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A mini-dissertation submitted in partial fulfilment of the requirements for the degree of Master of Public Health (Social and Behavioural Sciences), School of Public Health and Family Medicine, University of Cape Town.
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PART O: PREAMBLE

Plagiarism Declaration

I, Yolanda Gomba (GMBYOL001) hereby declare that the work on which this
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Thesis Abstract

Experiences and perceptions of participants and staff involved in HIV research in Gugulethu, South Africa

It is important to understand the experiences and perceptions of HIV research from the perspectives of persons who have either participated in or worked on HIV research in low-resource settings. Obtaining such information is important because research in low-resource settings presents several ethical challenges that result in the vulnerability of participants due to factors such as low literacy levels, high rates of food insecurity and unemployment. Conducting research on the aforementioned can help researchers to design studies that mitigate some of the ethical challenges associated with conducting HIV research in low-resource communities. This dissertation adds on to existing literature on the experiences and perceptions of HIV research participants and staff involved in HIV research in low-resource settings.

This dissertation is divided into three parts. Part A (Research protocol) discusses the importance of evaluating research participants’ experiences and perceptions of HIV studies conducted in low-resource settings. The section also outlines the purpose of the study, research questions, methodology, ethical considerations, rigour, reimbursement and dissemination of results. Part B (Literature review) presents an overview of the literature on HIV research in low-resource settings, with a specific focus on: ethical challenges, factors that contribute to participants’ decisions to participate in HIV research and findings from other studies which examined experiences and perceptions of HIV research in low-resource settings. The section also identifies gaps in the existing literature. Part C (Journal article) presents the findings of the study and the implications thereof.
Acknowledgements

I would like to thank my supervisors Ms. Zara Trafford and Assoc. Prof Chris Colvin. Thank you for your guidance, support, patience and kindness throughout this entire process.

I would also like to thank Mr. Phumzile Nywagi for his support in the data collection of this project.

I am grateful to all participants of this project for trusting me with their experiences.

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PART A: RESEARCH PROTOCOL

Title: Experiences and perceptions of participants and staff involved in HIV research in Gugulethu, South Africa

Background

Human immunodeficiency virus (HIV) research provides important context-specific information which can be utilised to improve quality of life, particularly for people living with HIV and AIDS (PLWHA) (1). With that said, conducting such research presents ethical challenges for PLWHA and other vulnerable populations, such as sex workers, men who have sex with men, illegal drug users and young women (2). Over the past two decades, global inequalities have heightened concerns about poor communities’ risks of exploitation by HIV researchers, particularly because HIV is more prevalent in marginalised and oppressed communities (3). Research participants in low-resource settings are often vulnerable to exploitation owing to factors such as low literacy levels and economic vulnerability (4). HIV research harms for participants may also include being stigmatized and discriminated by their communities because of their participation (5-7). Examining research processes such as informed consent, recruitment and compensation of participants is one way of studying how HIV research is conducted on these vulnerable populations.

Informed consent is a critical component of research ethics. The informed consent process is crucial to participants' understanding of their rights in research (4). Evaluation of HIV research processes such as informed consent in low-resource settings is important. This is especially important when research is conducted on populations with low literacy and low education.
levels. Low literacy and low education levels need to be considered in informed consent because they might mean that informed consent, that is usually presented in text, could be misunderstood by participants (8-9). A study conducted by Reed et al revealed that participants were unaware of their right to withdraw from the study after signing the informed consent form (10), this is one example of informed consent not being fully understood by participants. Knowledge of participants' research experiences can help researchers to understand participants' experiences and perceptions of the informed consent process. Khalil et al, cited in Mfutso-Bengo et al, concur that, if researchers have knowledge of study participants’ experiences of research, informed consent processes can be improved (11). A recent community feedback study by Folayan et al revealed that some communities have reported unethical consent practices by researchers, such as: not discussing the risks associated with participation and participants not being told about their right to withdraw from participating (12). Such stories can only be revealed if participants’ experiences of research are investigated.

Factors such as: reimbursement, increased access to health care through research participation, and coercion during participant recruitment processes are known to play a role in determining whether or not one agrees or refuses to take part in an HIV research study. Literature has identified financial reimbursement, undue inducement and power dynamics such as those in clinical settings as some of the reasons why people agreed to take part in HIV research (6,10,13,). More often than not, offering money to research participants from poor settings can put them in positions whereby they have no meaningful reason to participate, other than to be remunerated for their participation (14-16). A review by Evans et al revealed that some participants took part in research studies because they believed they would gain
access to better health care due to their participation (17). Therapeutic misconception occurs when participants take part in research for treatment and medication instead of generating data (11,18). Therefore, more studies need to be carried out in order to examine why people participate in HIV research, and this can be done by investigating the research experiences of HIV positive research participants.

Barnett et al and Tarimo et al posit that knowledge of participants’ experiences of HIV research in Low-Middle Income Countries (LMICs) is crucial, given that the majority of infections occur in these settings (19-20). The World Health Organization (WHO) reports that in 2015, 36.7 million people were living with HIV, globally, with 25.5 million being based in Africa. 1 in every 25 people is living with HIV in Sub-Saharan Africa, and it is the leading cause of death in that region. South Africa has the largest number of HIV infected people (21). In 2015, 11.2% (7 million) of the national population was living with HIV, representing almost 18% of HIV infections globally (22) and as a result 5.5% of South Africa’s research between the years 1996-2006 was HIV research, compared to less than 2% in European countries and 0.5% in Japan (21).

Despite the increase in HIV research studies in South Africa, participants’ experiences and perceptions thereof are often disregarded in research designs (23). It is therefore important to consider how best to conduct HIV research in low-resource settings. For example, by examining the research experiences of HIV-positive participants from settings where PLWHA are widely stigmatised, low education levels exist, and pressure to find cure or prevention is high.
Researchers can minimize the exploitation of vulnerable populations such as poor communities during research. This could be achieved by considering feedback from PLWHA who have participated in HIV studies when deciding on processes such as obtaining informed consent, recruitment and reimbursement for new studies. Ssali et al and Evans et al also agree that, because of the ethical issues associated with HIV research in poor communities, it is necessary to explore the experiences of those who have agreed to participate in HIV studies (17,24).

**Statement of the Problem**

Literature emphasizes the importance of knowing and understanding the research experiences of participants. Review processes in business and government sectors contribute to the improvement of services and products. Therefore, studies conducted in low-resource settings should also include feedback processes so as to identify ways to mitigate challenges that come with conducting research in these settings, thus improving the ethical conduct of research, quality of data that is produced and participants’ research experiences.

**Purpose of the study**

Participants’ research experiences can inform ethical guidelines and practices, particularly in low-resource settings. This study sought to investigate the research experiences and perceptions of HIV positive participants and HIV research staff in a low-resource setting with a high prevalence of HIV. The findings add on to existing literature, with a particular focus on how research processes such as recruitment, retention and informed consent can be improved in low-resource settings. Gugulethu is a peri-urban area, situated in the City of
Cape Town, within the Western Cape province of South Africa. It has a high unemployment rate and one of the highest HIV prevalence rates in South Africa thereby making it a suitable context for the study.

**Research Question**

**Main Question**

How do HIV research participants and HIV research staff in Gugulethu South Africa, experience and perceive research processes?

**Sub Questions**

- How does the way recruitment is conducted influence a participant’s decision to take part in HIV research?
- What impact does reimbursement have on participation in HIV research studies?
- What are the participants’ experiences of the informed consent process?
- What role do HIV-positive participants perceive they play in HIV research?
- What is the impact of HIV research participation on the participants’ experiences and perceptions of HIV?

**Methodology**

**Study Setting**

The study was conducted in Gugulethu Township in Cape Town. Gugulethu has a population of 98,468, of which 99% are Black Africans. 39.84% of Gugulethu’s working-age population is unemployed, and 71% of households have a monthly income of less than R3200 or less (25). Gugulethu is situated in the Klipfontein district in Cape Town. Klipfontein district has one of the
highest prevalence of HIV in the country. The prevalence of HIV in the district in 2010 was around 45% (26). As a result of the high HIV prevalence, numerous HIV research centres operate in Gugulethu. The setting is chosen due to its high HIV burden, low socioeconomic status, and prevalence of HIV research studies therein. As an employee at one of the research sites in Gugulethu, it will be relatively easy for the primary researcher to access the study context through already existing networks. However, the study will be conducted at a different research site to evade bias and mitigate factors influenced by familiarity.

**Study Design**

The researcher will adopt the interpretive qualitative approach which is suitable for studies aimed at exploring how individuals experience and interact with their social world. The process of research will be inductive in nature (27). In-depth interviews conducted by the primary researcher will be the main source of data collection. The interviews will be audio-recorded, transcribed and then analysed thematically. Qualitative studies allow one to explore people’s experiences better than quantitative studies. Therefore, without a qualitative lens, it is difficult to understand how people experience health and illness and how they encounter health care systems and health research (28).

**Sampling and Recruitment**

The study population will be made up of research participants and research staff from one of the HIV research sites in Gugulethu. The aim is to recruit participants from one research site, who have participated in multiple studies and have already consented to participate in future studies. All participants will be purposively selected, with the aim of recruiting up to 25
participants, 20 of them being people who are participating or have participated in an HIV research study in the past year and 5 of them having worked as research staff for studies which involve interaction with HIV positive participants.

i. **Research participants:** The 20 research participants will include men and women. 50% of the sample will be between the ages of 18 and 30, and the other 50% will be aged between 30 and 45. The aforementioned disparities are aimed at maximising variations in the participants’ profiles. All participants are supposed to be HIV positive. The researcher believes that this common trait will allow her to obtain richer data from such participants in terms of their personal experiences of HIV research. Research participants are also required to have participated in an HIV study in Gugulethu within the last year. I will approach the Manager(s) of the targeted research site to inform them about the intended study and sought permission to recruit participants from the site from the Principal Investigator(s). I will ensure that the participants had already agreed to take part in future HIV research studies. These could be cross-sectional studies, clinical trials or cohort studies. Participants will be targeted for recruitment when they come to the research site for study visits. Each of them will be briefly informed about the study verbally, in a private room, to ensure confidentiality and privacy. The information provided will include the purpose of the study, risks of participating in the study, benefits of participating in the study and the inclusion criteria, the right to refuse participation and the right to withdraw from the study at any point. If a participant is interested and if they meet the researchers’ inclusion criteria, they will be scheduled for an appointment during which the primary researcher will conduct an in-depth interview. At least two days before the scheduled interview time I will contact them to remind them of the scheduled interview.
ii. **Research staff:** I am also interested in collecting data from research staff; therefore, I will request that the site manager refer me to staff that has been involved in recruiting or interviewing HIV positive participants. I will inform the selected research staff about the study and set up appointments for interviews with those who are interested in participating. Their interviews are aimed at giving the interviewer valuable insight into the research topic from a different perspective. The research staff should be 18 years or older, and currently working on a study that includes HIV positive participants.

During recruitment, I will emphasize that participation or non-participation in this study does not affect participation in current or another research study and all information shared with me will be kept private and confidential.

**Data Collection**

The in-depth semi-structured interviews will be conducted either in the local language (IsiXhosa) or English, depending on interviewees’ preference(s). The primary researcher will be guided by a semi-structured interview guide (Appendices C and D). The interview guide will be written in English then translated into isiXhosa. Interviews will be conducted on a one-on-one basis.

Participants will only be interviewed once, for periods no longer than 30 minutes. The interviews will be conducted in private rooms at the research site. Informed consent forms will be administered in either IsiXhosa or English. Participants will allowed to read the informed
consent forms or the forms will be read to them in a language of their choice, between IsiXhosa and English. Participants will be presented with the opportunity to ask questions before the interview sessions. If they still agree to participate thereafter, they will sign consent forms, together with the primary researcher. Illiterate participants’ informed consent processes will be conducted in the presence of a 3rd party witness to ensure that consent is truly informed.

All interviews will be audio-recorded with a tape recorder with participants’ consent. Recording the interviews minimizes disruptions during the dialogue process thus ensuring good quality research. In addition, the researcher will compile some notes after each interview is concluded in order to minimize the loss of information.

**Data Analysis**

The audio recordings will either be translated from isiXhosa to English and/or transcribed in English. Transcripts and interview notes will then be analysed using the inductive thematic analysis approach. Inductive thematic analysis includes: (1) Familiarising yourself with the data collected, (2) Producing initial codes from the data, without a pre-existing coding frame, (3) Sorting out identifying codes into potential themes, (4) Reviewing themes that have been identified from the data, (5) Defining what each theme is about, and (6) Final analysis of themes (23). The researcher will aim to identify themes relating to informed consent, recruitment, compensation, barriers and facilitators for research participation. The coding of data will be the responsibility of the primary researcher; however, the primary researcher will involve supervisors in an iterative process of reviewing findings derived from data. Analysis will
also involve the search for variations in age, gender and type of studies participated in. It is worth noting that the analysis will be conducted simultaneously with data collection.

**Data Management**

All interview audio recordings will be transferred to a password protected computer and deleted from the recorder within 24 hours of recording. No names will be written in the interview notes and the saved recordings will not be labelled using participants’ names. Rather, a study ID will be assigned to each participant. Only I and the research supervisors will have access to data collected in this study, and we are all trained on research confidentiality and privacy issues. Copies of raw data (audio recordings, transcripts and notes) will also be saved in a password protected folder on Dropbox for backup. All raw data will be completely erased from the backup storage after one year from the data collection process. The primary researcher’s journal which will be used as a reflexivity tool during the research process will be kept securely in a locked cabinet which will only be accessible to the researcher.

**Ethics**

**Ethics Approval**

Ethics approval for the study will be obtained from the University of Cape Town’s Faculty of Health Sciences’ Human Research Ethics Committee. Permission to recruit participants and conduct interviews at the research site will be requested from the Site manager and Principal Investigator(s) at the study site.
Written Informed Consent

Informed consent will be administered in the participants’ preferred language, between IsiXhosa or English. During recruitment, potential participants will be informed of their right to decline participation in the study. They will also be informed about the purpose of the study, the freedom to exit the study at any point, potential risk and benefits of participation, and confidentiality and privacy issues. For those who agree to participate in the study, the informed consent process will be repeated before the commencement of the interview sessions. Both, the researcher and participants will sign final consents forms for participation. At all points of the consent process, participants will be given the opportunity to ask questions regarding the process. A copy of the informed consent is attached in the appendices (Appendices A and B).

Privacy and Confidentiality

The primary researcher will recruit the participants individually. Privacy and Confidentiality during recruitment will be ensured by conducting the process in a private room. It is worth noting that, the primary researcher is trained on research confidentiality and privacy. Only the primary researcher and supervisors will have access to the data.

Potential Risks

The potential risk of loss of confidentiality and privacy due to study procedures, such as the participant being recognized by another participant during recruitment, could occur. Study participants also face the risk of experiencing distress associated with reporting information relating to their HIV statuses. Even though the interviews are generally low risk, should a
participant require any psychological assistance, they will be referred to a social worker at the nearest health facility. Study participants will be informed of these risks as part of the consent process and they will be given the option to refuse to answer any questions that they are uncomfortable with answering.

Potential Benefits

There might not be any direct benefits for the participant. Information obtained from participants’ involvement in our study could contribute to the literature on participants’ experiences in settings such as Gugulethu Township. The study could also inform how HIV research will be conducted in the future for the benefit of participants. Therefore, participants may benefit in this way if they participate in future studies.

Rigour

The following strategies will be employed to strengthen the rigour of the study (29).

- **Data Triangulation (Credibility):** Data will be collected from different sources: (1) male and female participants, and (2) research study participants and recruiters. This will help the investigator to gain a deeper understanding of the topic under study.

- **External Audit (Dependability):** As part of the requirement process, the primary investigator will work with a supervisor and a co-supervisor, who will act as external auditors, examining both, the research process and findings produced.
• **Thick descriptions (Transferability):** Findings and the study setting will be described in great detail in to provide adequate information which can apply when conducting research in similar settings.

• **Audit trail (Confirmability):** A record of all interview transcripts, interview notes, reflexive notes (investigator journal), study proposal and analysis process will be kept for other investigators to understand/track the process that led to the findings of the study.

• **Reflexivity (Confirmability):** According to Ulin et al, for researchers to practice reflexivity in their research, they need to observe and record their roles throughout the research process; this will reveal any assumptions or biases that might impact the different stages of the research process (30). I will be reflexive by acknowledging that I, as the interviewer, am also a researcher, therefore in asking participants to relay their research experiences, my perspectives as a researcher may influence my interpretation thereof. My position as an isiXhosa speaking, black female in higher education, enrolled with a prestigious institution such as the University of Cape Town affects the research process. On one hand, I may be considered an insider because I will be operating in a community of Xhosa speaking black people. On the other hand, I might also be considered an outsider by male participants because I am female. I could also be considered an outsider because I am a researcher. In line with the practice of reflexivity, I will document my interactions with the study participants and the collated data in a journal, throughout the research process. The journal will be safely stored in a locked cabinet and only researchers involved in this study will be able to access it. This will be done to minimize the loss of confidentiality.
Reimbursement

Participants will be reimbursed for their transport costs, up to the amount of R20.00. A grocery voucher to the value of R80.00 will be given to each of them as a token of appreciation. This is in line with most research studies conducted in the area.

Study Period and Time Frame

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Dissemination of Results

The results of the study will be submitted in partial fulfilment of the requirements for the Master of Public Health Degree at the University of Cape Town. They will also be disseminated to participants and the site of recruitment for the study in the form of a pamphlet written in the local language, IsiXhosa.
References


5. Nyblade L, Singh S, Ashburn K, Brady L, Olenja J. “Once I begin to participate, people will run away from me”: Understanding stigma as a barrier to HIV vaccine research participation in Kenya. Vaccine. 2011;29(48):8924-8


26. Western Cape Department of Health. Provincial Strategic Plan on HIV/AIDS, STIs and TB


PART B: LITERATURE REVIEW

Introduction

South Africa has the highest number of people living with HIV in the world. 7.5 million South Africans were living with HIV in the year 2018 (1). Advancement of what we know about HIV/AIDS because of health research has led to great improvements in the quality of life of those living with HIV/AIDS (2). Health research needs to involve human participants and because of its involvement of human participants, there will always be ethical concerns when it is conducted. There is increased concern about the ethical conduct of HIV research in low-resource settings. This has been caused by the increase of HIV/AIDS studies conducted in low-resource settings and how this increase interacts with global inequalities. In addition, the effects of such interactions on people who participate in HIV/AIDS research are of great concern (3).

People in low-resource settings are particularly at a higher risk of experiencing coercion and exploitation during research participation. Furthermore, they are more likely to misunderstand research objectives due to factors such as, low literacy levels and low education levels if research objectives are presented in methods that do not accommodate these levels (4-6). Studying how HIV/AIDS research is conducted is important. For example, examining ethical conduct in HIV research is especially important if research is being conducted on vulnerable populations, such as PLWHA in low-resource settings (7). When researching on the conduct of HIV/AIDS research in low-resource settings, it is important to not only engage researchers but participants in the communities under study as well. However, collecting information on participants’ experiences and perceptions of research is often excluded from research design and activities (8).
Objectives of the literature review

The objective of this literature review is to situate the issues raised in the rest of this manuscript within the context of existing evidence. As such, this review will present an overview of the discourse on HIV/AIDS research in low-resource settings in terms of ethical challenges, factors that contribute to participants’ decisions to participate in HIV/AIDS research in low-resource settings and the experiences and perceptions of HIV/AIDS research from those who participate in such studies. Although the study described in this manuscript was conducted in Gugulethu, South Africa, the literature reviewed includes evidence from other low-resource settings and vulnerable populations in different contexts. This was done to compare or contrast literature review themes with those that emerged from the study. This section also presents a brief overview of the burden of disease of HIV/AIDS in South Africa. Lastly, it outlines some of the gaps identified during the literature review process.

Literature search strategy

Online literature (including peer-reviewed articles, editorials, book reviews etc.) was located using the following platforms: PubMed, EBSCOhost and Google Scholar. Reference lists on selected articles were also used for further referral and to find specific titles online. Statistical data and other reports were retrieved from Statistics South Africa (Stats SA), UNAIDS and Avert.org websites.

Search phrases used included the following terms: HIV research in Africa; HIV research in poor settings; Recruitment in HIV research; HIV research in low-income countries; Why do people
participate in HIV research?; Facilitators of participating in HIV research; Barriers to participating in HIV research; Therapeutic misconception in HIV research; Coercion in HIV research; Experiences of HIV research; Compensation in HIV research; HIV/AIDS global statistics.

**Inclusion and exclusion criteria**

The search was restricted to literature written in the English language. Literature published between 1997 and 2019 was prioritised. Studies conducted in low-resource settings were also prioritised due to their relevance to the subject matter. Studies from high-resource settings which were considered included analysis of factors relating to marginalized groups (to investigate issues around vulnerability).

**Summary and Interpretation of literature**

**HIV/AIDS research in low-income settings**

HIV is a global health issue. In 2017, 36.9 million people were living with HIV, globally. Low- and middle-income countries are home to the majority of people living with HIV. 66% of people living with HIV in the world are estimated to be living in Sub-Saharan Africa (9). South Africa has the largest number of people living with HIV in the world; by 2018, 7.5 million South Africans were living with HIV (1). Advancements in medicines and medical technologies need to continue if researchers are to control diseases in the settings in which they cause the most harm (10). The past two decades have seen an increase in HIV/AIDS research in low-resource settings. This increase has mainly been caused by the heavy burden of disease in these settings which gives researchers access to large populations to conduct HIV/AIDS research on (3).
Challenges of conducting HIV/AIDS research in low-income settings

Conducting any form of research comes with ethical concerns and worries about the potential for unintended harm or ethical misconduct. This is especially true for research conducted on vulnerable populations, such as PLWHA in low-resource settings, although such participants provide the most valuable knowledge on HIV/AIDS issues (7,11). The vulnerability of people living in low-resource settings stems from factors such as low literacy levels, low socioeconomic statuses and food insecurities. These factors increase the risk of undue inducement and coercion to participate in research, whether intentionally or not (7,12-13). Lack of research infrastructure, lack of research development and poor health care systems may also lead to the vulnerability of populations in low-resource settings (5,12,). Public health facilities in some low-resource settings do not have the infrastructure needed to conduct clinical trials, such as institutional review boards (IRBs)(5). In many low-resource settings, clinicians are discouraged from becoming researchers because research positions and educational opportunities are not aligned, this contributes to the shortage of trained researchers in these areas. Clinicians are also discouraged from becoming researchers because non-research clinicians acquire more prestige than research clinicians, this also contributes to the shortage of trained researchers in these settings. The shortage of trained researchers is a challenge in conducting research in these settings because it can lead to the poor conduct of clinical trials. (5,14).

Most people living with HIV are from poor and marginalized communities which are often associated with additional challenges such as lack of access to information and good quality
education (7). Research has revealed that informed consent in low-resource settings is a concern due to the reality that low literacy levels can affect participants’ understanding of informed consent because it is often presented in written documentation (12-13,15). Illiteracy is a limiting factor when it comes to the voluntariness of written informed consent, and participants may take part in trials without understanding the risks and benefits of participation (5) or lack understanding of basic concepts central to research if these concepts are presented to participants only in text form(7,14). Additionally, miscommunication or misunderstanding can arise from the translation of consent-related documents from one language to another (14-15). Informed consent designed in developed countries then applied to developing contexts whose cultures are different, has also raised concerns regarding the cultural appropriateness of the language used for informed consent processes (11-12,16). However, some studies have found ways to adapt the universal requirement of the informed consent process to suit their local standards of literacy and different cultures. One example of this is the obtention of participants’ thumbprints instead of their signatures (15). Mabunda suggests that studies may need to recruit local leaders as mediators (12).

Power differences between researchers and research participants can also have an impact on the voluntariness of participants in low-resource settings (16). Factors such as differences in socioeconomic status and education levels between investigators and participants determine power relations in research. Researchers tend to have higher educational levels and socioeconomic status than participants; hence participants’ reluctance is less likely in such instances (13). The influence by the researcher’s position of power is further intensified when
the researcher is also the health care provider or if they work in the health care setting where recruitment into the research study occurs (12,13,17).

“Undue inducement” can occur when individuals are offered goods or services for participating in a study that could lead them to make poor judgements informed solely or mainly by the desire to acquire these goods or services as opposed to scrutinising their roles in research, leading them to take serious risks (6). Financial reimbursements provided to participants during research have raised ethical concerns, especially when participants are poor and marginalized persons from low-resource settings (6,18). Financially reimbursing those in low-resource settings raises ethical concerns including the concern that the risk of undue inducement into research participation is intensified when the offer is given to those who truly need the reimbursement (18). Studies in poor settings have been found to have a higher risk of coercing participation through financial reimbursement, compared to studies conducted in higher-income settings (11).

However, some literature argues against undue inducement being an ethical concern in research. This literature argues that participants should be reimbursed and that reimbursing participants for their time should not raise any ethical concern the same way that paying employees for their time doesn’t (19-21). It argues that researchers should not be worried that providing reimbursement to participants would cause them to take risks as that is the norm in research, that participants always must weigh the risks associated with participation against the benefits of the research (19-20). Instead, research studies should not have risks that are so excessive that participation in them, whether for reimbursement or not, is an ethical concern. If there are no excessive risks associated with participating in a study, as there should not be,
the influence that reimbursement has on the decision to participate or not, should not be of any concern (19-20). This literature argues that if participants are making poor judgements to participate in research, then the problem is not the reimbursement but the processes that should be providing the participants with adequate information about the study and the risks involved such as the informed consent process and the recruitment methods (19-21).

Therapeutic misconception is a misconception that occurs when research participants misunderstand the meaning and purpose of research, believing that the purpose of the study is to benefit the individual by providing them with therapeutic services such as health care (15,22-23). Research participants may believe the purpose of research studies is the same as the mandates of health care facilities. The provision of better health care services by researchers is believed to have an impact on people’s decisions to participate in research, or act to act research facilitators (24-25), however not all participation for health care is a result of therapeutic misconception. Therapeutic misconception is an ethical concern, particularly in low-resource settings because they are more likely to have conditions that drive therapeutic misconception (22). Research concepts are often difficult to comprehend, people in low-resource settings may be likely to misunderstand research concepts due to low-education levels as these concepts are often presented in methods that require reading. As a result, they might misunderstand the research objectives. Furthermore, exposure to poor public health services may also contribute to the occurrence of therapeutic misconception.

Many research organisations which are based in developed countries that conduct research in developing countries obtain ethics approval from their own institutional ethics board (IRB).
However, ethics approval also needs to be obtained from the research ethics committees in developing countries (5). Sometimes, the research ethics committees in developing countries are burdened with issues that make the task of overseeing ethical conduct difficult. Issues such as conflicts of interests amongst committee members are a cause for concern, especially if (1) they are researchers themselves, having to review studies that are run by colleagues; (2) if they are academics they may not necessarily represent the poor because of differences in socioeconomic status or educational levels; and (3) the committees themselves might be under-resourced and lack expertise to judge research procedures and ethical conduct (5,12,16,26). These issues open up opportunities for ethical misconduct to occur and this could result in the exploitation and harm of participants in these settings as research is not closely monitored.

**Factors that influence participation in HIV research studies in low-income countries**

*Facilitators of HIV research participation in LMIC*

Poor public health care systems and expensive private health care in developing countries have led to people willing to accept alternative forms of accessing health care (13). People may choose to participate in research for the health services provided even when they understand that health care provision is not the objective of the research. Participation in research to gain access to better health care services, whether deliberate or not, is more prevalent in countries where public health care systems are overcrowded and under-resourced, and private health care is too expensive for most of the population (22).
Literature indicates that people have participated in research to access health care services such as free treatment (22-23), free testing and free health checks (27). This is especially true for people who have been recruited by health care providers or in health care settings. The recruitment of people by health care providers or in health care settings, coupled with the promise of better health care services can encourage one to participate in research (23). Access to health information has also been shown to influence one’s decision to participate in research (27). Altruism and the offer of incentives are also facilitators of HIV research participation (28-30). Studies in low-resource settings show that studies offering reimbursements encourage people to participate. Reimbursement may include but are not limited to: money, food vouchers, groceries etc, (28-30).

**Barriers to HIV research participation in LMIC/poor settings**

Literature shows there are various reasons why people do not participate in HIV research studies. Some studies have shown that factors such as: perceived personal harm due to study procedures (31-32) and fear of loss of confidentiality (23,28-29) by participating in research inform potential; participants’ decisions on whether to take part not to take part in research. Reasons which are cited by those who have declined research participation can serve as evidence of how research studies need to be designed with the local research setting in mind. Lack of such considerations deters people from getting involved in research (13). Reasons for non-participation include the failure of researchers to involve community members in the recruitment process (30-31) and lack of cultural sensitivity during research procedures (31). These reasons reveal that research designs that are suited for high-resource contexts are not appropriate for low-resource settings. Lack of or perceived absence of benefits such as monetary reimbursements and improvement to health care facilities, researchers’ failure to
explain the aims and objectives of the study (31) and previous bad research experience have also been identified as barriers to research participation (23,31).

Experiences and Perceptions of HIV research

Dissemination
Dissemination of study results in low-resource settings is a rare occurrence. However, participants are starting to make their expectation of dissemination of study results to them known to researchers. More and more research participants from low-resource settings are requesting for compulsory dissemination of study results to participants, after the completion of studies (24,33). Dissemination of results to participants is valued by participants as it involves them in research processes beyond data collection. It is also useful for researchers as it allows them to validate their data with participants (33).

Stigma
Participants who are PLWHA may experience stigma from their communities as a result of their participation in HIV studies (7,29). In a study conducted by (23), participants suggested that researchers include other diseases in HIV research studies to reduce the stigma associated with participating in HIV research. The stigma is multiplied when participants are not only labelled by their HIV status but by other indicators such as sexual orientation (28). Therefore, participation in HIV studies on gender minorities or some key populations such as sex workers or men who have sex with men is further stigmatized.
Recruitment

Various studies relating to the research experiences of participants revealed that their experiences of recruitment are often linked with health care factors. Health care is a driver for research participation (25, 34-). The recruitment process being so closely linked to health care has caused serious ethical concerns in some studies, such as a study conducted by Reynolds et al (34), in which some participants were not even aware that they had been part of a trial because of its close link to a health care facility.

Reimbursement

Financial reimbursement often perceived as a necessity, attract research participants. Some participants will go as far as taking risks if they feel the financial reimbursement is worth it. In a study conducted by Slomka et al, in an underserved community in the United States of America (USA), participants stated they would participate in research despite any risks. All they want is to acquire financial reimbursements (35). Studies in African settings have also shown that positive experiences reported by participants are sometimes linked to financial reimbursements (26) and lack of reimbursements for participants discouraged enrolment (23).

Informed consent process

Participants’ experiences of the informed consent process confirm that informed consent is not always truly voluntary and is sometimes influenced by the promise of things that people are desperate for, such as access to proper health care (24). Ongoing informed consent has been highlighted as important (25), as well as developing relationships by engaging the
community before informed consent, to minimize misunderstanding of informed consent (11,34). This is especially true for studies whereby recruitment processes involve approaching vulnerable persons, patients, the poor or illiterate.

**Conclusions**

In conclusion, several gaps have been identified in the literature concerning the conduct of HIV research and the experiences of those involved in HIV research in low-income settings.

The literature reviewed revealed that ethical issues in HIV research focus on the ethical conduct of clinical trials. There is a dearth of literature on ethical conduct or issues associated with different forms of research such as qualitative studies and observational studies. Much of the focus has been on clinical trials, perhaps because they generally come with the highest risks compared to other research studies. What is worrying is that they are usually linked to several concerns about research ethics and human rights violations, compared to other forms of research studies. Much of the literature on factors that motivate research participation is mostly from clinical trials. This could also be because of the higher risks associated with clinical trials. Researchers could be more interested in understanding why PLWHA are willing to participate in studies with higher risk as opposed to examining participation in low-risk observational studies or qualitative studies.

Since the early 2000s, there has been a decline in the number of studies examining ethical conduct in HIV research in low-income countries. This could be because HIV research in low-income countries increased more rapidly between the 1990s-2000s. It was during the same
period that the prevalence of HIV/AIDS increased rapidly in low-income countries thus inviting international attention to the area of study. Debates on the ethics of conducting transnational research also came about. This study contributes to existing research by discussing the experiences and perceptions of those involved in HIV/AIDS research in a low-resource setting.
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PART C: JOURNAL ARTICLE

Title: Experiences and perceptions of participants and staff involved in HIV research in Gugulethu, South Africa

Abstract

Background: HIV research in low-resource settings presents major ethical challenges. People in these contexts tend to be more vulnerable due to low literacy levels and high rates of food insecurity and unemployment. These factors can make research participants in low-resource settings more susceptible to exploitation, coercion and misunderstanding of research concepts when participating in HIV studies. Research participants are uniquely positioned to relay first-hand experiences of participation in studies, but their perceptions of research processes are rarely investigated. Research staff holds valuable information about how research is conducted and understood. This paper reports on feedback from participants and recruiters for HIV research in the low-resource area of Gugulethu in South Africa.

Methods: Individual in-depth interviews were conducted with 20 people who had previously participated in HIV studies in Gugulethu and surrounding areas, and 5 who had worked on HIV related studies in the said context. Interviews were conducted by the primary researcher in isiXhosa. The data were fully transcribed and analysed thematically.

Results: Key factors described as motivating participation in HIV research were: seeking better health care, an opportunity to engage with other HIV-positive people, and the possibility of financial reimbursements. Findings show that many participants still misunderstood the objective of research. Participants believed they might obtain some health or social benefits from
participation in the study. None of them had ever received feedback on the results of the studies they had participated in or worked in.

**Conclusions:** Conducting research in low-resource settings requires awareness of how research processes affect the voluntariness of participation. Researchers may need to adapt research processes for the context in which research is conducted to minimize ethical concerns and improve the quality of results. One way to address this is for researchers to involve participants and communities in the design and conduct of research in low-resource settings. The lack of dissemination of study results and the absence of channels for participants and communities to provide feedback about research are missed opportunities, particularly for people from low-resource settings.

**Keywords:** Informed consent, HIV, HIV research ethics, South Africa, Dissemination, Therapeutic misconception.
Background

The Southern and Eastern regions of the African continent have the highest HIV prevalence rates in the world. South Africa has the highest number of people living with HIV (PLWHIV) in the world, with an estimated 7.5 million South Africans being HIV-positive (1). Communities with high HIV prevalence are often ‘go to’ areas for researchers conducting HIV studies because the burden of disease in such areas provides large populations on which to conduct HIV research (2). Conducting research in communities that have high HIV prevalence rates also makes sense as these communities are the ones that stand to benefit more from changes implemented as a result of HIV related research (3).

Research in low-resource settings has raised ethical concerns because people from such settings experience vulnerability due to factors such as poverty, illiteracy, low socio-economic statuses and poor health care services (2-9). Low-resource areas and marginalized communities are more likely to be exploited or coerced and have a higher risk of misunderstanding research concepts when participating in research studies (5,10-11). HIV-positive participants who take part in HIV research can become vulnerable owing to challenges such as stigma and discrimination. Participating in HIV research could intensify these challenges by increasing their visibility to others (8,12-13).

Exploring experiences and perceptions of research from those involved in research in low-resource settings is important (8,14). Lack of knowledge about how participants experience research is a disadvantage to both, participants and researchers. Understanding participants’ experiences could reveal how research is conducted, especially on vulnerable populations such as those in low-
resource settings. Exploring how research is conducted could help those who are responsible for designing, conducting and monitoring research to better understand how studies are perceived by participants. It could also help researchers truly reflect on how they conduct research in low-resource communities, to gain a better understanding of the impact of research on individuals and communities. Knowledge of research participants’ experiences helps researchers to understand how to design research studies that are suitable for the contexts they conduct research in.

Few studies have explored participants’ experiences and perceptions of research (15) and the collection of participants’ experiences and perceptions of the research they participate in is usually not included in research designs (16). This study sought to add to the literature on how HIV-positive participants and research staff in low-resource, high HIV prevalence settings experienced and perceive their involvement in HIV/AIDS-related studies. More importantly, the study contributes to literature based on first-hand experiences. The study could help inform research design processes for future studies in similar settings. It is also hoped that the experiences captured in this study will encourage researchers to consider participants’ research experiences more often.

Methods

Study Design

This study aimed to investigate the experiences and perceptions of HIV-positive people who participate in HIV research and recruiters for HIV research studies in a low-resource community with a high HIV prevalence in which many research studies are conducted. The study was
conducted using a qualitative approach. Data was collected using a semi-structured interview guide with open-ended questions, to encourage participants to describe their experiences and perceptions of HIV research studies in-depth.

**Research setting**

All interviews were conducted in Gugulethu, a peri-urban area outside Cape Town, in the Western Cape province of South Africa. Gugulethu is part of the Kilpfontein district in Western Cape. The prevalence of HIV in this district is one of the highest in the Western Cape, reported around 45% in 2010 (17). As a result of the high HIV prevalence, multiple HIV research organisations operate in this area. The population of Gugulethu is approximately 98 468; it is predominately isiXhosa speaking and more than 71% of the population live on less than R3200 per month (18). Conducting this type of study is important, as it allows one to identify and examine the different vulnerabilities experienced by research participants living in areas where education levels are low, HIV prevalence is high and socioeconomic statuses are low.

**Sampling and Recruitment**

A gatekeeper in HIV research in Gugulethu was used to purposively and conveniently sample participants. Purposive and convenience sampling methods were used because the criteria for recruiting participants was very specific, one of the criteria being that a participant needed to be HIV-positive. The gatekeeper recruited from HIV networks and support groups that he had previously worked with. Eventually, snowball sampling occurred as participants referred other
people who they knew as living with HIV. Before informed consent was conducted by the primary researcher, she asked the participant to confirm their HIV status.

Convenience sampling was used to recruit the first recruiter and snowball sampling for the rest of the recruiters as they were referred by another recruiter who had already been interviewed.

**Research participants**

Two groups of participants were interviewed. The first group consisted of participants who had participated in research and were included in this study for their experiences as ‘research participants’. The second group was made up of recruiters who were research staff members responsible for recruiting participants for HIV research. In the pages that follow, I will refer to research participants as ‘participants’ and research recruiters as ‘recruiters’.

In total, the sample included 25 people (20 participants and 5 recruiters). All ‘participants’ had participated in at least one HIV research study in the 12 months prior to their interview. 50% (n=10) of these participants were female and the other 50% were male. All research participants were 18 years old or older, HIV-positive and lived in the Gugulethu area. Participants had previously participated in different kinds of studies including qualitative, cross-sectional and cohort research.
Research recruiters were also interviewed. Recruiters who were interviewed in this study were currently or previously (12 months prior interview) employed in a research study in Gugulethu. The studies they worked on included clinical trials, cohort studies, cross-sectional studies and qualitative studies.
Table 2: Biological sex of recruiter and the number of studies they had worked on

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<th>PID</th>
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Data collection

25 semi-structured in-depth interviews were conducted by the primary researcher. Interviews were conducted using a semi-structured interview guide that contained open-ended questions. Open-ended questions allowed for the primary researcher to probe and for participants to elaborate on their responses. Interviews were conducted in isiXhosa and the primary researcher is fluent in isiXhosa. Interviews took approximately 25 minutes each. All interviews were conducted in a private room. They were audio-recorded after being granted permission to do so by participants. Recordings were moved from the recording device to a password-protected computer less than 24 hours after recording. Interviews were transcribed and translated into English. All participant identifiers were removed from transcripts.
Before the interviews were conducted, written informed consent was obtained. Informed consent forms (ICFs) were available in isiXhosa and English, and participants were given the option to choose their preferred language for conducting informed consent. They were also given the opportunity to ask questions about the contents of the ICF.

**Data analysis**

Audio recordings of interviews were translated and transcribed into English by two University students who are fluent in both IsiXhosa and English. The primary researcher checked the transcripts against the audio for quality assurance. Transcripts were analyzed using a Thematic analysis. The first stage of analysis involved the primary researcher familiarizing herself with the data by reading over the transcripts and then reading the transcripts whilst listening to the audio recordings. In the second stage, the primary researcher coded the transcripts. Initial codes were developed from reading a selection of the transcripts. The primary researcher then created a codebook based on the initial codes and then adjusted the codes where necessary. The third stage of analysis involved the primary researcher searching for themes in the transcripts. Potential themes were developed by grouping related codes. In the fourth stage of the analysis, the primary researcher reviewed the potential themes to check if they captured what the codes meant and if they related to the data. In the fifth stage, themes were named and defined to ensure that they captured important parts of the data. In the last stage, the primary researcher compiled a write up of the findings. This method is explained in more depth by Braun and Clarke (19). Quotes were also extracted from interview data to demonstrate some of the reported themes. The coding of
data was the responsibility of the primary researcher. Supervisors and the primary researcher were involved in an iterative process of reviewing findings derived from data.

Findings

The following section will discuss the main findings of this study. The first part discusses findings from participants’ interviews about their experiences and perceptions of HIV research and the second section will discuss findings based on recruiters’ thoughts on experiences and perceptions of HIV research participants they have interacted with.

Findings from participants

Factors that influenced participation in HIV research studies

Participants participated in HIV research for various reasons. Some of them described seeking health care and wanting to acquire more knowledge about HIV as reasons for having participated in HIV research. Others described their participation as a strategy for closing the gaps in care services provided at public health facilities. They felt that research studies could give people living with HIV and AIDS (PLWHA) valuable support and information since public health facilities were lacking in these respects.

"I went because I told myself I am going there to get knowledge"
"...I wanted to know that, like what do the people who have studied this (HIV) say"

People also used participation in HIV studies as an opportunity to find and engage with other PLWHA. One participant said he was always encouraged to attend his study visits by seeing other
HIV-positive people looking healthy, which gave him hope that he too could live a healthy life. Some participants explained how they enjoyed talking to people in studies and how attending HIV studies was therapeutic because it gave them a platform to talk about their HIV statuses.

"...when you are sick and you are surrounded by people and you are laughing and having fun, you forget about all this..."

Reimbursements or being incentivized for participation were also identified as reasons for participation. Some participants stated that they were encouraged to participate in studies because of the reimbursement offered, while others admitted to taking part in research for the sole purpose of receiving remuneration (such as vouchers and money) for their participation. One participant stated that she did not think people took the objectives of HIV research studies seriously because their focus was more on the money (reimbursement). This shows that participants did not always participate in research for the purposes of research but rather to received something in return.

"... Most people join studies for what they are going to get afterwards"

This study also showed that the decision to participate in a study was also influenced by others. One participant described the decision to participate in the study as the collective decision of a support group she/he was attending.

"... we also have a support group at church.... we all got together and decided to join that study..."

Experiences of HIV research study procedures

This section will describe how participants experienced research processes such as recruitment, informed consent and reimbursement.
The researcher found that there were various ways that people found out about and enrolled in HIV studies in the community. Most participants reported being recruited into HIV studies by someone they knew. Often these recruiting participants were already participating in HIV studies themselves. A few people had heard about research studies through HIV networks such as community-based HIV support groups. This type of recruitment indicated that there was an awareness of HIV research in the area, especially amongst PLWHIV and their social networks. Some participants were recruited into studies by health care providers.

Participants were generally satisfied with the treatment they received as study participants. Most reported being treated well and not experiencing any ill-treatment. One participant compared study nurses and public health facility nurses and stated that study nurses were 'nicer'.

Participants admitted that the offer of reimbursements or remuneration to people who are living with no or little income did put some pressure on people to agree to take part in a study when they did not want to. For many, the reimbursements went beyond just being reimbursements; they helped them to secure basic needs such as food.

"Some people, yes, do have that pressure. Some people have no income at all"

"We Blacks... we are hungry...another person would think, no man, the money is available, let me risk my life"

"Like those things that we are given do assist, with that you can buy maybe a braai pack (packaged meat)"

"It(reimbursement) does assist at times because the other person (might) not even have money for bread..."
The study revealed that participants appreciated being reimbursed for the costs that they had incurred or the time they had spent participating in studies. Even though they were appreciative of the reimbursements, some stated that they did not feel it was supposed to be compulsory. They felt that the knowledge they gained from research participation was enough. However, a few participants described studies that did not offer reimbursements as unfair.

“They are unfair a lot because you wasted your time, sometimes you don’t go to work, and you go there for your appointment..."

“The whole day you talk and talk, and you don’t get anything in your hand, they must thank you at least.”

A few participants could not clearly describe the informed consent process when asked to describe the informed consent processes of the studies they had participated in. This inability could be due to participants not remembering the process but could also point towards the fact that sometimes informed consent processes are not carried out accordingly or they are not carried out at all. Those who remembered the process described being given the consent form to read and complete. They also stated that the form had described what the study was about. Participants stated that they were given the option to choose a language that they would like to read the form in, and they indicated that research staff had explained the form afterwards. This is important because it shows that when informed consent was conducted, ICF was provided in a language that participants were comfortable with.
Knowledge of research procedures

Participants understood their rights in terms of research procedures differently, but most were aware of their rights and the rights they mentioned aligned with good ethical research conduct. One participant stated that they needed to be aware of what they were agreeing to do by taking part in the study. Another participant understood his right as being treated with dignity and not being intimidated by research staff. Acknowledgement that the conducting of interview processes in private was a right, was also a positive indicator. Being catered for by consuming meals at the study site was also defined as a right. Another participant understood that she had the right not to answer a question she did not want to answer. One participant cited being recorded with her permission as a right whilst another stated that participation in a study was her decision to make. One participant described receiving reimbursement as their right as a participant. The rights mentioned by participants indicate their awareness of some of the key concepts of research participation, which include privacy and confidentiality, voluntariness and informed consent.

"My right ...that I know in a study is that...it is my right for there to be something that I get after I am done with the study"

"I think my right is to be made aware of what exactly I am putting myself into and then I think if I do not understand something very well, I must ask how it goes, what is it that is going to be done to me."

Attitudes towards HIV research

This study showed that there is a range of attitudes toward HIV research studies. Some participants recognized the role they played by participating in research as important. They knew that there was something they possessed (information) that was of interest to researchers and that offering that information was helpful in some way. One participant thought that the fact that
HIV research was still being conducted meant that researchers still cared about PLWHA. In other words, the presence of research studies indicated to this participant that, ways to improve the lives of PLWHA were still being investigated therefore PLWHA had not been forgotten.

Participants generally felt that research studies did not have an impact on the community. However, expectations that HIV studies might create immediate change and offer immediate support were common in the findings. One participant said that research studies did not have any real impact in the communities they were conducted in because people's sexual behaviour and HIV prevention methods had not been changed by participation in HIV studies. This understanding of studies as agents of behavioral change was shared by another participant who said:

"I take a study as trying to fix you as a patient......

Another participant stated that HIV studies existed to create (HIV) awareness and give participants information about HIV. One participant stated that research studies do not change anything in the community because they had complained about the local clinic in one study and nothing had been done about it. A few participants identified research staff as pseudo counsellors who assisted them when they were faced with social issues related to their HIV status.

"... We talk in that way; some stress gets reduce instead of sitting with anger and isolating myself...”

When asked specifically about willingness to participate in clinical trials, participants’ responses differed. Some had no problem with participating in clinical trials, but others were hesitant.
"I said 'please doctor, I cannot. I am not a guinea pig... you cannot test a pill on me'"

Influence of participation on the relationship with HIV

Findings show that some participants felt that participation in HIV research had influenced how they saw themselves as PLWHA and how they handled some of the challenges they, as PLHWA, are faced with. They reported gaining some form of confidence to handle issues such as disclosure and stigma. A participant explained how participating in a research study had helped him disclose his HIV status at home. This effect was shared by another participant who stated that participation in HIV studies gave him the confidence to talk about his HIV status. Another participant stated that participation in HIV research had given him confidence because research participation had given him information at a time when he was confused about how to handle his HIV status.

"It was only after I joined the study that I brought it out"

Findings from recruiters

Factors that recruiters believed influenced participant participation

Our study shows that some factors mentioned by research participants as motivators of research participation were also mentioned by recruiters. Recruiters believed that some participants agreed to take part in HIV research with the hope of receiving better health care from the study than they did from public health care facilities. Recruiters also stated that participants also saw studies as a source of health information. One recruiter stated that she thought that sometimes participants agreed to take part in research because they thought they have no choice and...
believed it formed part of the health care because they were often recruited in health care facilities.

“Some agree because they think that they are forced to agree, right.”

“Firstly, when they have come for a checkup in the public sector and then they see maybe the way they are being treated. So, a person would think that if I do not agree, maybe I will be shouted more here or maybe I will not be helped here.”

Experiences of HIV research study procedures

Some of the interviewed research staff agreed with participants that, generally participants seemed to be happy with the way they were treated in studies. However, some of them shared a different perspective that they felt that research interviewers did not always treat participants as their ‘first priority’ and sometimes staff members quarreled in front of the participants. However, these were recruiters’ views, and such sentiments were not echoed by any of the participants.

“(Participants have given) positive feedback (about research) because they feel they are being taken care of”

Most recruiters believed that participants understood informed consent. One recruiter said that sometimes, due to time constraints, the informed consent process was rushed, and the participant may not have fully understood what participation in the study entailed.

“Sometimes, some of them, a person is running against the time since there is a lot of people, so now they are not able to, for example, sometimes there is something that speaks about blood, maybe they would not follow it properly that they will be drawing bloods, so when the time comes for drawing the bloods, they refuse because you did not explain it on the informed consent, you understand.”
Findings from recruiters show that research results from studies were often not disseminated to research participants. When asked if any of the studies they had worked in had ever given study participants results from the study, recruiters answered:

“Not that I know of”
“There are few that did that. There are a few that did it
“Honestly, no.”

One recruiter mentioned how the lack of dissemination of study results to participants affected participants’ enrollment into studies due to mistrust.

“Ok. Some that we meet, ... those that are clever would say... ‘I have done this before and no one came back to me’, you see. To explain... that this is what we are researching, these are the results of this research”

Attitudes towards HIV research

This study also revealed some research staff’s reflections on research processes and how those processes affected participants. Recruiters stated that, when participants gave feedback about their experiences in the research studies, it was often not solicited by the researchers and there were rarely feedback platforms in place for participants. One research staff member felt that what research participants received from research studies did not compare to what research studies took from participants.

“I feel like we treat our participants more like... I do not know...like we (are) sucking so much things...we expect them to come through for us and then we do not reward them as much as we should.”
Discussion

This study explored the experiences and perceptions of participants of HIV research studies and research recruiters in Gugulethu, Cape Town. Recurring themes within their responses and narratives are discussed below.

Participation for access to health care

Public health facilities in low-resource settings are faced with challenges relating to insufficient staffing and low resources (20-21). As a result, those who are presented with an opportunity to access health care elsewhere at no monetary cost to them may be keen to do so (6,8,22). In this study, access to better health care services and health information were reported as motivators for research participation. In this case, participants talked about deliberately enrolling in studies for access to perceived better health care, even when they were aware that the provision of health care was not the purpose of the study. This facilitator has also been reported in other studies in low-resource settings (8,22-27).

The hope to access better health care as a research participation facilitator may reveal more than just the failures of public health systems in low-resource settings and people deliberately seeking out better health care in research participation. Our study shows that access to better health care as a facilitator may also reveal something about how recruitment and informed consent procedures are conducted in these settings. For example, one recruiter stated that participants may feel obliged to participate in a study offered in a health facility because they believe that if they do not agree, they will not receive the help they are seeking in that facility.
Mabunda describes how, in resource-poor settings, the use of health care providers as recruiters for research can cause ethical constraints because participants may believe that their health care will be negatively affected if they refuse to participate (28). A break down in or unclear recruitment and/or informed consent processes might cause misconceptions about research. Participants may feel that if they do not participate in the study, they are being recruited for in a health care facility, their access to care to health care will be compromised or limited.

Some recruiters in the study felt that participants might not truly understand the difference between research participation and routine health care visits because they were recruited into a study during their visit in a health care facility or were recruited by a health care provider. Recruiters also felt that participants might think that the research study is part of the health services provided at public facilities and that they have no choice but to participate in those studies. However, findings from the participants in this study did not indicate this misunderstanding. Instead, participants indicated that they deliberately enrolled in a study because they believed they could access better health care by so doing.

Previous studies in low-resource settings such as (8, 25-27) revealed that participants take part in research because they believe or hope that their participation will lead to the provision of better health care. The commonness of using health workers as recruiters and health care settings as recruitment spaces may contribute to ‘therapeutic misconception’. Therapeutic misconception occurs when participants mistake the aim of research (i.e. believing it will help them by providing or facilitating access to health care) instead of the true objective, which is
usually to obtain data from participants (23, 29-30). Even though not all decisions to participate in a study for better health care are as a result of therapeutic misconception (23), examples of therapeutic misconception noted in this study revealed that there are still gaps that need to be addressed in research processes, such as informed consent and recruitment in low-resource settings.

Participants in a study by Mfutso-Bengo et al suggested that because informed consent might be compromised when recruitment occurs whilst people are seeking health care, informed consent should be ongoing and not only done at the beginning of the study (22). Participants in a study by Reynolds et al, also confirmed that being recruited while seeking care for their illness affected their understanding of what was said during recruitment (8). The suggestion for an iterative informed consent process could minimize participants’ lack of comprehension of informed consent processes. In the study, some participants indicated that they had forgotten the informed consent process as it was conducted only once (8). Ongoing consent throughout the study duration could minimize this issue.

These findings suggest that researchers who conduct studies in low-resource settings need to be aware of the possible implications of recruiting participants in health care facilities or using health care providers to recruit participants for their studies. Researchers need to ensure that recruitment methods and material, and informed consent documents are customized to meet contextual needs. Informed consent should also be a procedure that research staff and participants continuously come back to during the study period. Perhaps in longitudinal studies
with multiple study visits, informed consent could be revisited at every study visit. This could help ensure that participants understand what they have agreed to participate in and still stand by their decision to participate in the study. Continuous informed consent might allow participants to review their participation under different conditions, and this may change the way they feel about their initial decision to participate. Ethics committees/institutional review boards that oversee the conduct of research in low-resource settings may also need to monitor studies whereby recruitment is conducted in health facilities or by health providers even more closely.

**Participation for social support**

Our study shows that participants do not only seek health care services from participation in research, but they also seek social support. Participants reported using studies as networks or platforms to interact with other PLWHIV and research staff. These findings indicate that participants also seek some forms of counselling from studies, therefore they participate in research to share their experiences of living with HIV and draw strength from experiences of other PLWHIV. These findings are similar to those of Rodrigues et al, where some participants reported sharing their experiences with researchers as a facilitator to their research participation (11).

PLWHA in low-resource settings remain widely stigmatized in their communities. The fear of being stigmatized is a barrier to the disclosure of one’s HIV status to family, friends and the community. Stigmatization has also been shown to discourage PLWHA from seeking social
support and the provision of social support to PLWHA (31-32). It is within this context that participation in research for social support becomes significant. Participants might find comfort in sharing experiences of living with HIV with people who they feel will not judge them and sharing these experiences might be therapeutic. The benefits of these social interactions during research participation are evident in our findings. A few participants reported the positive impact that research participation had on their ability to disclose their HIV status and how they felt about living with HIV. Even though these social interactions are not the purpose of research, they are useful in helping participants to deal with issues related to disclosure, stigma and discrimination.

**Participation for reimbursements**

The offer of reimbursements for enrollment in research studies in developed countries has been widely acknowledged as a facilitator of participation (6,33). Our study shows that reimbursements for participation motivate people to enroll in studies. This facilitator is also common in research conducted in low-resource settings (3,12,14,25).

The influence of reimbursement has been widely debated as an ethical challenge, especially when offered to people in low-resource settings and marginalized populations (27,34). Ethicists fear that paying people in low-resource settings may result in coerced participation. For example, “undue inducement” can occur when an individual is offered goods or services for participating in research, which may lead to them deciding to participate based on the promise of a reward rather than because they want to participate. This kind of implicit coercion increases
the risk of exploitation and it reduces voluntariness. A few participants in this study stated that offering reimbursements for participating in research does particularly motivate people with a low socioeconomic status to participate because of their lack or need for resources. A suggested solution for undue inducement has been to standardize financial reimbursements in order to offer an amount that would not induce participation. However, there is a concern that in low-resource settings, any amount of financial reimbursement may be considered coercive and could cause undue inducement (6). Researchers might need to consider other methods to reimburse participants for their time and effort. Some researchers such as Colvin have reported reimbursing participants by allowing participants to make use of his skills. Colvin did volunteer work for a group that his participants belonged to, as ‘payment’ for their participation in his research (35). Researchers can use their expertise to provide skills that are much needed in the settings they conduct their research. For instance, if researchers know that their participants do not have any computer skills, they could provide participants with basic computer lessons as reimbursement for their time and effort.

Not only do our findings show that reimbursement can influence the decision to participate but also that participants feel entitled to receiving reimbursement for their time and information. A study by Chakrapaniund et al also had similar findings (12). This sense of entitlement to receiving something for participation could be a result of misunderstanding research. This misunderstanding could be attributed to the failure of the informed consent process to clearly explain the purpose of research to participants. This could also be a result of how people are recruited and what is said to them to convince them to participate. If research objectives are not
clearly explained during the recruitment and informed consent processes, or if the focus of these processes is on what the participants will receive for their participation, it is easy for any participant to be misled into believing that they have the right to receive some form of reimbursement. Participants who feel entitled to being reimbursed for their participation might also feel that, because they are providing researchers with their data and time, it is fair to receive something in return or that reimbursements should exist simply as tokens of appreciation.

These findings are evidence of how complex it can be to offer reimbursements in low-resource settings. Researchers are faced with navigating between the ethics of not offering reimbursements to ensure participation is completely voluntary or offering reimbursements to increase enrolment numbers. Researchers may need to have pre-study discussions in communities they conduct studies in, to share research aims thus minimizing misunderstanding and improving the management of expectations. Researchers may also need to have discussions with communities and participants on preferred non-monetary forms of reimbursement.

**Dissemination and feedback opportunities**

Dissemination of study results to participants and the community is the researcher’s ethical responsibility (36). We found that dissemination of results rarely occurred, and this could negatively affect research processes. One recruiter indicated that not disseminating results to participants led to mistrust of researchers, as participants felt that they do not know whether the information they had given during research was truly used for what they had been told it
would be used for. This would affect further participation in similar studies. A study by Mfutso-Bengo et al found that dissemination of results could minimize levels of mistrust and misconceptions about research (22). Researchers need to disseminate study results, not only to participants but to their communities (contexts of study) as well. This could be beneficial to both researchers and the community as it not only provides them with the findings of the research but also allows for communities to understand the full process of research (22,37). The lack of community and participant engagement could perhaps explain why participants sometimes misunderstand the aims of research, as they are only involved in studies when data is being collected.

Some recruiters who were interviewed for the study indicated that the research studies they had worked on, rarely had opportunities for participants to provide feedback or to share their experiences with researchers. Lack of feedback opportunities is therefore a missed opportunity for researchers, as they could better understand participants’ experiences of research by seeking feedback. Understanding participants’ research experiences allows researchers to critically assess how they conduct studies. This is especially important when researchers recruit participants who are vulnerable to unethical conduct.

The need for research to do more

Our study shows that participants expect research to create immediate change in the community. Other studies in low-resource settings reported similar findings, whereby participants stated that research needed to improve the general welfare of the community (3)
while the study is ongoing by providing social services needed by the community even if they are not related to the study objectives (22). Participants in our study talked about how their complaints to researchers, about poor public health facilities, had not created any positive change. Participants knew that although they were not given any feedback directly, research results would at some point be disseminated to a wider audience. By sharing their complaints and concerns about services at facilities, they seemed to be trying to communicate these problems more widely, hoping that sharing these issues would result in changes to service provision. Participants might also believe that there is a link between studies and health facilities; that those who conduct research studies are always the same people as those who work in local health facilities. They might also assume that researchers might have some authority within or over health care facilities. Participants in this study also expressed that studies had not changed people’s behaviours in terms of preventing the spread of HIV. These perceptions could stem from various factors, such as participants expecting researchers in their communities to raise awareness about HIV and related issues even to non-participants. Furthermore, such expectations are expected to have immediate positive outcomes.

These expectations and perceptions indicate that the participants felt the need for research studies to do more for communities. There is a sense that participants want research to improve the community they live in quickly, even if those improvements are not aligned with the research objectives. Our findings and findings from the other studies referenced above indicate that there is a desire for researchers to contribute directly towards improving communities, even if those activities are outside routine research procedures, not specific to their research. Such
expectations also indicate the misunderstanding of research objectives. However, participants might believe that even though these expectations are not research objectives, researchers still need to contribute towards such changes.

**Study limitations**

As is common for a qualitative study, the sample size of this study is relatively small and it is not representative of all HIV-positive participants and HIV research recruiters who were involved in HIV research in Gugulethu, South Africa. However, the effort to interview a sample of persons who participated in different studies, considering gender parity, age difference, and different research roles (participants and recruiters), allowed for a range of perspectives to be documented. The findings of the study cannot be generalized and some of the data may have been subjected to recall bias, as participants were asked to describe informed consent processes of studies they had already participated in; participants not have been able to describe routine procedures as clearly as they described experiences and perceptions.

As a researcher, my interviews with participants could have also been subject to bias. A researcher interviewing participants about research might have some influence on how participants respond to the questions asked, which could cause participants to exaggerate or minimize their experiences and perceptions of research. Participants might have considered me to be an outsider because I am a researcher, or they might have considered me to be an insider because I am a black IsiXhosa speaking person, just like the majority of the community where the study was conducted.
My experiences as a researcher prior to conducting this study might have caused me to have some biases or assumptions about the research. During the research process, I kept a journal to keep my assumptions and biases in check.

Conclusions

Any form of research on human participants is complex and it raises ethical concerns. Research in low-resource settings where populations are more vulnerable because of high HIV rates, low literacy levels, food insecurity and unemployment presents complex ethical challenges. Researchers need to consider the effects of conducting procedures such as recruitment, informed consent and reimbursement in low-resource settings. Generally, research concepts are difficult to understand for anyone who does not work in research. However, people with low literacy levels such as participants in low-resource settings have an increased risk of misunderstanding research studies and associated procedures because of the methods in which these are presented. Researchers need to find ways to better adapt research processes to mitigate identified challenges.

Facilitators for research participation may be more than one of the facilitators discussed in this paper or others not discussed in this paper at the same time, meaning participants may have more than one motivator for their research participation. Motivators for research participation could also change over time. The reasons people choose to participate in a study may not be the same reasons why they choose to remain participants in that study. Once a participant has
enrolled in the study, their experience of the study may influence why they choose to remain or opt-out of the study. Reasons for participation may also not be the same across studies even when study designs are the same. This study did not look at these changes and differences however longitudinal studies looking at these factors and what influences these factors could bring interesting data.

Findings in our study have supported exiting literature in terms of how access to health care services and the offer of reimbursement facilitate participation in HIV research, and more importantly how these facilitators may cause ethical problems. Reimbursement for research participation in a low-income setting may induce participation, whereby one would not have chosen to participate if reimbursement was not offered. The use of health care providers and recruitment being conducted in health care facilities may cause misconceptions about the objectives and procedures of research, thus contributing to participation that is not completely voluntary and is influenced by the fear of health workers and desperation for access to health care.

The study also brought to light, information about facilitators of research participation that were not widely reported in the literature reviewed for the study. Participating in HIV research for social support from fellow participants and research staff and using studies to connect with other PLWHIV are two such factors. Findings from this study therefore indicated how HIV research in settings such as Gugulethu can be used for benefits other than the research objectives.
It is also evident from our findings that, participants expect research to provide some immediate benefit, especially to the community. These expectations could be as a result of misunderstanding the objectives of research. In order to minimize such, researchers may need to engage communities further than what is currently provided for in current research designs.

Researchers may need to involve communities at different stages of research and not limit research involvement to participants. This could help demystify research.

Participants’ expectations that research should provide a more immediate contribution to the community cannot only be attributed to a misunderstanding of research objectives. Participants may want to researchers to have some immediate investment into the community even if they understand that it is not what research intends to look at. To fulfil these expectations, researchers may need to advocate for additional funding so that they can provide some form of service to the community during the duration of the study.

Not disseminating research results to participants and communities harms communities and researchers. According to this study, not sharing research results with participants leads to mistrust of researchers, thereby creating barriers to future research participation. Participants need to have access to knowledge that they have helped create and the knowledge needs to be available in formats that are accessible to participants and their communities. Oftentimes, researchers only disseminate study findings in platforms accessible to certain groups of people, mainly academics and fellow researchers. Researchers need to invest more effort in ensuring
that study results reach participants and host communities. This may require researchers to disseminate results in other creative forms through different platforms.

Our study shows that opportunities for participants to provide feedback about their research participation to researchers are uncommon. The literature on studies that have investigated the experiences of those who have participated in research shows that these investigations are mostly conducted on clinical trials’ participants. Researchers who conduct other forms of research also need to investigate the experiences of their participants because there is value in each participant’s experience, regardless of the type of research they have participated in. Lack of feedback opportunities is a disservice to both participants and researchers, as they do not have the opportunity to engage in conversations beyond the data collection phase. Feedback could ensure that misunderstandings associated with research in low-resource settings are mitigated. Furthermore, conversations between participants and researchers may also help researchers to strengthen the quality of their studies and assist in the design of new studies that cater to identified research challenges.
List of Abbreviations

HIV: Human immunodeficiency virus
AIDS: Acquired Immune Deficiency Syndrome.
PLWHA: People living with HIV and AIDS
PLWHIV: People living with HIV
LMICs: Low-Middle Income Countries
WHO: World Health Organization
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PART D: APPENDICES

Appendix A: Informed Consent for Research participant

Informed Consent form

Version 1.0, 04 August 2017

Title of study: Experiences and perceptions of HIV research participants in Gugulethu, South Africa

What is the purpose of this study?

I am a student at the University of Cape Town. I am conducting this study as a requirement for my studies in Master in Public Health. The purpose of this study is to understand the research experiences of people living with HIV who participate in HIV research.

This form will give you information to assist you in deciding whether to participate in this study or not.

What do you have to do if you decide to take part?

If you agree to take part in my study, you will be interviewed. I will ask you about your experiences and perceptions of HIV research. The interview will be conducted in Xhosa or English, depending on which language you are comfortable with. The interview will be conducted in a private room and will take approximately 30 minutes. The interview will be audio-recorded and I will also take notes during the interview to ensure that I capture all the information you will be providing.

What are the potential risks?
I, the interviewer, am trained in confidentiality however there is some risk of loss of confidentiality due to study procedures such as being interviewed on a research site that does HIV research. You might also feel uncomfortable with sharing of personal experiences; you may refuse to answer you do not want to answer.

**What are the potential benefits?**

There might not be any direct benefits to you. Information obtained from your involvement in our study could make a contribution to literature on participants’ experiences in settings such as Gugulethu Township. This literature may contribute to how research is conducted in the future and benefit future participants. You might benefit from this if you participate in research studies in the future.

**Do you have to participate in the study?**

You may choose not to participate in this study. Not participating in this study will not affect your participation in any current studies you are participating in.

**Confidentiality and Privacy**

If you decide to participate in this study, all data collected during this study will be kept confidential. The interview will be conducted in a private room. Audio recordings of the interview and notes take during the interview will not have your name. Results of this study will also not include your name. All notes and audio recordings will be transferred to a password protected computer within 24 hours of the interview. Only the study supervisors and I will have access to your interview. The study supervisors and I are trained on confidentiality. This study
will not ask you to report on potential self-harm, suicide or harming others, however, should you reveal such information, I will need to disclose that information to a third party.

Will you be given anything for your participation in this study?

You will be reimbursed for your transport costs in the amount of R20 and you will receive a R80 grocery voucher as a token of appreciation.

Do you have to pay to take part in this study?

No, there are no costs for participating in this study.

Can you withdraw from the study?

Yes, you have the right to stop the interview at any time. This will not affect your participation in any other study that you might be enrolled in.

Do you have any questions?

If you are unclear about anything, feel free to ask me questions.

Additional Information

Yolanda Gomba

School of Public Health and Family Medicine

Faculty of Health Sciences, University of Cape Town

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CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been given a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I also provide consent for audio recording of the interview. I know that after choosing to be in this study, I may withdraw at any time. My participation in the study is voluntary. I understand that whether or not I participate will not affect my participation in any other research studies.
Please indicate your consent with your signature.

Volunteer’s name ________________________________________

_____________________________________________________

Signature of Volunteer Date

Interviewer’s name_____________________________________

_____________________________________________________

Signature of Interviewer Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:

I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: __________________________________________________________

Signature: ________________________________________________________

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Appendix B: Informed Consent for research staff

Informed Consent form

Version 1.0, 04 August 2017

Title of study: Experiences and perceptions of HIV research participants in Gugulethu, South Africa

What is the purpose of this study?

I am a student at the University of Cape Town. I am conducting this study as a requirement for my studies in Master in Public Health. The purpose of this study is to understand the research experiences of people living with HIV who participate in HIV research.

This form will give you information to assist you in deciding whether to participate in this study or not.

What do you have to do if you decide to take part?

If you agree to take part in my study, you will be interviewed. I will ask you about your experiences and perceptions of HIV research. The interview will be conducted in Xhosa or English, depending on which language you are comfortable with. The interview will be conducted...
in a private room and will take approximately 30 minutes. The interview will be audio-recorded, and I will also take notes during the interview to ensure that I capture all the information you will be providing.

**What are the potential risks?**

I, the interviewer, am trained in confidentiality however there is some risk of loss of confidentiality due to study procedures. You might also feel uncomfortable with sharing of personal experiences; you may refuse to answer you do not want to answer.

**What are the potential benefits?**

There might not be any direct benefits to you. Information obtained from your involvement in our study could make a contribution to literature on participants’ experiences in settings such as Gugulethu Township. This literature may contribute to how research is conducted in the future and benefit future participants. You might benefit from this if you participate in research studies in the future.

**Do you have to participate in the study?**

You may choose not to participate in this study. Not participating in this study will not affect your work in the research study you are employed in.
Confidentiality and Privacy

If you decide to participate in this study, all data collected during this study will be kept confidential. The interview will be conducted in a private room. Audio recordings of the interview and notes taken during the interview will not have your name. Results of this study will also not include your name. All notes and audio recordings will be transferred to a password protected computer within 24 hours of the interview. Only the study supervisors and I will have access to your interview. The study supervisors and I are trained on confidentiality. This study will not ask you to report on potential self-harm, suicide or harming others, however, should you reveal such information, I will need to disclose that information to a third party.

Will you be given anything for your participation in this study?

You will not be given anything for your participation in this study.

Do you have to pay to take part in this study?

No, there are no costs for participating in this study.

Can you withdraw from the study?

Yes, you have the right to stop the interview at any time. This will not affect your participation in any other study that you might be enrolled in.

Do you have any questions?

If you are unclear about anything, feel free to ask me questions.

Additional Information
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Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been given a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I also provide
consent for audio recording of the interview. I know that after choosing to be in this study, I may withdraw at any time. My participation in the study is voluntary. I understand that whether or not I participate will not affect my participation in any other research studies.

Please indicate your consent with your signature.

Volunteer’s name ________________________________

______________________________________________

Signature of Volunteer Date

Interviewer’s name______________________________

______________________________________________

Signature of Interviewer Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: ________________________________________________________________

Signature: _____________________________________________________________

Date: __________________________________________________________________

Thank you
Appendix C: Interview guide for research participants

Title of study: Experiences and perceptions of HIV research participants in Gugulethu, South Africa

Qualitative Interview Guide:

Version 1.0, 04 August 2017

Introduction

Thank you again for agreeing to take part in this study. This interview will take approximately 30 minutes. As someone who has participated or is participating in a HIV study, I am going to ask you questions about your experiences and perception of the study/studies in general. Should you say anything like that can identify you like your name, it will be removed during transcription and will not be included in the final report.

History of study participation and Introduction into study participation

1. How many HIV studies have you been part of?

2. How many HIV studies have you been part of in the last year?

   Let’s talk about the last study you participated/current study you are participating in.

   Before joining that study, what did you know about research studies?

   (Probe: what did you hear about them?)

3. Please describe how you joined that study?

   (Probe: who told you about the study? Where were you told about the study? Generally, what were you told?)
4. Please describe your first study visit?

(Probe: how was the study procedure explained to you?)

Perception and Experiences of study participation

5. What do you understand your rights to be as a research participant?

(Probe: how did you learn about these rights?)

6. Please describe the informed consent process that you went through?

(Probe: Do you understand what informed consent is? Do you understand why consent is given? Who explained these concepts to you? Were you given an opportunity to ask questions? What language was the consent process in? Were you provided with contact details for anyone in the study? Were you given a copy of the ICF to take home?)

7. Why did you decide to take part in the study?

8. What do you look forward to when you have a study visit?

9. What do you not look forward to when you have a study visit?

10. What have you gained by taking part in that study?

11. What challenges have you experienced as a result of taking part in that study?

12. What would you change about the study?

13. How do you feel about study reimbursements? (Probe: does your current study offer some form of reimbursement? Did you know about the reimbursement when you joined the study? Would you have joined the study if it did/did not have reimbursement? Why or why not?)

14. Do you think HIV research studies benefit your community? Why? /why not?
15. Does/did your family and friends know about your study participation? Why did you tell them or why did you not tell them?

16. How does participating in that study/how did participating in that study impact your daily life?

   *(Probe: work life? Home life?)*

17. How do you think your participation in the study benefits the study of HIV?

18. How has your study participation impact the way you understand HIV?

19. Have you ever heard back from a study about their findings?

20. Knowing what you know now, If you could go back to the day you joined the study, would you still make the decision to join the study? Why or why not?

   *We have come to the end of this interview. Thank you for your time.*
Appendix D: Interview guide for research staff

Title of study: Experiences and perceptions of HIV research participants in Gugulethu, South Africa

Qualitative Interview Guide:

Version 1.0 04 August 2017

Introduction

Thank you again for agreeing to take part in this study. As someone who is working in HIV research, I am going to ask you questions about your experience and views of the study/studies in general. Should you say anything like that can identify you like your name, they will be removed during transcription and will not be included in the final report.

This interview will take approximately 30 minutes.

Work Background

1. How many HIV research studies have you worked in?
2. What has been your position/s in the study/studies you have worked in?
3. What were your responsibilities in those positions?

Perceptions and Experiences

4. What do you think are the reasons people agree to participate in a research study when they are recruited?
5. What do you think are the reasons people do not agree to participate in research study when they are recruited?
6. What do you think are the things/factors that affect participant retention?

7. In your experience, how do you think participants understand ‘Informed Consent’?

8. Can you please share some of the feedback participants have given you about their experiences as participants? And how was this feedback requested?

9. Have you ever been asked to disseminate study findings to study participants?

10. What would you change about the way research is done in the community generally?

We have come to the end of this interview. Thank you for your time.
### Appendix E: Summary Budget

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<td>/</td>
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<td>Transport</td>
<td>R20</td>
<td>25 visits to study site</td>
<td>R500</td>
</tr>
<tr>
<td>Photocopying/Printing of consent forms</td>
<td>R0.50/page</td>
<td>200 pages</td>
<td>R100</td>
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<tr>
<td>Reimbursements for participants</td>
<td>R80</td>
<td>20</td>
<td>R1600</td>
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<td>TOTAL</td>
<td></td>
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<td>R2200</td>
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</table>
04 December 2017

HREC REF: 691/2017
A/ Prof Chris Colvin
Social and Behavioural Science
Public Health & Family Medicine

Dear A/Prof Colvin

PROJECT TITLE: EXPERIENCES AND PERCEPTIONS OF HIV RESEARCH PARTICIPANTS IN GUGULETHU, SOUTH AFRICA (MS Y GOMBA)
Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee dated 15 November 2017.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study. Approval is granted for one year until the 30 December 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.
Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator must obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Yolanda Gomba will also be involved in this study.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON FHS HUMA

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DOH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.
Appendix G: Ethics Approval annual renewal

FHS016: Annual Progress Report / Renewal

- **Approved**
- Annual progress report approved until next renewal date: 30/11/2019
- Signature Chairperson of the HREC: signature removed
- Date Signed: 7/11/2018

**Principal Investigator to complete the following:**

**1. Protocol Information**

- **Date form submitted:** 2 November 2018
- **HREC REF Number:** 691/2017
- **Protocol title:** Experiences and Perceptions of HIV research participants in Gugulethu, South Africa
- **Protocol number (if applicable):** 200

- **Are there any sub-studies linked to this study?** Yes
- **If yes, could you please provide the HREC Ref’s for all sub-studies?** Note: A separate FHS016 must be submitted for each sub-study.

- **Principal Investigator:** Prof. Christopher Colvin
- **Department / Office:** Rm 3.4

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)
Appendix H: BMC Public Health Submission Guidelines

Research article

Criteria

Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research will not be considered.

Authors who need help depositing and curating data may wish to consider uploading their data to Springer Nature’s Research Data Support or contacting our Research Data Support Helpdesk. Springer Nature’s Research Data Support provides data deposition and curation to help authors to follow good practices in sharing and archiving of research data. It can be accessed via an online form. The services provide secure and private submission of data files, which are curated and managed by the Springer Nature Research Data team for public release, in agreement with the submitting author. These services are provided in partnership with figshare. Checks are carried out as part of a submission screening process to ensure that researchers who should use a specific community-endorsed repository are advised of the best option for sharing and archiving their data. Use of Research Data Support is optional and does not imply or guarantee that a manuscript will be accepted.
Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
  - or for non-clinical or non-research studies a description of what the article reports

- list the full names and institutional addresses for all authors
  - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the “Acknowledgements” section in accordance with the instructions below

- indicate the corresponding author
Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background**: the context and purpose of the study
- **Methods**: how the study was performed and statistical tests used
- **Results**: the main findings
- **Conclusions**: brief summary and potential implications
- **Trial registration**: If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration.

**Keywords**

Three to ten keywords representing the main content of the article.

**Background**

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.
Methods

The methods section should include:

- the aim, design and setting of the study

- the characteristics of participants or description of materials

- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses

- the type of statistical analysis used, including a power calculation if appropriate

Results

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

List of abbreviations
If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.