exploring stakeholder perceptions of the notion of the "over-researched community" under the supervision of Prof. Doug Wassenaar. We believe that exploration and analysis of the meaning and use of the concept could be useful to researchers, communities and research ethics committees. You have been identified as someone we would like to talk to because of your involvement in research or community participation

Please understand that your participation is voluntary and you are not being forced to take part in this study. The choice of whether to participate or not is yours alone. However, we would really appreciate it if you do share your thoughts with us. If you do not choose to participate you will not be affected in any way whatsoever. If you agree to participate you may stop at any time and discontinue your participation. If you refuse to participate or withdraw at any stage, there will be no penalties and you will not be prejudiced in any way.

We will be talking with people who are involved in research in communities like researchers, members of research ethics committees and community representatives (probably Community Advisory Board (CAB) members). We want to explore each group's opinions on this issue. The questions we will be asking relate mainly to your experience in research. Some of the questions might relate to things about which you have not thought before. We know that you cannot be absolutely sure about the answers to these questions, but we ask that try to think about them. There are no right or wrong answers to any of the questions that will be asked. Each interview will last between 30 minutes and 1 hour.

If you agree, I hope to record your interview. This recording is only for our own purposes, so that we can get an accurate record of what is said. The tape recording will only be used to transcribe our discussion. It will be stored in a safe place. Only authorised research staff will have access to it. Your name and other identifying details will not be stored with your transcript. The data will be kept for 3 years then destroyed.

The results will be written into a Masters Thesis and a report for participants in the study. They may also be written into a peer-reviewed publication. Confidentiality of your personal and institutional identity will be maintained. No identifiable details of individuals or organisations will be released, only averaged information.

This study has been approved by Research Ethics Committee of the Faculty of Human and Social Sciences at the University of KwaZulu-Natal, approval No.: HSS/0283/07M

If you have any questions about this study you can contact me on this number: 033 260 5566, or e-mail at koenj@ukzn.ac.za. My supervisor is Prof. Doug Wassenaar of the School of Psychology. You can contact him on (033) 2605373 or e-mail at wassenaar@ukzn.ac.za .

Yours sincerely,

Jenny Koen (BA Hons) Researcher
Supervised by Prof D R Wassenaar

HIV AIDS VACCINES ETHICS GROUP
School of Psychology   University of KwaZulu-Natal
Postal Address: P/Bag X01,Scottsville, 3209  Tel:  +27 33 260 6166 Fax:  +27 33 260 6167
Email: haveg@ukzn.ac.za
Website address:http://www.saavi.org.za/haveg.htm

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# *Information Sheet*

Hello,

My name is Jennifer Koen and I am a Research Psychology Masters student at the University of KwaZulu–Natal (Pietermaritzburg). I am also working at the university for the HIV/AIDS Vaccine Ethics Group (HAVEG), who are supporting this research. I have a BA and Honours (in Psychology) from the same University. I hope to interview you for the purposes of a study I am currently conducting.

### What is the purpose of this study?
This study is exploring the issue of so-called 'over-researched' communities.

### What will this research involve?
The researcher will be talking with people who are involved in research in communities like researchers, members of research ethics committees and community representatives (probably Community Advisory Board (CAB) members). We want to find out each group's opinions and understanding of  this issue.

### Why have you been chosen?
You have been identified as someone we would like to talk to because of your involvement in research or community participation or ethical review.

### Do I have to take part?
No. You can refuse to take part. Even if you agree, you can change your mind at any time.

### What do you need to do?
If you agree to participate in this study, we will need about 60 minutes of your time to talk to you in person.

### What will happen to the recorded data?
If you agree to be interviewed and to be recorded, I hope to record your interview using a tape recorder, but this recording is only for our own records, so that we can get an accurate record of what is said. The tape recordings will only be used to transcribe our discussion. It will be stored in a safe place. Only research staff will have access to it. Your name and other identifying details will not be stored with your transcript. The data will be kept for 3 years then destroyed. If you don't agree to tape recording I will take detailed notes.

### How will the results be reported?
They will be written into a Masters Thesis and a report for participants in the study. They may also be written into an academic publication. No individuals will be named.

You can contact me on this number: 033 2605566, or by e-mail at koenj@ukzn.ac.za. My supervisor is Professor Doug Wassenaar, of the School of Psychology and South African Research Ethics Training Initiative (SARETI). You can contact him for further information on (033) 2605853 or by e-mail at wassenaar@ukzn.ac.za.

The research ethics committee of the University of KwaZulu-Natal, approval number HSS/0283/07M, has approved this study.

DECLARATION

I, ……………………………………………………………………… (full names of participant) hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating in the research project.

I understand that participation is entirely voluntary and that I am at liberty to withdraw from the project at any time, should I so desire.

SIGNATURE OF PARTICIPANT                                    DATE

……………………………                                    ………………………
I, ……………………………………………………………………… (full names of participant) hereby consent to the tape-recording of the interview.

SIGNATURE OF PARTICIPANT                                    DATE

# APPENDIX 4: Interview Schedules

**INTERVIEW SCHEDULE FOR COMMUNITY REPRESENTATIVES**

**Background/ previous experience**
- Tell me about your community?
- What kinds of research have come to/happened in your community?
- What effect has research had on your community? Please tell me about some of these effects – any positives? Any negatives?

**Community Entry/Engagement**
- When researchers first come to your community what steps do you expect them to take to access your community?
  - With whom? Why?
- What are some of the reasons you would give for stopping research in your community?
- Who should decide if research can be done in a community?
- Who should decide what research is done in a community?

**Fair selection issue**
- Why do you think this research is being done here/your community has been chosen for this research?
- How do you think researchers should choose the communities that they work in?

**Fair benefits**
- What should communities get from research? Does this happen?

**Multiple Projects**
- Could you give me a guess of how many projects there are in your community?
- Are there members of your community who have been involved in more than one research project? At the same time?
- What would you say the reasons for this are? Do you think there are any problems with this?
- How would you say this affects the research in your community?
- Do you think that communities ever feel like too much research has been conducted or that they have had enough of research? What would cause them to feel like this?

**Over-researched communities**
- Have you ever come across/heard of the term the 'over-researched community' before? Where?
- What does this term mean to you?
- If you, or someone else said that a community was 'over-researched' what could this mean?
- Do you think there are communities that are, 'over-researched'? – Can you give an example?
- How would you identify an 'over-researched' community – what would an over-researched community look like?
- What ethical problems are there in an "over-researched" community?
- What are the effects of 'over-research' on a community?
- What about 'under-research'? What do you think this means?

INTERVIEW SCHEDULE FOR REC members

**Previous Experience**
- How long have you been in your current position?
- What is your background/training?
- Have you had specific training in Research Ethics? If yes – what?
- What types of conditions have been the focus of the research protocols which your REC reviews?
- Primarily what types of studies are/have been the focus of these protocols?
- What are some of the main ethical challenges you would expect in research involving communities?

**Community entry/engagement**
- What kind of community entry or engagement process would you require researchers to go through?
- How involved do you think community members should be in negotiating access to communities?
- What are some of the reasons you would give for disallowing research to be conducted in a particular community?
- Who do you think should have the ultimate say about whether or not research should be conducted in a community?
  - Community representatives
  - CABs
  - REC's
  - Dealt with via IC

**Fair selection**
- What would you say are the key considerations when communities/populations are selected for research?
- In general how would you say communities are selected for research?

**Fair benefits**
- What do you think researchers and sponsors should be required to provide to the communities in which research is conducted?
- Does this happen and how do you make sure that it does?

**Multiple Research Projects**
- What are some of the factors you would consider when reviewing research proposed in a setting in which other research is ongoing?
- What are some of the complexities, which could arise when conducting research in settings such as these?
- What are some of the factors you would consider when reviewing research which is proposed in a setting in which other research has been conducted?
- What are some of the complexities, if any, which could arise when research is conducted in settings where other research has been completed?

**Over-researched communities**
- Do you think that communities reach a saturation point where too much research has been conducted? How would you describe this point?
- Have you ever come across/heard of the term 'over-researched community' before? In what context?

- What do you understand by the term? If you, or someone else said that a particular community was 'over-researched' what would [could] this mean?
- Are there any communities that you would consider to be, or that you are aware of which are, 'over-researched'?
- What are the effects of research on a community?
- What are [could] the effects of over-research on a community [be]?
- How would you identify an 'over-researched' community – what criteria would you use to apply this label?
- Could there be a saturation point/ specific number of research projects to a proportion of a community's population? How would you decide this?
- What could the ethical dilemmas or challenges involved in an 'ORC' be?
- What about the term 'under-research'? What would you understand by this?
- Would your REC consider withholding approval of a research protocol because of community characteristics? Would this include the extent to which research has been conducted and please explain this reasoning.

INTERVIEW SCHEDULE FOR RESEARCHERS

**Previous experiences with research in communities**
- How long have you been involved in research?
- What type of conditions has been the focus of your research experience – especially in community settings?
- What types of studies have you been involved in? (basic, epidemiology, pathogenesis, clinical trials etc.)
- What are the main ethical challenges you have faced or are facing in conducting research with communities?

**Community entry/engagement**
- Have you had to negotiate your access to and presence in communities?
  - How have you negotiated your presence in the communities in which you've worked?
  - Have gatekeepers ever prevented you from conducting research in a particular site?
  - If yes, which gatekeepers, and what reasons were given by gatekeepers for disallowing you from conducting research in a particular community?

**Fair selection issue**
- How did you select the populations in which you've worked? / What were your reasons for selecting the sites you did, for research?
- In general how would you say populations/communities are selected for research?
- What would you say the key considerations are when selecting a population for research?

**Fair benefits**
- What are some of the expectations that communities hold of health researchers? Are these reasonable expectations?
- What do you think researchers and sponsors should be required to provide to the communities in which research is conducted? Does this happen?
- What do you think should happen at the conclusion of a research project?
- Do you think that researchers benefit more from research than communities/participants do? How so?

**Multiple research projects**
- Have you attempted to or have you conducted research in a community in which there is an ongoing research project or researcher presence?

[IF YES]
- Did you negotiate access to the community with these researchers?
- How did you go about doing this?
- Were there any complications in negotiating access or gaining access in this regard? Please describe these
- Are you aware of communities in which there are several simultaneously ongoing research projects?

[IF YES]
- Do you have any concerns about this?
- Have you ever experienced any complications when conducting research in a community where someone else's research has previously been conducted?
  - Are you aware of participants in your research who had previously been involved in research?
  - What impact do you think this had on the way in which the participants interacted with you or engaged in your project?
- Are you aware of participants in your research who have simultaneously been involved in other research?

- Would you have any concerns about this?

**Over-researched community**
- Have you ever come across/heard of the term 'over-researched community' before?
- What do you think this term means? If someone said that a particular community was 'over-researched', what could they mean by this? – Can you give an example?
- Are there any communities in which you've worked or that you know of which you would consider to be 'over-researched'?
- Would you say that this might be a "problem" for or term used in connection with specific kinds of research or specific sorts of research centre (e.g. DSS)?
- What do you think are the effects of being researched?
- What do you think are the effects of being "over-researched"?
- Do you think that "over-research" is an ethically relevant concept?
- Do you think that access to communities should be determined by community consultation or by an REC, or some other process?
- What about the term 'under-researched'? How would you understand this term?

# APPENDIX 5: Transcription conventions

[                    Left square bracket indicates point at which a current speaker's talk is overlapped by another's talk

                    E.g.

                        R: One of the [considerations?

                        P:                [as to whether]  you would say that a community (.) er::: (.) whether it's its reasonable for the researcher to go to that community (R: Ja) That community

[[laughter]]         Words in double, closed square brackets indicate observations – like laughter; interruptions etc.

(.)                  stop in parenthesis indicates a pause of less than half a second (a comma)

(0.5)                Indicates a pause of half a second (a full stop with no pause / comma)
(1.0) or (2.0)       Indicates an approximation of the amount of time in seconds for which there is silence (either a pause OR a full-stop OR silence)

____                 Underlining indicates particular emphasis or stress on a particular word

.hh                  fullstop + hh indicates an audible intake of breath

hh .                 hh + fullstop indicates a sigh/ outbreath

(unclear)            indicates inaudible bits of speech

(words) words in brackets indicate that the transcriber is guessing at what is being said, because speech is unclear – transcriber is not certain that this is exactly what is being said.

The/the/the         words separated by a forward slash indicate corrections to what is being said without a pause OR words said without a pause between them OR a rapid change in direction in a sentence (new thought without completing the old)

# APPENDIX 6: Coding Framework

### 1. Collaborative partnership

[Partnership between stakeholders including researchers, sponsors, ethics committees, communities, NGOs and government]

Emanuel et al (2004) argue that a collaborative partnership between host country researchers, policy makers and communities and sponsoring country sponsors and researchers minimises the possibility of exploitation. The developing country/ host community involvement determines whether the study is acceptable in the host country and whether it is responsive to the needs of the community. In addition to this it helps to ensure a lasting impact. Collaborative partnership demonstrates awareness of cultural differences and respect for these.

1. Equal representation
2. Collaboration – sharing responsibility for assessing value of the study, planning & conducting, disseminating & impl
3. Mutual respect – consider host community's culture, values when designing and implementing a study
4. Minimise disparities through skills transfer
5. Benefits to community
6. Fair distribution of rewards of research between partners

   a. Community engagement
   This incorporates the idea of establishing partnerships with host communities. It also involves the process of informing and education the community at a broader level about the research and getting community input into various aspects of the research conduct and design.

      i. Community entry
      How communities are accessed/ entered by researchers

      ii. Community education
      Educating the broader community about the research and issues relating to the research and about the issue being researched

      iii. Community participation
      Community involvement in various aspects of the conduct and design of the research as well as in contributing to the research agenda

      iv. Community Representation
      How community interests are conveyed to researchers

   b. Collaborative Partnerships with other stakeholders
   Partnerships between researchers and other stakeholders (excluding the community, and including other researchers); Also includes involvement of these stakeholders in the design, implementation of the research and actions on the outcomes

   c. Community perceptions of research
   How communities view or perceive research

### 2. Social (and scientific) Value

[Research should be meet an identified need [be responsive], should be translatable into action and policy and should ultimately lead to improvements in health.]

Ethical research must have social value. Emanuel et al (2000; 2004) argue that research generates knowledge that should lead to improvements in health or our understanding of health and wellbeing or that will contribute to knowledge. Without social value, research exposes participants to risk for no good reason and wastes resources (Lavery et al, 2007)

The problem with determining social value is that it often takes time for research to have an impact on policy and practice – so determining the social value of research is often probabilistic.

a. Responsiveness
Social value also requires an evaluation of the health and research priorities of the participants, host countries and host communities and requires that research is responsive to these.

b. Contribution to policy and practice
Emanuel et al (2004) also argue that researchers should develop mechanisms which could enhance the social value of the research including strategies for the dissemination of research results to key stakeholders (as a means of encouraging action and ensuring contribution to knowledge).
Long term collaborative research strategies (so that the specific project forms part of a more comprehensive research and healthcare delivery strategy) enhance the social value of research and make the findings more likely to be implemented.

c. Contribution to knowledge
While the research may not have immediate practical ramifications it generates and contributes to important knowledge.

d. Existing healthcare services
A research project should not undermine a community's existing healthcare services. [so burdening or 'stealing' resources from existing facilities may be a violation of social value]. Social value can be enhanced if improvements are made to these facilities

## 3. Scientific Validity
[The idea that research should generate valid and reliable data]

"Valid science is an ethical requirement. Unless research generates reliable and valid data that can be interpreted and used by the specified beneficiaries of the research, it will have no social value, and participants will be exposed to risk for no benefit…International clinical research should be designed so that the results will be useful and appropriate in the context of the health problem of the developing country…The study design should realise the research objectives while neither denying healthcare services that participants are otherwise entitled to nor requiring services that are genuinely not feasible to deliver in the context of the country's healthcare system " (Lavery et al, 2007, p.9).

1. Researchers must ensure that the design of the research realises social value for the intended beneficiaries
2. Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health-care interventions to which they are entitled.
3. Ensure that the research study is feasible within the social, political, and cultural context or with sustainable improvements in the local health-care and physical infrastructure.

There are several concerns relating to scientific validity
a. Co-enrolment
Enrolments in more than one study (simultaneously)

b. Contamination

Outcomes/results of one study are affected by factors outside the study e.g. another study.


## 4. Fair selection of study populations / Fair Subject and Community Selection

[Refers to how communities and participants are selected for research and on what basis these decisions are made.]

"A challenge for research everywhere is fair selection of target villages, tribes, or city neighbourhoods from which individual participants will be recruited. Study populations should be selected to ensure valid science. Yet scientific considerations alone are likely to underdetermine which community or individuals should be selected. Minimising risk, enhancing benefits and the value of science, opportunities for collaborative partnership, feasibility, and protecting vulnerable participants are all important considerations of fair subject selection." (p.10)

a. For reasons of convenience

Participants or communities are selected for the researcher's convenience (might include easily accessible, proximity to urban centre or health facility)

b. For scientific reasons

Participants and/or communities are selected in order to provide valid answers to the research questions (this may include considerations about generalisability)

c. On the basis of need or potential for benefit

Participants and/or communities are selected because they have an identifiable need which the reason that the research may be able to address or because they are likely to be the beneficiaries of the research.

d. Political influence

Participants and/or communities are selected to further political agendas or on the basis of their political affiliations.

e. Previous experience

Participants and/or communities are selected on the basis of previous research experience and previous successful research (might include reasons like researchers have previously invested in research facilities and community engagement in the community; other researchers have had successful outcomes of research with these people)

f. On the basis of vulnerability

Participants and/or communities are selected on the basis of levels of vulnerability. (This may include selection because of vulnerability OR not selection to protect vulnerable populations)

## 5.  Favourable Risk-Benefit ratio/ Risks and Benefits

[Benefits refer to the positive outcomes/rewards of research. Risks refer to the negative consequences of researchers. Both might be (in)tangible. The risk-benefit ratio refers to an assessment of the potential benefits of the research in relation to the risks; it is argued that the benefits must outweigh the risks for the research to be justified]

 "All clinical research should offer participants a favourable risk-benefit ratio, or when potential risks outweigh benefits to participants, the social value of the research must be sufficient to justify these risks. Only benefits that accrue to participants from the interventions necessary to achieve the research objectives or those deriving from the knowledge to be gained from the research should be used to justify risks to participants….the risk benefit ratio for individuals must be favourable in the context in which they live" (Lavery et al, 2007, p.11) "Similarly, the risk benefit ratio for a particular study may be favourable in communities where the social value is high but may be unfavourable where potential value is lower…the risk benefit ratio should also be favourable for the community and the community itself should determine whether the risks are acceptable in light of the benefits to be derived from the conduct and results of the research" (Lavery et al, 2007, p.12)

a. Benefits
[Refers to the benefits (positive outcomes/rewards) that participants and communities accrue from their participation in research; Benefits may be concrete or they may be social goods.]
  i. Concrete benefits
     Tangible, immediate or direct benefits of participating

  ii. Social goods/ indirect benefits
     Benefits that accrue to the community that may be indirect and may not be tangible

b. Risks
Harmful consequences of research either to participants or communities
  i. Physical risks
     Biological harm to participants
  ii. Social harms
     Harms to participants and communities which are not physical/concrete; may include things like stigma

c. Risk-Benefit ratio
The potential risks of study participation to individuals and to host communities must be outweighed by the benefits to individuals and host communities. Assess the potential risks and benefits of the research to the study population in the context of its health risks.

Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations

## 6. Independent Review

[Mandatory review by independent bodies (without vested interest in the research) including ethics committees and regulatory authorities]

Emanuel et al (2004) argue that "to minimize concerns with regard to researchers' conflicts of interest and to ensure public accountability, independent ethical review of all clinical research protocols is necessary." (p.934)

    a. REC role

This refers to the role of Research Ethics Committees in the research and review process (this may include ideas like RECs as gatekeepers – able to protect communities by preventing research from happening in a community); who has the final say?

    b. REC Capacity

This refers to the REC's capacity to fulfil its role and to conduct thorough review with an in-depth and informed understanding of the issues involved

## 7. Informed Consent

[Participants and/or communities should be fully informed about the research and its potential implications]

    a. Community consent

    b. Understanding

Refers to the importance and complexities of ensuring participant understanding and comprehension of the research (may include things like research literacy)

    c. Voluntariness

        i. Autonomy and the right to withdraw: Participants and communities should be able to freely decide whether or not to participate in research and to withdraw if they wish

        ii. Incentives: balancing fair compensation with undue inducements to participate, especially in resource limited settings.

## 8. Ongoing respect for recruited participants and study communities

"Researchers have ongoing obligations to participants, former participants and the host community, to safeguard their interests and well-being." ( Lavery et al, 2007, p.14). This includes: ensuring confidentiality, post-trial access to the successful products and feeding back trial results to the community

    a. Confidentiality

Involves ensuring that the way in which information is collected, stored and disseminated reflects the right of participants and communities to confidentiality.

    b. Ongoing feedback

Involves the provision of information arising during the course of the study to participants and host communities; this includes information regarding newly emerging risks or potential benefits, as well as information regarding the study's progress. Participants and study communities should also be provided with the results of the study and be informed of, and have a say in, what happens to the information collected.

    c. Maintaining the welfare of participants and study communities

Monitoring participants (and study communities) for exacerbations of/ infection with the condition under study, any research-related injuries or harms, and other problems which may emerge (health-related)

        i. Access to treatment & care:

The provision of care and treatment for infection by the condition under study – either by investigators or via referral to appropriate facilities (what are the obligations? What standard?)

    ii. <u>Ancillary care</u>

The provision of care and treatment services for conditions that are not directly related to the research but which may be discovered through screening and follow up procedures (What obligations are there to provide directly or to refer?)

    iii. <u>Post-trial obligations</u>

Refers to what should be provided to communities at the conclusion of research, particularly in the case where interventions are found to be beneficial, but also refers to the sustainability of other services and interventions.

## 9. Notions of the ORC

[Stakeholder perceptions of the construct of the 'over-researched community' – largely elicited through direct questions about ORC]

    a. <u>ORC definitions/ understandings</u>

What respondents understand the term 'ORC' to mean:

        i. <u>Research Saturation</u>

Over researched community is viewed as a community where there are too many studies relative to the size of the population

        ii. <u>Research Fatigue</u>

Refers to a sense that participants/communities are tired of being involved in research and do not want to participate in research any longer

        iii. <u>Hypothetical concept</u>

Over researched community is viewed as theoretical - there are no concrete examples

        iv. <u>Concern about Collaborative partnerships</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *collaborative partnerships.*

        v. <u>Concern about Social Value</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *social value.*

        vi. <u>Concern about Scientific Validity</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *scientific validity.*

        vii. <u>Concern about Fair Selection</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *fair selection of participants and communities.*

        viii. <u>Concern about Risks and Benefits</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *a fair risk-benefit ratio.*

        ix. <u>Concern about Independent Review</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *independent review.*

        x. <u>Concern about Informed Consent</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *informed consent.*

        xi. <u>Concern about Ongoing Respect</u>

The concern raised in relation to over-research seems to reflect a concern about the EWKG principle of *ongoing respect for recruited participants and study communities.*

    b. <u>Consequences of over-research</u>

The effects of over-research on study communities

    c. <u>Characteristics of 'over-researched communities'</u>

The characteristics of an ORC

    d. <u>Criteria for determining 'over-research'</u>

Indicators of over-research or the potential for over-research

e.  <u>Legitimacy of the notion of 'over-research' and ORC in ethics</u>
Evaluations of use and legitimacy of the notion by respondents