

UNIVERSITY OF KWAZULU-NATAL

HOW DO KENYAN RESEARCH FIELDWORKERS CONCEPTUALIZE THE CONSENTING PROCESS?

Implication for Training in Health Research Ethics

Francis Kombe

School of Applied Human Sciences

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Supervisor: Dr. Nicole Mamotte

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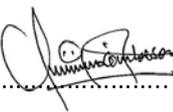
DECLARATION

This research has not been previously accepted for any degree and is not being currently considered for any other degree at any other university.

I declare that this Dissertation contains my own work except where specifically acknowledged.

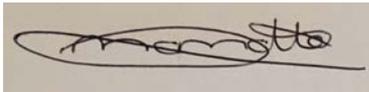
Name: Francis Kazungu Kombe

Student number: 216074144

Signed: 

Date: 28 June 2017

Supervisors name: Dr. Nicole Mamotte



Supervisor's signature:

Date: 03 July 2017

DEDICATION

This thesis is dedicated to my loving family, who sacrificed and endured extremely difficult times as they patiently waited for me to accomplish this course. For their selfless love, care, fortitude, everlasting support and desire to see me achieve a distinguished career, I salute them!

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ABSTRACT

Fieldworkers are an important cadre of research staff due to the critical roles they play in health research not just in Africa but globally. In Africa, most international research centres employ fieldworkers to provide support in seeking informed consent; collecting basic samples and maintaining good relationships with communities involved in research.

Seeking informed consent is an especially important role. It does not only ensure the promotion of autonomy for those involved in the research but has an important implication on the quality and reliability of data collected from research participants. According to most international ethical guidelines, ensuring potential research subjects voluntarily participate in research after fully understanding all key elements of the research they are involved in is essential. Although research in most international research centres is overseen by highly qualified and renowned researchers and scientists, the influence of fieldworkers, who are the cadre of health research staff involved in the day to day operationalization and ground application of this important ethical principle, has received little focus and continues to be understudied. Understanding how fieldworkers conceptualize the informed consent process can provide important insight on fieldworkers' ethical practices and how ethical guidelines are operationalized on the ground.

We conducted four Focus Group Discussions (FGDs) with health research fieldworkers and eight In-depth Individual Interviews with field managers/supervisors at the Kenya Medical Research Institute (KEMRI-Wellcome Trust Programme (KWTRP) to develop an in-depth understanding of how this cadre of staff conceptualize the process of informed consent. Data were captured using digital recorders and transcribed before being analyzed thematically.

The results indicate a good understanding of health research for both fieldworkers and field managers. The relationship between KWTRP and the community was described to be of mutual benefit sharing, with the community benefiting from new interventions and improved health care while KWTRP got research subjects from the community. Informed consent was described as an important part of getting people to participate in research voluntarily. There was, however, some mixed attitude and perceptions regarding the value and key elements of the informed consent process. Several factors were said to influence informed consent process, including the environment where consenting was done, recruitment targets, support and supervision and the training that was given to fieldworkers. Fieldworkers perceived their work as critical in health research. However, lack of recognition, capacity building and clear approaches for professional development affected their motivation and attitude about their roles. The findings support the need for further research to identify specific mechanisms for supporting fieldworkers to undertake their roles more effectively.

TABLE OF CONTENTS

DECLARATION.....	i
DEDICATION	ii
ACKNOWLEDGEMENTS	iii
ABSTRACT	iv
TABLE OF CONTENTS.....	vi
LIST OF FIGURES	ix
TABLE OF FIGURES.....	x
CHAPTER 1 – BACKGROUND.....	1
1.1 Introduction	1
1.2 The Informed Consent Process.....	1
1.3 Background to KEMRI-Wellcome Trust Research Programme	3
1.4 Roles of Fieldworkers	3
CHAPTER 2 – LITERATURE REVIEW	5
2.1 Introduction to health Research.....	5
2.2 Health Research and Social Development.....	6
2.3 Fieldworkers’ roles in health research.....	7
2.4 Challenges faced by fieldworkers in undertaking their roles.....	8
2.5 Informed Consent Process	9
2.5.1 Background	9
2.5.2 Valid Informed Consent Process.....	13
2.5.3 Voluntariness.....	13
2.5.4 Undue Influence	15
2.5.5 Coercion	15
2.5.6 Understanding.....	16
2.6 Individual Mental Status.....	18
2.7 Social Economic Status	18
2.8 Trust	19
2.9 Challenges associated with the informed consent process.....	20
2.10 Study Justification.....	22
CHAPTER 3 – STUDY AIMS AND OBJECTIVES	23
3.1 Introduction	23
3.2 Study aims	23

3.3	Study objectives	23
3.4	Study Questions	23
CHAPTER 4 – METHODOLOGY		25
4.1	Introduction	25
4.2	Study Setting	25
4.3	Study Design	26
4.4	Sampling fieldworkers for focus group discussion	26
4.5	Data collection.....	28
4.5.1	Focus Group Discussion with Fieldworkers	28
4.5.2	Individual In-depth Interviews with Field Managers	29
4.6	Data Validity, Reliability and Rigour.....	30
4.7	Data analysis.....	32
4.8	Ethical approval and gate keepers’ permission	33
4.9	Data storage and disposal	33
4.10	Dissemination of research findings	34
CHAPTER 5 – RESULTS		35
5.1	Introduction	35
5.2	Demographic details.....	35
5.3	Attitudes and Perceptions about Health Research.....	37
5.4	Community Health Research Benefits.....	39
5.5	Negative effects associated with participating in Health Research.....	40
5.6	Attitudes and Perceptions of fieldworkers’ roles in health research.....	43
5.6.1	Attitude about who fieldworkers are	43
5.6.2	Roles of fieldworkers in health research	48
5.6.3	Role of fieldworkers in Social Development.....	50
5.6.4	Attitude and understanding of the value and meaning of informed consent process	51
5.7	Factors affecting Informed Consent process.....	54
5.8	Participants complaints about Informed Consent Process.....	59
5.9	Fieldworkers’ levels of interaction with research participants.....	61
5.10	Ethical dilemmas experienced by fieldworkers	62

5.11	Support mechanisms and recommendations.....	66
5.11.1	Lack of systematic approach	66
5.11.2	Lack of structural support	67
5.11.3	Capacity Building	68
5.11.4	Fieldworkers’ Clinics.....	69
5.11.5	Motivation.....	70
5.11.6	Youth friendly informed consent forms	71
5.12	Chapter Summary.....	73
CHAPTER 6 – DISCUSSION		75
6.1	Introductions.....	75
6.2	Attitude and perceptions about health research	75
6.3	Conceptualization of the informed consent process.....	76
6.4	Attitude and perceptions about fieldworkers’ roles.....	80
6.5	Fieldworkers’ level of interactions with research participants.....	81
6.6	Participants’ Recommendations.....	82
6.6.1	Recommendations on the Informed Consent process	82
6.6.2	Fieldworkers support.....	83
6.7	Study Limitation	84
CHAPTER 7 – CONCLUSION AND RECOMMENDATIONS.....		86
7.1	Conclusion.....	86
7.2	General recommendations.....	89
7.2.1	Strengthening of institutional structural systems.....	89
7.2.2	Training in health research ethics	92
REFERENCES		94
APPENDICES		98
9.1	Appendix 1: Participant’s Informed consent form for FGDs.....	98
9.2	Appendix 2: Participant’s Informed consent form for IDIs	101
9.3	Appendix 3: Interview guide for Focus Group Discussion	104
9.4	Appendix 4: Interview guide for Individual In-depth Interviews.....	107
9.5	Appendix 5: Thematic Framework.....	110

LIST OF FIGURES

Figure 1: Sampling process: Illustrating the sampling process	27
Figure 2: Fieldworkers as a steering wheel: Illustrating how fieldworkers drive research	44
Figure 3: Fieldworkers as a tap root: Illustrating the importance of fieldworkers in research	45
Figure 4: Fieldworkers as a Donkey: Illustrating hard work and resilience of fieldworkers	46
Figure 5: Tired and overworked man: Illustrating fieldworkers' loyalty & harsh working conditions ...	47

TABLE OF FIGURES

Table 1:	36
Table 2:	36

CHAPTER 1-BACKGROUND

1.1 Introduction

Fieldworkers are considered an important cadre of staff in health research due to the critical role they play, not just in Africa but globally (Molyneux. et al., 2013). In Africa, most international research centres employ fieldworkers to provide support in seeking informed consent, collecting basic biomedical measurements and maintaining good relationships with communities involved in research. In Kenya, fieldworkers are used by health research centres that conduct longitudinal surveillance studies such as Health Demographic Surveillance Studies (HDSS), biomedical and social science studies, especially those that interact directly with human subjects/participants. Specifically, fieldworkers play a critical role in recruiting research participants and in undertaking the informed consent process, especially in major international health research centres in Africa.

1.2 The Informed Consent Process

The importance of seeking valid informed consent from research participants prior to taking part in research cannot be overemphasized. Major international ethical guidelines, including the Nuremberg code, Belmont report and Council for International Organizations of Medical Sciences (CIOMS) guidelines underscore the need to ensure all research participants voluntarily agree to take part in research after having been fully informed about the research and the implication of their participation, including their rights and the risks and benefits involved in the proposed research. (CIOMS, 2002; Nuremberg, 1949; Resea & Ryan, 1978)

Informed consent has been described as the corner-stone to ethical research; understandably due to its ability to promote individual autonomy and respect for persons when appropriately applied (Guillemin & Gillam, 2004). However, it has also emerged as one of the most controversial and contested ethical concepts due to controversies surrounding differences in understanding key elements of research, and its operationalization, especially with regards to disagreement on context-specific issues around the best ways to promote respect and autonomy (Lindegger & Bull, 2002; Lindegger & Richter, 2000; Macklin, 1999; Siminoff, 2003). While these controversies continue to exist, especially regarding whether the universal ethical principles are indeed universal; and whether or not respect for persons/autonomy is indeed the most important ethical principle in research, there appears to be a reasonable consensus on the fact that blanket application of these principles is a failure to appreciate and respect global cultural diversities. The ability to achieve valid informed consent is largely dependent on the interpersonal interactions, including the adequacy, sensitivity and cultural appropriateness of the information shared, the approaches used to disclose the information and the ability to create a conducive atmosphere that promotes and facilitates comprehension and understanding by those involved in seeking informed consent (Lindegger & Bull, 2002). Indeed, these views place fieldworkers, who are the key players in seeking informed consent, at the center stage of health research and begs for more investment in research to unpack and develop a deeper understanding of both the roles fieldworkers play in the quality and integrity of health research, as well as their own knowledge, attitude and practices related to the process of informed consent.

1.3 Background to KEMRI-Wellcome Trust Research Programme

The Kenya Medical Research Institute/Wellcome Trust Research Programme (KWTRP) is one of the biggest international multidisciplinary biomedical research centres in Kenya. It was established in 1989 to conduct research on diseases that are of importance to the coastal region in Kenya (Scott et al., 2012). Over the years, the programme has developed a strong international reputation for its wide-ranging interdisciplinary research covering clinical, basic science, epidemiological and public health aspects of major childhood and adult diseases, including Malaria, Pneumonia, Tuberculosis, HIV/AIDs and Malnutrition among others. In addition, the research centre provides support to the hospital to ensure a good standard of care is available to those using the departments where research is conducted, regardless of their involvement in research (Scott et al., 2012).

The expansion of the programme in its areas of focus in research is exemplified by a significant growth in infrastructure and human resources. At present, there are over 750 members of staff working in different capacities and studies, over one-third of whom are fieldworkers. The same pattern is true for most of the major centres involved in health research in Africa (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015).

1.4 Roles of Fieldworkers

A lot of studies have been conducted on the practices and experiences of health research fieldworkers. More recently, researchers conducting ethnographic and social science studies on fieldworkers have published data describing some important challenges which fieldworkers experience in their day to day activities, which can undermine fieldworkers' scientific and ethical practices. For example, Kingori (2013) presented a detailed

ethnographic account of the practical challenges and dilemmas fieldworkers face and how these shaped their ethical practices in research (Kingori, 2013). At KWTRP, fieldworkers' social relations and how this influenced decision making and participation in research were recently examined (Kamuya. *et al.*, 2013). However, to date, no studies have been done in Kenya to try to understand how fieldworkers conceptualize the process of informed consent and how this influences their scientific and ethical practices. Understanding how fieldworkers conceptualize the informed consent process can provide important insight into fieldworkers' ethical practices and how ethical guidelines are operationalized on the ground. Findings of this study may be used to design tailored and effective community engagement approaches, performance management strategies and capacity building interventions aimed at supporting fieldworkers to appreciate their role and understand how this contributes to promoting the ethical conduct of research.

CHAPTER 2-LITERATURE REVIEW

2.1 Introduction to Health Research

Health research is a multidisciplinary field of scientific investigation that systematically collects data on how health conditions, social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect health, access to health care, the quality and cost of healthcare, and ultimately health and well-being (Lohr & Steinwachs, 2002). According to Gibbons *et al.* (1994), health research enables the production of new knowledge which is then consumed by stakeholders from different disciplines through the facilitation of change or improvement of existing practices (Gibbons *et al.*, 1994).

It is widely agreed that scholarly and scientific endeavors are anchored in a foundation of trust. Communities and the world-at-large trust in the outcomes and products of research because these are understood to convey truth, to be verifiable and replicable, and to reflect honest and hard work (Leisinger, 2002). Within the academic community, researchers also place an enormous amount of trust in the data fellow researchers generate; with the belief that their colleagues collect data honestly, using accurate and appropriate methods. In contrast, inability to adhere to these principles not only undermine the trust in an individual researcher but the entire research enterprise itself (Leisinger, 2002). This view places those involved in data collection at the forefront of research integrity.

Although research is considered a cornerstone of innovation and social development, it has not been without controversies. One of the most controversial ethical issues in research is the conduct of clinical trials in developing countries that will lead to therapies that benefit the citizens of these countries (Varmus & Satcher, 1997). Many social determinants affecting

developing countries, such as poverty, endemic diseases, high burden of diseases, level of education and poor investment in health care systems — affect both the ease of performing trials and the selection of trials that can benefit the populations of the countries (Varmus & Satcher, 1997). Although trials that apply scientific knowledge to interventions that can be used to benefit such populations are appropriate, they have often been attributed with a range of ethical challenges, including but not limited to therapeutic misconceptions, undue influence, mutual benefits sharing and how such research contributes to the social development, social value and the general social-economic well-being of communities that are already over-burdened by numerous social challenges (Appelbaum, Lidz, & Grisso, 2004; Lairumbi, Parker, Fitzpatrick, & English, 2012; Molyneux, Peshu, & Marsh, 2004).

2.2 Health Research and Social Development

Social development is about improving the well-being of every individual in the society so that they can reach their full potential. According to Huitt & Dawson (2011), human beings are inherently social and the development of competencies in this domain enhances a person's ability to succeed in school as well as positively influence mental health, success in work, and the ability to be a citizen in a democracy (Huitt & Dawson, 2011). Social development, therefore, implies investing in people, removal of barriers so that all citizens can journey toward their dreams with confidence and dignity. It is about refusing to accept that people who live in poverty will always be poor. Castells & Development (1999) described social development as the process of helping people to move forward on their path to self-sufficiency and encompasses the establishment of synergistic interaction between technological innovation and human values (Castells & Development, 1999). Empirical studies have shown that improving the health of the society provides a significant boost to economic

growth in developing countries. This leads to the view that health, like education, is a fundamental component of human capital, and suggests the notion of health-led growth. Better health leads to higher income, but there is also a positive feedback effect, giving rise to a beneficial situation where health and income improvements are mutually reinforcing (Bloom & Canning, 2000). In health research, the direct effect attributable to the potential to improve health through new health research intervention and services, exposure to health messages and reinforcement of such messages could have implications for the communities' habits and understanding about health. Fieldworkers, who are the frontline staff in health research, play a key role in disseminating health-related information from the studies they work for as well as responding to general health-related issue from the community (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015)

2.3 Fieldworkers' roles in health research

Generally described as health research frontline staff, fieldworkers are also referred to as interviewers, research assistants, recruiters, data collectors and village reporters, among other titles. Depending on the setting where they work and the specific roles they play, these titles are all used interchangeably (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015). For purposes of this research, the term fieldworker(s)-(FWs) will be used.

The critical role FWs play in health research has been widely described (Kamuya. *et al.*, 2013; Molyneux. *et al.*, 2013). FWs support research by seeking informed consent; translating research terminologies into simple language and providing a vital link between research institutions and the community they come from (Kamuya. *et al.*, 2013; Molyneux. *et al.*,

2013). According to Alexander and Richman (2008), fieldworkers are ultimate insiders who, because of their familiarity with the social and physical environments of the target research population, possess important contextual knowledge that improves access to some restricted groups of people, enhanced rapport-building capabilities, and greater understanding of the language unique to the study population. Most importantly, by virtue of their knowledge of the local culture and values, fieldworkers can make it easy to conduct research with communities that would otherwise be hard to reach (Alexander & Richman, 2008). Their relationship and unlimited access to the community means they are more likely to be trusted and appeal to the community as their own hence receive a more positive response from the community (Molyneux. *et al.*, 2013; Molyneux., Kamuya, & Marsh, 2010; Simon & Mosavel, 2010). This may enhance mutual respect and understanding between research institutions and the community, hence lead to long-term relationships, which is essential in the sustainability of research programmes in Africa and beyond (Marsh, Kamuya, Rowa, Gikonyo, & Molyneux, 2008). At KWTRP, fieldworkers are employed to provide support to various research studies. Their roles include but are not limited to seeking informed consent, taking basic physical measurements such as temperature, Mid Upper Arm Circumference (MUAC), height, making participants' follow-ups, conducting survey interviews and providing an important link between the community and the research programme.

2.4 Challenges faced by fieldworkers in undertaking their roles

Despite the above advantages, the role of seeking informed consent often presents fieldworkers with important ethical challenges and dilemmas. For example, their commonalities and close relationship with the community they live in and work from have been linked to increased social risk for study participants, including but not limited to

potential to breach participants' confidentiality, which can ultimately compromise the validity of data (Ahmed & Palermo, 2010; Alexander & Richman, 2008; Molyneux. *et al.*, 2010). Supporting this view, Chantler *et al.* (2013) argued that, fieldworkers who live and work in the same communities face unique ethical dilemmas because the community is likely to trust them more than ordinary health research workers. As such, community members might be more willing to participate in studies when the fieldworker (who consents them) is someone they know and live with. Conversely, fieldworkers may "persuade" people to take part in studies when they both understand the situation an individual is going through and truly believe such an individual has the likelihood of benefiting from the services/benefits offered in the study. Emphasizing the challenges experienced by fieldworkers, Molyneux *et al.*, (2013) contends that fieldworkers play an intermediate role between very different priorities and concerns of well-resourced research institutions, and relatively poor communities without good access to quality affordable health care. In doing so, fieldworkers are not just ordinary employees and simple neutral observers, who adhere to formal, externally derived ethical rules, but instead play a vital, creative, and under-recognized role in research and ethics practice (Molyneux & Geissler, 2008; Molyneux. *et al.*, 2013). Furthermore, fieldworkers are also expected to delicately balance their own individual interests, the policies and guidelines of the organizations they work for and the expectations of the community they live in and work from (Chantler *et al.*, 2013; McKinney, 2002; Molyneux. *et al.*, 2013).

2.5 Informed Consent Process

2.5.1 Background

The concept of informed consent in research took center stage in the early 1930s after some widely documented historical injustices and atrocities were conducted in the name of

research. In the past, vulnerable populations such as prisoners of war, poor black African-Americans and patients with cognitive disabilities were involuntarily involved in harsh and inhumane experiments that led to severe disabilities and loss of life (Ghooi, 2011; Shuster, 1997). Following these atrocities, several international guidelines were developed and revised, all aiming at protecting and ensuring human research participants are respected (CIOMS, 2002; Resea & Ryan, 1978; WMA, 2002). Importantly, during the trial of the German physicians who were involved in the infamous Nazi experiments, the bench of judges came up with a list of ten codes of conduct-commonly known as the Nuremberg code; which was forthwith to be adhered to in the conduct of human research (Nuremberg, 1949). The first of these codes states that:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision (Nuremberg, 1949).

This specific code, which relates to the ethical principle of autonomy, went on to become the most important principles in present-day ethics (Weindling, 2004). According to Beauchamp and Childress (2001), autonomy comes from the Greek words *autos* (self) *nomos* (rule/governance), which translates to meanings such as liberty, free will, privacy and self-governance among others (Beauchamp & Childress, 2001). In the context of health research, autonomy is related to respect for persons and includes capacities of self-governance understanding, reasoning, deliberating and independent choice (Beauchamp & Childress,

2001). Thus informed consent, which denotes the application of the principle of autonomy in research is critical in the conduct of ethically sound research (Weindling, 2004).

Informed consent is viewed and understood differently in different fields and contexts, making it the most contested, complex and controversial ethical principle in health research. At the same time, authors argue that informed consent is the cornerstone of ethical conduct of research and regulation of research (Bhutta, 2004).

The Council for International Organizations of Medical Sciences (CIOMS) guidelines (2002) define informed consent as the process that is initiated when initial contact is made with a prospective participant and continues throughout the course of the study and is fulfilled by fully informing the prospective participant about the proposed study, answering their questions and ensuring that each individual understands each procedure, before eliciting their informed consent and in so doing manifests respect for their dignity and autonomy (CIOMS, 2002). Conversely, Berg *et al.* (2001), define informed consent as:

Legal rules that prescribe behaviours of physicians and other healthcare professionals in their interactions with patients and provide for penalties; under given circumstances, if physicians deviate from that expectation; to an ethical doctrine rooted in our society's cherished value of autonomy, that promises patients right for self-determination regarding medical treatment; and to an interpersonal process whereby these parties interact with each other to select an appropriate course of medical care (Berg, Appelbaum, Lidz, & Parker, 2001).

Berg's (2001) view about informed consent points to the complexities and tensions surrounding the definition, understanding, and application of informed consent by different people working in different fields/professions. Importantly, there are bound to be tensions

and lack of agreements where, for example, decisions should be made based on two conflicting viewpoints such as legal and ethics or even using different lenses within the same viewpoint e.g. individualistic vs communitarian. It is, however, important to note that, regardless of the viewpoint taken, there are key elements that are necessary to consider when determining whether or not truly informed consent has been achieved.

In Kenya, ethical conduct of research is enshrined in chapter two, article 11.2 of the new Constitution of Kenya (2010), which was promulgated on 27 August 2010 and recognizes the role of science and indigenous technologies in the development of the nation (Constitution of Kenya, 2010). It is the same chapter, which set forth the establishment of the Bill of Health (2015), under which an act of parliament (section 32) was enacted to pave the way for the establishment of the National Council for Science, Technology, and Innovation (NACOSTI). NACOSTI is the body mandated to coordinate health research in Kenya. It is NACOSTI that supported the development of the guidelines for ethical conduct of biomedical research involving human subjects in Kenya (Constitution of Kenya, 2010).

According to the guidelines, all local and international organizations that conduct research in Kenya must adhere to three main ethical principles, namely respect for persons, beneficence, and justice. The guidelines also emphasize the need to adhere to seven key requirements, including scientific value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review, informed consent and respect for potential and enrolled subjects. Informed consent is therefore considered as a key requirement in the ethical conduct of research. Thus, as a renowned international research organization, KWTRP must adhere to the requirements as stipulated in the guidelines and the constitutions of Kenya (Constitution of Kenya, 2010).

2.5.2 Valid Informed Consent Process

Most research ethics guidelines identify three mutually inclusive elements of the informed consent process, including information sharing/disclosure, understanding, and voluntary decision making/free informed choice (Dixon, 1999; Lindegger & Bull, 2002; WMA, 2002). Although these principles may sound straightforward, several challenges, including differences in the meaning and application of autonomy, cultural differences in practicing individual respect, high disease burden, illiteracy and poverty, have been attributed to difficulties in achieving valid informed consent, especially for research conducted in developing countries (Frimpong-Mansoh, 2008; Lindegger & Bull, 2002; Lindegger & Richter, 2000; Miller & Boulton, 2007). These challenges call for the need to rethink models of informed consent (Lindegger & Bull, 2002). In addition, they underscore the importance of the researchers' obligation to promote autonomy and voluntariness during the process of seeking informed consent and to protect vulnerable populations or those whose autonomy is diminished (Macklin, 1999; Siminoff, 2003). For example, although information disclosure may be deemed straightforward, the emphasis on sharing information in a way that facilitates comprehension and understanding and promotes voluntary informed choices free from undue influence and coercion makes the process worthier of more consideration than the signing of the consent form itself.

2.5.3 Voluntariness

The concept of voluntariness in research first came to light in the Nuremberg code (1949) where the tribunal of judges codified the first principle as "the voluntary consent of the human subject is absolutely essential" (Nuremberg, 1949). Following this code, several international guidelines, including the declaration of Helsinki, the Belmont report, and

CIOMS; among others, underscored the importance of informed consent and voluntariness before research participants are involved in studies (National Commission for the Protection of Human Subjects of Biomedical Behavioral Research, 1978; WMA, 2002).

Indeed, the concept of voluntariness is one of the most important ethical aspects related to the principle of autonomy or respect for persons in research. According to Nelson *et al.*, (2011) voluntariness encompasses two necessary and jointly sufficient conditions, including intentional action and the absence of controlling influences (Nelson et al., 2011). In their arguments, Nelson *et al.* (2011) described voluntariness in terms of the degree of control an individual has over his or her own behavior. Other international guidelines, including the Nuremberg code (1949) also put emphasis on the ability for a research subject to maintain a free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion” (Nelson et al., 2011; Weindling, 2004). This view places an important focus on the people involved in seeking informed consent. In the context of this study, fieldworkers must ensure that the way they communicate study information and their relationship with research participants give research participants the freedom to express their decision without feeling prejudiced, unduly influenced or coerced (Chantler *et al.*, 2013). For example, in order to promote voluntariness, it may be important for those involved in seeking informed consent to understand and assess whether or not the benefits offered in a study represent undue inducement and have the potential to compromise the participant’s voluntariness (Njue, Kombe, Mwalukore, Molyneux, & Marsh, 2014). On the other hand, those involved in seeking consent, as well as Research Ethics Committees (RECs) should articulate and understand how voluntariness can be compromised and the implication of the same on study participation, and advice Principal Investigators (PI) appropriately (Kombe. et al., 2013).

2.5.4 Undue Influence

According to Ezekiel Emanuel, undue influence occurs when an individual is offered something that makes them assume substantial risks of harm that compromise their welfare against their best judgment (Ezekiel J Emanuel, 2005). In other words, the individual must be given too-good or an irresistible offer that is too large to the extent that it distorts their judgment. Most importantly, that poor judgment should lead to a high probability of a serious risk of harm that contravenes the individual interest. (Ezekiel J Emanuel, 2005). There have however been serious debates on what constitutes a “good offer” or “excessive offer” with some authors arguing that “goodness” and “excessiveness” is dependent on the context where the research is done (McGregor, 2005). Some authors have also argued that payment or research offers cannot be against a subject’s better judgment if the study is not risky and that whether or not research subjects are unduly influenced rests on the RECs ability to evaluate whether or not the study poses a favorable risk/benefits ratio and to what extent the process of informed consent is truly informed and voluntary during the recruitment of research participants (Ezekiel J Emanuel, 2005; VanderWalde, 2005).

2.5.5 Coercion

According to Nelson *et al.* (2011), coercion happens when a person intentionally either forces another person or uses a credible and severe threat of harm to control another person (Nelson et al., 2011). There is general agreement among scholars that coercion consists of threats that propose to make the person “worse off” than his or her normal baseline if the proposal is not accepted, (McGregor, 2005). Coercion is often reported to take place within a doctor-patient relationship, where physicians may impose their patients to accept certain procedures/take part in the trial or withdraw treatment (Wertheimer, 2012). Coercion within

a research context is rare but possible. In this context, coercion may occur if individuals are given offers with no other good alternative options of choice, leaving the offer the only eligible choice and especially where foregoing that offer possess a threat for harm. (McGregor, 2005). In developing countries, studies working with poor communities may be deemed coercive when they offer free health care services that are relatively better than the existing standard of care. However, Nelson *et al.* (2011) argue that, although such offers may be a form of irresistible pressure for such individual to refuse participation due to lack of alternative choices, their participation would not necessarily be deemed as coercion. Indeed, their miserable circumstances may influence them to accept offers presented to them even when they would not otherwise have accepted them, but that would not be similar to coercion (Nelson & Beauchamp, 2011).

2.5.6 Understanding

Major international ethical guidelines emphasize the need for researchers to ensure research subjects are only allowed to participate in research when they fully understand what they are involving themselves in. According to the latest CIOMS guidelines (2016), the person obtaining consent must ensure that the potential participant has adequately understood the information provided by using evidence-based methods for imparting information and ensuring comprehension (W. H. Organization & Sciences, 2016). We are however aware that achieving valid informed consent is not as linear as it usually happens on the ground, as it is compounded by quite complex contextual issues including the individual participant's own agency, cultural decision-making norms, poverty and level of education among others. As stated in the CIOMS guidelines (2016), the potential participant's ability to understand the information depends; among other things, on the individual's maturity, educational level, and

belief system. In addition, studies and reported experiences of informed consent in many settings highlight challenges in ensuring potential participants have an adequate understanding of specific aspects of proposed research, or even of research in general (Kamuya, Marsh, & Molyneux, 2011). The participant's understanding also depends on the researcher's ability and willingness to communicate with patience and sensitivity, as well as the atmosphere, situation, and location where the informed consent process takes place (W. H. Organization & Sciences, 2016). Several studies have been done to understand some of the main barriers to effective informed consent in a bid to identify important strategies for promoting valid informed consent (Jefford & Moore, 2008). A recent systematic review and meta-analysis conducted by Nishimura et al. (2013), that compared different approaches for enhancing informed consent found that extended discussions were the most effective way to enhance understanding compared to multimedia interventions, enhanced forms and post-consent tests (Nishimura et al., 2013). These findings support views by other authors who have suggested a more inclusive and dialogic approach to enhance informed consent (Lindegger & Bull, 2002). Using extended dialogue and discussions to enhance comprehension and understanding is embedded within the individual interpersonal skill, making fieldworkers who interact with research participants a central pillar to effective informed consent process in health research. Yet, extended discussion alone cannot guarantee a perfect informed consent process. The health of the individual, social economic status and the level of trust have equally been seen to affect understanding during consenting (W. H. Organization & Sciences, 2016).

2.6 Individual Mental Status

The CIOMS guidelines state that competence or decisional capacity is key in determining a participant's ability to understand information, appreciate the situation and its consequences, consider the treatment options, and communicate their choice (W. H. Organization & Sciences, 2016). Consequently, a person's capacity can be compromised by their health status. Illnesses such as dementia, some psychiatric conditions, and other mental illnesses have been known to affect an individual capacity to articulate and comprehend issues adequately. In Sub-Saharan Africa, high disease burden coupled with dilapidated health systems, frequent drug stock-outs and long waiting lists have been described as important factors that can affect potential participants' rational decision making and their ability to make a free and voluntary choice to participate in research (Kamuya et al., 2011; Taylor, 1999). Therapeutic misconception has also been associated with situations where individuals are asked to participate in research when their priority is to seek care, or they perceive research procedures as routine health care services (Macklin.,1999; Molyneux *et al.*, 2004). Researchers are therefore expected to assess the individual participant's capacity to make a free informed choice and decide whether to involve the participant or the legally acceptable representative in the process of decision making (W. H. Organization & Sciences, 2016).

2.7 Social Economic Status

The notion that socio-economic status plays an important role in the increasing amount of transnational research being conducted in Sub-Saharan Africa has been at the center of recent debate, with some authors equating it to structural and economic inequities (Emanuel, Wendler, Killen, & Grady, 2004; G. M. Lairumbi, Michael, Fitzpatrick, & English,

2011; Uthman. *et al.*, 2015). Many authors contend that Africa faces unique challenges related to economic, social, disease burden, structural and systematic inequalities that have a strong influence on health research participation. In addition, low levels of education and research illiteracy have been associated with therapeutic misconceptions (Molyneux, Peshu, & Marsh, 2004). Studies done in developing countries have shown that unemployment, lack of alternative options and poverty increases participants' vulnerability where participants may find it difficult to resist even the smallest offers extended to them during recruitment as part of study benefits, hence affect their voluntary participation (Kamuya *et al.*, 2011; Njue *et al.*, 2015). Arguments leveled along this view indicate that although such benefits might look so little, to a participant who is barely able to make ends meet and has little or no other alternative, such benefits can present a form of undue influence and affect their decision for voluntary participation (McGregor, 2005; Njue *et al.*, 2014). In these situations, fieldworkers often play an important intermediately role, having to balance the needs and expectations of communities that are sometimes in genuine desperate need against the policies and requirements of well-resourced international research institutions. Failure to manage this delicate balance can undermine the trust established between the community and the research institutions (Gikonyo *et al.*, 2008; Marsh, Kamuya, Rowa, Gikonyo, & Molyneux, 2008; Molyneux, Peshu, & Marsh, 2005).

2.8 Trust

Empirical research describes trust as playing a critical role in influencing research participants' decisions on whether or not to participate in research (Kerasidou, 2016). To this end, community engagement has recently been promoted as the most effective way of building trusting relationships with participants and communities, making it an essential

requirement to ethical research (Marshall & Rotimi, 2001). Supporting this view, Faden *et al.* (2005), argued that informed consent is by extension a method of building trust (Faden, Mastroianni, & Kahn, 2005).

According to Molyneux *et al.* (2005), establishing trust is critical in ensuring potential research participants trust the information given to them about studies and that all the procedures are indeed safe as explained by the one seeking informed consent. Additionally, the level of interpersonal trust in an individual can have a profound impact on how research is communicated and understood (Molyneux, Peshu, & Marsh, 2005). In another study done in Kenya, Kamuya (2013), described complex social relations involving dialogue, information sharing and negotiations and ever-shifting relations which had important implications for the informed consent process, access to benefits as well as mutual understanding and trust between the community and the research institution (Kamuya. *et al.*, 2013). Fieldworkers have therefore been described as central in establishing and maintaining trust and long-term relationships with research communities and participants during and beyond the lifespan of the studies they work for (Kamuya. *et al.*, 2013).

2.9 Challenges associated with the informed consent process

The recent decade has seen a dramatic increase in the number of studies conducted in Africa (Uthman *et al.*, 2015). Some authors have attributed this increase to attempts by the global north partners to narrow the 10-90 gap; while others have been more critical and attributed it to some global forms of structural inequities which arise as a result of weak regulatory systems, poverty and the availability of a population that is vulnerable and overly desperate to participate in research (Benatar & Singer, 2010; E. J. Emanuel, Wendler, Killen, & Grady,

2004). This notion has often raised fierce debate, with some authors arguing about the potential for exploitation and taking advantage of the ignorant state of the Southern population to benefit the global north (Emanuel *et al.*, 2004; G. M. Lairumbi, Parker, Fitzpatrick, & Mike, 2011; Uthman. *et al.*, 2015).

Indeed, Africa faces unique challenges related to economic, social, disease burden, structural and systematic inequalities that no doubt have a strong influence on health research participation. In addition, therapeutic misconceptions (Molyneux., Peshu, & Marsh, 2004), maintaining perceived important relationship between members of the community and the research team (Kamuya. *et al.*, 2013), as well as the cultural values of the community (Frimpong-Mansoh, 2008; Gikonyo, Bejon, Marsh, & Molyneux, 2008) all influence decision making and voluntary participation in research. This calls for the need to take a much wider view when interrogating the concept of informed consent and look at participation in research as an intrinsically important action embedded within an individual's moral choice that should be well informed; facilitated with good understanding and the ability to weigh all the risks and benefits associated with specific research studies and not merely the process of signing the informed consent documents. This process can only be achieved if those involved in seeking informed consent understand its value and the influence of their own behavior in the process. To achieve this, it is important for FWs to see themselves as key facilitators of understanding and decision making and providers of accurate information and knowledge that promotes genuine informed consent process and not merely recruiters of research participants. However, it is unclear to what extent fieldworkers perceive the role they play in health research and how they value and understand the process of informed consent.

2.10 Study Justification

The complex relational realities and dynamics experienced by fieldworkers as they go about seeking informed consent present important implications of how ethical principles are applied on the ground. If not well managed, this can undermine the ethical standard of the studies fieldworkers are employed to work in (Chantler *et al.*, 2013). This may further be exacerbated if fieldworkers are not fully aware of the implications of their actions on the quality of ethical standards and the overall integrity of research. We suspect that the way fieldworkers understand the value and meaning of the informed consent process and the degree to which they understand its importance in relation to the overall ethical and scientific standards of research may influence how fieldworkers undertake the informed consent process in practice. This view is supported by existing literature suggesting that people who understand the reasons behind the roles they are assigned to do are more likely to reflect constructively on their actions, engage in positive reinforcement practices and be motivated towards achieving desired goals with limited support (Chantler *et al.*, 2013). Although numerous studies have been done to understand the role of fieldworkers and their experiences in health research, little has been done to unpack and understand how fieldworkers conceptualize the process of informed consent and how this influences their scientific and ethical practices. Understanding how fieldworkers conceptualize the informed consent process can provide important insight on fieldworkers' ethical practices and how training and ethical guidelines are operationalized on the ground.

CHAPTER 3-STUDY AIMS AND OBJECTIVES

3.1 Introduction

This chapter gives a summary of the aims and objectives of this study.

3.2 Study aims

Overall, this study aimed at developing an in-depth understanding of how fieldworkers conceptualize health research, understand their role in the consent process and how they value the process of informed consent. In addition, we sought to understand field managers' views and perceptions on health research and the role of fieldworker in Informed Consent.

3.3 Study objectives

Specifically, the study aimed to

- Describe fieldworkers' and field managers' understanding of and attitudes to health research.
- Define fieldworkers' and field managers' perceptions of the role of fieldworkers in the process of informed consent.
- Describe fieldworkers' and field managers' understanding and attitudes to the value and meaning of the informed consent process.
- Recommend appropriate fieldworkers' training to address any gaps identified.

3.4 Study Questions

Several questions were explored during the study, including

- How do fieldworkers and field managers understand the concept of health research;
- How do fieldworkers and field managers understand the role of research in development;

- What attitude do fieldworkers and field managers have towards health research;
- How do fieldworkers and field managers perceive their role in health research;
- How do fieldworkers and field managers conceptualize the process of informed consent and
- How do fieldworkers and field managers perceive informed consent process in health research ethics?

CHAPTER 4-METHODOLOGY

4.1 Introduction

This chapter provides an overview of the methods that were used to answer the study questions. In addition, the study setting, population, sampling and development of the tools are also described. Two methods were used to achieve the study objectives, including Focus Group Discussions (FGDs) and Individual In-depth Interviews (IDIs). Forthwith, this chapter provides an overview of how FGDs and IDD were triangulated to provide a clear understanding of the issues under research. The methods of analysis and the shortcomings of each method are also discussed

4.2 Study Setting

The study was conducted at the KEMRI-Wellcome Trust Research Programme (KWTRP) in Kilifi Kenya. KWTRP is a large international biomedical research Programme that conducts research in a wide range of research fields, including malaria, pneumonia, TB, adult bacterial diseases, HIV/AIDs among others. It has a workforce of about 750 members of staff working in various fields (Scott *et al.*, 2012).

Fieldworkers are the single largest cadre of staff constituting over 30% of the total workforce within KWTRP (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015). This study sampled thirty (30) KWTRP fieldworker and engaged them in discussions in order to develop an in-depth understanding of issues described above.

4.3 Study Design

The study used a qualitative approach to collect data from a purposive sample of fieldworkers working at the KWTRP. The qualitative approach enables researchers to understand and respond to multiple social and physical facets of human lives by exploring the complexity of human behavior beyond the scope of numbers and statistics (Liamputtong & Ezzy, 2005). Using a qualitative approach enables the researcher to elicit evidence from diverse individuals, population groups, and contexts. A qualitative approach is, therefore, a type of social inquiry which seeks to understand how individuals make sense of their experiences and the world in which they live and is useful in understanding meanings, interpretations and subjective experiences of individuals. Its flexibility and ability to capture feelings and opinions made it particularly suited for this study (Liamputtong & Ezzy, 2005; Taylor, Bogdan, & DeVault, 2015).

4.4 Sampling fieldworkers for focus group discussion

A list of all 202 fieldworkers working at KWTRP was obtained from the KWTRP human resource department, with a list of the studies they work with. Based on this list, the fieldworkers were grouped based on their level of interaction with research participants.

Two groups were generated from this process; Group A comprised of fieldworkers working in studies with limited or moderate participants' interactions while Group B comprised of fieldworkers working in studies with high participants' interactions. For each group (A and B), one group of male and one group of female fieldworkers were purposively selected to participate in FGDs involving male fieldworkers only or female fieldworkers only, respectively.

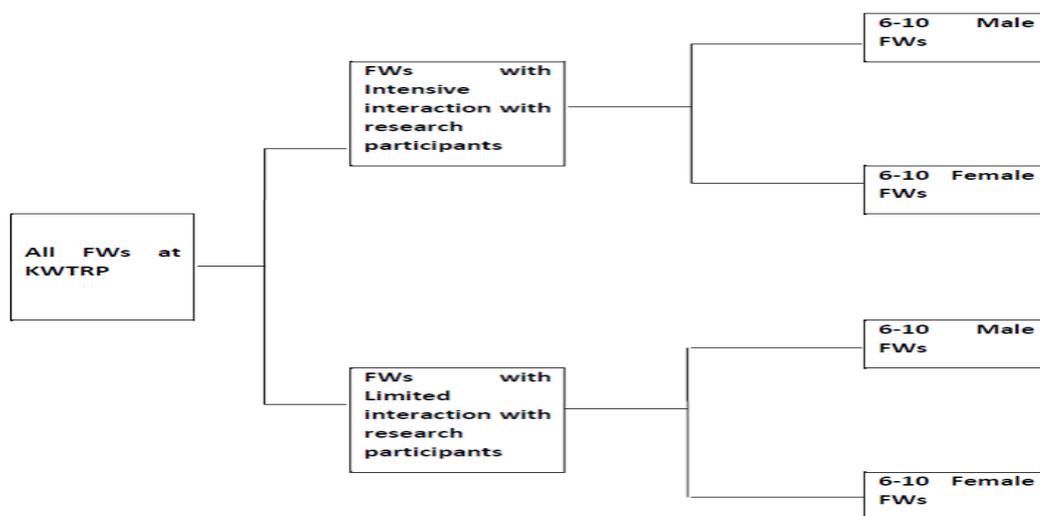


Figure 1: Sampling process. Illustrating the sampling process

In summary, we obtained a list of 202 fieldworkers from KWTRP human resource office. Within KWTRP, fieldworkers work in different departments that have different levels of interaction with research participants. For example, studies conducted in the community and in hospital wards usually expose fieldworkers to more intensive interaction with study participants. However, other studies undertake more operational activities that do not necessarily involve seeking informed consent from research participants *per se*. We suspect that the level and frequency of interaction and exposure to research participants might influence the fieldworkers' understanding and perceptions of the value and meaning of informed consent, as well as their practices. For this reason, we purposely selected fieldworkers based on the studies they work for. We did this by first splitting all the 202 fieldworkers into two groups- i) fieldworkers with limited interaction with participants and ii) fieldworkers with intensive interaction with participants. Further, we purposely selected between six and twelve fieldworkers and invited them to take part in a focus group discussion. HIV/ AIDS and other behavioral empirical studies have shown that demographic information such as gender, age, religion and level of schooling are important drivers of

attitude, practice and behavior change (Akwara, Madise, & Hinde, 2003). However, no empirical studies have been done to understand how these factors influence fieldworkers' perceptions and practices. In this study, participants were grouped according to their gender and level of interaction with participants to allow any commonalities and variations on the views, attitude, and perceptions of these participants to be examined. As such, male and female fieldworkers belonging to the two groups (A and B) were interviewed separately.

4.5 Data collection

4.5.1 Focus Group Discussion with Fieldworkers

Focus group discussions (FGD) were conducted with a purposive sample of fieldworkers working in various studies at KWTRP to assess their understanding and conceptualization of the concept of informed consent.

FGD is a qualitative research method that allows a small group of between 6 and 10 participants to discuss and share their perspective on a topic through interaction with the facilitator and fellow participants. FGD is common due to its ability to promote interaction between participants and tap information that could otherwise be inaccessible through other forms of data collection (Akwara et al., 2003).

In this study, fieldworkers were invited to attend a focus group based on common demographic characteristics, including gender and the departments they work in; which determines the level of interaction they got with research participants. All participation was voluntary. Those who agreed to participate in the discussion were given an appointment detailing the date, time and venue of the FGDs. A discussion guide (see Appendix 1) was used to guide data collection.

Individual informed consent was obtained prior to the beginning of the discussions. This was done by giving each participant a copy of the information sheet after which, the principal investigator read and explained every section written on the informed consent form. Each participant was given a chance to ask questions and a response was given before explaining the next section.

After reading and explaining every section of the information sheet, the participants were taken through the informed consent form where each section was read out and explained before asking those who agree to participate to append their signatures.

4.5.2 Individual In-depth Interviews with Field Managers

Individual In-depth Interviews (IDIs) is a qualitative research method that allows for an in-depth discussion and exploration of key issues. In this study, we used IDIs to explore the field managers' individual views and perceptions of the discussion topic as well as triangulate the issues generated through the fieldworkers' FGDs. The topics covered in the managers' IDIs mirrored those of the fieldworkers' FGDs, to allow close comparison of information provided by each of these groups of participants. This was especially important because field study managers and coordinators play an important role in FWs' performance management which has implication on their attitude and practices. Incorporating managers views was therefore not only important as a method of triangulating the FGDs data collected but also as a way of generating valuable information from the managers' perspective.

A total of 8 field managers were invited to participate in individual in-depth interviews. Prior to attending the interviews, an information sheet with details of the study was sent to all the field managers through email. A total of eleven field managers were invited to participate. Out of these, eight agreed to participate in the interviews. Despite having received the

information sheets and consent forms by email, every field manager was taken through the study information and given a chance to ask questions before signing the informed consent form.

All the interviews, including the FGDs and the IDIs were moderated by the study Principal Investigator (PI), assisted by an experienced rapporteur who took field notes during the discussion, gave feedback on the outcome of the discussion and highlighted any important insights necessary for the moderator to be aware of or that need to be followed-up after every discussion. The rapporteur checked all transcriptions against the field notes, to identify any gaps and discrepancies before the final draft was adopted.

4.6 Data Validity, Reliability, and Rigor

Focus Group Discussions and Individual In-depth Interviews were the main sources of data collection. To ensure validity, reliability, and rigor, all participants were contacted directly and gave individual informed consent before participating in the study (Alam, 2005; Roberts, Priest, & Traynor, 2006). Care was taken to ensure influence from supervisors and direct managers was eliminated by holding discussions during the participants' free time, out of their working hours. Focus Group Discussions were first held with fieldworkers before Individual In-depth Interviews were held with their field managers. This was necessary to ensure information collected from discussions with fieldworkers was cross-checked and validated through other independent sources that have a close interaction with the fieldworkers such as the field managers, during the Individual In-depth Interviews.

Discussions were held at a venue and time that was appropriate and convenient to the participants. This was to ensure all participants could freely share their experiences, without fear or discomfort. Before being involved in the discussions, all participants were reminded of

their right to voluntary participation and freedom to withdraw from the discussions without compromising any privileges or entitlements. Participants were encouraged to only share information they felt comfortable sharing.

FGDs were facilitated by the principal investigator, who is an experienced moderator in focus group, individual and consultative discussions. Permission to record discussions was sought during the informed consent process, with discussions commencing only after participants voluntarily gave the go-ahead to record the discussions. Flexible and open-ended discussion guides were developed with the support of the supervisor and reviewed by the School of Applied Human Sciences; Department of Psychology and the University of KwaZulu-Natal Biomedical Research Ethics Committee that approved the research (approval number BE517/16) prior to being adopted for use. Iterative questioning techniques, involving probing and allowing participants to engage with each other during discussions was used to allow for counter-checking and validation of information collected within the groups (Shenton, 2004). Throughout the discussions, participants were encouraged to share their experiences freely and openly.

After every FGD, the moderator and rapporteur had a debriefing session that involved cross-checking and agreeing on the main issues that emerged from the discussion and the completeness of the notes captured. Detailed field notes were developed and used alongside the transcripts during analysis. This was important in building consensus between the moderator and rapporteur on the main issues that emerged from each discussion. Initially, we had agreed to review the tools based on the data that was collected during the first interviews. However, no new issues emerged from the discussions that warranted amending

the discussion and interview guides. As such, the same guides were used throughout all the IDIs and FGDs.

Data analysis started immediately after the first FGD and continued throughout and after the data collection period. This ongoing analysis allowed for a continuous reflection of the emerging issues and following up and crosschecking of these in subsequent discussions. This process provided a basis for internal and on-going validation of the information as data collection continued (Polkinghorne, 2005).

4.7 Data analysis

The main language used during the FGDs and IDIs was English. However, there were a few instances when participants deviated and spoke in Kiswahili; the second national language in Kenya, either to explain things more typically or emphasize a point. Either way, all transcriptions that were not in English were translated into English by an independent translator who was not present during the interview before being reviewed by the study PI to check any loss of meaning or gaps. After translation, all transcripts were read in detail to familiarize with the data before commencing a more detailed and systematic analysis. Although the analysis was done concurrently and throughout data collection (Creswell, 2009), a more detailed analysis was important in order to capture key, higher order themes as opposed to seeking deeper meaning. As such, a framework approach was used for the data analysis using Nvivo software. The framework was developed by combining common issues that arose from the discussion into specific themes along with the original themes developed as part of the study discussion tools. This was necessary to allow for a schematic presentation of the concepts and themes generated from the transcripts. To organize the data into the themes and nodes, Nvivo 10.0 was used. This allowed for easy navigation and

interrogation of the data during analysis and writing up. Appendix 5 presents the thematic framework generated from the data collected.

During FGDs, participants were asked to discuss and agree on a picture that they believed represented a typical fieldworker at the KWTRP. After the discussion, the PI engaged a professional artist who used the descriptions given by the fieldworkers during the discussions to draw the picture described. After drawing, the picture was pre-tested with some fieldworkers to ascertain if the meaning was the same as described during the FGDs. Revisions were made and pretested again until the picture reflected what was described during the FGDs. The pictures that fit the description given during the FGDs were then adopted and included in the analysis and the report.

4.8 Ethical approval and gatekeepers' permission

The research was conducted with fieldworkers who are employees of the KEMRI-Wellcome Trust Research Programme (KWTRP). As such, the proposal was submitted to the Centre Specific Committee (CSC) and the Scientific and Ethics Research Unit (SERU) as well as the UKZN BREC for ethics approval. Participants were contacted directly to seek their individual consent to participate in the research. No authorization was sought from their immediate supervisors. All interviews were conducted at a time and place that was convenient to the participants; to encourage open and free participation. Only participants who gave individual consent participated in the study.

4.9 Data storage and disposal

Data was stored in the PI's password-protected computer, to ensure data safety and confidentiality. Digital voice files were transferred from the digital recorders to the PIs'

computer and deleted from the recorders immediately once they were successfully transferred. We made electronic copies of all other study materials such as field notes and analysis prior to shredding the hard copies, as stipulated in the UKZN dry waste disposal policy. All data will be stored for five years before being disposed of, in accordance with the UKZN data governance policy.

4.10 Dissemination of research findings

During FGDs, participants were given special tags that were used to identify them throughout the discussions. These unique identifiers were also used during the analysis. Although demographic data was collected during interviews and discussions, this could only be linked to the participants' unique identifiers and not their individual names. All study findings, including this thesis, reports and scientific presentations that may be done in future will be presented in summary form and will not be linked to participants' individual names. Participants' individual details, including their names, gender, and age were removed from all transcripts prior to developing any study reports.

A summary of this report will be presented to all the fieldworkers and field managers who participated in the discussions. In addition, a presentation on the finding of this study will be made to researchers and scientists at KWTRP, during one of their weekly presentations. Since findings from this study may have important implications regarding fieldworkers' training and their ethical practices, a summary of the findings will be presented to the programme Heads of Training and Field Surveillance at KWTRP.

CHAPTER 5-RESULTS

5.1 Introduction

This chapter describes findings from the Focus Group Discussions (FGDs) and Individual In-depth Interviews (IDIs). We conducted the four FGDs before conducting the IDIs. This approach is known as methodological triangulation (Seale, 1999). Doing triangulation in this manner was helpful in developing understanding of the issues under consideration, and presenting social research results (Wilkinson, 1998). The findings are organized thematically.

5.2 Demographic details

A total of four FGDs were successfully held with male fieldworkers (n=2) and female fieldworkers (n=2), both of which comprised of fieldworkers working in studies that had intensive interaction with study participants (1 male FGD and 1 female FGD) and those working in studies that had limited interactions with study participants (1 male FGD and 1 female FGD). In addition, a total of 8 Individual In-depth Interviews were successfully held with field managers working in studies with both intensive (4 IDIs-2 male and 2 female) and limited (4 IDIs-1 male and 3 female) interaction with study participants. Tables 1 and 2 below give a summary of the FGDs and IDIs conducted.

Table 1:
Number of Focus Group Discussion Conducted with fieldworkers

<u>Gender</u>	<u>No with Intensive Interaction</u>	<u>No with Limited Interaction</u>
Male	1 FGD (7 FWS)	1 FGD (6 FWS)
Female	1 FGD (11 FWS)	1FGD (4 FWS)
Total	2 FGDs	2 FGDs

Table 1

Table 2
Number of Individual In-depth Interviews conducted with field managers

<u>Gender</u>	<u>No with Intensive Interaction</u>	<u>No with Limited Interaction</u>
Male	2	1
Female	2	3
Total	4 IDIs	4 IDIs

Table 2

The age range of the fieldworkers who attended the FGDs was between 24 and 54 (mean-34 years old). Eleven percent (n=3) of those who participated in the FGDs were Muslims, while 89 percent (n=25) were Christians. Education level ranged from O'level (secondary) to college (tertiary level) with 36 percent (n=10) reporting having attained O'level education and 64 percent (n=18) reporting having attained college education level.

5.3 Attitudes and Perceptions about Health Research

To explore participants' attitudes and perceptions about health research, participants were asked to describe what they thought health research was and how it was related to the concept of social development. Further, participants understanding of the relationship between the roles of fieldworkers and social development was explored.

Generally, participants described health research as a process of seeking to understand more about the human body with the aim of finding better ways to prevent or treat problems related to health. Fieldworkers as well as field managers associated health research with a systematic investigation aimed at answering questions related to health, as described by one of the participants below.

“What I understand about health research is, it is the type of research or investigation made towards answering certain health issues or questions, problems related to health, so finding solutions or interventions in problems related to health” IDI 006F

Most participants associated health research with social development by describing how health research attributes to better health, which eventually influences the community's ability to engage in socio-economic development activities. Repeatedly, participants said *“a healthy community is a wealthy community”*, implying that when a community is healthy,

they could invest their time and energy to economic activities that would eventually contribute to social development.

The way health research and more so how fieldworkers' roles contributed to the wellbeing of the community was described in various ways. For example, some participants associated fieldworkers' roles with social development because fieldworkers were usually involved in educating community members about various aspects of health as they interacted with them. Others, however, thought fieldworkers' roles were directly related to social development given that they were part and parcel of research, which influences health and which eventually influences social development. Some participants argued that, as fieldworkers interacted with study participants and the community, they directly or indirectly passed on important information, which affected the community knowledge and understanding about different diseases, with the potential to influence them to make healthy choices and engage in healthy behaviors. Reportedly, this enabled the community to engage in social economic activities that contributed to the general development of the society.

There were also some participants, who thought new interventions which were discovered through health research, contributed directly to reducing the burden of disease through, for example, avoiding unnecessary health expenditure incurred through time invested to manage illnesses, as well as direct cash expenditure incurred when managing illnesses without proven treatment.

“it's true that it makes a community healthy; a healthy society is a wealthy society...let's say there is already a treatment and prevention against a certain illness, e.g. malaria, before, [a treatment was discovered] somebody suffering from malaria would go get injection today, goes home, goes back tomorrow and again and again, in that back and forth, if somebody

had 500 shillings they would spend it on the road, going for injections. But through health research, one is now given a full dose and after 3 days, you are done with malaria and you only used fare once. The savings from this can now be used for other community developments activities” P7FGD003F

5.4 Community Health Research Benefits

The relationship between the community and the KEMRI-Wellcome Trust Research Programme (KWTRP) in Kilifi was generally described as cordial and of mutual benefits. Both fieldworkers and field managers described the relationship as positive and friendly because of the community engagement efforts and strategies put in place by KWTRP. This belief was attributed to diminishing rumors and misconception about KWTRP.

Participants described numerous benefits which the community had gained directly through research participation as well as indirectly by having KWTRP within the community. Areas where the community was described as having benefited most included improved health services that were described to have directly improved through new research discoveries as well as infrastructural improvement in facilities associated with KWTRP activities. The community was, therefore, said to enjoy better health due to the research KWTRP conducted. Other benefits included socio-economic benefits associated with job creation; especially for the locals, that went back to inject their money into the county's economy. Direct benefits extended to study participants during studies, including free treatment and health checks, reduced death rate from common illnesses, transport reimbursement as well as humanitarian support that was sometimes extended to the community during catastrophic times were also described as important benefits the community enjoyed by

having KWTRP conducting research within the community. The community was therefore generally described as the biggest beneficiary of the existing relationship.

A few participants described the relationship as mutual and symbiotic, where both KWTRP and the community benefited from each other.

“The programme [KWTRP] has benefited in the relationship with the community since they have been able to get study subjects and the community has also benefited from the results of what KWTRP has been researching on” P3FGD002M

The sentiments expressed by fieldworkers in the FGDs were similar to those expressed by field managers with regards to the relationship between the community and KWTRP. Further, there was an emphasis on community benefits resulting from exposure to health research education which was described as useful in enhancing the community knowledge about health research, with the potential to influence their health-related behaviors and decisions.

5.5 Negative effects associated with participating in Health Research

Despite the benefits associated with health research, participants described several examples where they thought the community was exposed to research activities with potentially negative consequences/inconveniences. For examples, fieldworkers interviewed in FGDs believed exposing the community to health research “robbed” them of important indigenous knowledge. This was especially attributed to the doctors and nurses strike that was going on at the time the discussions were held. Participants argued that, traditionally, people would have alternative ways of treating the people who were dying as a result of the doctors’ strike. Reportedly, due to exposure to health research and dependence on modern

medicine, indigenous knowledge related to alternative forms of medicine had become extinct, resulting to loss of human life, as witnessed during the doctors' strike.

"I will support what my friend was saying here, so like if we had some traditions, we had some trees or some medication which were traditionally used before, [but] now the knowledge which we are giving the community or these scientific studies which we are now doing here, we are also educating the community, so it's like they are abandoning some of these things which they used to do before but now they are capturing or they are now being transformed to the scientific way of life..." P2FGD002M

One of the most important negative consequence attributed to community participation in research was time. Participants from both the FGDs and IDIs overwhelmingly agreed that the community had invested a lot of time in research participation. It was reported that, although this was not usually accounted for, participating in research involved commitment in time to respond to study questions, travel for study appointments or participate in study procedures which one would not necessarily have been involved in were it not for the research. Coupled with working in a community that is considered relatively poor, devoting such time demands a lot from the community, which could result in research fatigue, especially when involved in longitudinal studies.

"I don't know, [but] I consider it a bother, you know like, for example, there was a malaria RTSS study running in several villages within Kilifi, where they were looking for healthy toddlers and field workers would comb the area moving from one household to another, I mean that's a bother, and you wouldn't compare that with another village elsewhere that have never had such kind of intrusion; so to call it and time spent for purposes of the research...So there is an inherent risk [inconveniences] all the time" IDI005

Contrary to research fatigue, some participants reported that because of the long-term relationship between the community and KWTRP and lack of alternative options for some community members, some community members have become over-reliant on research participation and use this as a means to enjoy attractive research benefits. This has reportedly resulted in some community members readily volunteering to participate in research without taking time to understand the potential risks involved. Explaining this kind of a risk, a participant said:

“Because KEMRI has free treatment for children less than 5 years, and because the community does not have enough money to go for treatment somewhere else and do not want to spoil the relationship they have had with KEMRI, they will end up coming to KEMRI, allow their children to participate in research and get the free treatment but they do that just because they do not want to strain the relationship in addition to not having any other alternative place to go” (P4FGD002M)

Participants also reported instances when they believed community members participated in the research, not because they understood what the research was all about, but because they were attracted by the study benefits. Reportedly, this would expose research participants to potential harm, without being aware of the consequences. One called them “career research participants” (IDI007F), meaning they participate in research for financial gain. Participating in research was also reported to cause tensions and misunderstandings among families. For example, some families were reported to quarrel or even fight when one of them, especially women participated in research without consulting their spouse/partner. This was often described as a consequence of misconception.

Other risks described were related to lack of study feedback after participating in research, which reportedly left the community feeling disillusioned. Participants also described instances when research participants were exposed to trial research products, such as new vaccines or drugs, which according to the participants interviewed exposed them to some level of harm. Although both FGDs and IDIs participants were quick to note that there were some measures that were usually put in place to ensure such products caused no harm, they stated that there was always a potential for some level of unknown risk, as stated by a participant who said:

"...but then even so, individually some studies by nature of what it is they are investigating, generate risk both to individual participants and sometimes collectively. So, for example, if you have a new vaccine, for example, it has never been tested or they are here for safety testing; and we have had quite a number, there is always a level of some risk that something could happen...you know even the risk of identity, for example, you being identifiable that you participated in this research, your samples have been taken and for some reasons have even been shipped out of this country and probably even genetic characterization has been made.....so there is always some level of risk in that manner IDI005M"

5.6 Attitudes and Perceptions of fieldworkers' roles in health research

5.6.1 Attitude about who fieldworkers are

To explore the fieldworkers' attitudes towards their roles, all FGD participants were taken through a process of developing a rich picture. According to Fougner and Habib (2008), a rich picture is a methodological approach meant to capture attitude in a pictorial form by, for example, representing a human activity system that makes up a problem situation. A rich picture may comprise of drawings, symbols and "word bubbles" used to represent actors,

institutions, objects, and processes that play a role in the human system, as well as the connections between them (Fougner & Habib, 2008). In this study, fieldworkers who participated in FGDs were asked to draw a picture that they believed represented a typical fieldworker and their role within KWTRP. Since this was done in a group, participants were advised to discuss and agree on one rich picture between them. During FGDs and IDIs discussions, participants discussed what they believed were the roles of fieldworkers and how important these were towards health research.

Because participants were not expert artists, their sketchy drawings /descriptions were later given to a professional artist who drew them more clearly based on the descriptions given during the FGSs. The pictures drawn by the artists were then cross-checked with some fieldworkers, to ascertain if they indeed presented/communicated the same description as the one given by the participants during the FGDs.

Fieldworkers were described as an important cadre of staff which researchers and the research institution depend on to carry out their [institutions and researchers] work. They likened themselves to a steering wheel, which directs motor vehicles on which direction to take. This was captured by one participant who said

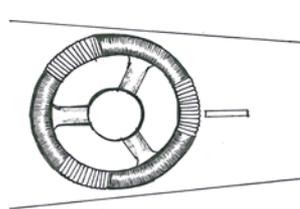


Figure 2: Fieldworkers as a steering wheel illustrating how fieldworkers drive research

“A fieldworker is a steering [wheel] because a steering [wheel] is a component of the whole vehicle; that big vehicle you see but although it has a lot of other things, they have to be guided by the steering. There is a driver but even with that driver, if there

isn’t any steering, s/he can’t know if the vehicle is taking a corner or going this way. So, we are saying [a fieldworker] is the steering because it’s like the key thing that directs each and everything that is happening in research”. P4FGD002M

In the same FGD, one participants said, *“When you put this in the context of a fieldworker, because we are the ones who collect information from the field and bring it at the unit, we should be very keen and responsible when we collect data, so that we can give credible final results”* P5FGD002M

P1 added, *“I think we have suggested steering because...let me say personally, as a fieldworker, if I consent you in the wrong way, then it’s like am giving you [KWTRP] wrong information and when I give you wrong information obviously, I think the whole study will be... the results will not be good so when something like steering drives the car in the wrong way, then eventually I think it will cause an accident”* P1FGD002M

The importance of the role of fieldworkers was also captured in the depiction of a fieldworker as a taproot. Participants interviewed in FGD 1 emphasized that fieldworkers were like a taproot because a root is the strongest hold, meaning without them being there

to give information to the local community, the progress of research would be jeopardized.

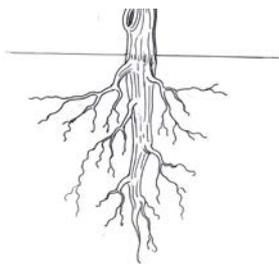


Figure 3: Fieldworkers as a tap root. Illustrating the importance of fieldworkers in research

One participant in the group said; *“a fieldworker is a [tap] root because we could say that KEMRI is the tree and the tree can’t grow or be nourished, or can’t stand without a root...there must be roots below and a fieldworker is a root of that big tree. A*

fieldworker does a lot of things that hold that tree, for example; a fieldworker must go to the field, and collect the information needed. So, if there is a certain research going on, the fieldworker must be used to collect the information and bring it. If it’s research involving discussions or collecting samples, the fieldworker must go and collect the samples, and if the fieldworker is not there, then no research can take place” P4FGD001F

Another participant said; *“I also concur with my colleagues, the root is everything, so even the plant to thrive, it requires the root. We, fieldworkers, are roots that hold the tree, if the root is uprooted or cut then that tree won’t survive, it will whether or die, meaning that, maybe the time this fieldworker withdraws or is removed from the research study then there won’t be any research with significance/importance”*. P1FGD001F

Others associated fieldworkers’ roles with hard work, endurance, and resilience. To illustrate this, one FGD depicted a typical fieldworker as a donkey carrying a heavy load, while another used a picture of a tired and overworked young man to represent a fieldworker.

Describing why a donkey represented a fieldworker, one participant said; *“it is true, if you are*

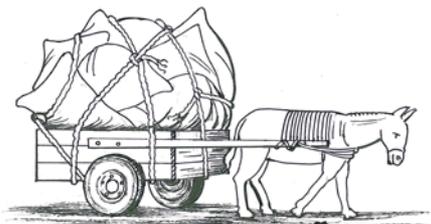


Figure 4: Fieldworkers as a Donkey. Illustrating hard work and resilience of fieldworkers

in the ward you are the first person to receive the patient, it is very true you are an ambassador. To me, a donkey represents a fieldworker; that luggage; everything we have discussed, [represents any work] that is given to you, you are ready to carry it.. but what

if you reach the end after carrying all that luggage? What do you receive in return? What are you made to feel? Let’s take a very small example maybe you are going on leave, do you have leave allowance? What about your PI? What about that doctor? Look at your salary, you do everything, somebody is just seated there and what is he earning? So we do everything that we believe is right but the reward!...[is not commensurate with the work we do]”

P4FGD004M

Supporting the above view, another participant said, *“what we do is like the donkey that has been described. As already described, most of the researchers use us [FWs] as a stepping stone...somebody comes, he has something to do, you are used then he or she goes. After*

some time, the person comes back and finds you still working at KWTRP as a fieldworker”

P6FGD004M

In another FGD, participants agreed that a drawing of a tired and overworked young man



Figure 5: Tired and overworked man: Illustrating fieldworkers' loyalty & harsh working conditions

represented a fieldworker who is hard working, unquestioning to the authority and loyal. Describing the picture, some, participants described fieldworkers as a cadre of staff that work under very tough condition, as

explained by one of the participants who said “A

fieldworker does a lot of work and also passes through

difficult situation...there might be sunshine or rain but all in all, he or she will make sure they

have protected themselves and the work. If you compare with others [other staff] in the office,

although their work is difficult, fieldwork is harder, that's why you see that guy [in the picture]

is looking so tired...You might think he is old, but he is not old, it is just because of a lot of

work” P10FGD003F

Describing the same picture, some participants likened it to staff that receives instructions

from the manager and sets out to follow the instructions diligently, regardless of the

prevailing conditions. In their descriptions, despite the tough conditions, the fieldworker still

must put on a smiling face and endure all the hardship to maintain a warm and cordial

relationship with the community they interact within their line of duty. This was well

captured by a participant who said, “A *fieldworker is a very important person in research*

because he links the community, the supervisor, and the principal investigator. you can also

see the fieldworker [in the picture] is bent meaning the luggage on his back is too heavy...that

is what happens when one is in the field. There are some studies, you'll be given a heavy

luggage [Literary].... You will carry hyetometer, cooler box, and a bag on the other side, it's raining you carry an umbrella so it's a lot of things, yet you still have to smile and do your work well" P08FGD003F

Generally, fieldworkers perceived themselves as an important cadre of staff in health research, but they had some mixed feeling attributable to workload and workplace recognition/appreciation. These sentiments were also echoed by the field managers, who described fieldworkers as a central pillar of research, whose contribution towards research deserved better recognition.

5.6.2 Roles of fieldworkers in health research

In discussions with both fieldworkers and field managers, fieldworkers' key role was candidly described as educating research participants about health research. Educating research participants was said to involve explaining research concepts to research participants before seeking consent. In undertaking this role, fieldworkers constantly addressed misconceptions about research and the research institution, ultimately contributing to participants understanding of health research and the importance of health research, hence promoting mutual understanding and voluntary participation in research.

"If as a fieldworker, I know my responsibility, when I'm in the field maybe, there is that state of concern which says KEMRI is involved with devil worshipping, they are collecting blood, now if I am aware, I've been told what KEMRI is, I know whatever is happening here. So, once I reach there, I'll educate/ explain to this person until he/she understands. After understanding, maybe in that community there are around five people with that concern and didn't want to participate because of a, b, c, d but once I have explained and they are aware, they will agree to participate in the research" P1FGD001F

Education was therefore described as the initial step towards helping people to appreciate the research and understand the difference between it and routine care, as described by one of the participants who said.

“even in the process of explaining what KEMRI is or what research is, you also make these people able to understand research or to understand the difference between research and medicine. So, when they understand and come to KCH [Kilifi County Hospital] they understand they went there for medication when they go to KEMRI they know they have gone there for research” P2FGD002M

Both fieldworkers and field managers described the role involving fieldworkers educating research participants as important and synonymous with their role to consent and recruit participants into research studies.

“[Fieldworkers] have a responsibility of convincing the community that we are not doing things to harm them but because the community does not understand what health research is...their biggest responsibility is to ensure the community keeps on understanding research...if we have information like Informed consent or about a new study, the community tends to really trust fieldworkers because they are children of their own, so they are there also to enhance quick understanding and uptake of studies because they are trusted by the community” IDI007F

In addition to educating and seeking informed consent from research participants, fieldworkers were also said to have the responsibility of collecting data and samples. Over and above their primary roles, both the fieldworkers and their managers described fieldworkers as playing an important role in linking the community involved in research with researchers and the research institution.

5.6.3 Role of fieldworkers in Social Development

Both fieldworkers and field managers associated fieldworkers' roles with social development, mainly by educating research participants about research and health problems associated with the studies they do. Fieldworkers were said to educate participants and the community on various aspects of health, prior to consenting them into research. In addition, the work fieldworkers do was said to be directly related to health research, which aims to improve health by finding better ways of preventing and treating illnesses. The data fieldworkers collected and the research they were involved in was said to have an important implication on health policies and interventions. Reportedly, improved health services, new health interventions, and policies were all aimed at creating space for better health outcomes which ultimately contributed to social development. The roles of fieldworkers were therefore directly associated with social development by virtue of them [FWs] being employed from the same community they worked, hence directly contributing to social development in their community. In addition, the roles they undertook were ultimately expected to contribute to better health of the community which would eventually promote positive social development. This was expressed by one of the participants in FGD002 who said,

"As fieldworkers, we play a very major role especially to the policymakers and the stakeholders involved in the ministry of health. We have contributed a lot of information which they use to better the lives of the community. Like the other day we were carrying out a study on the usage of mosquito nets in the community, so after that, information was submitted to the ministry of health and mosquito nets were distributed. This was very good, especially to the social economic development of the community" P5FGD002M

5.6.4 Attitude and understanding of the value and meaning of informed consent process

Both fieldworkers and field managers described informed consent as a process of seeking permission from research participants in order to involve them in research. Most participants explained that this process involved explaining the details of the study to research participants, including the risks, the benefits, and the procedures involved. Explaining the study and voluntary decision making were the element most participants described as key to the informed consent process. However, a few participants singled out understanding as the “mother” of all elements of informed consent as described by the below participant.

“Even if this person doesn’t agree but if he or she understands the information he can still be a source to pass the information to others who may understand very well because he is one of their own if I may term it that way; and when they go to ask some questions from that person... [the person can say] well I didn’t agree because its voluntary but they said they are doing 1, 2, 3, 4 and I know the benefits they mentioned...It is [the research] good, but I didn’t agree, the next person may agree and that will be good for the community and the programme” P4FGD002M

Some of the fieldworkers and field managers interviewed attributed informed consent to a process of informing research participants about the potential risks involved in health research to ensure they understood what they were about to get themselves involved in before taking part in the research. Asked why this was important, some argued that this was to protect the researcher in case the participants suffered any serious adverse events in future. Stating this view, a participant said,

“Health Research deals with human beings and every human being has their own stand and remembers we are dealing with human beings from day 0 to very old, there are some who are

able to consent willingly and others who are too young or too old to make the informed consent. So, you need to be aware and in-cooperate the guidelines which are there in Good Clinical Practice guidelines, whenever you take consent so that you make sure you protect your study participant and in case of anything, you as the researcher you will not be implicated for doing shoddy work” IDI001F

Other participants associated informed consent to the process of showing respect and empowering research participants prior to participating in research as was stated by one participant who said:

“There is also the final bit which is voluntary decision making. For me, this is the point where without coercion or anything the person can voluntarily make the decision without any external forces pushing on that decision and with acceptance of the likelihood of any outcome to come through. So, empowering the participants, for example, to know that a no is as good as a yes, you know and there are no repercussions, so there are no consequences” IDI005M

Some fieldworkers described informed consent in an entirely different context. To them, informed consent was not only the process of informing participants about research and getting them to make free informed choices but an opportunity to establish and maintain long-term relationships with research participants and the community at large. In these interactions, fieldworkers were not only expected to seek consent by their Principal Investigators (PIs) but were keen to adhere to the norms and expectation of the community members they seek to recruit in studies as described by one of the participants in the quote below:

“If you come to my home, for example, I am an old man and you are a fieldworker, if you come to me, your entry to my home and your introduction and where you begin matters a

lot...if you start from the women I may not be comfortable because I don't know you and you are seated in my wife's house. So, when this relationship has to be good for the rest of all the days then the entry also matters and when you get to that home you don't want that day to be the first day you are getting there and the last day you will wish to go back again, but you have to have developed a good relationship which means it entails adhering to the norms of that locality, trying to fit yourself into the cultural rules or norms of that community"

P4FGD002M

Fieldworkers also perceived informed consent as an opportunity to demonstrate respect to participants' rights, which promotes easy data collection through the explanations given to potential research participants about research. Doing this ultimately contributed to achieving reliable research results.

Although several participants believed informed consent was an important process to enable participants to make informed choices, other participants thought informed consent would sometimes hinder participants from taking part in health research. This was attributed to how informed consent would instill fear about some study risks or cause inconveniences, such as taking too much of participants' time, hence making participants decline participation to avoid such inconveniences. Sharing these experiences, a participant said:

"I'll take an example of a study we carried out three years ago, that was among these adolescents and a number of these young people were willing to take part in the study but then they wouldn't want to commit themselves, like they wouldn't want to sign documents, but they were really willing to take part, saying I can't sign but you can recruit me, just the signing. So I'd say in a way explaining to the participant in full what the study is about at times may create that fear to participant just because now they understand what the study is

about and this may cause them not to take part in this and at the same time if fieldworkers give partial information and maybe leave out some areas that they feel might influence the participant then, that is another thing [problem] again and it can... maybe the participant might take part in it but them without the knowledge of all the details”

Emphasizing this view, participants argued that the aspect of voluntary participation that is included in all informed consent forms hindered participation and was unnecessary. One participant clearly captured this view when he said:

“Every consent form has the words... your participation is voluntary... so they take that as an advantage for them to refuse without taking it seriously” P5FGD004M

5.7 Factors affecting Informed Consent process

Several factors were said to affect the process of informed consent both positively and negatively. For fieldworkers to feel comfortable and seek proper consent, they were said to be influenced by both contextual and structural factors.

Regarding contextual factors, seeking consent from a person or household that is welcoming and devoid of any tensions was said to encourage fieldworkers to relax and to follow a truly informed consent process as opposed to when they get rowdy, unwelcoming or violent participants. There were also factors that were believed to further affect how the environmental and contextual factors play out, including the ability of fieldworkers to observe cultural norms, use of common language and how well a fieldworker can manage his/her own emotions. The state or condition of the study participant, including their state of ill-health, decision making capacity, level of patience to listen to the information (e.g. do they have existing misconceptions or are they open minded) was also said to negatively affect fieldworkers’ ability to consent properly, as captured by a participant in a FGD.

“I think the nature of the situation also matters..am looking at an expectant mother in the maternity and you want to consent her and she is yelling I mean she is rubbing herself at the back and you may end up saying just fill here, and get some medicines for your conditions and... because.... I mean the mind of that person is not settled, she is not sober, she is thinking about how the baby will come out and then you are there having a three-page ICF... if you are not very careful you may end up just giving bits and pieces of the information because you are feeling for that mum” P4FGD002M

Structurally, factors that were said to promote fieldworkers’ ability to seek true/valid consent included existing supervision practices, recruitments targets and being well informed about the research they were involved in. Lack of feedback from previous studies was also associated with having a disgruntled community that made Informed Consent difficult.

“The other circumstance that brings hardship in seeking informed consent from participants is where you get pressure from the bosses. The boss is expecting ten participants per day and out in the field, it’s the opposite, so you go in the first homestead you find a refusal, you go to another one...so if you get to the third one definitely you won’t pass the right information or you may pass it but in a hurry, because you want to finish [recruiting] this one so that you can go and look for another one... your boss is waiting for ten participants. So, the pressure from the bosses can make it difficult sometimes to consent” P6FGD002M

The effect of recruitment targets on informed consent was passionately discussed by field managers as well as the fieldworkers, all of whom consistently expressed concern that high and unrealistic targets hindered fieldworkers from adhering to appropriate informed consent seeking procedures.

“When the focus is more towards the number of participants recruited, as opposed to whether these people have been enrolled into the study in the correct way, that would mean fieldworkers do not spend so much time to know whether the participant has understood or not..they end up getting that permission bit very fast...So the fieldworker will not appreciate the importance of this whole process if it has just been reduced to signing the consent...field workers themselves will not appreciate the risks involved in the study, the benefits bla bla bla, then I think it’s also easy like I said to skip one either the understanding bit or the information giving bit” IDI008F

According to fieldworkers, high targets did not only affect their ability to consent participants properly but also forced them to use dubious means to collect information in order to look competent before their managers. This was also compounded by long and technical informed consent forms, which made communicating about such studies complex. Expressing this view, one FGD participant said:

“If I can put it this way, ok I am pushed or I am pressured to bring 20 participants on that day, again the consent or the informed consent form that I have it’s a huge document that requires more time to explain step by step..., so definitely I won’t give myself that time to go a step after a step through that consent because although I know about the need to go through the consent form step by step, if my boss doesn’t understand, he or she is expecting 20 participants and if I go there with 2 it turns to be a problem on my side, so sometimes I’ll be pushed to use many techniques so that I can get participants to please the boss for the sake of my job that’s why am saying the pressure from the boss side, it brings a difficult time when it comes to obtaining informed consent from participants” P6FGD002M

Using shortcuts when seeking informed consent was also associated with fieldworkers being too familiar with study participants. As such fieldworkers were said to avoid giving all necessary information during informed consent to avoid looking too formal or monotonous.

Lack of fieldworkers training was also described as an important factor that affected their ability to carry out truly informed consent process. Well trained fieldworkers were said to exhibit confidence and clearly communicate study information while fieldworkers who were not well trained lacked confidence and misinformed participants during the informed consent process due to their limited knowledge. Emphasizing the point, one IDI participant said:

“training is key...if they [fieldworkers] have not been trained well, then they can’t perform...training is key. They have to be fully equipped with training..the knowledge of what it is that they will be doing, and then the rest of the things will move smoothly” IDI004F.

Training was associated with building knowledge about the studies fieldworkers’ work for as well as building self-confidence and empowerment of the fieldworkers. Participants empathized the need to train fieldworkers on the reasons behind doing the study and the importance of doing certain procedures (protocol) as opposed to training them about informed consent only. This was described as an important approach towards nurturing more informed and empowered fieldworkers

Community engagement was also described as an aspect that created a conducive environment for informed consent. Participants described how community engagement is useful in addressing existing misconceptions and concerns within the community. A community that goes through sensitization as part of community engagement was said to be welcoming and responsive to studies during the informed consent process.

The type of consent was also said to influence fieldworkers' ability to seek informed consent. For example, seeking verbal consent was said to promote a truly informed consent compared to seeking a signed consent. As described by one participant in the IDI, the two types of informed consent posed a challenge to fieldworkers because they either create anxiety (signed consent) or encourage participation (verbal consent) based on the sensitivity attached to signing

"Of course, you have to abide by the study requirement, but then when you talk about them or if you get to know what their views, you realize they [fieldworkers] are comfortable just doing verbal Informed Consent" IDI002M

Reflecting on fieldworkers' preference for verbal consent, a manager said:

Maybe let me use an example of where we wanted to carry out or were carrying out this biometric registration, getting the data of the community members into a biometric kind of system or a computerized system and just on finding out, carrying out a pilot just to get to know what the views of the people were, we found that most of the community members felt like, if they give this information out, they leave us with this physical information of their data or bio data literally, they think this might be used maybe against them at some point maybe by the police or the authorities. So, they feel they'd rather give you a verbal consent, just you can use my permission but then let me not leave any of my physical identity with you so that you can... so it's more or less tied to what the community members feel" (IDI002M)

Certain study procedures were also associated with difficulties in seeking informed consent. For example, study procedures that the fieldworkers perceived to be invasive or inappropriate made them feel nervous and affected their ability to clearly explain them to participants. Procedures such as withdrawing of blood, lumbar puncture, and other invasive

procedures were said to be difficult to explain to research participants during consent.

Emphasizing the effects of study procedures on informed consent, a fieldworker said

“another challenge is when you ask for blood samples, when you prick them they feel pain a bit, now at times pricking or collection of nasal swabs make them say [No]...they don’t feel comfortable”. FGD001P2F

The same fieldworker added that.

“[the community thinks] ...collecting blood samples through heel prick might make a child not walk for several days or if the study involves taking a stool sample, the adult can say, now I don’t feel like defecating.... they feel it’s disturbance” FGD001P2F.

5.8 Participants complaints about Informed Consent Process

Most managers reported lack of awareness of issues that study participants complained about. One of the field managers interviewed however reported being aware of a report from participants regarding rushing through the informed consent process, which resulted to the participant not understanding what the study was about. Another complaint was related to giving insufficient/incomplete information which resulted in misinformation. The limited understanding about the issues participants complained about could have been a result of the managers’ limited interaction with study participants.

Supporting this view, one of the managers interviewed said

“One of them is the issue of rushing.... some of the participants feel that some of the fieldworkers are rushing them through that process such that they really don’t get to understand very well what they are doing, what the study is about. The other one is

insufficient information, the field workers giving partial information or incomplete information and also... yeah I think that its” IDI002M

Some managers not only had limited knowledge of participants’ complaints but also viewed them from a different perspective as was reported by one manager who said...

“I think I may have encountered one or so, but I wouldn’t call them complaints. If a father or mother comes later and says I wasn’t told it would be like this and that, I wouldn’t call that a complain per se but it’s more like a report or rather a feedback.”

There was, however, a feeling among managers that it might be difficult for participants to raise complaints to the research team, as most research participants were not educated, hence lacked adequate agency to speak their mind, as one manager said.

“if you are using complain as a check on fieldworker’s ability or how well they work, I think it’s difficult getting it from the participant’s perspective because in our world we all know participant are already disadvantaged because of [lack of] education and everything so you require a very elite population to get complaints and good feedback about your staff giving consent” IDI005M

On the other hand, fieldworkers described several issues that participants complained about during the informed consent process. These were classified according to study procedures and inconveniences, study benefits and issues related to communication. With regards to study procedures, participants were said to complain most when a study involves invasive procedures. Withdrawal of blood was the most common procedure complained about. In addition, the time involved was also reported to inconvenience research participants, causing

them to complain after being recruited into the research. Time inconvenience was particularly reported to be a key complaint where a study involves healthy volunteers.

Lack of tangible benefits was also said to influence participants to complain about research participation. Participants were said to be more patient and accommodative when a study offered direct tangible benefits such as free treatment, meals or free transport to research appointments. However, participants complained when they deemed the compensation given to them as low and if the study lacked direct tangible benefits for those taking part.

Issues related to communication, use of technical language and jargon and staff presentation, such as dress code were also complained about by participants.

5.9 Fieldworkers' levels of interaction with research participants

A total of four FGDs were held with fieldworkers with two different levels of patients' interaction. Of the four FGDs, two (one with male and one with female fieldworkers) had more intensive interactions with research participants while the other two (one with male and one with female fieldworkers) had limited interactions with participants. Fieldworkers that were categorized under the group that had intensive interaction with participants mainly worked in studies involving field epidemiology and demographic and clinical surveillance studies, where they were expected to consent research participants daily. On the other hand, fieldworkers that were categorized as having limited interactions worked in studies that did not have regular recruitment of participants, although once in a while, they would be involved in following up research participants and discussing with them about specific studies before seeking consent but on an *ad hoc* basis.

During the analysis, information collected from the two categories of fieldworkers was compared to identify any similarities and differences in opinion, including the way they

conceptualized, articulated, perceived and understood different concepts related to informed consent. No difference was noted between the two categories of fieldworkers.

5.10 Ethical dilemmas experienced by fieldworkers

Various complex experiences were shared which were often too complicated for the fieldworkers to address. Fieldworkers interviewed in FGDs narrated situations where they had difficulties in balancing cultural norms with the ethical requirement, challenges related to participants' autonomy, maintaining relationships between study participants and experiences of fieldworkers struggling to balance study requirements and participants' expectation.

Regarding difficulties in balancing cultural norms with ethical requirements, participants reported several experiences when ethical requirements conflicted with the cultural norms of the community. For example, fieldworkers were often required to consent women. In these instances, ethics demand that the main (target) participant makes the decision on whether or not to participate in the research. However, the setting where the fieldworkers work recognizes the husband as the final decision maker. In this case, although fieldworkers consented the women, the husband would be expected to give the final say, something that was contrary to what the ethical guidelines stated. Additionally, certain families discourage long discussion to be held between people of the opposite sex. This posed a complex challenge when male fieldworkers had to interview female participants and the vice versa. In addition, some questions are usually considered as taboo to talk about in the community. Where studies use culturally "condemned" word, including but not limited to anal sex, men who have sex with men and other sensitive parts of the human body, fieldworkers would find it extremely hard to discuss such words.

“Most of the time when you get to a homestead you’ll get the mother, you’ll talk to the mother but, traditionally the decision maker is the father, now the mother will tell you fine I have understood but I have to wait until my husband comes for me to know if I’ll join the study or not” (P4FGD001F)

The above example also cuts across issues related to autonomy. Other dilemmas related to autonomy concern participants who were said to be readily available to participate in any research. These participants were said to care less about understanding what the research is about. Instead, after explaining the study, they would insist that they were ready to participate in the research, without making any attempt to understand the study. Fieldworkers interviewed could not clearly explain the reasons behind the participants’ actions. However, based on the fieldworkers’ description, it was clear that their motivation was far from altruistic. Sharing this experience, one participant said...

“Most of the time even the parent, it’s not that he or she has agreed, you explain and you can see this parent hasn’t understood but needs the service, at times it [the service] makes the community members not to understand....as a fieldworker, I try to explain to them, so you talk to the mother but she doesn’t get anything...I mean she tells you I’m fine, I’m very ok. Now you don’t know she is ok in what way, you try to ask her questions, have you understood? I’ve understood I’m ok, I just want my baby to get treatment” P3FGD003F

Supporting this view, a field manager narrated how participants sometimes agree to participate in research because of the benefits offered in studies. Emphasizing the appoint, the manager said:

“One thing I have seen in the community is, studies are viewed as a source of income as opposed to a way of bettering the health research on its own. So, some of the things that the

participant would equate this to, is if you recruit me then how much am I going to get out of it? Or this study gave these people this much for lunch, how much are you going to give us? So, I think they [fieldworkers] get those kinds of questions when they are recruiting or even during the Informed Consent process so I think it would be sort of an ethical dilemma because you wouldn't exactly know whether this participant understood..." IDI008F

Participants interviewed in FGDs discussed some cases of protocol violation in relation to ethical dilemmas. For example, in their effort to balance study requirements and participants' expectation, fieldworkers may deliberately "mislead" participants, in order to perform certain study procedure. Such an experience was shared by a participant who said:

"there are days you tell the parent we will take this much sample, but you know according to the samples, it's not enough to fill what you want to distribute, so you can tell the mother 6 or 7 mls, and you take 8 or 9 because once you start distributing they can't fit, so you'll have to jump that bit [about the amount of blood] because if you tell the mother we usually take 5 mls of blood, in those 5mls we are asking you we add 1ml and that 1ml is what we will use in research, but 5ml is for her treatment, that 1ml is not enough to put in orange top, another 0.5 EDTL...I don't know red top 1ml it's not enough so you'll be forced to draw extra because if you tell the mother we will take 8 or 9 mills..." [She'll refuse] P2FGD003F

Other ethical dilemmas arose as a result of the long-term relationship between fieldworkers' and the potential research participants. Descriptions given by the fieldworkers showed that when community members interact with fieldworkers for a long period, they developed a high level of trust hence demand less accountability of them. Where this happens, participants would insist on signing the informed consent form before full information is

given. Even when fieldworkers insist on giving the information, such participants would not pay attention and just insist on being involved in the study.

The relationship between research participants and fieldworkers was also reported to create dilemmas when a fieldworker gets entangled in domestic/family tensions by virtue of being a neighbor, relative or just someone closely known by the family and doing their work.

“There are challenges like, you are from there and you are working there...there are some challenges, for example, there might be domestic problems, not work related but because you come from that homestead now, I mean it’s not about the study but there are misunderstandings in the homestead, and you don’t know from where but they draw you into these issues” P3FGD003F

Most of the ethical dilemmas shared by the fieldworkers were similar with those shared by the field managers. There were, however, a few unique dilemmas the managers shared, which the fieldworkers never raised. For example, managers described situations when fieldworkers have to invite participants to consent to study procedures which they [FWs] cannot agree/allow their children to participate in; for example, recruiting study participants to do lumbar puncture, while knowing well they would not allow themselves or their child to go through such a procedure if someone were to seek their consent. In addition, fieldworkers were said to sometimes make follow up to participants who are in dire situations. Such participants may not be able to afford even a meal, yet the fieldworkers would not be allowed to intervene even when they were able to assist. Related to this dilemma are situations where study participants ended up in an urgent need for help that falls outside the mandate of the study.

“Fieldworkers sometimes make a visit to the community and find very dire situations at home and they are in dilemma on what to do, do they help, do they not, at whose capacity.....”

IDI005M

Generally, both fieldworkers and field managers interviewed shared a range of ethical dilemmas which fieldworkers experience in their day to day activities. During the discussion, participants were asked to describe any available approaches and mechanism which are at their disposal to help them address the challenges they experience. In addition, participants were asked to identify ways through which fieldworkers could be supported to address the myriad of challenges that affect their ability to carry out appropriate Informed Consent processes. The last sections of this chapter present the participants’ recommendations on the various approaches for addressing the range of challenges raised.

5.11 Support mechanisms and recommendations

Recommendations were discussed with regards to mechanisms to support fieldworkers to handle ethical dilemmas as well as general challenges they face in their day to day activities. In addition, recommendations on changes that should be included in the informed consent process and forms, especially those targeting youth participants were also discussed.

5.11.1 Lack of a systematic approach

It was reported that fieldworkers did not have any mechanism in place to support them to address the ethical dilemmas they face. Acknowledging the lack of a standard approach to address the dilemmas, one manager described how managers were usually happy when fieldworkers share experiences of how they handled some complex issue on their own, yet they [managers] could neither attempt to handle them for fear of breaching existing ethical guidelines and policies. Explaining this approach, the manager said:

“I don’t think there is any formal structure to help them, most of them are dealt with on a need by need basis and for me as a manager sometimes am happy when they report I think I did this and that am like ...eeeh! that’s a good idea, whooo!, thank you for solving it on my behalf but I don’t think there is any formal mechanism to assist fieldworkers to deal with those ethical challenges. IDI005M

The above sentiments were shared by most participants interviewed, both in the IDIs as well as in the FGDs. Acknowledging the lack of a formal mechanism to address ethical dilemmas, a manager explained the casual manner in which managers handle ethical dilemma:

“The worst thing is even acknowledging or logging the existence of those challenges [is a problem], it ends up being just that casual talk, ooh! we did this, by tomorrow its forgotten but we don’t have even ways we log or acknowledge that our fieldworkers have encountered this number of ethical challenges, the situation, this is how they dealt with, this is how we propose... it’s not something that is handled actually” IDI005M

5.11.2 Lack of structural support

The Community Liaison Group (CLG) was reported as an important mechanism for addressing challenges. As such, participants expressed the need to ensure CLG promptly addressed all issues, especially those related to misconceptions and misunderstanding about research and the institutions’ activities. To complement this approach, participants also shared how failure to send study feedback to the community was a source of poor reception from the community. As such, participants felt there was a need to encourage studies to communicate back study finding at the end of the study, to complement the CLG activities. To them, this would be an important step towards building trust and avoid tension that resulted from a

failure by researchers to disseminate study results to the community as usually promised during study initiation.

In addition to seeking support from CLG, participants expressed the need to ensure research participants' privacy was respected. To this end, they described the need to create a good and conducive environment for seeking informed consent from participants. The current situation was described as too open and unfriendly to research participants. Reportedly, this affected the quality of consent. Associated with this issue was the need to ensure the number of studies a fieldworker was allowed to work and seek consent for was controlled, to avoid confusion, as captured by one participant who said:

"I wanted to say this, each study comes with its funding for vehicles and everything including staff. For us who are in the field at times there are studies which come up, so each study that comes, because we are already there, you'll find that it will be piled on you, you'll be doing around 3 or 4 studies at a go, so in such a situation, when seeking informed consent at times you get mixed up, thinking you are explaining about this study but instead you are explaining about a different one." P6FGD003F

5.11.3 Capacity Building

Training was also described as one of the most important support mechanisms, necessary to build the capacity of fieldworkers to address the challenges they face. Expanding on this view, participants suggested the need for fieldworkers to be supported to undertake certified training to make them professionals. Fieldworkers training on study protocols as well as Informed Consent was emphasized as an important approach toward building fieldworkers' confidence and ability to address the complex challenges they face. Participants expressed a

need for PIs to allocate ample time for this kind of training to ensure the fieldworkers were taken through the study protocol and ICF training thoroughly.

“Any consent let it be given [to the fieldworkers] in good time; somebody should not be starting his/her study, and the consent which could take 5 or 6 or 1 week to be discussed in-depth, is given and fieldworkers have to go through it at once...this way, you find that you are only given the main points and then you use your knowledge for you to go and work in the field, or in the ward. Let PIs plan in good time for people to be able to understand these consents well and have a good time for [fieldworkers] to deliver them in the best way to the people concerned” P1FGD003F

5.11.4 Fieldworkers’ Clinics

Both manager and fieldworkers interviewed expressed the need to encourage discussions among fieldworkers to share experiences of what they are going through as well as engage their colleagues in coming up with a solution to the problems, especially the ethical challenges they face. Although discussions are reportedly already being conducted, they are reportedly being done during team meetings, which leaves limited time to discuss all issues exhaustively. Thus, various managers recommended the need to carry out more open fora to discuss field experiences, as a way of helping fieldworkers cope with the challenges they experience. Addressing this view, a manager said:

“it can be thought of a study, just tell guys we are coming to you guys in February we have a fieldworkers clinic we are sending one of us or somebody to help moderate the discussions, let us hear from the fieldworkers how they are getting on with their work and explain what they have been and how it can be reflected on the side, if any changes can be addressed. If these [discussions] are structured and made formal, then that would be a good away and it would

provide a moment where fieldworkers can now tell, their managers...tell us to do this and this...what we are finding and all that and they are minuted and the moderator can give some direction or can refer the matter to the existing system within the programme” IDI005M

Fieldworkers also proposed a similar but slightly different approach. According to them, it is important for fieldworker to come together in the form of an open day, once in a while, to share their experiences and get to learn from each other. This would create an opportunity to discuss the different challenges they face and identify solutions. These sentiments were captured in one of the FGD when a participant said:

“I think this year we came together for an open day... if we have such open days like twice per year here, we as fieldworkers first we would interact, talk about the different type of problems we are facing and I think that can help us in a major way” P1FGD003F

5.11.5 Motivation

Although motivation was not described as an important factor that affected Informed Consent, discussions with both the field managers and fieldworkers identified motivation as an important form of support for fieldworkers. Many approaches to motivate fieldworkers were discussed, including improving contractual terms of employment, having a clear career progression plan and being facilitated with the right equipment to allow smooth fieldwork. Supporting this view, one field manager said,

“support comes in various forms, I think I’ve talked about equipment, in terms of access to a computer for them [fieldworkers] to read emails, getting boots for them to go to the field....If you’ve never gone to the field to do Informed Consent, you’ll not understand what it means for this person who you have set 7 targets to come back with 2..you will not understand that. I know there are some PIs and there are some supervisors who will never go to the field and

they expect everything to be done. They only go to the field at the setup stage and then they never go during the data collection, but that is where all these challenges rise....The other one is exposing them to opportunities both internally and externally, I think I have seen people who have worked here for 15 years as fieldworkers, the only thing that has gone up is their salary but they have never gone above the salary grade. And I ask myself why is that? I think we should support them also intellectually” IDI003M

Motivation was also described in relation to making fieldworkers feel respected, valued and important. Both field managers and the fieldworkers expressed concern that, despite being an important cadre of staff, fieldworkers were not adequately acknowledged for the kind of work they do. To support this view, one participant emphasized the need to make fieldworkers feel part and parcel of the research team by respecting them through for example involving them in the planning of research and involving them in decision making. This includes but is not limited to inviting them to seminars when PIs are disseminating study findings, being acknowledged in publication and being given opportunities for career progression and personal growth.

5.11.6 Youth-friendly informed consent forms

There was divided opinion on whether or not the current Informed Consent Forms (ICFs) were youth friendly. Some participants argued that the forms were adequate and took into account all that youth would expect.

“I think yes, and I think in every study they state the age limit in every study, and so the information is tailored towards meeting the expectation of these age groups. So, every study, for example, the study that is dealing with youth like this [name withheld] study where we

were dealing with the youthful population, the information was actually specifically designed to be able to meet the needs of these age groups” IDI007F

However, other participants believed that current ICFs lacked clarity on what ought to be done for different scenarios related to the involvement of youth in studies. For example, current Informed Consent procedures were still silent on what should be done should a youth become a parent in the course of the study, who should make the decision to allow the baby to participate in research? Besides, the youth was described as a dynamic population that is mostly attracted to audio-visual and social media materials. It was reported that the current ICF were rarely designed in a manner likely to attract the attention of the youth. A participant recommended the need to carry out more research on informed consent process for youth, in order to gain a better understanding and develop recommendations. This was well captured by a participant who said:

“I will be very honest, I think the youth in this particular age this is the digital era, they are more visual than either audio or other and by this, I mean I think the information would be passed better if the consent forms were more attractive to their eyes. So, using a pictorial sort of presentation of that informed consent form, I suspect it’s happening in other areas of the world, I have not seen it here, it’s usually like a book, it is written. if you have young people in your study they don’t want to read a lot of things, I think they do a lot of that in schools, so if we could have questionnaires that resonate or the youth can relate to, so when you are telling about blood draws and there is a picture of injection aaaha!, then this flows... ooh this is what they use, so when they come to the actual procedure they are like yeah this is a photo of what they use, I remember this, ok so they are able to really understand that and take that in, and it’s just with the generational shift...” IDI008F

5.12 Chapter Summary

In this chapter, we have seen that fieldworkers are perceived as an important cadre of research in health research. Both field managers and fieldworkers interviewed described fieldworkers as central in conducting community-based health research. At the same time, fieldworkers described important limitations related to the perceived recognition of their roles, workload and working conditions. Both fieldworkers and managers described the primary role of fieldworkers as educating research participants and collecting samples. In addition, fieldworkers were described as an important channel for linking the community with the research institution.

There was generally a good level of understanding about health research amongst all participants interviewed. Both field managers and field workers described health research as a process of information seeking and attributed it to wanting to understand more about health and finding better ways of solving health problems. Social development, on the other hand, was associated with the general socio-economic development, which was said to thrive in a healthy population. *“a healthy community is a wealthy community”* was often used to describe the relationship between health research and social development. Although fieldworkers were reportedly not directly involved in promoting health, they perceived their role to educate the community about health research and other health-related issues as key in ensuring the community made healthy choices and had better health.

Both field managers and fieldworkers described Informed Consent as a continuous process involving sharing information about a study in order to get the potential participant to take part in a study, but at the same time transcends beyond the signing of the consent form. While some managers described the process from the perspective of empowering research

participants to decide whether or not to participate in the research, there were other managers and fieldworkers who believed this process was meant to protect researchers, in the event of a research-related harm. Additionally, fieldworkers perceived Informed Consent as a process of relationship and trust building, entailing adherence to cultural norms and manifestation of respect to research participants, their families and the community at large. To them, trust and respect created a good and friendly environment which facilitated smooth Informed Consent.

The factors that were said to affect Informed Consent by field managers and fieldworker were similar. Participant's health and psychological condition, the context or environment where the consent is done, the fieldworkers' knowledge and emotional state, as well as the perceived support and supervision approaches, were all said to influence the effectiveness of the consent process. To strengthen the process of Informed Consent, both fieldworkers and field managers identified the need to enhance the training of fieldworkers in ethics and Informed Consent and ensure support and supervision practices mirror the ground realities experienced by fieldworkers. Other recommendations included adopting consent forms to make them more youth-friendly and educating communities through community engagement approaches.

CHAPTER 6-DISCUSSION

6.1 Introductions

This chapter summarizes and discusses the study finding according to existing theories and frameworks related to the process of Informed Consent.

6.2 Attitude and perceptions about health research

This study demonstrated a good level of understanding from the participants about the meaning and value of health research. All the participants interviewed described health research within the context of systematically looking for better ways, either to treat or prevent specific human health challenges. This level of understanding is important in ensuring fieldworkers address any misconception that might arise when seeking informed consent from research participants, especially those related to therapeutic misconception, which is prevalent in most developing countries (Molyneux et al., 2005). The value of health research was associated with community well-being, which was ultimately associated with social development. Most participants had a good understanding of the relationship between health research and social development and often used the statement *“a healthy society is a wealthy community”* to express this link. Only a few participants could link the role of fieldworkers with social development. This has implications for the value of the roles undertaken by fieldworkers in health research and can influence both fieldworkers’ and their managers’ attitude toward fieldworkers. There is, therefore, a need to strengthen fieldworkers’ training to ensure they do not only understand health research as key in social development but they are also able to appreciate that the roles they play contribute to enhancing health and social development in the long run. Despite the inability to link social development to the roles of fieldworkers, the description given about health research and its association with social development was similar to the one described under the Word Health

Organizations conceptual framework on health research and social development. The above describes access to and utilization of health care as vital to good and equitable health and emphasizes the fact that without good healthcare, many of the opportunities for fundamental health improvement are lost and people are pushed into poverty making it become a cyclic process (World Health Organization, 2017).

Health research was associated with an array of benefits, such as direct health improvement, prevention of diseases as well as indirect long-term benefits associated with new research discoveries, low disease burden, and reduced mortality rate. Reported risks associated with research participation were minimal, mainly related to time investment, creating tensions within families and perceived potential harm resulting from exposure to trial products.

These findings demonstrate a positive understanding of health research by the fieldworkers and their managers, which has implication on the fieldworkers' ability to communicate about health research with potential research participants and the community at large. This knowledge is an important resource for addressing issues and concerns within the community and complimenting existing community engagement practices within research institutions (Molyneux. et al., 2013).

6.3 Conceptualization of the informed consent process

All participants interviewed described Informed Consent as a continuous process which transcends beyond signing the consent form. Although most participants could accurately describe the three key elements of Informed Consent, including information disclosure, competence/understanding and voluntary participation/decision making (Appelbaum, Lidz, & Klitzman, 2009), there were differences in the way fieldworkers and field managers perceived the value of Informed Consent. For example, some managers described Informed Consent

from the construct of respect for autonomy and individual participant empowerment, especially with regards to making free choice and self-determination (Nelson & Merz, 2002). Both the fieldworkers and managers put a lot of emphasis on the enlightenment approach where they described fieldworkers' role as to educate as oppose to merely recruit participants (Appelbaum et al., 2009). Interestingly, some fieldworkers and managers perceived Informed Consent as a way of protecting the interest of researchers and research sponsors at the expense of undermining the rights of research participants. Participants who held this view believed decision making, and more so, the signing of the consent form was the most important element in the consent process hence fieldworkers could easily avoid the other element (information disclosure and understanding), so long as they were guaranteed of the participants signing the consent. Unfortunately, studies have shown that signing an informed consent form does not guarantee free choice to participate (Macklin, 1999). This could explain why participants related signing of the consent form with internal checks for obtaining consent as oppose to demonstrating informed and free choice to participate *per se*. This view also supports existing literature which identifies complexities involved in ascertaining participants capacity to understand as a key reason why understanding could easily be ignored during Informed Consent (Marshall, 2006). This study has shown that there is a gap with regards to what fieldworkers believed were the most important element of the Informed Consent process. The fact that they perceived signing of the consent form as the most important element means, fieldworkers may not put much effort into ensuring potential participants understand the studies they invite them to take part in, before signing the consent forms. This has implications for the standard/quality of Informed Consent fieldworkers uphold when seeking consent from potential research participants (Chantler *et al.*, 2013).

One of the most important findings of this study is that fieldworkers' application of the standards of Informed Consent is affected by multiple factors, ranging from pragmatic, social-cultural, contextual, situational as well as structural constraints. These constraints have various effects on the fieldworker practice, including but not limited to being disillusioned about the value of their contribution to the health research enterprise. Importantly, structural and pragmatic constraints such as having high recruitment targets, pressure from supervisors, inadequate supervision and support and lack of motivation has been shown to create a conflict of interest exhibited by having a strong desire to get high numbers at the expense of adhering to Informed Consent standards. This can result in fieldworkers persuading participants, cutting corners and promoting what Appelbaum *et al.* (2009) referred to as impaired voluntariness (Appelbaum *et al.*, 2009). Fieldworkers described instances where they deliberately avoided talking about study risks and procedures and only concentrate on the study benefits. To them, this offered participants an incentive for participation and made the environment easier for them to handle. This is however similar to what Marshall (2006) described as explicit forms of coercion (Marshall, 2006). While under normal circumstances, fieldworkers are expected to respect participants and facilitate comprehension and informed decision making, the circumstances described by fieldworkers has the potential to affect fieldworkers' agency and conduct, for example by being more concerned about reaching recruitment targets as opposed to following proper Informed Consent requirements, feeling demotivated as a result of perceived lack of recognition and collecting low quality data due to lack of proper supervision. Coupled with the negative attitude associated with their "professional personhood", there is indeed a need for further research to understand what interventions could be done, not just to change the perceptions and attitude of fieldworkers but to come up with more strategic and standardized

approaches to address the challenges identified, such as work targets, career progression, pressure from supervisor, poor supervision and lack of motivation. Similar approaches have been suggested by Kombe *et al* (2015) who called for an increase in institutional recognition of fieldworker's roles and the need for systematic and comprehensive capacity building approaches (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015).

Participants also reported having to deal with long and technical informed consent forms. Rebers and Aaronson (2016) attributed the use of long and technical ICFs to the widening gap and power distance between medical research and the community. The authors argued that too much information is as dangerous as too little information (Rebers, Aaronson, van Leeuwen, & Schmidt, 2016). Unfortunately, there are no guidelines or agreement to date, to guide how much information to give to research participants to facilitate comprehension. However, creating time to hear feedback from the fieldworkers, who use such ICFs to consent participants can go a long way towards identifying appropriate mechanisms to address this challenge. In this study, we call upon researchers and principal investigators to regularly meet with their fieldworkers and encourage them to share their experiences about Informed Consent and executing the consent forms. Involving fieldworkers in the planning of research project can also provide important insights on where the informed consent is difficult to comprehend and what can be done to make it easy to understand (Chantler *et al.*, 2013).

Societal ties and relationships were also reported to play a key role in compromising Informed Consent practices. Fieldworkers who live in the community often get intertwined into domestic wrangles or face scenarios where they have to deal with over-trusting

participants, who find it unnecessary to be informed about a study by someone they know too well and trust, prior to participation. This could imply that study participants are not willing to hold accountable, fieldworkers who they consider to be in the position of authority or too close to them. One reason for avoiding holding fieldworkers accountable is to show respect and nurture existing relationships. This has a potential to create what Marshall (2006) referred to as situational pressure that makes participants feel obliged to participate in research. This challenge has also been described by other authors, but no solution has ever been identified (Marshall, 2006).

6.4 Attitude and perceptions about fieldworkers' roles

All the field managers interviewed had high regard for the role fieldworkers play in supporting health research. There were, however, mixed feelings on how fieldworkers viewed themselves and the roles they play. While some fieldworkers perceived their roles as the key determinants of the data and overall institutional research output, some painted a picture of a cadre that was struggling to cope with acute forms of structural violence and inequalities. High recruitment targets and workload, inadequate supervision, lack of institutional support were all associated with the pictures of a donkey and a tired overworked man. Despite painting a gloomy picture when describing the support extended to fieldworkers, all participants interviewed described fieldworkers as a loyal and resilient cadre of staff that passionately and creatively maneuvered through the difficult situations to deliver quality and reliable data. Although some of the conditions described above were said to negatively affect their informed consent process practices, they were not associated with any of their data collection practices. The above situations and tensions support other documented data on fieldworkers' roles and experiences, and the challenges they experience

in undertaking their roles (Kingori, 2013; P. Kingori & Gerrets, 2016; Kombe & Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research, 2015). These findings call for a need to strengthen existing supervision approaches and establish more responsive performance management practices that can enable fieldworkers to develop more a positive attitude about themselves.

6.5 Fieldworkers' level of interactions with research participants

This study set out to interview fieldworkers with limited interaction with research participants and those with intensive interaction with research participants. Two FGDs were held with fieldworkers who had limited interactions with participants (one FGD with male and one FGD with female fieldworkers) and two FGDs with fieldworkers who had intensive interaction with research participants (one FGD with male and one FGD with female fieldworkers). During analysis, we looked for any differences in the way the two groups conceptualized informed consent, including how they articulated, perceived and understood the different concepts under discussion. No clear difference was noted between the two categories of fieldworkers. The number of FGDs compared was, however, few (two FGDs per category), which could have influenced the comparisons made. In addition, all fieldworkers employed at KWTRP usually go through a five day of training that cover important Informed Consent, health research and research ethics concepts, similar to those discussed during the FGDs. This could have affected how the two comparison groups perceived and understood the issues under discussion, and demonstrate the influence of training on how fieldworkers conceptualize the informed consent process. Exploring the influence of the training given to fieldworkers at KWTRP, on their understanding and conceptualization of informed consent was beyond the remit of this study.

6.6 Participants' Recommendations

The recommendations given by fieldworkers and managers were summarized in two broad areas, including recommendations on the Informed Consent process and support to fieldworkers.

6.6.1 Recommendations on the Informed Consent process

Fieldworkers interviewed expressed concerns that the Informed Consent process was sometimes too lengthy and technical, which took up too much time or resulted in some participants just declining participation in order to save their time. Additionally, some participants argued that some of the information contained in informed consent forms created unnecessary fear and deterred participants from agreeing to take part in research. These concerns have also been raised by Macklin (1999), who argued that participants have an irrational fear of the nature of research and could easily refuse if some detailed information is disclosed. Instilling fear has implications on the conduct and delivery of important research output. Supporting this view, Macklin (1999) appreciated the apparent lack of agreement on how much information is enough to facilitate comprehension and alluded to the fact that too much and too little information can both interfere with the participant's ability to grasp what is relevant (Macklin, 1999)

Against this backdrop, there is a need to ensure adequate support is given to fieldworkers to help them understand and explain study information to potential participants. Developing Informed Consent templates for various research studies, with simple non-technical language can help researchers to use common and easy to understand language and avoid the use of scientific jargon. Similar approaches are already being used in Kenya (Boga et al., 2011) but it is not yet clear how effective the use of the template is in promoting comprehension and understanding to research participants.

6.6.2 Fieldworkers support

Both fieldworkers and field managers interviewed acknowledged the absence of standard approaches for assisting fieldworkers to handle the challenges they face. According to one of the managers, who talked passionately about the need to put in place some systems to support fieldworkers, field managers were aware of the challenges faced by fieldworkers and some of the informal approaches they used to handle them. However, field managers and by extension PIs preferred to let the fieldworkers handle them “in their own way”. Acknowledging the complexity of the issues, several managers underscored the need to establish a regular forum with fieldworker to allow them to share their experiences and come up with the best ways to handle the challenges they face. One manager called this forum “fieldworkers clinics”. A similar approach was proposed by the fieldworkers interviewed who proposed the need to have annual fieldworkers’ open days to create space for fieldworkers to dialogue and learn from each other. A similar approach was proposed by Kombe *et al* (2015) and Kamuya (2013), who identified the need to create space for deliberative discussions amongst fieldworkers and promotion of interactions between fieldworkers and their PI and managers. Giving fieldworkers an opportunity to interact with their peers and PIs, share their experiences, including their achievement and challenges, can help to demystify some of the complex challenges fieldworkers face. In addition, sharing experiences and discussing them with colleagues and senior members of their team will build their (FWs) confidence and skills-set to deal with the complex challenging situations in the field.

Training and capacity building was also described as an important approach to build fieldworkers’ skills. Training on the informed consent forms, the value, and principles of the informed consent process, as well as the protocol, was said to be an important approach towards empowering and building fieldworkers’ confidence in handling study related issues.

Importantly, both fieldworkers and managers felt there was a need for fieldworkers to understand the reasons behind the studies and the procedures involved. Underlying this approach was the need to develop standardized training that would promote the professionalization of health research fieldwork. Training fieldworkers can go a long way in building their skills in data collection, quality data control as well as the importance of adhering to ethical standards. These findings support data in the available literature on the need to develop a harmonized curriculum for training fieldworkers in Africa (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015).

6.7 Study Limitation

All interviews were conducted by the PI, who is a fieldworkers' training coordinator at KWTRP. As such, it is possible that study participants' views were influenced by his position and exposed the data to social desirability bias. This is likely to have happened if, by their participation, participants expected to gain any kind of direct benefit or suffer from any kind of "harm". For example, fieldworkers might have believed their jobs would be at risk if they report about specific behaviors or attitudes, which would have led to them skewing the discussions in favor of protecting their jobs. To counter this social desirability effect, time was dedicated to explaining to all participants, the overall goal of the study and its potential benefit to the research enterprise. Through this process, participants' concerns were addressed. All participants were assured of their confidentiality by giving them participant numbers and tags which were used to refer to all participants instead of their names. All participants participated in discussion voluntarily and were informed about how their data would be de-identified and presented in summary both in scientific presentations as well as any study reports, including this thesis (Roberts, Priest, & Traynor, 2006). It is also important

to note that since this was a Masters study with limited funding, the PI could not afford to employ a research assistant to support in data collection.

Given the role the researcher plays in the programme, his personal views could have influenced the discussions, analysis, and interpretation of the data. To address this challenge, the researcher engaged the supervisor during the development of the thematic framework as well as a colleague who supported the development of the framework. It is important to note that, although the experience and positionality of the PI may have posed as a limitation, it also provided an important advantage due to his vast experience, evolving from first working as a fieldworker to the current position of training coordinator. This experience also provided an important impetus to critically look at and interrogate issues both from an emic and etic point of view. These viewpoints were important, especially in triangulating data collected from different viewpoints, which would have been difficult to achieve if the discussions were moderated by a completely independent person, with no experience of fieldwork in a health research setting.

A second limitation is that this study was conducted with fieldworkers and field managers working at KWTRP, in Kilifi, Kenya. Findings from this research may not be generalizable to other settings or regions. However, findings from this study could have important implications in designing effective training for fieldworkers and strengthening the informed consent process and their ethical practices both at KWTRP and other places where fieldworkers are used to offering support in health research.

CHAPTER 7-CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

This study has shown that health research and informed consent is well understood by both fieldworkers and field managers. Fieldworkers are the central pillar in the informed consent process. However, the way fieldworkers undertake the process of informed consent is influenced by many factors. Although fieldworkers have shown loyalty and resilience, there is a potential for external factors that are beyond their direct control to undermine their agency. For example, this study has shown that fieldworkers' moral intelligence is undermined when a conflict between fieldworkers' structural and social imperatives arises. This results in a transgression of the fieldworkers' ethical practices. As documented by Kingori (2013), there is a need for a pragmatic approach to identifying the most effective strategies for supporting fieldworkers (Kingori, 2013). More research should be done to understand the structural and performance management factors that have the greatest impact in shaping the perceptions and practices of health research fieldworkers (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015).

In section 6.6, the recommendations proposed by participants were highlighted. Most importantly, the recommendations were attributable to problems associated with: -

1. The use of complex, technical and lengthy informed consent forms which made their execution difficult.

- Participants talked about complexities associated with the design and language used in informed consent forms which had implication on the fieldworkers' own

understanding of the information that they would be expected to communicate to potential research participants as well as the participants' ability to comprehend such information. Several authors have also raised concerns about the volume of information researchers ought to give to potential research participants and the length and language that should be used in informed consent forms. Unfortunately, the consensus is yet to be reached on how much information is enough to facilitate adequate and reasonable comprehension. Given that neither too little nor too much information is likely to result in the desired outcome on participants' understanding, more research should be done to come up with clear guidelines on how to develop effective informed consent forms and how best to deliver such information to research participants, without compromising on their understanding (Rebers, Aaronson, van Leeuwen, & Schmidt, 2016). In addition, during the study planning phase, researchers should put enough effort to ensure fieldworkers are involved in the development of study materials and especially participants' information, including the designing of informed consent forms. This would help them to internalize the study information and advice on the best way to executive informed consent forms based on their local language and cultural competencies. At the institutional level, developing templates for informed consent forms for various study types using simple non-technical language could help fieldworkers to avoid common pitfalls, and use internally reviewed common local and easy to understand words. This would enable fieldworkers to avoid the use of scientific jargon and enhance comprehension and understanding. Similar approaches are already being used in Kenya (Boga et al., 2011) but it is not yet

clear how effective the use of the template is in promoting comprehension and understanding to research participants.

II. *The absence of standard approaches for assisting fieldworkers handle the challenges they face.*

- There is a need to put in place some systems to support fieldworkers. Some field managers interviewed proposed the need to establish regular fora where fieldworkers would be allowed to share their experiences, including the challenges they face and best practices in handling such challenges. Similar approaches have been proposed by scholars who proposed the need to have annual fieldworkers' open days to create space for fieldworkers to dialogue and learn from each other and the need to create space for deliberative discussions amongst fieldworkers to promote interactions between fieldworkers and their PI/managers. Giving fieldworkers an opportunity to interact with their peers and PIs, share their experiences, including their achievement and challenges, can help to demystify some of the complex challenges fieldworkers face. In addition, sharing experiences and discussing them with colleagues and senior members of their teams would build their (FWs) confidence and skills-set to deal with the complex challenging situations in the field (D. M. Kamuya et al., 2013; Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015).

III. *Lack of capacity for fieldworkers*

- Training and capacity building of fieldworkers was described as an important approach towards enabling fieldworkers to address the myriad of challenges they

face. Training on the informed consent forms, the value, and principles of the informed consent process, as well as the protocols, can empower fieldworkers and build their confidence in handling study as well as non-study related issues. This would make fieldworkers understand the reasons behind the studies and the procedures involved. One way to address this challenge is by developing a standardized training curriculum which would be used to instill some generic skills and knowledge to fieldworkers working in various studies. This can also go a long way in enhancing fieldworkers' skills in data collection, quality data control as well as the importance of adhering to ethical standards. These findings support data in the available literature on the need to develop a harmonized curriculum for training fieldworkers in Africa (Participants of an International Workshop in Kenya on the Role of Frontline Staff in Biomedical Research & Kombe, 2015)

7.2 General recommendations

Given the findings presented in this study and previous literature on fieldworkers practice and experiences, we propose the following recommendations.

7.2.1 Strengthening of institutional structural systems

Generally, field managers and fieldworkers exhibited a good understanding of health research, Informed Consent, and social development. The link between social development and the role of fieldworkers was well articulated, albeit to a limited extent. Although fieldworkers were perceived as a critical cadre of staff in health research, there was a perceived limited recognition and appreciation of their roles. The description of field workers as a donkey and an overworked man, cast a dark shadow on how fieldworkers perceived their roles and their own importance as key health research staff. The results present a

skewed attitude, which has potential implication on the fieldworkers' personal and professional conduct. Issues around professional career development, especially related to skill transfer and training were expressed by some field managers as a major cause of demotivation, which can undermine the fieldworkers' ability to undertake their roles effectively. Furthermore, lack of adequate and responsive supervision, pressure to meet recruitment targets and limited avenues to discuss and share field experiences were expressly described as important factors that affected whether or not fieldworkers adhered to appropriate recruitment and Informed Consent processes.

Against this backdrop, there is a need for research institutions to develop policies and guidelines that can be more responsive to the expectations and needs of health research fieldworkers. As described by both managers and fieldworkers, unrealistic recruitment targets put irresistible pressure on the fieldworkers to use sloppy means of recruiting and Informed Consent potential participants. This practice can be improved if research institutions adopt effective supervision mechanisms that provide clear and objective guidelines on recruitment targets and management of fieldworkers.

The fact that fieldworkers could not clearly describe the relationship between health research and social development means there is a disconnection regarding the way fieldworkers roles are perceived and understood, and the ultimate output of health research in general. Ensuring fieldworkers understand the value of their work from the perspective of improving health and social development can nurture fieldworkers' positive attitude about their work. As suggested by the fieldworkers during the FGDs, this requires researchers to show appreciation and acknowledge fieldworkers for the work they do and involve them not just in data collection but in the planning, implementation, and dissemination of their study

results. Developing policies that ensure researchers do this as a standard practice can address this gap. This is the same gap that existed before researchers started involving communities in research planning and implementation. Researchers can involve fieldworkers by having consultative discussions during the planning phase of their research as well as presenting the findings to them at the end of the studies if research institutions develop policies and guidelines that promote this as standard practice. During these sessions, fieldworkers can be given opportunities to share their views and suggestion that can be used to strengthen community engagement and Informed Consent practices for the studies. Such efforts would mirror progress made in relation to community engagement, where community consultation and engagement have gradually become a common practice in community-based health research.

In this study, both fieldworkers, as well as field managers, described unclear and inadequate support for fieldworkers in relation to their professional career development. As explained by one of the managers, some fieldworkers were said to have been employed for over 15 years, yet there was little to show for the years they had worked, apart from the change of employment grade awarded every year. Similar sentiments were expressed by some fieldworkers who said they were used to seeing people join their team and within a short while, they achieve senior academic qualifications such as Masters and PhDs while the fieldworkers remain with the same qualifications, with no support year in, year out. This description highlights the perceived structural inequalities fieldworkers face, especially those related to continuing professional development and general career progression, and underscores the need for research institutions to establish policies and guidelines that take into account the academic levels of fieldworkers and identify clear professional and career

progression guidelines, which will be responsive to the fieldworkers' expectations and capabilities.

7.2.2 Training in health research ethics

Both fieldworkers and field managers described challenges that presented fieldworkers with practical as well as ethical dilemmas during Informed Consent. For example, fieldworkers described how they felt confused when a participant they were supposed to consent presented with extreme pain or a severe health condition that undermined their capacity to consent. According to accounts given by some of the fieldworkers interviewed, this gave them an opportunity to either circumvent normal Informed Consent procedures, so long as the patient signed the consent form. While this is an outright breach of the participant's individual autonomy, to some fieldworkers, signing of the consent form, regardless of the capacity of the participants, was the most important element of Informed Consent as it provided proof for agreeing to participate and protecting the researcher in the event of any serious adverse event. On the other hand, managers agreed that some of the experiences fieldworkers went through were too complex and difficult to handle. As such, they often avoided discussing them with the fieldworkers, as there was little they could do about it.

The findings above provide strong justification for encouraging research institution to institutionalize regular fieldworkers training on health research ethics and build their skills to deal with the complex ethical dilemmas in the field. Some authors have suggested the need to create deliberative spaces where fieldworkers hold open discussions with their peers, supervisors and subject matter experts, to allow them to share their experiences and come up with standard ways of dealing with the complex issues they face. Similarly, some of the supervisors recommended starting fieldworkers "clinics", where an expert can visit them at

their area of work and hold a discussion with them. Furthermore, there is a need to review current training on health research ethics and Good Clinical Practice (GCP) to ensure they respond to the needs of fieldworkers. Current training guidelines, including ethics and GCP, outline the responsibilities of Ethics Review Committees/Institutional Review Boards (REC/IRB), investigators, sponsors, and monitors, but are silent on the responsibilities of fieldworkers who are central in community-based trials. This omission may prevent fieldworkers from taking responsibility for mistakes that they do in the field. This has potential to undermine fieldworkers' scientific and ethical practices. Strengthening fieldworkers training and building their skills to handle complex practical and ethical challenges on the ground has the potential to improve the quality of data and the Informed Consent process.

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APPENDICES

9.1 *Appendix 1: Participant's Informed consent form for FGDs*

ADD STUDY TITLE: How Do Kenyan Research Fieldworkers Conceptualize the Consenting Process? *Implications for Training In Health Research Ethics*

Date:

Hello. My name is (Francis Kombe) from Kilifi-Kenya, working at KEMRI-Wellcome Trust Research Programme.

You are being invited to consider participating in a research study about how Kenyan fieldworkers conceptualize the consent process. The aim of this study is to develop an in-depth understanding of how fieldworkers conceptualize their role in and the value they place on the consent process. The study is funded by South Africa Research Ethics Training Initiative (SARETI) The study is expected to enroll 60 fieldworkers for focus group discussions and 6 field managers for individual in-depth interviews.

Your participation

In order to assess how Kenyan fieldworkers, conceptualize the consent process, I would like to ask you to participate in focus group discussion. The focus group discussion will take approximately 120 minutes to complete. I would also like to ask your permission to audio record the interview.

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. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. If you do this there will be no penalties and you will not be prejudiced in any way.

Confidentiality

I will not be recording your name anywhere on the notes during the focus group discussion. You will be assigned a participant code. If your name is mentioned during the interview and audio recorded, it will be replaced with your participant code during transcription [writing out the audio recordings]. All study data will be stored in lockable file cabinets accessible only to the study researcher and electronic data will be stored in password-protected files on the researcher's computer and destroyed after five years.

Risks/discomforts

At the present time, we do not see any risks in your participation.

Benefits

You will not benefit from participation in this study. However, this study will potentially contribute to understanding how Kenyan fieldworkers conceptualize the process of Informed Consent. This information will help in developing appropriate training for fieldworkers in Kenya

Reimbursement

We will provide refreshments during the discussions and reimburse for transport cost incurred at the local public transport rate.

This study has been ethically reviewed and approved by the UKZN Biomedical Research Ethics Committee (approval number_____).

In the event of any problems or concerns/questions you may contact the researcher at +254 722459046 or +27 620487715 or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto: BREC@ukzn.ac.za)

CONSENT

I have been informed about the study entitled **how do Kenyan research fieldworkers conceptualize the consent process? Implications for training in health research ethics** by Francis Kombe

I understand the purpose and procedures of the study

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.

I agree with my information being audio recorded

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at +254 722459046 or +27 620487715

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: BRECE@ukzn.ac.za

Signature of Participant

Date

Signature of Witness
(Where applicable)

Date

Signature of Translator
(Where applicable)

Date

9.2 Appendix 2: Participant's Informed consent form for IDIs

ADD STUDY TITLE: How Do Kenyan Research Fieldworkers Conceptualize the Consenting Process? *Implications For Training In Health Research Ethics*

Date:

Hello. My name is (Francis Kombe) from Kilifi-Kenya, working at KEMRI-Wellcome Trust Research Programme.

You are being invited to consider participating in a research study about how Kenyan fieldworkers conceptualize the consent process. The aim of this study is to develop an in-depth understanding of how fieldworkers conceptualize their role in and the value they place on the consent process. The study is funded by South Africa Research Ethics Training Initiative (SARETI) The study is expected to enroll 60 fieldworkers for focus group discussions and 6 field managers for individual in-depth interviews.

Your participation

In order to assess how Kenyan fieldworkers conceptualize the consent process, I would like to ask you to participate in an individual in-depth interview. The interview will take approximately 60 minutes to complete. I would also like to ask your permission to audio record the interview.

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. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. If you do this there will be no penalties and you will not be prejudiced in any way.

Confidentiality

I will not be recording your name anywhere on the notes during the interview. You will be assigned a participant code. If your name is mentioned during the interview and audio recorded, it will be replaced with your participant code during transcription [writing out the audio recordings]. All study data will be stored in lockable file cabinets accessible only to the study researcher and electronic data will be stored in password-protected files on the researcher's computer and destroyed after five years.

Risks/discomforts

At the present time, we do not see any risks in your participation.

Benefits

You will not benefit from participation in this study. However, this study will potentially contribute to understanding how Kenyan fieldworkers conceptualize the process of consenting. This information will help in developing appropriate training for fieldworkers in Kenya

Reimbursement

We will provide refreshments during the discussions and reimburse for transport cost incurred at the local public transport rate.

The duration of your participation, if you choose to enroll in the study, is between one to two hours.

This study has been ethically reviewed and approved by the UKZN Biomedical Research Ethics Committee (approval number _____).

In the event of any problems or concerns/questions you may contact the researcher at +254 722459046 or +27 620487715 or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto: BREC@ukzn.ac.za)

CONSENT

Ihave been informed about the study entitled **how do Kenyan research fieldworkers conceptualize the consent process? Implications for training in health research ethics** by Francis Kombe

I understand the purpose and procedures of the study

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.

I agree with my information being audio recorded

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at +254 722459046 or +27 620487715

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto: BREC@ukzn.ac.za)

Signature of Participant

Date

Signature of Witness
(Where applicable)

Date

Signature of Translator
(Where applicable)

Date

9.3 Appendix 3: Interview guide for Focus Group Discussion

Study title: How do Kenyan research fieldworkers conceptualize the consenting process?

Implications for training in health research ethics

FGD code [][][][] Date _____ Place _____

Participants:

No	Age	Gender	Education	Religion	Location	Comments
P1						
P2						
P3						
P4						
P5						
P6						
P7						
P8						
P9						
P10						

General comments on the discussion:

Appendix 3: Interview guide for Focus Group Discussion

Study title: How do Kenyan research fieldworkers conceptualize the consenting process?

Implications for training in health research ethics

FGD code [][][][] Date _____ Place _____

Ice Breaker: Before the discussion, participants will be asked to draw a pictorial presentation of a typical fieldworker at KWTRP and discuss it

Discussion Guide

1. What is health research?

- How does research relate to social development?*
- To what extent does the local community benefit from the research conducted at KWTRP*
 - What benefits has the community had*
 - What inconveniences/risks has the community been exposed to??*

2. What are fieldworkers duties and responsibilities at KWTRP

- Which of these are FWs primary responsibilities?*
- How important are these responsibilities to FWs?*
- How do FWs roles relate to the concept of social development*

3. What is consenting?

- What does it entail?*
- How important is the process of consenting in undertaking FWs roles*
- How important is consenting in health research*
- Under what circumstances do FWs feel most comfortable to seek consent?*

- Under what circumstances do FWs feel uncomfortable taking consent?*
- Under what circumstances do FWs avoid taking consent?*
- What are the key elements of consenting?*
 - How do FWs apply these elements of consenting?*
 - How important is it to fulfill all the key principles of FWs*
 - Which elements do FWs **EASILY** ignore during consenting and why?*
 - Which elements do FWs **NEVER** ignore during consent and why?*
- What factors promote the application of all the elements of informed consent?*
 - Which of these are the most important and why?*
- What factors hinder the application of all the elements of informed consent?*
 - Which of these are the most important and why?*

4. What issue does FWs encounter that are considered to be ethically challenging?
- Give some examples?*
 - Which are the most important/common ones and why?*
 - What are the formal/informal systems in place to address these challenges?*
 - How well do these systems work?*

1. What can be done to support the roles of fieldworkers at KWTRP?

9.4 Appendix 4: Interview guide for Individual In-depth Interviews

Study title: How do Kenyan research fieldworkers conceptualize the consenting process?

Implications for training in health research ethics

IDIs code [][][][] Date _____ Place _____

Participants:

No	Age	Gender	Education	Religion	Location	Comments
P1						

General comments on discussion:

Appendix 4: Interview guide for Individual In-depth Interviews

Study title: How do Kenyan research fieldworkers conceptualize the consenting process?

Implications for training in health research ethics

IDIs code [][][][] Date _____ Place _____

Discussion Guide

What is health research?

How does research relate to social development?

To what extent does the local community benefit from the research conducted at KWTRP

What benefits has the community had

What inconveniences/risks has the community been exposed to??

What are the duties and responsibilities FWs at KWTRP

Which of these are their primary responsibilities?

How important are these responsibilities?

How do these roles relate to the concept of social development

What do you understand by consenting?

What does it entail?

How important is consenting in health research

Under what circumstances do you think FWs feel most comfortable to seek consent? Why?

Under what circumstances do you think FWs feel uncomfortable to seek consent? Why?

Under what circumstances do you think FWs may avoid taking consent? Why?

What are the key elements of consenting?

How are these elements applied in research?

How important is it to fulfill all the key elements?

*Which elements do you think FWs **EASILY** ignore during consenting and why?*

*Which elements should think FWs **NEVER** be ignored during consent and why?*

What factors promote the ability for FWs to apply all the elements of informed consent?

Which of these are the most important and why?

What factors hinder FWs from applying all the elements of informed consent?

Which of these are the most important and why?

What situations are considered ethically challenging for FWs?

Share some examples?

Which of these are most important and why?

What are the formal/informal systems you used to support FWs address these challenges?

How well do these systems work?

What do you think can be done to support the roles of fieldworkers at KWTRP?

9.5 Appendix 5: Thematic Framework

Name	Created On	Created By	Modified On	Modified By
Attitudes and perceptions about health research	4/8/2017 2:56 PM	FK	4/8/2017 2:56 PM	FK
Community's health research benefits	4/8/2017 2:56 PM	FK	4/8/2017 2:56 PM	FK
Risks exposed to the community	4/8/2017 2:57 PM	FK	4/8/2017 2:57 PM	FK
Attitudes and perceptions of fieldworkers 'roles in health research	4/8/2017 2:57 PM	FK	4/8/2017 2:57 PM	FK
Attitude about who fieldworkers are	4/8/2017 2:58 PM	FK	4/8/2017 2:58 PM	FK
The attitude of the role of fieldworkers in health research	4/8/2017 2:58 PM	FK	4/8/2017 2:58 PM	FK
Perceptions of the role of fieldworkers in social development	4/8/2017 2:59 PM	FK	4/8/2017 2:59 PM	FK
Attitudes and understanding of the value and meaning of the consenting process	4/8/2017 2:59 PM	FK	4/8/2017 2:59 PM	FK
Ethical dilemmas experienced by fieldworkers	4/8/2017 3:00 PM	FK	4/8/2017 3:00 PM	FK
Factors that affect the consenting process	4/8/2017 2:59 PM	FK	4/8/2017 2:59 PM	FK
Issues that participants complain about regarding consenting	4/8/2017 3:00 PM	FK	4/8/2017 3:00 PM	FK
Support mechanisms and recommendations	4/8/2017 3:00 PM	FK	4/8/2017 3:00 PM	FK

Capacity Building	4/8/2017 3:01 PM	FK	4/8/2017 3:01 PM	FK
Fieldworkers "Clinics"	4/8/2017 3:02 PM	FK	4/8/2017 3:02 PM	FK
Lack of a systematic approach	4/8/2017 3:01 PM	FK	4/8/2017 3:01 PM	FK
Motivation	4/8/2017 3:02 PM	FK	4/8/2017 3:02 PM	FK
Structural support	4/8/2017 3:01 PM	FK	4/8/2017 3:01 PM	FK
Youth-friendly Informed Consent Forms	4/8/2017 3:02 PM	FK	4/10/2017 9:45 AM	FK