Exploring research participants' perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study in Zimbabwe: A case study

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Declaration

I, Sithembile Ruzariro, declare that this research report is my own work. It is a research report submitted in partial fulfillment of the requirements for the degree of Master of Social Sciences in Health Research Ethics, University of KwaZulu-Natal, and has not been submitted before for any degree or examination at this University or any other tertiary institution.

Signed

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ABSTRACT

Background

An inherent challenge in HIV prevention studies is making sure that trial participants understand the information. This study explored trial participants' perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study.

Method

Face-to-face in-depth interviews, using a study guide, were held with twenty interviewees purposively selected from ex-participants of an HIV prevention study. Audio-recorded data were transcribed, translated, coded using NVivo 8, and analysed according to themes.

Results

The participants were all women between the ages of 18 and 40. Participants felt that key information had been given during the informed consent process. Most felt that the process of obtaining informed consent was rushed with some participants citing a need for more time to make a decision regarding participation. Some participants felt pressured to sign consent forms. Some found it difficult to ask questions and mixed feelings existed on male partner involvement in the decision-making process.

Conclusions:

Participants experienced the consent process as rushed and most only fully comprehended study concepts with time. Their concerns necessitate the reassessment of informed consent processes in a developing world setting.

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CHAPTER 1

1 INTRODUCTION

1.1. Background Information

Ensuring informed consent during a clinical trial is one of the most complicated aspects of biomedical research, especially in HIV prevention studies that are mostly carried out in resource poor settings (Mystakidou, Panagiotu, Katsaragis, Tsilika & Parpa, 2009). Communities in resource poor settings are often characterized by low levels of education, which could make it very difficult to understand some of the research concepts used. Their decision-making styles are often very different from those of western communities where most of the research protocols emanate from. In HIV prevention studies, the informed consent process is characterized by problems of making the research participants understand that participating in the clinical trial does not protect them from getting infected with the virus that causes AIDS (Macklin, 1999; Shaibu, 2007). They need to understand that the study drug being used is still under investigations, and it is not known whether it provides protection to participants or not.

Researchers must explain this fully so that participants understand the concepts of randomization and placebo, so that they do not have a false sense of protection because they are participating in a trial and possibly taking protective medication (Mantell, Morar, Myer & Ramjee, 2006). In some studies that have been carried out on the informed consent process including anecdotal evidence, it clearly indicates existence of a large gap between the ideal informed consent process and what is happening on the ground during research implementation.

Arguments had arisen that the current research ethics guidelines should be modified to suit their application during the informed consent process in resource-limited countries

(Shaibu, 2007). This is mainly because certain principles of individual informed consent, for example autonomy, may be interpreted differently from culture to culture (Hyder & Wali, 2006). Most researchers who have done research in the developing world have realized the need to revisit the informed consent standards in the developing world so that differences in culture and norms within communities are taken into consideration (Macklin, 1999; Shaibu, 2007).

A participant`s agreement to take part in any research is regarded morally acceptable if it is genuine. A participant must be provided with all the relevant information pertaining to the study and must be in a position to understand the information adequately and voluntarily participate in research with no undue controlling external influence. Despite all this, research that has been done so far, has indicated that the information given to research participants is too technical for a lay person to comprehend and at times the information written on the consent form, versus the reading capabilities of the research participants, do not match, making it very difficult for a genuine consent..

A study carried out by Priestley, Campbell & Valentine (1992), compared how well research participants could read 50 clinical trials consent forms against 10 British newspapers. They found out that research participants had more difficulties in reading the consent forms from the 50 clinical trials than reading the newspapers. Signing the informed consent document might be symbolic signing which does not always represent understanding. Research participants just sign the consent form without proper understanding of the research details because it is a requirement for one to sign the piece of paper before entry into the study. In a cross-sectional survey of participants in a clinical trial, Joffe (2001) found out that 90% of them said they had no problems concerning the informed consent process and considered themselves well

knowledgeable about the research details. But, surprisingly, on further questioning, majority had no knowledge on some important aspect of the clinical trial, like, that it was research, whether they were to benefit or not as participants and even failed to articulate the major reason why the research was being done. Researchers, at times, do not adequately discuss features of clinical trials and participants might not have the opportunity to ask questions. In a study done in South Africa on disclosure of information to research participants, it is common for research participants to receive scanty information about the study and at the same time the information is not adequate enough for an individual to decide whether to participate or not. Researchers rarely checked the type and amount of information participants prefer (Ogunbanjo & Knap, 2004). Some participants might prefer more research information that might be too much for others. Researchers should treat research participants individually irrespective of their common educational and cultural backgrounds.

In order to make ethics operational in research, informed consent must be recognized as a critical dimension. Consultations and meetings held on ethics and clinical trials, among others Creating Effective Partnership for HIV Prevention Trials (UNAIDS, 2006), Stake Holder Consultation to Address Issues Related to Tenofovir Prophylaxis Research (International AIDS Society, 2005) and Rethinking the Roadmap for Clinical Testing of Microbicides (Global Campaign of Microbicides, 2005), have identified informed consent as a priority area.

There is also a need to revisit the understanding and information retention of participants over time. Practically, however, once the informed consent form has been signed and filed, it is rarely revisited. Both researchers and study participants tend to regard informed consent as merely a requirement to comply with legal and regulatory

codes to participate in research and the consent process thus effectively ends with the signing of the documents. However, many ethicists (Sastry *et. al.,* 2004; Joffe, 2001) have asserted that “genuine consent” requires more than satisfying the legal formalities, for example, signing the consent forms. This implies that, before participants sign the consent form, there should be some understanding of all the research aspects that could lead an average person to change her or his mind. Signing the consent form also confirms that participants understand the aim, the risks involved and their agreement to participate. Contrary to this, many research studies on informed consent have revealed difficulties with comprehension of clinical trials. Participants’ understanding might be incomplete or incorrect regarding issues that are in line with informed decision making to join a clinical trial.

Literature has it that truly informed consent is a difficult thing to achieve. A few specific concepts that form part of a clinical trial have been specifically highlighted, such as randomization and the use of placebo. Little is known about how randomization is explained or understood by research participants in randomized clinical trials. Randomization is a necessary scientific method, but generally poorly understood by non-scientists. The reason why randomization is done in clinical trials, and how it is done, therefore, require careful explanation to research participants if truly informed consent is to be achieved. There is little information on research participants' experience of the informed consent process in Sub-Saharan Africa, especially where randomized controlled trials are being implemented (Moodley, Pather & Myer, 2005). Research concepts like randomization and the use of placebos may be not well understood by research participants. Therefore, there is need to provide research participants with accurate information pertaining to the study, although it does not necessarily guarantee fully understanding of the research concepts.

In Zimbabwe, there is no published research on the informed consent process in clinical trials utilizing prevention technologies. Consent process theory and practice are two separate entities, and there is little research done to find out how the two complement each other during research implementation, (Lesko, Dermatis, Penman, & Holland, 1989) and how research participants perceive the quality of informed consent (Verheggen, Nieman & Jonkers, 2005).

There is little information on how the consent process is being carried out by researchers in research involving HIV prevention technologies. Very few studies have addressed informed consent in contraceptive and non-HIV vaccine trials (Riveira et al, 1992; Preziosi et al, 1992; Fortney, 1999; Leach et al,1999). Understanding research concepts like randomization, blinding, prevention study versus treatment study, and placebo remains a challenge. Ethics is still evolving and this calls for more and more innovative ways of conveying research concepts to participants. Research on HIV prevention technologies is on the rise and researchers have reported problems in obtaining genuine informed consent from participants. It is, therefore, important to implement the best way to obtain informed consent from research participants (Ramjee *et. al.*, 2000; Kilmarx *et. al.*, 2001; Coletti *et. al.,* 2003; Mariner, 2003).

There are currently multiple clinical trials ongoing worldwide with the aim of providing women with cheap and self-initiated HIV prevention strategies for the reduction of HIV transmission. Zimbabwe has ongoing pre-exposure HIV prevention studies and anticipates many more following the promising CAPRISA results on microbicides for pre-exposure HIV prevention.

The hypothesis that research participants perceive the methods used by researchers in conducting the informed consent process as negative, and that these methods make it difficult for participants to understand the research process, needs to be investigated. To achieve this, this study explored participants` perceptions of the informed consent process and the factors that inhibited or enabled research participants to understand the information provided during the informed consent process. The research further aimed to identify barriers to communication between researchers and research participants.

The information from this study will be used to come up with suggestions on how to improve the informed consent process in developing world contexts, particularly in randomized controlled trials. It is hoped that the study findings will assist in the process of refining this important ethical procedure and subsequently contribute towards empowering and protecting future study participants.

1.2 Study Main Aim

To explore research participants` perception of processes and comprehension of consent information in a pre-exposure HIV prevention study in Zimbabwe.

1.3 Study Specific Objectives

- To explore participants` perceptions of the informed consent process.
- To determine participants' comprehension of the information provided during the informed consent process.
- To identify research participants` expectations of the informed consent process.
- To determine the possible barriers to comprehension during the informed consent process.

CHAPTER 2

2. LITERATURE REVIEW

There is continuous evaluation of ethical challenges that arise during research in human beings. Policy issues regarding the framework of biomedical research are also continuously being evaluated (Bhutta, 2004). Policy issues regarding the ethical conduct of human subject research are articulated by Western societies with particular emphasis on international collaborative research in the developing world. The informed consent process has been cited as one of the most challenging areas of policy development in poorly resourced countries, (Dawson & Kass, 2005; Hyder & Wali, 2006). In developing countries, illiteracy and unawareness of human rights prevail, making it even more difficult to obtain truly informed and culturally acceptable consent.

Issues of informed consent acquire a new dimension when discussed in the context of clinical trials (Korn & Baumrind, 1991; Sankar, 2004). For example, one study found out that research participants did not understand about the concept of randomization, a characteristic that is very important in many clinical trials (Kimmelman & Palmour, 2005). Others found that research participants think that they are receiving treatment. They think that research is an extension of treatment that is likely to be even more effective than the standard of care, if there is any (Kimmelman & Palmour, 2005). Despite the prevalence of clinical trials, participants find it difficult to distinguish between research and treatment. The belief that they are getting treatment is worsened by the fact that research participants trust their general practitioners. They think that the doctor is always right and cannot give a participant a drug that does not work. Additional factors that might inhibit participants' understanding of the informed consent process, with specific reference to clinical trials, include cultural differences, diverse levels of education and personal expectations (Kanerva, Suominen, & Leino-Kilpi, 1999a;

Sankar, 2004).

The Helsinki Declaration states that participants who participate in any research must be fully informed about what the trial aims to achieve, methods that are going to be used to achieve those aims and potential risks and expected benefits (WHA, 2008). It is the explicit standard under which ethics committees evaluate medical research. Research on the informed consent process has shown that although the principles of informed consent are well engrained in medical practice, research participants do not always benefit from these principles because they are not being implemented during research implementation, and some of them are not accepted in some nations.

The informed consent process begins when people first hear about a study. It is a process, rather than an event. Researchers and research participants should continue to engage in conversation to make sure research participants are well informed, satisfied and continue with the consent process until study comes to an end. Voluntary informed consent is a universally recognized practice for ethical conduct in research involving human participants (Lavery, Grady, Wahl & Emanuel, 2007). It is the cornerstone of ethical research and without informed consent, the research loses its credibility. The process of informed consent is not as easy a task as people might think (Silverman, 1989). At times participants just sign the piece of paper as a formality; not because they understand the connotations behind the signing but because they believe they are supposed to sign it.

Consent Process Issues

Elements of adequate informed consent include the following four aspects: disclosure of study information, understanding the study information, decision-making capacity on the

part of the research participant and voluntariness to participate in the research study. Researchers have to ensure that all these elements are present during the informed consent process for the process to be genuine. The onus remains upon the researcher to exercise a degree of judgment during application of these elements. Each of these four aspects will now be briefly discussed.

1. Study Information Disclosure

In clinical trials, there are specific guidelines and ethical codes that are supposed to be adhered to by researchers in order to obtain genuine informed consent from research participants. These guidelines state some areas that are supposed to be addressed in an informed consent document. The main requirements of the informed consent document, as per the US. Code of Federal Regulations: 45 CRF 46:16 are as follows:

- A statement showing that the study involves research, stating the purpose of the study, duration, procedures to be done and mentioning of any products that are experimental
- A description of any anticipated risks and benefits to the research participant
- A description of any benefits expected from the research
- An explanation of appropriate alternative procedures that might be advantageous to the participant
- Extent of confidentiality of records of the participant
- Any compensation for participating in the study.

The Helsinki Declaration states that participants who participate in a research study must be adequately informed about what the trial aims to achieve, methods to be implemented, potential risks and expected benefits (WHA, 2008). There is a legal duty of

information disclosure by the researcher to the research participant before participant signs the consent form. The consent process consists not only of information disclosure to the research participant and a signature, but it is supposed to facilitate participants' understanding of the research project and the voluntary nature of their decision to participate (Brody, McCullough & Sharp, 2005). In a clinical trial, disclosure should generally cover aims and methods of the research, anticipated risks and benefits, any anticipated inconvenience or discomforts, and the right of participants to withdraw without punishment or compromised care from the research study team. Faden and Beauchamp (1986) have argued that there are three aspects to the necessary "core disclosure" to patients. These are (1) the facts that research participants usually consider material in deciding whether or not to refuse or consent to the proposed intervention or research, (2) what the professional believes to be material, and (3) what needs to be said to establish the purpose of seeking consent.

Disclosure is the responsibility of the researcher, but, practically, there are no agreed standards on how this disclosure should be done to research participants. A related problem emerges from empirical studies of whether research participants actually use this disclosed information to reach a decision whether to participate or not. In one study, although 93% of the participants believed they benefited from the disclosed information, only 12% used the information in their decision to consent (Faden & Beauchamp, 1980). In another study, irrespective of giving full information to research participants, participants generally made their decision prior to and independent of the process of receiving the information (Fellner & Marshall, 1970). This indicates that individual needs can differ. Research participants may have different cultural beliefs, different health conditions, or unique family histories that may warrant different informational base (Beauchamp & Childress, 2009).

2. Understanding of Disclosed Information

Understanding of disclosed information is one of the elements of the informed consent process. Several clinical trials have clearly shown that participants might have incomplete or incorrect understanding of the research study they are about to participate in (Cassileth, Zupkis, Sutton-Smith & March, 1980; Edwards, Lilford & Hewison, 1998; Joffe et al, 2005). Empirical data indicate that research participants exhibit wide variation in their understanding of information about research procedures, risks and probable benefits (Barbara & Bernhardt, 1996). For example, in a cancer clinical trial, 90% of participants indicated that they were satisfied with the informed consent process and most of them thought that they were well informed. However, about three quarters of them did not understand the nonstandard and unproven nature of the treatment, and approximately one quarter did not appreciate that the primary purpose of the trial was to benefit future patients and that the benefits to them personally were uncertain (Joffe et al, 2001). This limited understanding has been attributed to so many factors, including nervousness, distractions during the consent process, immaturity, or even illness. Deficiencies in the communication process, like using unfamiliar terms, may further hamper understanding. Some of these barriers to understanding can be addressed, but debate continues on how best it can be done in order to obtain valid consent from research participants.

Adult learning theory suggests that the way information is presented to individuals can affect their understanding differently. Generally, people are more likely to understand and remember information they use than information they only hear. Understanding given information is furthermore strongly influenced by the level of abstraction of the information presented. The consent form must be written in a language the participant

can understand. Guidelines often specify that the informed consent form should not be written above an 8th grade reading level as this is inappropriately high for many developing countries where the literacy level might be very low (Stanley, Doyle, Gabram, Nightingale & Phillipson, 1995: Lacey, Saunders & Sugar, 1993). On the other hand, researchers should bear in mind that even if an appropriate level of language is achieved in the informed consent form, it does not necessarily mean increased comprehension (Davis, Holcombe, Berkel, Pramanik & Divers, 1998; Mariner & McArdle, 1985), because research vocabulary like randomization, placebo or blinding, might not exist in the participants' local language. Individuals are unique and a participant`s reading-comprehension level might be several grades lower than the grade level achieved in school. Self-reported education levels do not accurately measure health-literacy (Burman et al, 1988). Some researchers have, therefore, argued that the informed consent should be written at least three grade levels lower than the average educational level of the target population (Barry, 1988). A researcher should be aware of the average level of education of the target population before writing the consent form

By right, participants are supposed to comprehend all the information concerning the research they are participating in. This is however proving to be a mammoth task and studies show that comprehension of risks and benefits is relatively poor in both the research (Miller et. al, 1994) and clinical setting (Jebbin & Adotey, 2005). A potential research participant must understand that he or she is being asked to participate in research. Resent publications on informed consent suggest that comprehension is enhanced when communities to be involved in research are engaged right from the beginning of the study to end. Some even say right from concept paper through meetings with local leaders or public forums (Crigger et al, 2001; Dickert & Sugarman, 2005; Muthuswamy, 2005). Some suggest that the research protocol should start and

end with the community (Crigger et al, 2001).

3) Decision-making capacity

Decision-making capacity is context specific and consists of the ability to make a choice in light of an accurate appreciation of the situation at hand and its consequences, and the rational manipulation of information (Appelbaum & Grisso, 1988). Considerations of autonomy, age and maturity are important elements to consider when assessing capacity. A participant`s mental capacity to consent or refuse to participate in research, is of course also closely related to an ability to understand relevant information of the study in terms of risks involved through participation and also benefits gained from participation. Consent capacity can be impaired, thereby affecting an individual`s understanding of key informed consent elements. When research is being implemented, it is always necessary to assess participant`s consent capacity by asking prospective participants to describe the important aspects of the research. A number of assessment methods have been used before a participant signs the informed consent Some methods now involve comprehension checklist on study related aspects (Jeste et al, 2007).

The most effective instruments to assess participant`s capacity to give consent in research are still to be agreed upon. There is no clear consensus on which instruments to use. Assessment of capacity to consent can include discussion of the research with prospective participants followed by a series of questions. Research still needs to be done on how this assessment can be improved (Stuman, 2005). Re-evaluation of consent capacity may be necessary for participants who experience disorders with progressive or fluctuating courses during study participation. This is applicable in long-term studies and additional safeguards and monitoring is required.

4) Voluntariness

Voluntariness is one of the important elements of informed consent. It is defined as a situation where the participant is well informed about the research him or her about to participate in, with no psychological compulsion and external constraints (Donchin, 1995). The individual exercises his or her autonomous action without being under the control of another individual`s influence. There are certain conditions that diminish or hinder voluntariness. In research, these can be internal factors such as debilitating diseases, or external factors such as reimbursements, usual health personnel carrying out research, and some free offers that go along with research. Voluntariness can be further compromised by factors such as poverty, limited access to health care, socio-economic status or culture (Benatar, 2002). In an HIV vaccine trial in South Africa, 93% of the participants stated that they were free to withdraw, but 98% thought that the study authorities would not allow them to withdraw (Karim, Karim, Coovadia & Susser 1988). Many research participants report feeling severe pressure to enroll in clinical trials even though their enrollment is voluntary (Hewlett, 1996).

When a research participant enters a study, there should be no coercion and undue pressure in reaching a decision to participate. Beauchamp & Childress (2001) asserted that “a person acts voluntarily to the degree that he or she wills the action without being under the control of another`s influence” (p.63). Voluntariness has been described as the most difficult aspect of informed consent to study, because it requires greater conceptual clarity (Pace & Emmanuel, 2005). As a result, policy-makers have been left with little guidance to ensure that research participants are able to exercise their choice about whether to participate in research or not.

Principal theories upon which the research project was constructed

The ethical principles that guide the informed consent are dominated by two theories. These are deontological theory and consequentialism. Deontological theory states that one has obligations and that these obligations must be fulfilled regardless of their outcome. They emphasise duty as the basis for moral value. It is a principle of right action. The principle of respect for persons is deeply imbedded in the deontological theory and leads to the idea that respect for another includes respect for autonomous decisions.

Kant's (1985) deontological ethics, in the form of his categorical imperative - that is, the claim that a human being is an end, not just a mere means to an end - forms the main justification for informed consent. Informed consent can therefore be viewed as an ethical doctrine rooted in our society's cherished value of autonomy. Autonomy provides research participants with the right to make their own decisions about participating in research and intends for it to be an interpersonal process by which researchers and research participants work together to make decisions about participating in research. Participants' autonomy is the ethical foundation of informed consent and by saying that participants are autonomous agents, we imply that they have equal status with the researcher and cannot be treated as means to another's ends.

Utilitarian theory holds that actions are right or wrong according to the balance of their good and bad consequences (Beauchamp & Childress, 2009). This theory also influenced the framework of the informed consent. It holds that morally valuable actions are those actions that bring about the greatest good for the greatest number of people. Arguably, more people will benefit if they are adequately informed and the overall

consequences will be positive, since all participants should then ideally partcipate of their own free will with adequate information.

On the other hand, communitarianism emphasizes the influence of society on individuals and contends that values are rooted in common history and tradition. (Beauchamp & Childress, 2001). Communitarianism can be a key theory in resolving ethical conflicts in the African context as it respects local community values, while downplaying the principle of autonomy or individualism.

Informed Consent Conceptual Framework

Based on experience with the HIV Prevention Trials Network, Woodsong and Karim (2005) outlined a full model designed to enhance the informed consent process. It focuses on both individual and community concerns. The conceptual framework allows an enhanced informed consent process as it is designed to ensure initial and continued comprehension by research participants. The framework focuses on both the research participant and his or her community in which he or she lives. The framework divides the consent process into three phases, namely pre-enrollment phase, enrollment phase and finally, the post-enrollment and continuation of study. At each and every stage, the framework has a different focus.

The pre-enrolment phase

The phase focuses on the community norms, expectations and how to convey research protocol concepts. This is in line with Emmanuel, Wendler, Killen, & Grady, (2004), one of the eight benchmarks which state that clinical research should involve the community in which it occurs.

The enrollment phase

Phase two is the enrollment phase, and focuses on the individual participant rather than the community. This is the phase where the researcher gets in contact with the research participants, explains the study details, and participants sign the informed consent form as an agreement to participate in the study.

The post-enrollment phase

The third phase focuses on continued information to be given to study participants and the community as a whole until end of research. This is an ideal situation especially if the research requires repeated visits by research participants or has a long duration. Participants should be informed of new information from the study data. The researcher bears in mind that community-level misunderstandings can influence continued participation and undermine adherence to the study procedures.

This study was guided by a framework for the informed consent process that evolved at the HIV/AIDS Prevention Network (HPTN) sites to ensure initial and continued comprehension of research participation. Zimbabwe was one of the participating sites. This framework attempts to ensure initial and continued comprehension of information by research participants. It is guided by utilitarianism in the sense that it also focuses on the greatest number of people understanding the informed consent process. The framework is currently being used to implement the informed consent process in randomized clinical trials for microbicides.

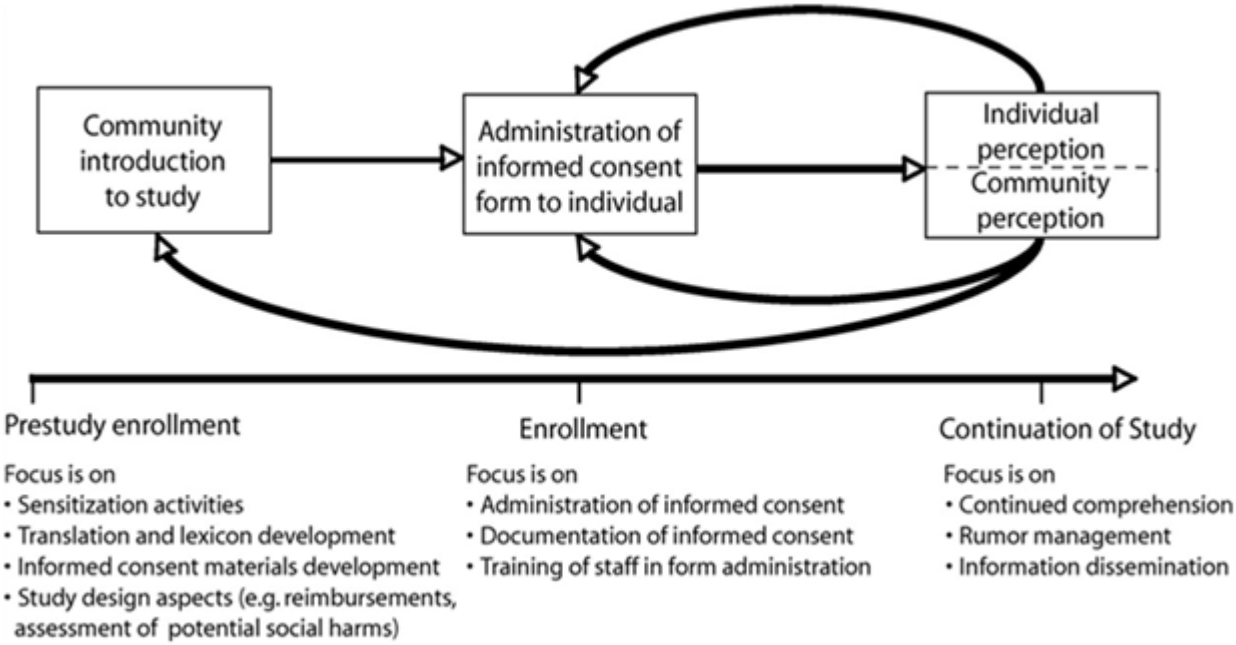

Figure 1: Conceptual Model of the Informed Consent Process (Woodsong & Karim, 2005)

The model recognizes the links between the community in which research is taking place and the individual who is participating in research. Clinical research should involve the community in which it is conducted for maximum support.

CHAPTER 3

3 MATERIALS AND METHODS

3.1 Study Design

The study was descriptive and cross-sectional and a qualitative methodology was employed to explore trial participants' perceptions and comprehension of the informed consent process. This methodological approach was appropriate for it explores a programme, an event, activity, a process or one or more individuals in depth (Bernard, 1995). It is very difficult to measure human emotions using quantitative methodology. To investigate these emotional responses, qualitative methodology seems to be a more effective method. The methodology also relies on written or spoken words or observations that do not have direct numerical interpretation and typically involves exploratory research questions, inductive reasoning, an orientation to social context, and the meanings attached by participants to events and to their lives (Schutt, 2006). This methodology allowed exploring women`s ideas, feelings and attitudes regarding the informed consent process and aided in the comprehension of research subjects' experiences and the meaning they attribute to it (Taylor & Bogdon, 1992).

3.2 Participants

The target population was women, aged between 18-40 years, all ex-research participants who had participated in a pre-exposure HIV prevention study. It was a vaginal microbicide study, conducted in five countries among sexually active, HIV-uninfected women between 2007 and 2010. There were two sites in Zimbabwe with a total of 520 participants. The main purpose of the HIV-prevention study was to find out if two vaginal microbicide gels were able to prevent women from contracting the HI virus

during vaginal sexual intercourse. Women were randomized into four arms, buffer gel, pro 2000 gel, placebo gel and the fourth arm was given condoms only and no gel. Study staff and community representatives worked together and developed suitable information materials about the study and a standardized approach to the informed consent process was implemented at the study site.

The informed consent form for the microbicide research described the purpose of the study, procedures to be followed, and the risks and benefits of participation. The process also included use of an assessment check-list for each potential participant`s understanding of research details prior to enrollment. It is becoming common for participants to be expected to demonstrate comprehension of consent elements before enrollment, (Silva & Sorrell, 1998). Participants who were not able to demonstrate adequate understanding of key concepts after exhaustive educational efforts were not enrolled. Written informed consent was obtained from each study participant prior to both screening and passing the assessment checklist.

The consent form for the microbicide research had 9 pages and was written in both Shona and English languages. All the twenty participants had signed the Shona version of the informed consent document. Before study closure, participants were requested to sign informed consent forms to show their willingness to be followed up for any study related to the study they had participated in. The principal investigator of the HIV prevention study made the list of names and contact details available to the researcher after due ethical clearance had been obtained from the University of KwaZulu-Natal and the Medical Research Council of Zimbabwe Ethics Committees.

It was not revealed to the researcher how many of the 520 participants consented to be contacted for any related research in future. The researcher received a list of names of fifty-five women. With the help of a former research nurse who knew the participants very well from the previous study, participants were purposively selected for the consent study from the two Zimbabwean sites. These women were specifically selected because they were known to be confident and able to state their opinions clearly. Participants were contacted and asked if they were willing to participate in the study through home visits and telephone conversations. If they agreed, they were given appointments on different dates for the informed consent process study. Researchers honored the decisions of potential participants who declined to participate even though they had indicated that they would be willing to participate in any research related to the one they had participated in. During the study visit and before administering the questionnaire, new informed consent was sought from participants.

3.3 Equipment and Measures

The researcher developed an interview guide using factual items in the participants` informed consent document from the pre-exposure HIV prevention study. Further adaptations of the questions followed comparison with other interview guides adapted from Kass, Maman & Atkinson (2005). Section A of the questionnaire had demographic data, and section B elicited how the participants perceived the informed consent process, their comprehension of information received, their expectations and possible barriers to comprehension.

To enhance the content validity of the instrument, a pilot study involving three participants from the same study was conducted. This managed to inform the researcher about the appropriateness of the interview questions, ability of the

researcher to conduct a good interview and the exact time required to complete the interview. Researchers are encouraged to contact a pilot study before the actual study in order to try out their interviewing design with a small number of participants (Seidman, 1998). The pilot study also helped the researcher to come to grips with some of the practical aspects of establishing access, making contact, as well as becoming aware of own level of interviewing skill. The interview guide did not need to be modified following the pilot study, however.

3.4 Procedure

A qualitative study is concerned with non-statistical methods and a small sample size, often purposively selected (MacRoy, 1995). In this study a non-probability, purposive sampling method was used. In total, in-depth interviews were conducted with twenty participants during the study period. The integrity of the study was not diminished because the sample size is deemed sufficient to reach saturation (a term used in qualitative research to indicate a point beyond which no new information or ideas arise, MacRoy, 1995; Bowen, 2008). No additional interviews were conducted as saturation was achieved with the 20 interviews.

The general purpose of the research, the role that the interview would play in the research, the approximate time required to complete the interview, and the confidential nature of the information were explained to the participants. Participants were informed of the manner in which the researcher would record responses, including the use of a tape recorder, that the tapes would be transcribed, locked in a secure cupboard and destroyed after five years. They were also informed that if they wished to withdraw from the research at any time, they were free to do so.

The interviews were conducted with each participant individually and in-person, in a private location and took about an hour to complete. The participants were made comfortable and at ease in a private room. The seating arrangement was such that it encouraged involvement and interaction between the researcher and participants.

The researcher memorized the interview guide well in advance in order to be able to concentrate on what the participants were saying during the interview, as well as monitoring the coverage of the scheduled topic. Interviews were conducted in Shona, the participants` home language, using an interview guide. Open-ended questions were asked as they allowed the participants to express themselves freely. Questions were focused to ensure that the interviews gave specific information required to answer the research questions. The researcher encouraged the participants to open up and express their ideas clearly by explaining and elaborating on their ideas and still keeping the interview focused. Participants were allowed to finish what they wanted to say and to proceed at their own rate of thinking and speaking. The researcher probed for more information so that the informed consent process was understood from the participants` perspective.

All interviews were audio-recorded. At the same time, detailed process notes of the interviews were taken in case of technology failure. The tape recorder was placed inconspicuously so as not to unnerve the participants. The tape recorder allowed for a much fuller record than taking notes alone. Both an electrical and battery operated high quality tape recorder and tapes were used to ensure continued data capturing. The notes were clarified and elaborated on as soon as possible after completion of the interviews, mostly within twenty-four hours.

Minimal demographic data, such as age, sex, marital status and level of education, were collected for each participant and these appeared on each interview as participant attributes. Throughout the study, conceptual memos were written daily to help sort out findings during data analysis. The researcher also maintained a daily log in which each day's activities were recorded (Bodgewic, 1999).

The individual audio-recorded data were translated from Shona, which is the local language, into English and then transcribed. For quality control purposes, the researcher randomly selected one in four interviews and monitored the quality of translations through back translations that was performed by another professional translator. Transcripts were entered into NVivo 7 (QSR International, Australia), a qualitative data storage and retrieval programme. Data were then coded using a coding scheme that was devised as coding progressed. Two people – the researcher and an assistant – coded the data independently. The researcher and the assistant then grouped the codes in themes and sub-themes following the general principles of thematic analysis. It was necessary to use two people for this process, in order to reduce operator bias. Participant attributes were used to explore differentials in views between groups of people e.g. the more educated versus the less educated. This was done by means of a narrative passage used to convey study findings where themes and sub themes were presented and illustrated with verbatim quotes.

All the interview guides were coded for confidentiality purposes. No personal identifiers were used. Tapes were kept by the researcher and are to be archived for five years as required by the Medical Research Council policy and kept under lock and key in the researcher's office. Transcribed data were entered on a password protected computer

belonging to the researcher and known by the researcher alone.

CHAPTER 4

4.0 RESULTS

A total of twenty participants were interviewed as planned and the study revealed a few overarching themes.

PARTICIPANT DEMOGRAPHIC DATA

The sample of participants was made up of twenty women who had participated in a vaginal microbicide HIV prevention trial.

Figure 1shows age distribution of the research participants. The ages were between 18 and 40 years. The median age was 23 years. The majority of the participants (6) were between 36 and 40 years of age. They were all urban, literate women.

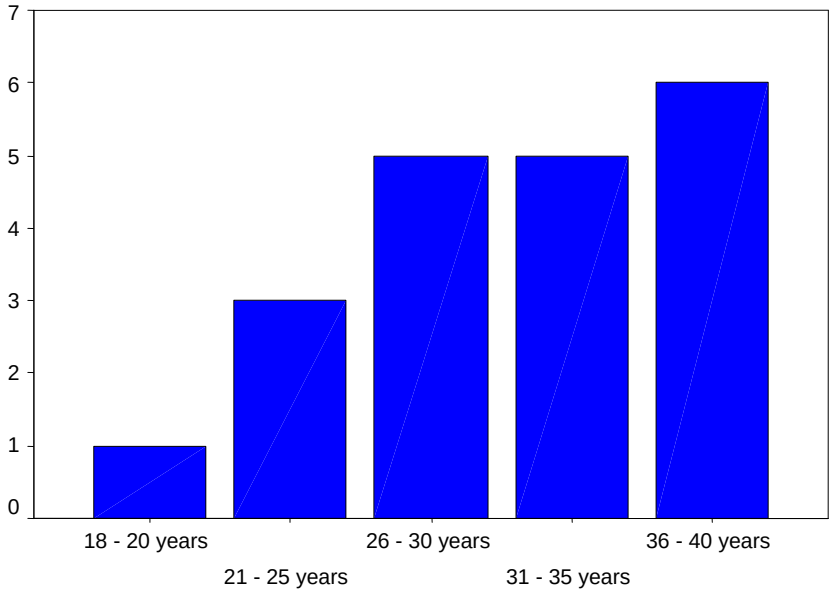

Figure1: Age distribution of participants.

Figure 2 shows the marital status of the research participants. The majority of the participants were married - 75% (15). Only one participant (5%) was widowed, two (10%) separated and 2 (10%) were divorced.

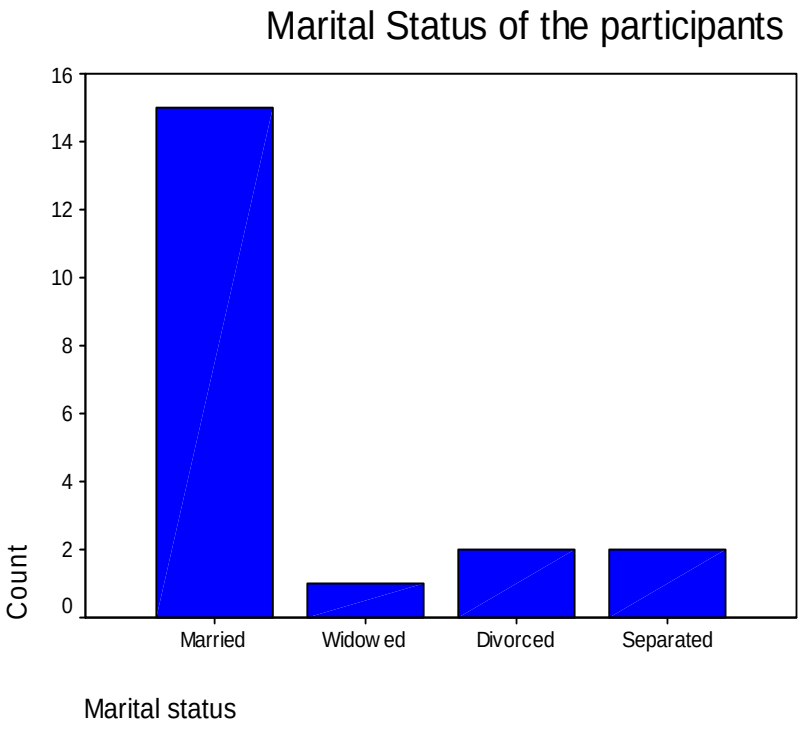

Figure 2: Marital Status

Figure 3 shows the level of education of the research participants. With regard to formal education, all participants attended and completed secondary school, and a futrher 6(30%) went on to tertiary education.

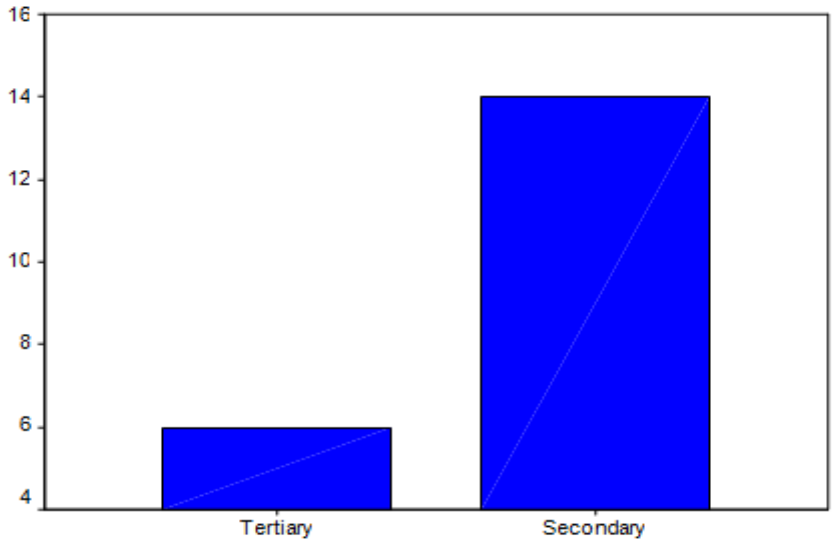

Figure 3: Participants` level of education

Figure 4

It shows the employment status of participants. The majority of the research participants, (15/20) 75%, were not employed at all. Twenty-five percent were self-employed and none of the participants were formally employed.

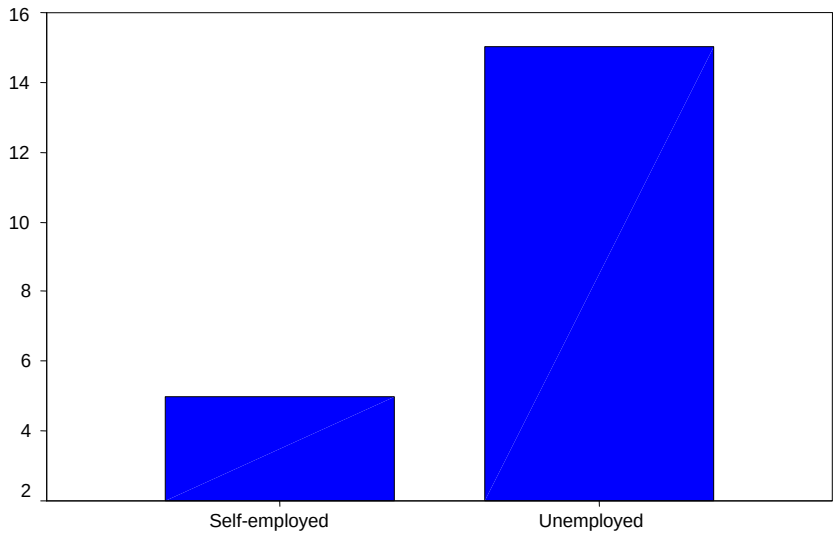

Figure 4: Employment status of participants

THEMATIC ANALYSIS

The following section describes the themes that emerged from the research fully and is illustrated with verbatim quotes from the research participants. The analysis of the twenty interviews yielded seven themes.

1) Key information had been given

Discussions with study participants suggested that they were given key information about the study. Participants could clearly explain the study purpose. '*It was a study about gels that they wanted to see if they can prevent people from HIV infection*' (35 year-old woman). However, six participants wrongly described the purpose of the study, and the research terms that were used, like randomization and blinding, suggesting that they were misinformed or they did not understand some study concepts. For instance, one participant thought the study sought to find a cure for HIV.

> '*I participated in a vaginal microbicides study whereby they were trying to find a gel that can cure someone with the HIV virus'* (38 year-old woman).

It was not clear whether the misinformation was partly due to the inadequacy of the informed consent process, a result of some participants being imperceptive, or both.

The other participant reiterated that;

> `*I did not understand how people can be grouped by a computer and why that was done. Participants should have been allowed to choose the group they felt comfortable with, without being grouped by a computer. If one is assigned to an arm she is not comfortable with, obviously she will not comply with all the research instructions*`(28 year old woman).

All the participants were able to state all the risks that were listed on the informed consent document, including the benefits of joining the study and alternatives that were

available in case they did not want to join the clinical trial. They all knew that it was research and not treatment.

The majority (14/20) however mentioned that they comprehended certain aspects of the study, much later, when they were already study participants and having visited the study site for a number of times.

> *'After reading the informed consent form, I was given the chance to ask questions but the thing is some of the concepts like randomization, blinding and placebo I was hearing for the first time and to understand them the very first day, it was very difficult. I understood them later when I was already in the study after a number of sessions: (31 year old woman).*
>
> `*There is need for repetition of some of these research words meaning. I was hearing these for the first time and understanding them was difficult first time*`(30 year old woman).

Another 28 year old woman needed to be familiar with the study staff first before opening up.

> *'I did not ask questions when I was asked to do so, not because I had grasped every step of the study, but because I was seeing these study staff for the first time, and was not used to them, one needs to get used to study staff and one will have freedom to ask'.*

2) Informed consent process had been rushed

Almost all participants mentioned that the informed consent process had been rushed.

> *'It [consent process] was done in a hasty manner. Before I even got to understand some of the procedures and concepts about the study, I was requested to sign the informed consent [form]'* (38 year-old woman).

Another participant concurred:

> *'It [consent process] was done hurriedly. The time was not adequate. They should have given us the informed consent form, go with it home and read it at our own pace. People are different in grasping some of these terms and research staff needs to be patient. They appeared as if they were in a race to recruit and have their numbers rather than having well-informed participants, I needed to take the paper home before signing it for consultation* (40 year-old woman).

Another participant felt that instead of the rushed informed consent process that they were subjected to, they should have been allowed to take consent forms home and make a joint decision about their participation with their partner or significant others.

> ` *I would have loved to take the consent form home, read it at my own pace, consult with my partner, but I was never given the chance*` (38 year old woman).

Although study information was given in Shona, some participants found it difficult to understand certain terms such as 'randomization' and 'placebo', primarily due to the fact that the informed consent process was rushed.

> *'The time was very short for me, how do you expect someone not medically trained to understand all those terms within such a short period? Mind you, even if you did O level, it does not necessarily mean that you are in a position to learn fast'* (38 year-old woman).

> ` *I expected them to give us more time than what they did before signing. The short time was a really barrier for me to comprehend some of the research concepts*`(35 year old woman).

3) Participants had felt under pressure to sign consent forms

Several participants mentioned that they had signed consent forms without understanding their content as they were under pressure to sign the documents.

'You know mob psychology, the moment I saw other participants standing up to go to the counselor to say they are through with the reading, I also stood up to say I was done before I even understood what was going on' (38 year-old woman).

Another woman remarked:

'I am a slow reader, and when I was given the paper to read, I read it and when other participants started standing up indicating that they had finished reading, I felt ashamed to remain alone sitted in the reading room. Actually I had not finished reading it but I just signed' (35 year-old woman).

Pressure to sign consent forms was sometimes triggered by excitement and anxiety plus the fear of being left out of the study.

'This was my first time, so I was so excited that I did not want to lose the chance' (38 year-old women).

Another participant noted:

'I signed so that I get enrolled in the study, this was my first time to enter a study and I wanted to have the feel of it' (35 year-old woman).

4) Participants found it difficult to ask questions

Although participants mentioned that they were given a chance to ask questions during the informed consent process, some stated that they did not ask questions even when they would have wanted to do so. This was partly because they did not want to appear as if they were slow at comprehending issues, which they felt would probably render them unsuitable for the study.

'*I was given a chance to ask questions. Because I wanted to be in the study, I thought if I ask some questions they will take me as someone who is daft and will not allow me into the study, so I did not ask any questions'* (38 year-old woman).

Discussions suggested that the participants often did not ask questions due to poor rapport-building during the informed consent process.

> *'You need to get used to a person for you to ask some of the questions because some of them will be personal. Trusting someone is very important. That relationship is built over time and that is only when you can ask some questions that are so personal'* (38 year-old woman).

5) Mixed feelings about partner involvement in decision-making

An exploration of partner involvement in decision-making during the consent process produced mixed feelings. Some participants felt that their male partners were not important in influencing their decision whether to participate in the study or not. Several participants stated that they told their husbands about their study participation just for formality sake.

> *'I told my husband just for formality'* (30 year-old woman).

Another woman also proclaimed:

> *'I told my husband when I had already joined the study'* (38 year-old woman).

The women further stated that even if their partners had not allowed them to participate in the study, they would still participate in the study, albeit clandestinely.

> *'…If he had declined my participation, I was still going to continue in the study secretly. My husband goes to work and I have the whole day of doing whatever I want without him knowing'* (38 year-old woman).

These sentiments were echoed by another female participant.

> *'If my husband had refused, I was going to participate secretly. I now know his routine and I don't think I was going to have problems'* (35 year-old woman).

Some participants however felt that their partners' decisions mattered.

'Actually I sought permission first before joining the study. I heard about the study at the community centre and went on to tell my husband about it. If my husband had refused, I was not going to participate in the study' (37 year-old woman).

Another participant concurred and went on to outline the implications of not consulting a partner.

'This research needed one to tell (one's?) sexual partner or husband because if you do it secretly and you happen to be assigned to the condom arm, how will you use the condom? … Again the gel had applicators and to hide those things in the bedroom is very difficult… If my husband had said no, I was still going to participate, but had I been assigned to the condom arm, I was going to refuse. My participation without telling my husband was going to be determined by the arm I was going to fall into' (31 year-old woman).

6) Study procedures and duration not fully explained

Almost all participants felt that actual study procedures were different from what was stated in the consent form and participants were subsequently inconvenienced.

'…A few things happened contrary to what was written on the informed consent, for example, time. One would literally spend the whole day at the site contrary to the time that was on the consent form' (39 year-old woman).

The same participant further remarked,

They [researchers] should actually say "Please give us your whole day, so that we can do whatever we want to do on you when you visit us" not to say we are going to take about 3 hours; it was all lies. You go to the site, spend the whole day. If they had said that at least one would make some arrangements to have children taken from school, cook for them.'

The time issue resulted in frustration and disillusionment, and the majority of participants said they were unwilling to take part in future studies due to the time factor.

> *'In future I will not participate in a similar study due to time spent at a research site. Time is precious; imagine spending the whole day at a research site'* (38 year-old woman).
>
> `*I expected them to be truthful and abide by everything written on the consent form. They did not respect the time they stated they were going to spend with an individual in the consent form. Three hours ended up being the whole day*` (38 year old woman).

7) Study concepts not well understood

The study concepts proved challenging because, due to their technical nature, they do not have direct Shona equivalents and are therefore difficult to translate. Often, a number of sentences and examples are used for one word like randomization, placebo or blinding. In the study consent form, placebo was explained as, "a gel that looks and feels like the same as Buffer gel and PRO 2000 Gel but does not have the medicine found in Buffer gel or PRO 2000, which may prevent HIV infection". Randomization was explained as "If you choose to join the study, you will be put into four groups. The group of the study which you will be in will be chosen by a computer" How the lot was to be done was not fully explained.

When participants did not comprehend technical terms, this sometimes resulted in misconceptions and myths. These in turn resulted in suspicion and mistrust, some of which still lingered after study completion.

> *'I did not understand everything, especially the concept of randomization, how was the computer supposed to do it. To me I thought they were putting their*

relatives and friends in the group that was getting the drug that works, but on the other hand, they prophesied ignorance about who was getting what. So I don't know the truth up to now. I still have doubts about what they said' (32 year-old woman).

`*They said they did not know what I was getting in terms of the actual active drug or the one they said had nothing in it, but how did they make sure that I got the same product each visit, since they said the drugs look the same. Wasn`t there a possibility of getting the active drug during a visit and then getting a placebo the next visit? I did not understand how they made sure I got the same product each and every visit*`(35 year old woman).

`*But how was the study vaginal gel supposed to work when I was using a condom each time I had sex during the study period?*` (38 year old woman).

`*I did not understand the study concepts first time. I finally did after a number of visits at the study site. The repetition of study concepts at each and every visit was quite helpful for me to pick up what was not understood first time*` (36 year old woman).

`*I wondered how the nurses who gave me the consent form to read expected me to comprehend medical language. They should have allowed us to carry those forms home, and then follow us up at home for a number of sessions before making us sign the forms*` (28 year woman).

Other issues

1) All the participants felt that the bus fare reimbursement they were given was not enough considering the time that was spent at the research site. Although the reimbursement was enough *per se* to enable participants to travel to and from the study,

participants felt they needed more change from the reimbursement as an incentive to keep them more spirited in the HIV fight.

2) All participants felt that the food they were given at the site, after spending almost the whole day there, was not enough at all. The portions were too small for adult participants.

> *"I was at the site for more than six hours. I was given a cup of tea and slice of bread only. I requested for some more food and I was told that the consent form I signed was silent about the amount of food I was supposed to be given, so we just give what we can afford"* (40 year-old woman).

3) 8/20 women were concerned that they were never told about the long-term effects of the vaginal gel. Possible long-term effects were not discussed in the informed consent document, causing participants to be afraid to use the gel. This 28 year old woman explained:

> *"They never told us about the long term effects of the gel, neither was it written on the informed consent document. I was lucky to be chosen for the condom arm. Had I been chosen for the gel group by the computer,, I doubt very much whether I was going to use the product because they never mentioned anything about the long term side effects. I imagined a scenario where I would use the gel during research with no problems at all and then develop long term side effects when the researcher is gone. Where was I to get help from when researcher had gone? If the gel had no long term side effects, this should have been mentioned and included on the informed consent document"*(28 year old woman).
>
> *`I did not see anywhere written about long term side effects of the gel. Up to now I don`t know whether the gel had long term side effects or not. I was in the gel*

group and each time I have a gynaecological problem, I associate it with the gel` (29 year old woman).

`*If I were to be asked to participate again in such studies, I am going to demand for literature on the drugs they will be giving me, especially the long term effects. I expected the informed consent form to have such information, unfortunately there was none*` (40 year old woman).

Summary of Findings

Participants felt that key information had been given during the informed consent process though some comprehended the concepts only later on after repeated visits. Many participants signed the consent form before comprehension of research concepts as they felt pressured to join the study. For many, this was their first encounter with a research study and they wanted to experience how it feels to be in a research study. They generally found it difficult to ask questions due to lack of comprehension, and some even conceded that they feared that asking questions might have barred them from being recruited.

Voluntariness was questioned since majority of the participants felt that the process of obtaining informed consent during the study was rushed with some citing a need for more time to make a decision regarding participation. There was a lot of pressure from within the participant group and mixed feelings existed on male partner involvement in the decision-making process.

CHAPTER 5

5.0 DISCUSSION

This study was conducted to explore research participants` perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study in Harare, Zimbabwe. The study was done on healthy women a year after participating in an HIV prevention study. This study is the first in Zimbabwe to examine the informed consent process in healthy individuals in an HIV pre-exposure prevention trial.

Formal assessments of how the informed consent process is being carried out in research studies should be considered a routine component of clinical research and such formal assessments may be a tool whereby research participants can reaffirm their consent. Every process always has aspects that can be improved. Sugarman et.al .,(2005) argues that it is imperative to routinely monitor the informed consent process with a view to improving its execution in order to ensure protection of study participants. Little empirical research has been done on how the theory of informed consent is applied in the daily practice of clinical trials (Lesko, Dermatis, Penman, & Holland, 1989) and how research participants perceive the quality of informed consent (Verheggen, Nieman, & Jonkers, 2005).

Socio-demographic profile

All the participants had reached secondary school level, suggesting that the literacy level in this community should be compatible with an acceptable appreciation of ethical and legal issues. This high literacy level tends to concur with the UNDP 2011 report, that Zimbabwe has an adult literacy level of 97%. This level increased from 63% at Independence and has overtaken Tunisia to become the country with the highest literacy level in Africa.

To go along with provision of basic information written on an informed consent form, as stated above, the researcher should make sure that there is understanding of the written information by the participant, the research participant is competent enough to make an informed decision and that the participant does so voluntarily, with no undue influence to participate in the research study.

Key information was given

In this study, it appeared that key information had been provided to the participants. This finding is similar to that of Oliver et.al (1995), who found that out of 100 cancer patients, 68 felt to have been given the right amount of information, 14 felt the information was insufficient, and only five felt they had received too much information. Participants showed a good understanding of the study purpose, risks involved and participated voluntarily with no coercion, although the majority of them felt that the time given to consider participation prior to enrollment was not sufficient. This is contrary to a study on participants` perception of the informed consent process for neuro-oncology clinical trials done in Toronto, Canada, that was carried out by Knifed, Lipsman, Mason & Bernstein (2008) who found that most participants were happy with the time they were given to consider participation prior to formal enrollment.

Contrary to other studies, this study revealed that participants did have a good understanding of the purpose of the clinical trial they had participated in (Forty, 1999). In this study, although some participants mentioned that they did not understand the study terms on the first day, 70% of the participants said they did develop a better understanding of the concepts after several meetings with the researchers. This shows us that with repetition of study concepts at every single contact with research

participants study concepts are understood better and this remind us of the fact that informed consent is supposed to be a process and not an event. This agrees with what Fitzgerald et. al. (2002) noted in their study on informed consent. They stated that as number of meetings between researcher and participant increases, comprehension also increases. They found the standard consent process of a single meeting to be insufficient. This implies that at each and every meeting with the research participant, study concepts should be repeated again and again. Every time a participant and a researcher meet, this should be seen as an opportunity for information disclosure, making it a continuous process. Informed consent should be considered as a continuous process rather than an event or a mere formality. Participants are supposed to be questioned on their comprehension of research information not only during recruitment into the study, but throughout the entire study.

Informed consent process was rushed

The rushed process mentioned by participants can indicate lack of time by those who were conducting the consent process. All ethical guidelines suggest that counseling prior to informed consent is of paramount importance and should be done in a private place that enables the participant to open up. At the same time the participant should be provided with accurate information. In this study, the environment was not conducive and enabling, since most of the participants mentioned that it was done in a hurried way. Some participants did not even read through the informed consent document. When obtaining informed consent from research participants, the manner and context in which research information is conveyed is of paramount importance, as is the research information itself. When information is presented in a hasty fashion, as reported by research participants in this study, it definitely affects participants` ability to make an informed choice.

Patience is required on the part of the researcher as this will allow participants to consult and deliberate over whether they should participate or not. Privacy is of paramount importance during the informed consent process. In this study, participants mentioned that they could see each other while reading the informed consent document and therefore knew when others had finished reading. This kind of scenario forced some participants, who are not fast readers, to also announce that they had finished reading the informed consent document, even though they had not, in order not to be outdone by the others. Again, after recruitment of a participant, the recruited participant had a chance to talk and mingle with participants waiting to be recruited. They had a chance to ask and tell each other what was being asked during the assessment check list in order to qualify for recruitment. Since the assessment checklist has to be objective, recruited participants should not be allowed to mix with those waiting to be recruited; this should be a closely guarded process.

The research setting should be private enough to allow participants to enter and emerge without observers learning the outcome of his or her decision about participation (Woodsong & Karim, 2005). This is contrary to what happened during this study. Participants got to see each other to the extent of telling each other some of the questions on the comprehension checklist. It is important to provide privacy during the informed consent process.

Participants had felt under pressure to sign consent forms

In this study, participants had felt under pressure to sign the consent forms because they wanted to know how it feels to participate in research since it was their first opportunity to do so. This implies that pressure to participate in research can come from within the participant or it can come from the researcher. Neither is ideal for informed

consent in research. Participants might also have expected possible economic gains and status associated with participation in a trial since they had never experienced it before. These research opportunities may be seen simply as “better than nothing”, like breadcrumbs, which may provide some immediate relief of hunger (Greco, 2000).

Participants found it difficult to ask questions

When information is given hurriedly, little time is allowed for deliberation by the research participant, resulting in curtailed opportunities to ask questions. This may have been the reason why participants in this study had found it difficult to ask questions.

Factors that limit women’s free choice were also identified. Some of them were socio-cultural and gender based issues, as was reflected through the women`s behavior, like not asking questions even if they did not understood some of the study concepts. Women are socialized to be submissive, to be humble and to be acceptant of their husbands or partners. This submissiveness and humbleness, at times, is extended to medical and research personnel, whom they think are not supposed to be questioned. All these factors indicate that signing the informed consent form by a research participant is not a sure sign that he or she understood the proposed research (Pace et.al.2005; Shapiro & Meslin, 2001; Upvall & Hashwani, 2001).

In some cultures women are not supposed to sign any paper, even if they are adults, and can comprehend well, without the consent of the husband. This study took place in an urban setting, and in urban settings, cultural norms are not strictly adhered to as much as they are in a rural setting. However, no matter how people get educated and mingle with other people of different cultures, some people do not change their culture.

This is the reason why there was a mixed feeling among women about the issue of getting permission to participate from their partners.

Long-term side effects of the vaginal gel information were not available on the consent and they did not ask any question concerning this, but only to mention it during the study. Unavailability of information on long-term side effects of the vaginal gel made some of the participants afraid to use the vaginal gel. The fact that long term side effects were not included in the consent form made them suspicious that the long term side-effects of the study products might be serious. When such a scenario prevails, there is a possibility of not using study products by research participants. Non-use of study products is one of the major issues why studies fail. A good example is the FEM-PrEP study whereby poor adherence has been blamed for the failure of the truvada® tablets to protect women against the acquisition of HIV infection. The FEM-PrEP team said that, "despite substantial counseling efforts, inadequate adherence may have undermined the trial's ability to assess the efficacy of truvada® for pre-exposure HIV prophylaxis".

Mixed feelings about partner involvement in decision-making

Participants had mixed feelings about partner involvement in the informed consent process. Vaginal microbicides are female-controlled HIV prevention methods and can be used without the male partner's knowledge, cooperation or consent, although disclosure is always encouraged. In a study that was done in Zimbabwe, both urban and rural men were willing to use microbicides with girlfriends and prostitutes, but not with wives. They said they would be angry if they found out that their wives were using such products without asking for permission first. Most men said that they would be supportive of their wives' participation in microbicide trials, if they are asked for

permission first and if proper medical care and insurance cover are provided. They supported the women since they were the users of the product. The same study found that most women were not interested in hiding microbicide use from their husbands, because they considered it too risky (Coggins, 1998). In this study, although some women wanted to inform their husbands, they confided that even if their husband had refused to give consent, they were still going to participate in the trial secretly.

Some studies have been conducted on covert use of vaginal microbicides. In a study that was conducted in Uganda, women were shown a variety of available vaginal products (sponge, film, tablets, foams, gel and female condoms) and they preferred those they could use without telling their partner and could not be seen by their partner. Some women believed it was their duty to tell their regular partners as it would be very difficult to hide the gel applicators without being seen by their husbands. Some women mentioned that if their husbands had prohibited them from participating in the study, they were not going to participate irrespective of them wanting to participate. These mixed feelings indicate that individuals are unique and calls for thorough assessments to find out what a research participant prefers.

Study procedures and duration not fully explained

This is one of the barriers to effective informed consent and can be indicative of the lack of researcher time to make sure participants understand trial information, failure of the informed consent document to give detailed descriptions, or inability of participants to comprehend or recall this information. Presumably, if researchers spent more time with participants, they would pay more attention to the description of the procedures involved, including how long the procedures will take to be completed at each trial visit.

Providing research participants with adequate and easy to understand information remains a prerequisite of the informed consent process. Every study related procedure, including different procedures to be done at different visits, should be clearly explained to the research participants. In this study, though the informed consent form had all the information on study procedures and duration of every visit, participants did not develop an adequate understanding of the procedures and duration they were to spend at the research site. Perhaps it was not fully explained, as researchers might be hesitant to draw attention to the long hours expected from participants as this might be a disincentive to enrolment. Alternatively, it had been explained, but participants did not understand or could not recall it. This again shows the importance of continuous information giving, to the participants at each and every visit.

Study Concepts not well understood

Understanding is one of the elements of informed consent process. A number of studies have documented problems associated with trying to explain fully the basic research concepts in developing countries where the scientific paradigm is not widely known and at times not accepted (Mitchel, Nakamanya, Kamali & Whitworth, 2002). This is consistent with the findings of this study where participants failed to understand why and how allocation of trial medicines could be done by the computer. Scientific words do not exist in the local vocabulary, so much so that one has to give an explanation of these scientific concepts. These explanations can actually make the consent document very long and tedious to read by the research participant.

Empirical data indicate that research participants display different levels of understanding research information about procedures, risks, probable benefits and research concepts (Bernhardt, 1996). For example, in a study of participants in cancer

clinical trial, 90% participants indicated that they were well informed about the research information. However, 75% of them did not recognize nonstandard and unproven treatment, and approximately 25% did not appreciate that the primary purpose of the trial was to benefit future patients and that the benefits to them personally were uncertain (Joffe, 2001). The researcher should bear in mind that there are so many reasons for such limited understanding, ranging from distraction, being nervous, and low level of education. Some participants will be attentive and calm and these obviously will understand better. In this study participants mentioned that all they wanted was to be enrolled and this might have contributed to not understanding some study concepts since their minds were focused on being recruited. They even mentioned that they did not complete reading the consent form.

Possible ways of improving the informed consent process

Use of audiovisual material

Barriers to understanding can actually be addressed if detected well before recruitment and debate continues about how best to do so. Some researchers have suggested that the use of audiovisual material, such as graphics and videos, might assist participants in understanding study concepts, but the evidence for this remains weak (Ryan, Prictor, McLaughlin & Hill, 2008)

Need To Take the Informed Consent Home

In this study, no participant reported to have taken or requested to take the informed consent document home. It might be that this option was not offered to them. This does however also reflect the fact that participants had not been informed about their right to take the informed consent home and explore the package at their convenience and independently seek assistance. When participants have a signed copy of the informed

consent form, they have the opportunity to revisit it when they reach home or whenever they are uncertain about certain elements of the study. This could have assisted them in understanding the trial procedures and duration of visits better, as these were clearly stated in the consent form.

In a study in The Gambia on participant perception of the informed consent process, where mothers were to sign informed consent forms for their children to participate in a vaccine trial, there was greater understanding of the research information when the information sheet was left at the home before consent was sought. This allowed the participant to consult family members although the mother was the key decision maker. Participants in this study, the mothers, recommended home visits by the researchers to allow more private discussions in the comfort of their homes, (Leach, Hilton, Greenwood, Manneh, Dibbah, Wilkins & Mulholland, 1999). This indicates that allowing time for family discussion, if it is agreeable with the research participant, is favourable.

In another study that was done in Canada on participants` perceptions of the informed consent process for neuro-oncology clinical trials, they reported a significant improvement in participants` understanding following a review of the consent form at home. Participants had a chance to read through the consent form at their own pace and would seek help independently with no interference at all. They had a chance to consult their own family practitioners who had nothing to do with the research.

Taking the consent form home can however also have problems, especially if the participant consults someone who is not well versed with research terms one who has negative feelings towards research. Participants need education on who to consult if they have to take the form home.

Conclusion

Participants` concerns necessitate the reassessment of informed consent processes in a developing world setting. Researchers should also take note of the communitarian theory that emphasizes the importance of community and common good. This way they will receive all the community support they require in order for the research to be successful. At the same time individual autonomy should not be forgotten.

CHAPTER 6

6.1 CONCLUSION AND RECOMENDATION

This study set out to explore research participants` perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study in Zimbabwe. It was conducted a year after participants participated in clinical trial and it was surprising that most of the participants vividly remembered what transpired during the informed consent process.

Obtaining genuine, informed consent in research has proven to be a very difficult exercise, even if one is dealing with literate participants, as shown in this study. Individual participant assessments and patience in all aspects of the informed consent process can measurably facilitate genuine informed consent.

In this study, participants did not feel free to open up before they got used to the research team. As time went on, when participants were already part of the study, they got used to the research team and then started opening up. Participants confided that they needed to be given more time to make a decision and the majority mentioned that they understood some of the concepts when they had already been in the study for some time. This implies that it is even more difficult to ensure informed consent in cross-sectional studies where participants are seen only once.

Although the sample size was small, the researcher was able to gain good insight into the experience of research participants during the informed consent process because of the qualitative nature of the study. However, further research utilizing quantitative methodology may be required to elucidate relationships between demographic data

such as age, level of education, duration in study, employment and comprehension of the informed consent information.

Based on the research results, the following recommendations can be made:

- There is need for provision of adequate time between the presentation of research information to participants and signing the informed consent. Participants should be allowed to have a wider consultation before joining research, provided the sources are knowledgeable.
- Adequate staff should be recruited in order to cope with the pressure of having to see more research participants as the study progresses, so that study teams stick to the documented times on the consent form.
- The informed consent process should include information on long term side effects of the study product in cases of clinical trials. If there are no long-term effects or if these are not yet known, this should be clearly stated.
- A similar study can be done using a larger sample size and drawing participants from different studies so that they can be compared and other variables included like previous research experience, staff experience and professional qualifications.
- Staff from different studies should share information regarding specific strategies for presenting research information to potential research participants.
- There is need to do the same study on ex-cross-sectional study participants to determine how best to approach the informed consent process in such studies.
- Exploration of the informed consent process is to be done in larger and varied populations, especially the minority groups (Jeckel, Carrese,& Pearlsman, 1995; Carrese, &Rhodes, 1995).

It is everyone`s responsibility involved in research, from researchers to the communities, to continue to evolve and improve strategies to enable genuine informed consent. There is need for researchers and ethicists to come up with acceptable standards for assessing the quality of informed consent. The informed consent process is useful as it allows research participants to take an active role in decision-making as well as bring relevant and helpful information to the research team. It is the duty of every researcher to design ideal strategies for the informed consent process for every community and possibly, even for every individual. They should bear in mind that every community and individual is unique.

6.2 Study Limitations

Limitations that are inherent to all studies that use qualitative methodology were encountered. The findings of this study are not easily transferable to another population because of the small sample size that was interviewed and the non-probability random sampling method that was used (Katzenellenbogen, Joubert & Karim, 1997). Furthermore, analysis of qualitative data is dependent on the researcher's skills to interpret the information elicited from the interviews and this is inescapable influenced by the researcher`s own subjective views (Katzenellenbogen, Joubert & Karim, 1997). To avoid this limitation, researchers are advised to use triangulation research method (De Vos, 2002). In this study, limited triangulation was included by means of document review. The use of more expansive triangulation methods was however logistically impossible since the research work was carried out on part time basis.

The research participants were drawn from a single previous study. It is therefore uncertain whether findings from this study will be similar in other studies that had different research personnel and different design. Although the researcher has no reason to

believe that the results would be different, it remains to be investigated. The fact that the study used qualitative methodology and used open-ended questions makes it possible that certain themes were overlooked. In this study, ideas were explored freely as they were brought up by research participants. It is however possible that some important questions were not posed. Although the researcher is of the opinion that saturation was achieved, a larger sample size might have changed the findings or could have allowed new themes to arise. The study results might also have been different if the study had taken place whilst the study was still in progress.

Despite the limitations mentioned above, the study managed to answer all the research questions. This was possible since the findings are based on the research participants` own narrative and not on numerical data, which could not have captured the full essence of their experience of the informed consent process. (Katzenellenbogen, Joubert & Karim, 1997). Qualitative research is subjective in the sense that it requires the researcher to make judgments about a research participant`s level of understanding. At the same time, it requires more extensive staff training and greater amount of researcher time and skill than qualitative research

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Appendix (A)

INFORMED CONSENT FORM

Exploring research participants` perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study in Zimbabwe: A case study

Principal Investigator - Sithembile Ruzariro

Phone Number - 0772 838 984

What you should know about this research:

- I give you this consent form so that you may read about the purpose, risks, and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help future patients.
- I cannot promise that this research study will benefit you.
- You have the right to refuse to take part, or agree to take part now and change your mind later.
- Whatever you decide, it will not affect your regular care.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your participation is voluntary.

PURPOSE

You are being requested to participate in a research study about participants` perceptions and expectations of the informed consent process. The main

purpose of the study is to explore research participants` perceptions/views and expectations of the informed consent process in a clinical trial that you participated in. This will help in making future consent processes better and friendlier to research participants. You have been selected as a possible participant in this study because you participated in the vaginal microbicide clinical and we think that since you have gone through the consent process before participating you can tell us about your experiences of the process. Your participation in this study will be of great help. We will be recruiting twenty participants in all.

PROCEDURES AND DURATION

If you decide to participate in the study, the following procedures will happen to you:

1) I will schedule to meet you in one of the private rooms at the Medical Research Council of Zimbabwe for an one-to-one interview which will take about an hour. The interview will be tape-recorded. The tape-recording will be written down at a later stage. I will also be taking notes while we are talking.

2) I will ask you some personal details like your age, marital status, level of education, employment etc.

3) I will ask you about the informed consent process that led you to taking part in the clinical trial that you participated in.

4) I will ask your views on the informed consent process and what you think could have been done to make the process easier or friendlier for you.

RISKS AND DISCOMFORTS

No harm is intended and we do not expect you to experience any harm by participating in the study, although answering personal questions may make you feel a little uncomfortable.

BENEFITS AND/OR REIMBURSEMENT

We cannot and do not promise that you will receive any direct benefits from this study. The study might benefit research participants to come since researchers will be in a position to use information from this study to make the informed consent process friendlier. You will be paid the amount of money that you used as bus fare to come for this important interview. The research results will allow researchers to make the informed consent process friendlier.

CONFIDENTIALITY

The information you will give us will be kept confidential. No one outside of the study, including your family, will know the results of your interview. All records will be locked away or kept on a password-protected computer. Any information that is obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. No name will appear on any paper. You will only be identified by a code. All tapes and documents of the interview will be kept locked in a filing cabinet at the Medical Research Council, in one of the offices, and only the researcher will have access to them. The documents will be kept for a period of three years according to the Medical Research Council policy . No name will be used in any reports or publications resulting from this study.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your future relations with the pre-exposure HIV prevention research team, associated clinics or with the Medical Research Council. However, we would very much like your participation in the informed consent process study. If you decide to participate, you are free to stop participation at any time without penalty. For questions about this study contact:

Sithembile Ruzario

Medical Research Council of Zimbabwe

Cnr. Josiah Tongogara / Mazowe Street

Tel: 0772 838 984

For questions about your rights as a research participant, contact:

The National Ethics Coordinator

Medical Research Council of Zimbabwe.

National Institute of Health Research, Cnr Josiah Tongogara/Mazowe St.

Phone :263 4 791792/ 263 4 791193, Cell:263 77 2 433 166

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

AUTHORIZATION

You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

The date you sign this document to enrol in this study, that is, today's date **MUST** fall between the dates indicated on the approval stamp affixed to each page. These dates indicate that this form is valid when you enrol in the study but do not reflect how long you may participate in the study. Each page of this Informed Consent Form is stamped to indicate the form's validity as approved by the Medical Research Council of Zimbabwe.

---------- ----------

Name of Research Participant (please print) Date

---------- ---------- AM

Signature of Participant Time PM

---------- ----------

Signature of Witness Name and signature of the Researcher

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant, or if you feel that you been treated unfairly

and would like to talk to someone other than the researcher, please feel free to contact the Medical Research Council of Zimbabwe on telephone 791792 or 791193.

STATEMENT OF CONSENT TO BE AUDIO TAPED

I understand that audio recordings will be taken during the study. (Mark either "Yes" or "No")

- I agree to **being audio recorded** **Yes** ☐

No ☐

_____ _____

Name of Research Participant *(please print)* Date

_____ _____

Signature of Participant Time

_____ _____

Name of Staff Obtaining Consent *(please print)* Signature

Date----------

Appendix B

GWARO RETENDERANO RINE RUZIVO - SHONA VERSION.

NHAMGA NYAYA

Muri kukumbirwa kuti mupinde muchirongwa chirikuongorora gwaro retenderano, matsananguririrwo arinoitwa kuvanhu vanoda kupinda muchirinwa cheongororo. Ongororo iyi iri kuitwa pamadzimai akapinda muongororo yekushanda kwemishonga inopfekwa munzira yababa inonzi BufferGel / Pro2000/5 Gel pakudvivirira hutachiona hweHIV kumadzimai.

KUPINDA KWENYU MUCHIRONGWA ISARUDZO YENYU

Gwaro retanderano iri rinopa umbowo hwuri pamusoro pechirongwa chamuchakurukurirwa nazvacho. Kana manzwisisa nezvechirongwa uyezve kana mabvuma kupinda moongororo, muchkumbiwa kusaina zita renyu kana kuisa X pagwaro retenderano iri. Muchapiwa rimwe gwaro kuti muende naro kumba. Musati mabvuma kupinda muongororo iyi, zvaka kosha kuti muzive zviri kutevera izvi:

- Kupinda kwenyu muongororo iyi isarudzo yenyu
- Munogona kusarudza kusapinda muongororo iyo kana kuti hamuchada matove pakati pekubvunzwa
- Kana masarudza kusapinda muongororo iyi, munogona kupinda mune dzimwe ongororo kana mada

CHINANGWA CHEONGORORO IYI

Chinangwa chikuru cheongororo iyi ndechekuda kuziva kuti pamakapinda muchirongwa chapfuura chemishonga yekupfeka kunzira yababa kudzivirira HIV kumadzimai, makanzwisisa here maererano nechirongwa chacho uye nzira dzakasevenzeswa kukutsananguirai maererano nechirongwa dzakabatsira here kuti munyatse kunzwisisa. Tiri kuda kuti mitiudze zvamunofunga kuti tingaite muzviringwa zvakafanana naichochi kuti nzwisiso ireruke. Tinoda kuziva zvakare zvamakashoora uyo zvamakafarira namaitirwo egwaro retenderano kutimupinde muchirongwa.

CHIRONGWA

Kana masarudza kupinda muchirongwa munongobvunzwa mibvunzo chete maererano nemapindiro amakaita muongororo yapfuura yatambotaura nezvayo. Munhu achakubvunza achange achinyora pasi mhinduro dzenyu kuita kuti asakanganwe uye manzwi enyu achange achitapwa namasasai (tape recorder). Izvi kuitira kuti muongorori agonzwa mazwi enyu nyangwe imi musipo kuitira kuti abate zvose zvamataura. Bhuku raachanyora uye netape yarekodwa zvichakiyirwa pakabata kuita kuti ani naani zvake asaverenga kana kuridza. Pachapera ongororo iyi izvi zvose zvichapiswa. Kubvunzwa uku kuchatora maminitsi anokwana kana kuti pfuurei makumi matatu

NJODZI

Hapana njodzi inotarisirwa kuti ingangoita kana mapinda muongororo iyi kunze kwekungotadza kugadzikana pamunenge muchibvunzwa imwe mibvunzo.

KUBHADHARWA

Muchadzorerwa mari yenyu yebhazi yamasevenzesa kuti musvike pano. Muripo wacho madhora maviri chete.

KANA MUNE MUBVUNZO KANA ZVINETSWA

Kana maita mubvunzo mave kumba maererano neongororo iyi muno ona Sithembile Ruzario ipo pahofsi pano kana kuridza runhare pa 077 2 838 984.

PEJI YOKUSAINA

Kana maverenga gwaro retenderano iri uye kana manzwisisa umbowo huri mariri, sainai zita renyu kana kuisa X

....

Zita remunhu apinda muchirongwa (print) Sainecha Date

....

Zita remushandi weongororo (print) Sainecha Date

....

Zita reachapa uchapupu (print) Sainecha Date

or 791193.

BVUMIRANO YEKUTORWA MAZWI

Ndinozwisisa kuti ndichatorwa mazwi pandinenge ndichipindura zviri maererano netsvagurudzo iyi

- Ndinobvuma kutorwa mazwi **Hongu** ☐

Kwete ☐

_____ _____

Zita remunhu abvuma kutorwa mazwi *(nyora zvinoonekwa)* Date

_____ _____

Sainecha Time Date

_____ _____

Zita remushandi wechirongwa *(please print)* Sainecha

Date----------

Telephone: 791792/791193
Telefax: (263) - 4 - 790715
E-mail: mrcz@mrczimshared.co.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CY 573
Causeway
Harare

MRCZ APPROVAL LETTER

Ref: **MRCZ/B/190**

30 March, 2011

Sithembile Ruzario
15 NorthCliffe
Cnr J Tongogara / Mazowe Street
Harare
Zimbabwe

RE: EXPLORING RESEARCH PARTICIPANTS' PERCEPTIONS AND COMPREHENSION OF THE INFORMED CONSENT PROCESS IN A PRE-EXPOSURE HIV PREVENTION STUDY IN ZIMBABWE: A CASE STUDY

Thank you for the above titled proposal that you submitted to the Medical Research Council of Zimbabwe (MRCZ) for review. Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study. This is based on the following documents that were submitted to the MRCZ for review:

a) Study proposal.
b) English and Shona ICF
c) In-depth Interview Guide

- **APPROVAL NUMBER : MRCZ/B/190**

This number should be used on all correspondence, consent forms and documents as appropriate.

- **APPROVAL DATE : 30 March, 2011**
- **EXPIRATION DATE : 29 March, 2012**
- **TYPE OF MEETING : EXPEDITED REVIEW**

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted one month before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices.
- **MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices.
- **QUESTIONS**: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrczimshared.co.zw.
- **Other**
- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

R Gutsire

.....

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

Student Number : 209541454

11 April 2011

Faculty of Development and Social Sciences UNIVERSITY OF KWAZULU-NATAL
King Edward Avenue, Scottsville, Pietermaritzburg
Private Bag X01, Scottsville, 3209, South Africa
Telephone (033) 260-5699
Fax (033) 260-6327
Email: jacobsen@ukzn.ac.za

Ms S Ruzariro
Medical Research Council of Zimbabwe
PO Box CY 573
Harare
ZIMBABWE

Dear Ms Ruzariro

Re: ETHICAL APPLICATION: Exploring research participants' perceptions and comprehension of the informed consent process in a pre-exposure HIV prevention study in Zimbabwe: A case study

This is to advise that the Faculty has approved your request for ethical clearance, and that you may proceed with your research project.

This permission is subject to review by the University Research Committee, who will be sending you a letter in due course.

Please let me know **if you change your title** before submitting your dissertation for examination, as your new title will also have to be submitted to the Faculty Higher Degrees Committee for approval.

Yours sincerely

MRS BE JACOBSEN
HIGHER DEGREES OFFICE

Appendix - (E)

Telephone: 791792/791193
Telefax: (263) - 4 - 790715
E-mail: mrcz@mrczimshared.co.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CY 573
Causeway
Harare

14 July, 2010

Prof.Z.M.Chirenje
UZ-UCSF
15 Phillips Avenue
Belgravia
Harare

RE: REQUEST FOR PERMISSION TO CARRY OUT A RESEARCH ON RESEARCH PARTICIPANTS` PERCEPTIONS AND COMPREHENSION OF THE INFORMED CONSENT PROCESS IN A VAGINAL MICROBICIDE CLINICAL TRIAL.

My name is Sithembile Ruzario and I am a Research Officer with the Medical Research Council of Zimbabwe (MRCZ). I do hereby request for permission to carry out a study on informed consent perception and comprehension on research participants in one of your studies. Currently I am a student at the University of Pretoria and University of KwaZulu-Natal (Collaborative) doing a Masters Degree in Health Research Ethics. In partial fulfilment of the requirements for the masters degree, I am required to carry out a study of my choice in line with health research ethics. I wish to carry out the study on research participants in one of your studies, **A phase 11B safety and effectiveness study of Tenofovir 1% gel, tenofovir disoproxil fumarate tablet and emtricitabine/Tenofovir Disoproxil Fumarate tablet for the prevention of HIV infection in women (MTN-003) version 1.0, dated 22 May 2008.**

The research topic is: **To explore research participants` perceptions and comprehension of the informed consent process in a vaginal microbicide clinical trial in Zimbabwe: A case study.** Find attached the proposal

Yours Faithfully

Sithembile Ruzario

nyaradzo mgodi (nmmgodi@uz-ucsf.co.zw) Search Mail Search Web Hi, Sithem

INBOX | CONTACTS | CALENDAR | SEARCH: nyaradzo... | RE: MSc PROPOSAL

Compose Delete Move Spam Actions

Inbox (185)
Conversations
Drafts
Sent
Spam
Trash
FOLDERS
MESSENGER
APPLICATIONS

RE: MSc PROPOSAL from Dr. Nyaradzo Mgodi to you 11 Oct 2010

Hi Sithe

Sorry I was out of office. I discussed your issue with Prof Chirenje and he still says we cannot use the current VOICE participants. As for the ex-035 ones, our problem was how to reimburse them. Do you have a solution to that? If this is OK with you then we can help you contact the women.

Nyaradzo

From: Sithembile Ruzario [mailto:sithembileruzario@yahoo.co.uk]
Sent: Wednesday, October 06, 2010 3:48 PM
To: nmmgodi@uz-ucsf.co.zw
Subject: RE: MSc PROPOSAL

Dear Dr. Mgodi

I am sorry to disturb you. I am doing a follow-up on my proposal. I have got a deadline and now afraid that i won't be able to make it.

Thank you

Sithembile

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This message has been scanned for viruses and dangerous content by MailScanner, and is believed to be clean.

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