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Enrollers' Perceptions of Communication during Informed Consent at a South African Tuberculosis Research Site

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List of Abbreviations

ACT4TB/HIV	Advancing Care and Treatment for Tuberculosis and Human Immunodeficiency Virus
ARV	Antiretroviral
CAT	Communication Accommodation Theory
FGD	Focus Group Discussion
HCRU	Health Communication Research Unit
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
HREC	Human Research Ethics Committee
ICF	Informed Consent Form
ICP	Informed Consent Process
RAQ	Risk Assessment Questionnaire
RR	Rifampicin-resistant
SAMRC	South African Medical Research Council
STI	Sexually Transmitted Infection
TB	Tuberculosis

Abstract

The informed consent process (ICP) in clinical trials is an interaction of communication: one in which important information should be adequately conveyed by the enroller and sufficiently understood by the potential participant. However, barriers to effective communication are often encountered during the process and result in participants' comprehension of information being compromised. This study aimed to use qualitative methods to explore the reported experiences of thirteen enrollers involved in the ICP pre- and post- the implementation of a communication training programme in a Human Immunodeficiency Virus (HIV) and tuberculosis (TB) research study in Rustenburg, South Africa. The communication training programme aimed to improve communication processes during the ICP and enhance participant comprehension of information. This study used journaling and FGDs as data collection methods. Inductive thematic analysis was used to explore the reported experiences of enrollers during the ICP, and to identify perceived barriers and facilitators to communication during these interactions. Findings revealed language-, procedure- and participant-related facilitators and barriers. Furthermore, communication and language strategies employed by enrollers to overcome reported barriers were discussed. Several strategies paralleled the communication and language skills taught during the communication skills training. Many of these strategies were found to facilitate communication processes within the enroller-participant interaction, improve understandings of the informed consent form (ICF) and obtain proper informed consent. These findings confirm that enrolment is a complex process impacted by many variables.

Keywords: informed consent, communication, enrollers, clinical research

Plagiarism Declaration

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Plagiarism declaration for written work

I ..... Samantha ..... Dale ..... as a postgraduate student registered for a MA in Social and Psychological Research at the University of the Witwatersrand declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and or without acknowledging the original source.
- I am aware plagiarism is wrong.
- I confirm that this written work is my own work except where I have stated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing of others.

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Date ..... 26/05/18 .....

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Introduction and Research Rationale

The informed consent process (ICP) is an interaction of communication between researcher and participant, one that facilitates continual discussion and education, even after signing of the consent form (SAGCP, 2006). Obtaining the informed consent of participants in clinical trials and studies is ethically essential and implies that participants have sufficient knowledge regarding the nature of the research procedure, specific aims and purposes, as well as alternatives to participation (SAGCP, 2006). The South African Department of Health (2005) recognises that obtaining informed consent presents with difficulties–notably when engaging with participants from communities with inadequate literacy and educational opportunities where language barriers are likely to be encountered. Moreover, the diversity of languages at South African trial sites may create further barriers in communication between enroller and participant (Penn & Evans, 2009). Persons with educational or economical disadvantages are classified as vulnerable and this may lead to ethical concerns about including them in trial research (Denny & Grady, 2006). Such concerns include possible impairments in decision making abilities due to low levels of education, receiving fewer benefits in exchange for risks and the exploitation of persons with limited economic options (Denny & Grady, 2006). Informed consent documents and explanations thereof should be specific to participants' local context, language and educational background (Barry & Molyneux, 1992). This is challenging when documents and forms are focused on the legal protection of stakeholders, making them lengthy and complex and are often not attuned to local norms and needs (Bhutta, 2004).

There is a large body of literature that has focused on the ICPs within clinical research. However, most studies have predominantly focused on participants' experiences and barriers to consent and less so on enrollers' accounts of the process. It is suggested to understand and improve the interactions between patients and healthcare professionals, the experiences of both should be accounted for (Penn, Watermeyer & Evans, 2011). There is a paucity of research on enrollers' experiences of the informed consent process within clinical research studies, despite playing a key role during this process.

Locating factors which contribute to impediments and developing modified consent practices have been identified as important to address barriers encountered in the ICP (Nishimura, Carey, Erwin, Tilburt, Murad, & McCormick, 2013; Brehaut, Fergusson, Kimmelman, Shojania, & Elwin, 2010; Penn & Evans, 2009). Penn and Evans (2009) have identified that flexible and modifiable communication training of enrollers at trial sites–in addition to identifying and addressing barriers–is required to enhance the consent process.

This study aimed to explore enrollers' reported experiences of the ICP in TB and HIV clinical research studies in South Africa. Perceived barriers and facilitators to communication during the enroller-participant interaction were identified and discussed. Furthermore, a communication training programme was implemented with enrollers and language strategies that enrollers employed prior and after training was evaluated. Enrollers reported to have used numerous effective communication and language strategies to facilitate participant comprehension of the ICF that paralleled strategies taught during the communication training programme.

This report has been divided into several sections. The literature review provides an overview of the healthcare context in South Africa, including challenges and barriers to care such as unemployment, poverty and inequality. The obtainment of informed consent in clinical studies and healthcare settings and barriers thereto are discussed. Moreover, challenges in clinical studies as well as language and literacy barriers to informed consent, and the consequences thereof have been expanded on. Several interventions to reduce language barriers in healthcare and improve multi-linguistic interactions and improving communication have been explored. A critical discussion on journaling as method to understand enrollers reported experiences of the ICP has been included. Lastly, the theories in which the study is framed are identified and discussed, namely communication accommodation theory (CAT) and systems theory.

The methodology section provides a description of the research site, participants, research design, data collection methods, data analysis methods, communication training, rigour and ethical considerations.

Data from the reflective journals and FGDs are analysed in the results section and discussed in the discussion section. Major findings and study limitations are further elaborated on and study recommendations are posited in the general discussion.

Literature Review

Tuberculosis and HIV/AIDS in South Africa

South Africa experiences one of the world's highest tuberculosis (TB) burdens including HIV-associated TB (WHO, 2016). TB is currently one of four of South Africa's concurrent epidemics (Coovadia et al., 2009; Mayosi et al., 2012)

Successful completion of tuberculosis treatment in South Africa has declined and control programmes have suffered from a lack of oversight and accountability of managers.

Few resources were allocated to controlling the HIV/AIDS and tuberculosis epidemic in South Africa between 1999- 2005 resulting in a failure to establish primary health care and an increased health burden (Coovadia et al., 2009). Complex economical, structural and social dynamics account for the distribution of HIV. Furthermore, poverty, violence, limited access to healthcare services and inequality increase risk for HIV infection (UNAIDS, 2016; HSRC, 2014; Hunter 2007).

Healthcare in South Africa

South Africa's healthcare system faces major impediments to improving local healthcare (Mayosi & Benatar, 2014). According to Mayosi and Benatar (2014), there is a complex relationship between health and wealth. The socio-economic context of South Africa is one of economic disparity between races, poverty, malnutrition, low income, overcrowding and poor sanitation, as well as limited access to quality healthcare (Coovadia et al., 2009; Karim, Churchyard, Karim, & Lawn, 2009; Mayosi et al., 2012). In addition to unemployment, poverty is a major challenge. Together these factors exacerbate the presence of poverty-related diseases as well as the country's current healthcare challenges (Wingfield et al., 2014; Chakraborty; Lönnroth, Jaramillo, Williams, Dye, & Raviglione, 2009; Kalichman, Simbayi, Kagee et al., 2006; WHO, 2005; UNAIDS, 2001).

In South Africa, the public health sector provides health care to over 40 million people, the majority of the population, yet public health infrastructure, skills and resources has drastically deteriorated due to neglect, mismanagement and underfunding.

South Africa's healthcare system is further challenged by poor and inadequate management. Management of healthcare workers is crucial to the performance, development, retention and quality of care. It was found that many district and facility managers were incompetent for their job or position (Development Bank of South Africa, 2008). Despite these persisting challenges, critical areas for improvement have been recognised by the South African government, who have recently proposed several strategies and policies on how best to approach current healthcare issues (RSA Department of Health, 2011). For example, community healthcare workers are seen as necessary for the improved access to healthcare and the encouragement of community participation therein.

Clinical research efforts aimed at improving South Africa's current healthcare challenges, including TB and HIV have also been prioritised. The National Health Research Committee has formulated several focuses in health research which aim to improve the quality

of health research in South Africa (Mayosi et al, 2012). Of these focuses, this study aims to train healthcare practitioners and provide recommendations to train healthcare workers.

An urgent need for research on improving HIV and TB prevention, care and treatment (Mayosi et al., 2012; Coovadia et al., 2009; Karim, Churchyard, Karim, & Lawn, 2009) as well as educating and retaining healthcare providers and staff (Petersen et al., 2017; Shah et al., 2017) has become paramount to addressing the local TB and HIV burden.

Language and Literacy Barriers in Informed Consent

In light of these priorities and proposals to address current health challenges, mentioned above it is important to examine certain related processes in order to ensure effective healthcare outcomes. In clinical research, one such related process, is informed consent.

During the ICP of a clinical research study, the participant is required to receive all the essential and relevant information pertaining to the clinical trial, or study, to make an informed decision to take part. Such an informed decision requires that the ICP and content be adapted to participant characteristics (SAGCP, 2006). The University of Cape Town's Human Research Ethics Committee (2014) re-iterates this notion by indicating that consent forms and documentation must be translated or adapted to participants' language of choice and communicated in a manner in which they can adequately understand. This is especially important for a multi-lingual, culturally and socio-economically diverse setting such as South Africa.

Research has shown that barriers to communication within South African patient-practitioner and participant-enroller interaction arise when the same first language is not shared (Hussey, 2012). The quality of communication within interactions declines when proficiency in a prevalent language is limited or lacking, or linguistic differences are present, thus language becomes a barrier to effective communication (Hussey, 2012). Many South Africans have limited literacy skills as a result of historical inequalities, a dysfunctional educational system, disparities in access to education and a failure of governmental recognition thereof (Coovadia et al., 2009; Hussey, 2012). A report on South Africa's quality of education found that most school pupils cannot read or write at grade-appropriate levels and many are illiterate and innumerate (Spaull, 2013). The National Education and Evaluation Unit recognises the lack of basic literacy and numeracy skills amongst a large proportion of pupils despite governmental investments in education (Murris, 2016).

Furthermore, language barriers in healthcare result from the multiple differing socio-cultural backgrounds of individuals (Hussey, 2012). In addition to the major challenges the

healthcare system of South Africa must overcome, the provision of healthcare service that is characterised as monolingual to a multilingual country is a challenge that is often overlooked (Hussey, 2012). The Constitution of South Africa states that practical and positive measures must be taken to promote and advance the use of indigenous language of which use has been diminished (Act 108 of 1996). Migrants from other African countries similarly experience language barriers in healthcare interactions as many do not understand the indigenous languages of South Africa (Crush and Tawodzera, 2014). Deliberate miscommunication and hostility of healthcare staff was reported to be the most common problem Zimbabwean migrants experienced with health service providers (Crush & Tawodzera, 2014). Those who attempted to communicate in newly-learnt local languages reported to have been ridiculed and publicly humiliated by healthcare staff. According to the Refugees Act (130 of 1998), all refugees in South Africa have the same right as citizens to access healthcare services. Despite this, it has been suggested that public hospitals widely ignore such policies and continue to deny healthcare services to refugees (Crush & Tawodzera, 2014; Shaeffer, 2009).

Language barriers in healthcare are often ignored by practitioners and policy makers (Hussey, 2012). The Bill of Rights further states that language barriers act as a barrier to accessing healthcare (Republic of South Africa) as those less proficient in the dominant language of the healthcare system are less likely to receive care (Jacobs, Chen, Karliner, Agger-Gupta & Mutha, 2006).

Consequences of Language Barriers in Healthcare

It has been suggested that the inclusion of all languages as stated by the South African Constitution in healthcare settings is required for the equitable rendering of healthcare to all citizens (Van den Berg, 2016). Furthermore, numerous studies have reiterated the consequences of language barriers that arise in healthcare settings (Ansar, Johansson, Vásquez, Schulze & Vaughn, 2017; Meuter et al., 2015; Rechel, Mladovsky, Ingleby, Mackenbach & McKee, 2013; Flores, Abreu, Barone, Bachur, & Lin, 2012; Hussey, 2012; Levin, 2006; Schlemmer & Mash, 2006)

Many interactions within the health setting are conducted in patients' or participants' second or third language (Levin, 2014; Hussey, 2012). In addition to limited access to healthcare, patients who lack proficiency in English have been found to experience difficulties comprehending their condition, treatment and care (Kazzi & Cooper, 2003) and adhere to instructions to follow up on visits less often (Kravitz, Helms, Azari, Antonius & Melnikow, 2000; Sarver & Baker, 2000). Moreover, in a study conducted in a Cape Town paediatric

hospital, isiXhosa-speaking parents stated that language barriers rather than socio-economic or structural barriers impeded their participation in the healthcare services that their children received (Levin, 2006). A survey conducted in another hospital in the Western Cape reported language barriers negatively affected attitudes of patients and healthcare staff, quality of, and satisfaction with, care decreased and misunderstandings were evident. IsiXhosa-speaking patients additionally confirmed their comprehension of explanations by healthcare providers even when they did not understand (Schlemmer & Mash, 2006).

Miscommunication resultant from language barriers can have additional implications for the healthcare of patients (Flores et al., 2012). Errors in interpretation and communication can result in the misdiagnosis of patients, mismanagement, serious injury and preventable harm, or overdose (Divi et al., 2007; Flores, 2006; Cohen et al., 2005), thus patient satisfaction, trust and care declines (Hussey, 2012). It has been found that patients, or participants, may not adhere to instructions due to a failure to communicate the risks or miscommunicate the risks involved in certain treatments (Meuter et al., 2015). In a review of language barriers reported in healthcare research, Jacobs et al. (2000) reiterate the need for additional research hereon, specifically how language affects patient-practitioner interactions and care.

Moreover, the National Health Act of South Africa (2003) necessitates that informed consent account for participants' literacy standing in all health-related procedures.

Additionally, trial forms, procedures and protocols may be devised by persons who have a limited understanding or knowledge of the specific cultural or linguistic needs of those involved in the research trial which implicate additional challenges to enrolment (Watermeyer & Penn, 2009a). The communication needs of participants are often not considered and trial documents and processes are not always contextually appropriate to local settings (Bhutta, 2004).

Interventions to reduce language barriers and improve cross-language in healthcare.

There have been several studies that have aimed to explore or address barriers in healthcare, specifically related to language and comprehension of medical information. Hussey (2012) suggests the development of a culture of multilingualism that aims to employ healthcare practitioners who are linguistically competent and proficient in the language of their patients or participants. Moreover, healthcare practitioners should be trained in the indigenous languages of those they service. In a review of interventions aimed at reducing language barriers in healthcare, Jacobs et al. (2006) found that the use of language-concordant pairs

produced higher satisfaction and better well-being among patients. Schlemmer and Mash (2006) highlighted the importance of creating a basic understanding of medical terminology and talk in respective indigenous languages through basic training. An intervention study aimed at exploring the impact of training on the comprehension of participants in a treatment trial found that the promotion of the use of home language, pictures and visual aids improved participants' comprehension and counsellors' confidence (Penn, Evans & Sanne, 2006). Penn (2007) noted that health professionals in South African health settings employ a variety of strategies to facilitate patient comprehension. Watermeyer and Penn (2009b) found that pharmacists and patients at an ARV clinic frequently made use of verbal and non-verbal strategies to enhance communication and comprehension.

The use of interpreters has been found to reduce language barriers and increase patient satisfaction and quality of care in some cases (Jacobs et al., 2006). Despite this, models aimed at the incorporation of interpreters in upper-income countries with high resources have been found to be expensive and limited in the South African healthcare setting (Benjamin, Swartz, Hering and Chiliza, 2016). A mismatch between languages of healthcare providers and patients is often present and although legislation promotes the incorporation of interpreters in healthcare, common practice has shown that a trained interpreter is seldom available (Penn, 2007) or interpretation is done on an ad hoc basis using available healthcare staff, family members or other patients (Flores et al., 2012; Evans, 2000; Jacobs et al., 2006; Drennan, 1999).

Interpreters are required to be proficient in both languages as well as familiar with medical terminology and jargon, yet these are often difficult to translate accurately. Additionally, proverbs, emotion and humour are often challenging for many interpretations to translate (Lesch, 2007). It is suggested that in addition to the practitioner, patient, and interpreter, institutional participants such as the government, health services and the community are constituents of the interpreter-mediated session (Benjamin et al., 2016; Zimanyi, 2011).

Studies on language barriers in health settings have reiterated the finding that patients often blame themselves for being unable to communicate effectively with healthcare providers (Levin, 2006; Schlemmer & Mash, 2006). The insistence that participants should acquire proficiency in English marginalises those with limited access or ability to learn English and can impair and replace notions of diversity with a hegemonic Western linguistic dominance (Hussey, 2012). The National Health Act (Act 61 of 2003) states that it is the healthcare

providers' responsibility to provide a multilingual service; a service that is central to the patient's language and literacy proficiency.

Jacobs et al. (2006) reiterate the need for research on interventions that effectively reduce language barriers in healthcare and the impact thereof on access to care, quality of care and reduction of medical errors. In a review of the impact of language barriers on healthcare services Van den Berg (2016) postulates the need for research that extends to parts of South Africa other than the Western Cape as well as the integration and collaboration of language practitioners and health practitioners to find practical solutions to cross-linguistic communication and language barriers. Penn (2007) suggests improving communication in healthcare by means of communication training that is site-specific and illness-specific. Despite language barriers, site-specific training has been found to facilitate effective communication and satisfaction of patients, healthcare workers, and interpreters (Penn, 2007). Meuter et al. (2015) suggest research with a focus on understanding communication and the linguistic constituents of interactions within health settings. They further suggest that the specificities of language barriers be addressed in a manner that informs language training for health practitioners.

Barriers in Clinical Trials/Studies

Despite the stringent regulations pertaining to the ICP, enrollers and participants are often challenged with not only overcoming language barriers, but are often faced with several other challenges relating to communication as identified by the Human Research Ethics Committee of the University of Cape Town (HREC, 2014).

Such challenges have been experienced by multiple studies conducted locally and internationally. The use of complex legalistic language and explaining concepts such as "randomisation", "placebos" and "the right to withdraw" poses difficulties in participants' comprehension of important information. This was found in studies on the ICP conducted locally and in developing countries (Marshall, 2006; Ssali, Poland & Seeley, 2015; Mandava, Pace, Campbell, Emmanuel & Grady, 2012; Nishimura et al., 2013; Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009). Such incomprehension may undermine the voluntary nature of consent. Frequent reference to scientific or medical jargon brings about additional challenges (HREC, 2014; Marshall, 2006). Multiple studies have demonstrated an imbalance between participants comprehending trial risks and benefits (Nishimura et al., 2013; Falagas et al., 2009; Mandava et al., 2012; HREC, 2014). Falagas et al. (2009) conducted a review of clinical trial and informed consent literature and found that only 50% of trial and

patient participants understood risks involved. Participants' lack of general knowledge pertaining to their specific condition or condition under study, and that of the trial, may be a further barrier to providing informed consent. Brandberg, Johansson, and Bergenmar (2016) found that greater knowledge of the trial was considered by participants to be important for consenting. Additionally, participants reported that information concerning their health condition was required to make an informed decision (Brehaut et al., 2010).

The research setting and broader contextual factors also contribute to the ICP of many research trials and studies. Ross et al. (1999) highlighted several such barriers to patient participation in a systematic review of international clinical trials. Additional demands such as travel and travel costs were reason for patients to refuse participation, miss follow-up appointments or drop out of the study. A distrust of hospitals or treatment was a further reported barrier to participation. Ross et al. (1999) noted facilitators to participation amongst patients. Altruism emerged as the most common motivation for participation, while an important person such as a family member, spouse or close friend had a considerable influence on the decision to participate.

Vulnerable Populations in Clinical Research

The inclusion of economically disadvantaged participants in clinical trials raises ethical concerns. Individuals who are ill, elderly, have cognitive impairments, illiterate or are educationally or economically disadvantaged are considered to be vulnerable populations (Kalabuanga, Ravinetto, Maketa et al., 2015; Denny & Grady, 2006). These populations may be vulnerable to impaired decision making, leading individuals to enrol in trials without fully comprehending study risks. Clinical trials should not exploit participants with limited economic options by offering a benefit that is less than fair (Denny & Grady, 2006). Additionally, to ensure the informed consent of illiterate participants, a witness should be present to confirm that consent was given. Attention should be given to methods of gaining IC with vulnerable populations (Denny & Grady, 2006). The adjustment of IC procedures to participants' socioeconomic context is essential for ensuring IC and following ethical principles (Kalabuanga, et al., 2015).

Recruitment, Retention, and the Informed Consent Process: Improving Communication

Peters-Lawrence et al. (2012) maintain that support and communication within the organisation involved is required for the successful recruitment of participants in clinical trials. It is further suggested that clinical trial monitoring involve an examination of process and

procedural issues such as communication quality to improve the assessment of comprehension. Similarly, Penn and Evans (2010) found that the effectiveness of the ICP requires the examination and feedback of enrollers invested in the participant-enroller interaction. The translation of questionnaires and forms, involvement of multilingual site staff and ensuring informed consent discussions are understandable is necessary when language and literacy barriers are evident in trials (Kaluzny et al., 1993; Lovato, Hill, Hertert, Hunninghake & Probstfield, 1997).

Recruitment was found to be dependent on establishing relationships of trust between clinical trial providers and participants (Lovato et al., 1997). This was in relation to reports of participants' distrust of medical personnel (Peters-Lawrence et al., 2012; Ross et al., 1999). Likewise, a study on recruitment strategies in clinical trials for Parkinson's disease recommend improving trust and communication by establishing relationships between participants, community members and trial personnel (Picillo, Kou, Barone, & Fasano, 2015, Delany-Moretlwe et al., 2011). This implies an expanded effort to maintain consistent contact with participants throughout the trial process. A case study conducted by Delany-Moretlwe, Stadler, Mayaud and Rees (2011) on researchers' accounts of communicating trial results revealed that a focus on communication from the beginning of the trial can build trust and participants understanding of the research in which they are involved. Penn, Watermeyer and Evans (2011) examined contextual, interactional and communication factors evident in patient-pharmacist interactions in antiretroviral therapy. It was found that despite health practitioners' identification of problems experienced within these interactions, they are unable to identify reasons and solutions thereof. It is stipulated that modified ICPs are no substitution for conversation that provides opportunity for interactive communication. This implies a move towards a focus on rich conversation between enroller and participant (Nishimura et al., 2013). Falagas et al (2009) highlights the importance of communication and suggests that adequate participant comprehension of trial risks may depend on the manner in which relevant information is communicated by an enroller rather than solely on what is written on a consent form. In addition, risk comprehension may depend on how questions eliciting verification of understanding are framed (Mandava et al., 2012).

One of the challenges within clinical studies is the adequate transfer of information from enroller to participant (Brehaut et al., 2010). Not only do they have the task of disseminating complex information to potential study participants, but they have to do so in an understandable manner so as to ensure proper consent. It is suggested that improvements in this aspect can be achieved by engaging trial personnel in discussions concerning the informed

consent process. Communication of medical information to participants has been identified as demanding for enrollers or healthcare workers (Falagas et al. 2009; Woodsong & Karim, 2005). It was found that physicians and enrollers elicited better participant comprehension of information by use of verification methods. Enrollers involved in the ICP of clinical trials have the supplementary role of providing simplified language as a means to assist comprehension of the multiple aspects of informed consent documents which are usually written in complex language. Using supplementary material can assist in ensuring participants understand explanations of procedures (Woodsong & Karim, 2005). Clarifying complex language is further complicated when participants are not familiar with the language in which the consent form is written (Penn & Evans, 2009; Marshall, 2006). Enrollers are challenged to provide translations of medical or scientific terms for which there may be no linguistic equivalent in the given language of the participant. White (2005), reiterates that technical complex language and terms be replaced with simple comprehensible language. Opportunity for reciprocal engagement and interaction between participant and enroller is required to ensure participants receive comprehensive answers regarding all aspects of the trial (White, 2005).

Enrollers are further involved in facilitating good decision-making and assisting in the improvement of quality decisions of participants (Brehaut et al., 2010). Despite this implication, there is little research on enrollers' experiences of being implicated in decision making and communication processes in clinical trials. Cox (2002) examined patients' experiences of the ICP as well as decision-making. Patients had difficulties with making informed decisions because they had limited knowledge to support their decision and subsequently expecting the clinician to take primary responsibility. Additionally, tension exists between satisfying legal requirements of fully informing participants and ensuring comprehension of information (Cox, 2002). Although the study found that patient's decisions may be influenced by the manner in which information is presented to them, it did not specifically focus on enrollers' experiences of the ICP.

Communication skills training of enrollers can further assist in ensuring better communication and more effective verification of comprehension of participants (Brehaut et al., 2010). It is suggested that enrollers who are bilingual are still not adequately equipped to ensure quality communication and require further training but should be involved in the planning, development and reviewing of the informed consent procedures (Penn & Evans, 2009). Identifying and addressing the barriers experienced by enrollers in the ICP and implementing a communication training programme could assist in enhancing communication and participant comprehension.

Modifying the way in which the informed consent protocol is presented and communicated, rather than the content, may be beneficial for enrollers. Penn and Evans (2010) compared a standard and modified informed consent protocol with regards to trial participant comprehension. Enrollers admitted to feeling inadequately equipped with regards to their knowledge on facilitating successful communication with participants before they underwent communication skills training. They further claimed that the communication training in the modified informed consent process increased their confidence as well as improved participant relationships.

Journaling About Experiences: Journaling as a Method to Understand Enrollers Reported Experiences of the ICP

When considering methods used to explore and understand participant-enroller communication in the ICP of clinical studies, literature has shown quantitative methods have predominantly been used (Lewin, Glenton, & Oxman, 2009; Gibson, Timlin, Curran & Wattis, 2004). Of the qualitative studies that have been conducted on the patient-practitioner interaction, methods used include: interviews, focus group discussions (FGD), and video and audio recorded interactions (Gibson et al., 2004, Pope & Mays, 1995).

The use of reflective journals has been under-utilised in research on the participant-practitioner/enroller interaction. The benefits and limitations of the use of journaling and FGDs as a method will be discussed in the Methodology section.

The use of journal writing has been found to be effective in stress and anxiety reduction amongst medical students and graduates (Pizarro, 2004; Ullrich & Lutgendorf, 2002; Lepore, 1997; Sgoutas & Johnson, 1998; Smyth, 1998) It has further been used in the promotion of personal development and self-change (Mercer, Warson, & Zhao, 2010), the facilitation of the integration of clinical experience with theory (O'Connell & Dyment, 2006), the improvement of mental and physical health (Ullrich & Lutgendorf, 2002), and the reflection on research processes in relation to knowledge and experience (Banks-Wallace, 2008). Reflective practice can be developed by means of journaling that involves self-examination. Such self-reflection should aim to improve practice and facilitate professional growth by reflecting on past practices, actions and complex interactions within particular contexts (Blake, 2005). Journaling can additionally help identify and establish resources and strategies for barriers between the self and others, enhance critical thinking about the processes in which one is engaged and to understand cultural narratives (Blake, 2005).

The combination of visual art with written journaling has been effectively used as an intervention aimed at reducing stress and anxiety and promoting positivity among nursing students (Walsh, Chang, Schmidt, & Yeopp, 2005). Mercer, Warson, & Zhao (2010) found that visual journaling helped medical students and staff acknowledge stress, provided opportunity for self-reflection and improvement and facilitated the transformation of stress inducing emotions into positive outcomes and solutions.

This study has made use of written journaling as the predominant mode of data collection. Written and visual journaling was used to encourage self-reflection of practices and processes in which enrollers were involved. It was further used to assist enrollers in the identification and exploration of language barriers that arose within interactions with participants during the ICP. The self-examination of enrollers' past practices and interactions was aimed at improving current practices and communication behaviours during enrolment sessions. The limitations of journaling as a method to understand enrollers' experiences will be discussed in Methodology.

Theoretical Framework

This study is framed within two theoretical approaches. The first aims to understand reasons as to why communication problems arise within medical and health settings, namely Communication Accommodation Theory (CAT). Communication Accommodation Theory particularly focuses on language-discrepant and language-congruent communication. The second, namely Systems Theory, focuses on the interconnection of all the subsystems within a system in relation to individuals to understand the complex processes at play (Visser, 2012).

The study will be further guided by the major principles of biomedical ethics (Beauchamp & Childress, 1994). A major guiding principle of biomedical ethics postulates that the ICP involves interactions that promote the participant's best interest through relationships of trust, which emerges from beneficence (Beauchamp & Childress, 1994). To better understand participants' best interests, beliefs and social structures, a relationship of trust should be established between participant and practitioner. Then only is the practitioner able to support the participant in the decision-making process and ensure full autonomy (Schmitz & Reinacher, 2006).

Communication Accommodation Theory.

In CAT, interpersonal interactions are examined in relation to social and contextual factors that implicate communication and its outcomes. Particularly, it is proposed that both

speakers and listeners modify their verbal and nonverbal behaviour while communicating to either diverge dialogue away or converge dialogue towards others within social interactions. Convergence constitutes a desired or perceived similarity within the interaction whilst divergence is indicative of perceived differences (Giles, 2008). The use of convergence has been used within interactions with patients to account for discordance such as differences in language (D'Agostino & Bylund, 2014). This includes the repetition of information, adjustment of dialogue style and the use of nonverbal communication (Jain & Krieger, 2011).

Moreover, personal and social factors are recognised to emerge during interactions and various modes of communication are made use of to establish and manage social distance. CAT further accounts for the mutual, interactive nature of communication within health settings with a focus on a holistic process of communication. Accommodation behaviour within interactions focuses on two-way, mutual interactions and the conscious adaptation of communication to meet patients' needs (D'Agostino & Bylund, 2014; Epstein & Street, 2007). Mutual accommodation in communication further establishes rapport and strengthens relationships between practitioners and patients or participants (D'Agostino & Bylund, 2014).

The modification of verbal and nonverbal communication behaviours can establish patients' preferences for their involvement in communication interactions and decision making, to meet emotional needs, and to facilitate shared understanding (D'Agostino & Bylund, 2014). Nonverbal communication involves how things are said, the emotion with which it is said and the recognition thereof. The practitioner-participant interaction is then reliant on the practitioner's ability to adapt their dialogue accordingly to demonstrate understanding and respond appropriately. This involves a focus and attentiveness to nonverbal communicative behaviour (Roter, Frankel, Hall, & Sluyter, 2006). The importance of nonverbal communication and its influence on communication outcomes has been reported in several studies (D'Agostino & Bylund, 2014). Nonverbal communication involves body posturing and positioning, facial expressions, gestures and eye contact. The maintaining of eye contact has been found to establish rapport, patient-centeredness, patient distress and an awareness of patients' cognitive and physical functioning. Furthermore, body posturing and positioning can have an impact on communication within interactions as well as the practitioner's proximity to the participant (D'Agostino & Bylund, 2014).

Limitations of CAT.

A limitation of CAT is that it solely focuses on communication behaviours within interactions. Thus, interactions are examined and understood at a micro-level. This study aims

to understand the enroller-in-context, which includes all the systems that he/she functions within and is influenced by. While CAT provides a critical and in depth understanding of the enroller-participant interaction, it does not provide a framework for understanding the broader organisational systems that influence the ICP. Additionally, this study analysed enrollers reported experiences of their interactions with participants, not the interaction itself.

Systems theory.

Systems Theory is formulated within an ecological framework that aims to understand the person-in-context with a focus on the complex relationships between individuals, groups, or communities and the systems in which individuals function (Stevens, 2007). A system is defined as two or more interdependent parts that are organised as a whole (Duffy & Wong, 2002; Hanson, 1995) and the relationships between these parts (Capra, 1997).

Individuals, interactions and relationships within these systems are understood by examining them as part of multi-level, multi-structured social processes and contexts (Stevens, 2007; Visser, 2012). The various parts of a system are constituents of a complex whole in which all subsystems interact with and are related to one another. Changes in one subsystem can affect the system as a whole (Visser, 2012).

The enroller is embedded within multiple complex systems which form part of a larger system. These levels are the microsystem, mesosystem, exosystem and macrosystem (Visser, 2012). To understand enrollers' interactions within these systems, it is necessary to understand the context within which they work. It is of further importance to understand enrollers in relation to the various parts of the whole (Visser, 2012).

The microsystem constitutes enrollers' immediate social interactions such as relationships and interactions with participants, work colleagues and direct site networks such as managers and employers. These interactions extend to interactions with community members during participant recruitment. The mesosystem acts as a linkage between enrollers' microsystems and the exosystem interconnects the micro- and mesosystems with systems that enrollers have no immediate interaction with but may affect the functioning of these systems. Lastly, the macrosystem is constituent of the broader organisation of the social institution in which enrollers function (Visser, 2012). This includes policies and procedures that influence and govern enrolment processes as well as the enroller-participant interaction.

Limitations of systems theory.

The use of Systems Theory alone in this study is limited in that it does not focus on communication within interactions at the level of the microsystem. Instead, it provides a framework to understand the context and relationships of the enroller at various systemic levels. This allows for the identification and explanation of procedural barriers related to trial protocol and understanding the enroller-in-context but does not provide an explanation of enroller-participant interactions and the various language and literacy barriers encountered therein. The integration of CAT aims to account for this limitation by focusing on communication and interactions between the enroller and participant during the ICP.

Summary of the key gaps in the literature

In order to understand the complexities of the ICP within clinical research and to improve the interactions between enrollers and participants, the experiences of both should be explored (Penn, Watermeyer & Evans, 2011). Communication during the ICP is crucial to ensure positive patient and research outcomes. Despite playing a key role in clinical trials and the ICP, there is a paucity of research on enrollers' reported experiences. Most studies have focused on participants' experiences of the ICP and barriers to consent; less so on enrollers' accounts.

Aims and Objectives

The primary aim of this study was to explore, using qualitative methods, the reported experiences of enrollers involved in the informed consent process in TB/HIV clinical research studies in Rustenburg, North West, South Africa. This research was focused on enrollers' accounts of communication processes and the interactions between them and potential participants before, and after, communication training.

The objectives of the study were:

- to identify perceived barriers and facilitators to communication during these interactions as reported by enrollers.
- to determine the perceptions of the effect of a subsequent communication training programme aimed at improving communication processes during the obtainment of informed consent and enhancing participant comprehension of information.
- to explore enrollers' reported impact of the communication training on

subsequent IC encounters with potential trial participants.

Methodology

Research Design

Study context.

This study was qualitative in nature and formed part of a larger ongoing qualitative research study conducted by the Health Communication Research Unit (HCRU). The HCRU is a multidisciplinary research team based at the University of the Witwatersrand that focuses on the challenges of communication in healthcare settings.

For the larger study, the HCRU formed part of the Advancing Care & Treatment for tuberculosis/Human Immunodeficiency Virus (ACT4TB/HIV) Consortium, a three-year South African Medical Research Council (SAMRC) funded collaboration between the Aurum Institute and several other collaborators. The collaboration brought together a multi-disciplinary team of HIV and TB experts and aimed to advance the HIV and TB fields through the development of interventions for treatment and care. It further aimed to improve patient, community and programme outcomes, implicate policy and practice, and align with local and international priorities. The HCRU's aim within this collaboration was to explore facilitators and barriers to the informed consent process within TB/HIV clinical research studies, as well as to develop, implement and assess a context-specific communication skills guide in order to enhance participant-staff communication at research sites.

As part of the larger study, participants (clinical research enrollers at a TB/HIV research centre) were divided into a pilot group and a control group. The pilot group received communication training in June 2016, whilst the control group proceeded with the standardised method of study enrolment. The control group received communication training thereafter in the month of September 2016. Enrollers in the pilot group received the training three months before the control group. Although the initial purpose of the control and pilot groups was to evaluate the effectiveness of the communication training, this study actually explored enrollers' reported experiences of the impact of the communication training. Therefore, this study is not an evaluative study of a training programme. Rather, it documents enrollers' reports of the impact of language strategies during IC encounters with potential trial participants. It was not

always clear from which study group enrollers' were as they did not explicitly state this in their journals. However, many of language strategies reported to be effective in facilitating communication and ensuring IC paralleled strategies taught in the communication training.

Additionally, data was collected from both the pilot and control groups in order to identify perceived barriers and facilitators to communication during IC.

Data was collected through various qualitative methods which not only enabled triangulation of data sources and strengthening of research design, but also allowed for a comprehensive interpretation of the data. These methods included reflective journals and focus group discussions conducted on clinic and community visits.

Reflective journals were guided by open-ended questions to facilitate enrollers' reports of their experiences of the informed consent process. Similarly, focus group discussions were guided by semi-structured interview schedules and conducted with the control and pilot groups to further explore enrollers' accounts of the informed consent process before and after communication training. Furthermore, communication training was conducted in the form of workshops by means of focus group discussions. Process notes of the communication training were taken throughout the data collection process.

Data analysis of the reflective journals and focus group discussions included the transcription thereof, followed by thematic analysis (Braun & Clark, 2006).

The research site.

The research site is a TB/HIV clinical research site in Rustenburg, South Africa that is part of the Aurum Institute. The Aurum Institute is an independent, non-profit, South African, public benefit organisation that focuses on TB and HIV prevention, care and treatment and further aims to create an awareness and understanding of health issues through research and the development of appropriate health systems ("Aurum | Where We Work - Clinical Research Centres - Rustenburg - Clinical Research Centre," n.d.).

Setswana is the predominant language of the Rustenburg area but English is the predominant language of enrolment at the site. In addition, there is a diversity of other languages spoken at the site. Rustenburg is a mining town, containing the world's largest platinum reserves varying in size (Hamann & Kapelus, 2004) and attracts a multitude of people with a diversity of languages.

The enrollers had to take into account all the numerous languages and language needs spoken by each participant during the informed consent procedure.

Although several on-going clinical studies are conducted at the site, two clinical studies were chosen for this study. Both studies were run simultaneously at the time of research. One was a twelve-month TB study involving several clinical visits, while the other study was a HIV and STI study which required participants to remain at the clinic for approximately two to three hours during one visit only.

In addition to the research studies, the site provides community services such as HIV and acquired immune deficiency syndrome (AIDS) counselling and testing, TB testing, family planning, testing for STIs, and the provision of contraceptives. However, the research site does not administer TB drugs or antiretrovirals (ARVs) outside the study but rather refers patients to local state-run clinics.

Participants.

Participants were enrollers who formed part of the staff at the specified Aurum Clinical Research Site and who partook in the enrolment process of the two selected studies. Despite not being first language English speakers, all enrollers were proficient and literate in English. Moreover, length of time employed at the research site, age and gender varied amongst enrollers.

Sample size.

The number of enrollers depended on the availability of enrollers at the time of the study, and their willingness to participate. Thirteen enrollers took part in the reflective journaling process, communication training and focus group discussions but only eleven journals were collected at the end of the study. Research and site staff were unable to locate these two outstanding journals. Despite this, in-depth data was collected from the eleven journals.

Sampling.

Participants were selected using convenience sampling and participation depended on enrollers' availability and willingness to take part in the study.

Inclusion criteria.

Staff members included in the study were primarily responsible for participant enrolment and recruitment. Their activities at the site included explaining the study purposes, obtaining informed consent and engaging with potential participants to address subsequent concerns and queries. In a typical enrolment, interactions between the enroller and potential

participant took place across a desk in a small consultation room. For the purposes of this study, enrollers were required to have an adequate literacy level and be proficient in English, due the selected data collection method, which will be elaborated in the sections below.

Exclusion criteria.

Patients involved in the clinical research studies concerned were excluded from this study as many of them were very ill and were already participating in research. Additionally, the focus of the study is on enrollers' accounts of the informed consent process and a subsequent communication training programme; therefore, it was felt that sufficient insight could be gained from the research site's staff.

Ethical considerations.

The balance between potential harm caused by the study and potential benefit to enrollers was considered (Bhutta, 2002). Enrollers may have experienced potential harm if they were not treated anonymously or felt that they would be held accountable by the institution for their responses. Therefore, the study took precautions to keep participant identities and responses anonymous. Research participants were given full autonomy, implying that they had authority to decide whether they wanted to participate in the study and were unrestrained by expectations of the researcher or institution of employment. Enrollers were not dictated by those with stakes in the research to partake in the study and were not disadvantaged for refusing to participate — participation was entirely voluntary. Since the research site is small, enrollers may have felt obligated to participate in the study. To account for this, enrollers were given clear explanations on the purposes of the study and of the benefits of participation and nonparticipation. Their full consent was obtained before they participated. Because communication training was effective in enhancing communication and comprehension in enroller-participant interactions, all enrollers at the trial site were given the opportunity to receive the training, regardless if they participated in the study or not. Training was all inclusive to ensure that all enrollers at the research site could benefit from the training.

The researcher was sensitive to any perceptions and views that emerged in the study and avoided treating certain accounts as right or wrong, accurate or inaccurate, or better or worse. The researcher additionally avoided imposing her own beliefs and values onto the research participants and refrained from steering the interviews and discussions according to expectations of study outcomes.

During the conducting of the focus group discussions and communication training, some enrollers refused to be audio recorded therefore responses had to be documented in writing. Several research assistants simultaneously documented participant responses.

This study was part of a larger ongoing study within the HCRU, namely "Training for Language Comfort: Enhancing the Informed Consent Process at TB/HIV Clinical Trial Sites", ethical approval was obtained from the Wits Human Research Ethics Committee (HREC) (Medical) (Clearance Number: M1600355), found in Appendix A. Moreover, as per the Aurum Institute and the research site's regulations, additional safeguards were complied with which included non-disclosure agreements and researcher confidentiality forms.

Data Collection

Data for this study was collected in the form of communication skills training workshops, focus group discussions and reflective journals. The latter formed the main method of data collection. The combination of several data collection methods was used to explore the reported experiences of enrollers involved in the ICP. Reflective journals focused on enrollers' accounts of communication processes and interactions between them and participants. Reflective journals, FGD's, and data from communication training workshops were used to identify reported barriers and facilitators to communication during these interactions and to determine enrollers' perceptions of the effect and their experiences of the communication training programme.

The researcher joined the larger HCRU study's researchers on two site-visits for data collection purposes. Data collection took place over two separate periods, first from the 8th-10th of June 2016 and then from the 20th-21st of September 2016. On both occasions, focus group discussions and communication training was conducted.

Communication training.

Extensive communication training was conducted in the form of workshops by means of focus group discussions. These workshops were led by a qualified language specialist with prior experience in implementing communication training programmes (namely Professor Claire Penn), as well as other members of the HCRU. Professor Penn was also one of the study's supervisors and primary research investigator of the larger HCRU TB project. Training extended for two to three days at a time and occurred at two stages of the research process depending on whether participants were in the pilot or control groups. Although the researcher was present and part of the communication training workshops, she did not conduct the training

herself. During the workshops, the researcher documented the discussions that were subsequently analysed and transcribed. An example of the content of the communication training programme can be found in Appendix B.

Enrollers reported on their experiences of the communication training in the form of a feedback report. These can be found in Appendix E.

Focus group discussions.

Focus group discussions (FGD) were conducted with enrollers in the pilot and control groups to further explore enrollers' accounts of the informed consent process before, and after the communication training. Six FGDs were conducted in total.

The first FGD included all thirteen enrollers and took place on the 9th of June, during the first site visit. This involved an introductory session and the discussion and explanation of the journaling process and the informed consent documentation.

Four FGDs were conducted during the communication skills training, two for the pilot group and two for the control group. The former two focus group discussions consisted of seven enrollers, and the latter two of five. The pilot focus group discussions were led by Prof. Penn and took place on the 9th of June 2016, whereas the control focus group discussions were led by Megan Scott, taking place on the 21st of September 2016. Findings from the journals were used to guide the focus group discussions conducted after the journaling process and to further strengthen insights gained from the journal reflections.

A final FGD took place after the completion of the study. This involved a discussion on enrollers' experiences of the journaling process and was conducted on the 21st of September 2016. This included all enrollers who were involved in the journaling process and was led by the researcher (Samantha Nolle) and Megan Scott.

The interactions within groups were analysed as discussions that occur in a specific and controlled setting. Additionally, groups were the main unit of analysis rather than individuals within groups (Kreuger, 1994). Focus group discussions were further seen as a social event from which language is seen as functional and constructive, and not as a means to neutrally convey information (Smithson, 2000). Possible limitations of using focus group discussions as a means of data collection was the permitting of one opinion by dominant individuals within the group and the obscuring of controversial perspectives by group dynamics such as the reproduction of normative discourses (Smithson, 2000). The use of anonymous reflective journals as a primary source of data collection addressed a major limitation of focus group

discussions: the tendency of socially acceptable opinions to emerge within focus group discussion.

Reflective journals.

Data collection was done primarily through reflexive journals. This was to encourage enrollers to report their experiences of the informed consent process on a daily basis and to allow them freedom to identify barriers and facilitators to communication during these processes as they were encountered. Moreover, the use of reflective journals encourages participants to reflect carefully on learning experiences which facilitates and develops critical thinking, critical self-awareness and self-development through the documentation of own experiences (Hogan, 1995; Loo & Thorpe, 2002). The journaling process further encourages participants to record their processes and progress; to develop an understanding of themselves within the work context (Hogan, 1995); to formulate ideas, beliefs and responses to the research study (Janesick, 1999); and facilitates new ways of thinking (Progoff, 1992). Journal writing additionally provides opportunity for the triangulation of data.

Participants in both the pilot and control groups were asked to keep reflective journals for a three-month period. The three-month period was chosen to enable and motivate in-depth writing and reflections over multiple enrolment sessions. Literature on journaling about experiences in multiple contexts revealed that journal keeping time ranged from two weeks, one month, to two years (Mercer, Warson, & Zhao, 2010; Ullrich & Lutgendorf, 2002; Banks-Wallace, 2008).

The journals integrated and encouraged visual art journaling in addition to written journaling. Reflective journals were compiled by the researcher and included lined-paper for writing, pages to colour in, stickers, a daily planner, and a stationery pack. The journals were guided by open-ended questions proposed and complied by the HCRU team but enrollers had agency to write about topics not addressed by the questions. Examples of the reflective journals can be found in Appendix C and types of questions proposed in Appendix D. These diaries were used to document their accounts of the informed consent process for the studies that they were involved in.

Journals were collectively handed to all enrollers by the researcher during the first site visit before the communication skills training commenced. An introductory session was given to all enrollers after the journals were handed out. This included an introduction to and description of the HCRU, the HCRU's past and current research, each researcher on the team and a brief description of the study. The process of reflective journaling and the guiding

questions were then explained to them by the researchers and enrollers were given an opportunity to ask questions on the journaling process or the study. The researchers took caution to avoid the discussion or mention of any of the study's specific aims, objectives and research question with enrollers, as to not guide their responses and accounts. Enrollers were expected to continuously write in their journals about their experiences of enrolment sessions and the ICP during this three-month period. In a focus group discussion conducted after the study, enrollers mentioned that they either wrote after every enrolment session, at the end of the day or at the end of the week. Due to geographical reasons which limited the researchers being on site on a regular basis, a site manager in Rustenburg was approached and agreed to assist the researchers in their absence. The manager agreed to monitor and encourage enrollers to continue to engage in the journaling process during the three-month period. The research team remained in frequent contact with the site manager when not at the site. For the journaling purposes, the researcher was blinded to the identity of the enrollers and was unaware of who had received the communication training and who had not. The diaries were anonymised through the allocation of numbers, each number representing a different enroller. The journals were collected on the second site visit.

Limitations of journaling as a method.

Journaling everyday experiences can be a time-consuming and intensive process, especially when enrollers have high job demands. In a focus group discussion conducted after the study, enrollers were asked about their experiences of the journaling process. Several mentioned that it was challenging to make additional time to journal after each enrolment session. Some enrollers were able to write about each enrolment session directly after but others only managed to write about sessions a few days later. Although writing about a session a few days later may have had implications on the accurate documentation of the event, detailed and in-depth accounts were still obtained. While many enrollers actively engaged in the journaling process, some did not write extensively. When further probed, it was found that some enrollers enjoyed journaling more so than others and found journaling to be an easier task. The integration of visual arts and aids was reported by enrollers to have made the journaling process more enjoyable and alleviated boredom associated with the task. The literacy ability of enrollers was a prior concern despite all enrollers being proficient in English. Although English was not the home language of all enrollers, enrolment sessions were predominantly conducted in English. Small literacy errors did occur yet these texts were still comprehensive.

Data Analysis

Data collected from the communication skills training workshops, focus group discussions and reflective journals was integrated in the analysis. Data from the FGDs and communication training programmes was used to inform findings from the journals, limitations of journaling as a method, and recommendations for future studies.

Reflective diaries, transcripts, and focus group discussions were analysed by means of thematic analysis as described by Braun and Clarke (2006). This method was used to identify and analyse themes within the data and report on the realities and experiences of enrollers, taking on a realist framework. Specifically, an inductive approach to thematic analysis was taken using a six-phase guideline (Braun & Clarke, 2006).

During the first phase, the researcher familiarised herself with the data by repeatedly reading the data and noting down initial ideas for coding. Next, codes were systematically coded across the entire data set and collated. Thereafter, codes were collated into themes and then reviewed to ensure that themes related to codes. Themes were further refined and definitions and names for each theme were generated and clarified. Lastly, excerpts were selected to provide an in-depth overall account of the data.

Thus, themes that were identified in the data were not necessarily driven by the research question or the researcher's theoretical interests, rather themes were coded without a pre-existing framework in which the data was expected to fit, although the researcher recognised that she cannot be entirely devoid of her epistemological interests (Braun & Clarke, 2006). Themes were identified at a semantic level which involved the description and interpretation of patterns of meaning and their broader implications. The use of thematic analysis as a method was used because it allows for the minimal organisation of data whilst allowing for an in-depth and detailed account thereof. It further allowed for the interpretation of the data in light of the research topic (Braun & Clarke, 2006; Boyatzis, 1998). Providing a rich overall description of the entire data set was preferable because enrollers' accounts of the informed consent process have not been researched extensively. Excerpts from the data were additionally used to illustrate the themes found, and to allow the "voice" of the participant to emerge from the data.

Academic rigour.

The researcher served as a moderator of the focus group discussions rather than dictating directionality. Thus, enrollers predominantly guided the direction of discussions rather than the researchers. Additionally, the researcher was cautious to exclude responses and include others to fit into answering the research question. All data was taken into consideration and all participant responses were analysed to provide a holistic view of enroller's accounts.

To ensure academic rigour, triangulation of data gathered was used to match the analysis with the data, ensured claims were empirically grounded (Braun & Clarke, 2006) and further improved the understanding of complex concepts (Jones & Bugge, 2006). Peer debriefing was done both with the research supervisors, as well as with peers not affiliated to the research study to explore any biases or assumptions the research may have had (Lincoln & Guba, 1985). All data was kept anonymous during this session.

Evaluative criteria for quality.

There is a broad and large variety of criteria used to assess quality in qualitative research. Harden's (1999) suggested criteria for assessing qualitative studies involve providing an explicit account of the theoretical framework, clearly stating aims and objectives, giving a clear description of content, the sample, and methodology and data collection methods, the analysis of the data by more than one researcher, and the inclusion of adequate raw data in the interpretation.

An account of the literature as well as the theories in which this study was framed have been provided, namely communication accommodation theory (CAT) and systems theory. Moreover, all aims, objectives, sample, methodology and data collection methods have been described in full. Data excerpts were quoted directly from enrollers' journals and have been included in the analysis section.

Data analysis, findings, and interpretations were further triangulated amongst the HCRU team of researchers for increased validity. The first data analysis session was conducted on the 9th of June, during the first site visit. Notes that were taken by the researchers on the FGDs and communication skills training were compared and discussed to validate the data. The notes and findings from the both site visits were collected, collated and stored. A second data analysis session was held on the 3rd of February 2017 to validate the findings of the reflective journals. Multiple members of the HCRU attended to triangulate data. Themes from the journals were validated and compared to findings and themes from the FGDs. Additional meetings were held throughout the course of the study with the researcher and supervisors to further validate data.

Alternatively, for Tooley and Darby (1998), quality is research that makes a real contribution to theory or knowledge, is relevant to practice, and is further coordinated with existing research. Although there is extensive research on clinical trials, there is less so with a predominant qualitative focus, and to the researcher's knowledge, none exploring enrollers' experiences of the ICF process in a South African context. This research study contributes to

the knowledge of enrollers' experiences during enrolment and informed consent in research trials and further aims to make insights gained relevant to the everyday practices of enrollers who "do" ethics-in-the-field.

Furthermore, research that is relevant in that it contributes to knowledge, increases confidence in that knowledge, informs practice, or can be generalised to other settings is another indicator of quality in qualitative research (Gutiérrez & Penuel, 2014; Nicolai, Schulz, & Göbel, 2011; Gough, 2007; Porter, 2007; Boaz & Ashby, 2003; Mays and Pope, 2000) The findings from this study will be used to inform practices surrounding the ICP and use of the Informed Consent Form (ICF) and to further inform and modify communication skills guides across multiple clinical research sites in South Africa.

Results

The enrolment process was found to be a difficult process that was impacted by multiple variables. There is much intersection between themes and subthemes which highlight the complexities of the ICP in research studies and enrollers' crucial role in obtaining informed consent. For example, lifeworld events, language fluency, and verification of understanding are prominent issues enrollers reported on having to deal with during enrolment sessions.

This section aims to identify and discuss the perceived barriers and facilitators to communication within the enroller-participant interaction, most notably, language and literacy barriers and facilitators. Further barriers relate to trial protocols and procedures, and participants' motivations for participation in trial studies. Additional facilitators to communication and enrolment into the trial are identified and discussed. These include altruism, knowledge on research, interactive communication behaviour and an interest in the study.

Communication and language strategies employed by enrollers during the ICP have been identified and discussed. These strategies were used to improve communication processes between the participant and enroller during the obtainment of informed consent and to ensure participants had a comprehensive understanding of information on the ICF. Various communication and language strategies reported on by enrollers paralleled those that were taught during the communication training. The impact of training for language comfort is further discussed in this section. This pertains to the impact of communication and language

strategies on communication processes during the ICP, the enrolment of participants and the obtainment of informed consent. The effectiveness of the communication training programme was not evaluated. The impact of language strategies during the ICP was reported on by enrollers collectively rather than separate evaluations from the control and pilot groups.

The majority of the analysis has been done on the written experiences of enrollers and all data excerpts have been taken from the reflective journals. The analysis of the reflective journals has been supplemented with data from the FGDs with enrollers.

A summary of the major themes can be found below in Table 1 and Figure 1. Several sub-themes within the major themes have been further identified and will be expanded on. The overlap of themes can be found in Figure 2.

Figure 1

Summary of Communication Processes in the Informed Consent Process

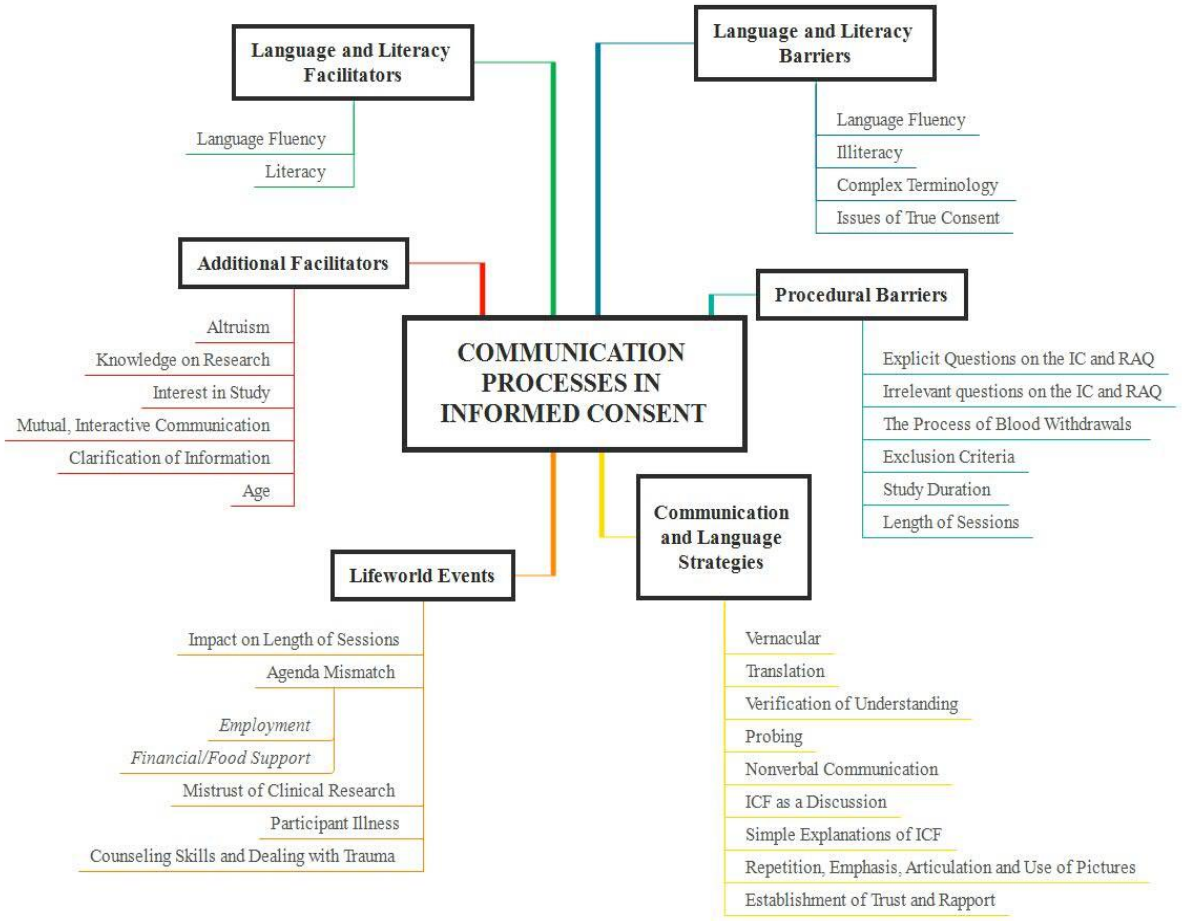


Table 1

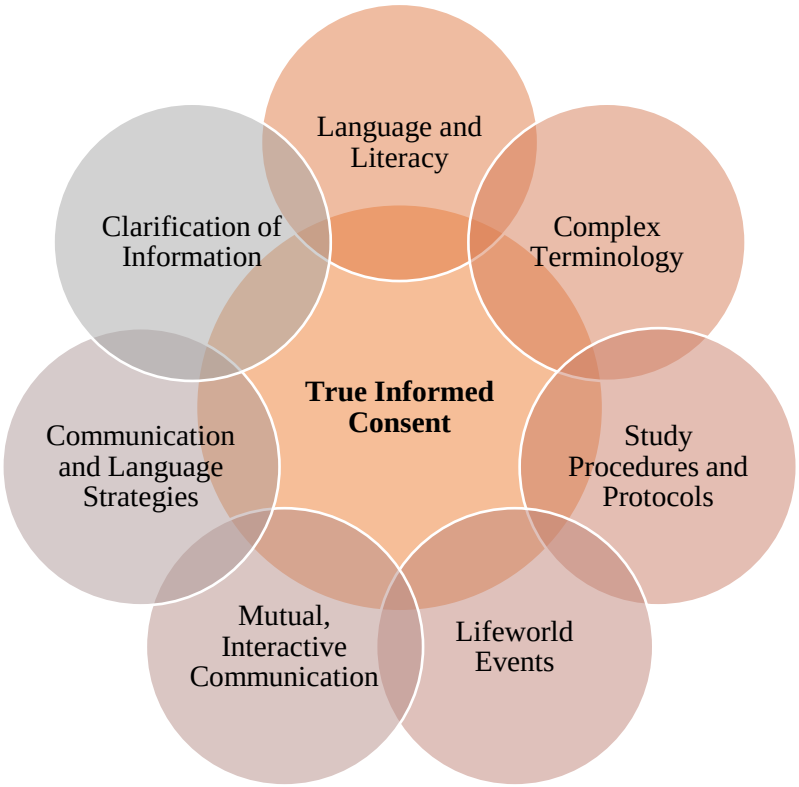
Expanded Summary of Communication Processes During Informed Consent

Theme	Description
Language and literacy barriers	Language barriers refer to participants' difficulty in understanding the language of choice of the ICF, comprehending complex words and medical terms, and the language comfort of both enrollers and participants.
	Enrollers found that participants had difficulties comprehending the ICF, the procedures of the trial, what is expected of them as research participants and what research is.
Language and literacy facilitators	Participants who were fluent in the language of the ICF and ICP were better able to understand information on the ICF. Literate participants were found to understand complex terminology more easily.
Additional facilitators to communication and enrolment	Altruism, knowledge on research, interest in the study and previous participation facilitated communication and enrolment. Interactive participants, clarification of information and age were further reported facilitators.
Communication and language strategies	Various language and communication strategies used by enrollers facilitated enrolment. These strategies included flexibility using the ICF, verification of participant comprehension, referrals to other staff and group sessions. The use of body language and the establishment of trust and rapport were additional facilitators.
The impact of training for language comfort	The impact of the communication skills training on enrolment and the ICF process was explored. Communication skills and language comfort facilitated enrolment and the ICF process as well as established trust between enroller and participant.
Procedural barriers	Procedural barriers included participants' fear of the process of blood withdrawals and the amount of blood taken, as well as a

	distrust of what happened to their blood afterwards.
	The process of informed consent, reading the informed consent form and ensuring participant comprehension thereof present as a practical difficulty for enrollers.
Participant barriers and lifeworld events	There was a mismatch between the expectations of the enroller and the participant. Participants often had ulterior motives for trial participation such as HIV/AIDS or STI testing and requesting STI medication, employment or cash donations.
Lifeworld events and enrollers' roles	Enrollers had multiple and complex roles that extended beyond the IC process and enrolment such as counselling of participants experiencing traumatic events, illness, and poverty.

Figure 2

Factors Impacting True Informed Consent During the ICP



Language and Literacy Barriers

A major barrier to communication in the informed consent process (ICP) and enrolment is that of language and literacy barriers. Literacy is defined as the ability to read and write whereas illiteracy is the inability or difficulty to do so. Moreover, language fluency is defined as the ability to speak and comprehend a language easily and well (fluency, 2010). This includes the ability to comprehend written language. Enrollers frequently noted language barriers between themselves and the participant. Participants were often found to be illiterate and had difficulties comprehending the informed consent form (ICF) and information that was explained to them. They were further found to not be fluent in the language of the chosen ICF, or found the complex language and terminology of the ICF difficult to understand. This section explores language and literacy barriers to communication and enrolment, the reasons thereof as stated by the enrollers, and the implications to informed consent. Several excerpts from the journals are provided. A summary of the identified themes pertaining to perceived language and literacy barriers can be found in Table 2.

Table 2

Summary of Language and Literacy Barriers

Language fluency and comprehension of the ICF
Terminology
Illiteracy and informed consent
Issues of true consent

Language fluency and comprehension of the ICF.

Language fluency was a major reported barrier to communication and the comprehension of the ICF. During the ICP, participants were given the opportunity to choose the language of the ICF as well as the language in which the session was to be conducted. Despite this, participants often chose a language in which they were not fluent or literate. Even when participants were familiar with or fluent in speaking their first language, many had difficulties comprehending the complex terminology and information on the written ICF.

Although the participant in E6's session was Setswana speaking she chose an English ICF despite not being fluent in English (journal 6, entry 5, table 2.1). It became evident that the participant did not understand the information on the ICF and study requirements when she enquired about the starting of the "class" at the end of the session. Moreover, the participant had difficulties comprehending certain terminology on the ICF. E6 subsequently expressed her desire for simpler terms to use when speaking to participants to assist in participants' comprehension of study requirements and their role as "research assistants".

The following four entries similarly demonstrate challenges with language fluency and comprehension of the ICF. In journal 11, entry 1 (table 2.1), the enroller describes how an English ICF was chosen by a Setswana speaking participant. Despite this, the participant did not understand the English ICF and the enroller then had to interpret the sentences from English to Setswana. The subsequent translation of information on the ICF Setswana facilitated the participant's understanding thereof. In a different session, the same enroller switched from the language of choice to English after she realised the participant could not understand Setswana (journal 11, entry 12, table 2.1). Even though the participant initially chose a Setswana ICF,

she understood the information much better when conducted in English. Similarly, enroller thirteen facilitated comprehension by simplifying difficult words when a Sotho-speaking participant found certain Setswana words difficult to understand and could not comprehend any English (journal 13, entry 5, table 2.1). It is not clear whether the participant chose a Setswana ICF. In a similar session, a Setswana speaking participant could not understand some Setswana words on the ICF despite Setswana being the chosen language (journal 13, entry 8, table 2.1). The enroller then explained the words until the participant understood them.

It has been recognised that the diversity of language at trial sites can pose barriers to communication within the enroller-participant interaction (Penn & Evans, 2009). Informed consent forms should be translated and adapted to participants' preferential language and communicated in a comprehensive manner (UCT HREC, 2014). In accordance with Hussey's (2012) findings, communication within interactions declined when participants' proficiency in the language of the ICF was limited. Language thus became a barrier to communication and participants' understanding of the ICF. Enrollers who were proficient in the language of the participant were able to interpret and translate the ICF in a manner that participants could understand. It is thus important that the ICP be conducted in a language in which both participants and enrollers are proficient.

Table 2.1

Data Excerpts for Language Fluency and Comprehension of the ICF

E6:	The session was conducted in English because she preferred English ICF and she is Setswana speaking. The session did not go well because she is not fluent in English and there were terms that she did not understand … after doing the ICF she asked me "when will the class start?" [entry 5]
E6:	I just wish that there were more easy terms/words to use when speaking to a participant in order for them to understand more about what we are doing and what is required of them and us as research assistants [entry 5]
E11:	English HSP …it also came to my attention that participant choose the language which she didn't understand. I tried to interpret every sentence in her language (Setswana), and it went better. [entry 1]
E11:	The participants choose Setswana ICFs, however when we go through the ICFs, the participants said that they do not understand the language (Setswana). The ICF language was then changed to English the participant's preferred language …participant understood the ICF that was conducted in English. [entry 12]
E13:	Participant was a Sotho person and, some words in Setswana when explain, seemed to be a bit difficult but eventually

	understood. Participant could not also hear English, so language difficulty became a bit problem but it was resolve. Those difficult words had to be simplified. [entry 5]
E13:	Participant choose Setswana ICF informed consent …participant did not understand some of Setswana words, hence she is Tswana, I explain them, she eventually understood. She understood those word. [entry 8]

Part of the reason that participants may have chosen a language other than their first language may have been due to the language complexities of their first language or their literacy abilities. For example, a Setswana-speaking participant chose an English ICF because it was simpler for him to read in English than in Setswana (journal 8, entry 1, table 2.2). Many enrollers switched between languages and translated words and/or sentences when they realised participants did not comprehend the chosen language of the ICF. It is thus important that enrollers recognise the language and literacy abilities of each participant so that the ICP can be modified to ensure all participants are sufficiently informed. In a FGD conducted prior to the communication training, enrollers noted that they did not switch between languages but rather were required to use one, that of the ICF. This was reported to have hindered effective communication between them and participants. During the communication training, enrollers were encouraged to conduct enrolment sessions in multiple languages to meet the language needs of participants. This was then found to be an effective communication strategy during subsequent ICPs.

Table 2.2

E8:	He chose English and explained that even though he’s home language is Tswana it will be difficult for him to read it. So English was simple for him. [entry 1]

Despite the employment of strategies to facilitate participants’ comprehension of the ICF, it was not clear whether participants did in fact fully understand the study requirements, aims or their role as participants. This highlights issues of true consent. If participants do not understand all the information on the ICF, then they are not able to give true consent. E4 provides an account of a session in which the participant could not verify her understanding of the IFC at the end of the discussion despite having participated in previous research studies

(journal 4, entry 2, table 2.3). This implies that having been a previous research participant does not imply participants understand informed consent and study objectives.

A frequently reported issue was that participants told enrollers that they understood the information being explained to them but could not verify their understanding when asked. If enrollers merely asked if participants understood, participants would confirm even if they did not understand. This implies that enrollers are required to ask participants to verify their understanding to ensure proper comprehension of the ICF. Schlemmer and Mash (2016) similarly found that isiXhosa-speaking patients were inclined to say they understood explanations given by the healthcare provider even when they did not and was attributed to the notion that verifying comprehension would be disrespectful towards the provider.

E4 asked the participant to explain to her what she understood about the study and study objectives, yet even after confirming that she understood, the participant became confused and was unable to do so. The enroller then contemplated whether she did not explain thoroughly enough or whether the participant did not pay attention during the session. Although the answer to this is difficult to know, as noted by E4, communication barriers may arise as a result of enrollers inadequately explaining the ICF. This highlights the need for enrollers to be sufficiently trained in communication skills, thereby enabling them to utilise strategies to facilitate participant comprehension of the ICF. Falagas et al. (2009) similarly suggest that participant comprehension of study information may also depend on the manner in which enrollers explain relevant information.

Table 2.3

E4:	…participant who preferred English language for the informed consent process …I somehow thought that this participant understood what research and informed consent meant already as she has been a research participant before …at the end of the informed consent discussion, I asked the participant to tell me what she understands about this particular study. Unfortunately the participant was just all over the place without telling or not being able to tell me what I have been explaining. She basically couldn't tell me the main purpose or the objectives of the study but she has been saying that she understands what I was explaining to her. That for me was a disappointment and was wondering if it was myself who did not explain thoroughly or if it was her who was just not paying attention. [entry 2]

In this study, language fluency and literacy ability were found to be major barriers to participants' comprehension of the ICF and successful enrolment. As was found in multiple

studies on communication in health settings (Hussey, 2012), quality of communication within interactions between enroller and participant declined when the participant's proficiency of the language in which the ICF was conducted was limited or lacking. Enrollers experienced difficulties explaining the procedures, study expectations, and terminology to such participants and therefore had to employ communication and language strategies to overcome language barriers. A major finding was the need for enrollers to actively verify participants' comprehension of the ICF even after participants told enrollers they understood. This allowed enrollers to pinpoint exactly what the participant did not understand and explain further.

Terminology.

Complex and/or medical terminology on the ICF presented as an additional barrier to communication and comprehension and had implications on the true consent of participants.

Participants frequently found the complex and medical terminology unfamiliar and difficult to understand and the explanation thereof was a demanding task for enrollers. This has further been found in studies on clinical trials and health settings. Participants and patients often find complex medical and legalistic terminology difficult to understand (Marshall, 2006; Ssali et al., 2015; Mandava et al., 2012; Nishimura et al., 2013; Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009) and may have implications on true consent (HREC, 2014; Marshall, 2006). Additionally, communicating medical information has been found to be challenging for healthcare practitioners (Woodsong & Karim, 2005).

Even when participants were fluent or comfortable in their language of choice, they still asked for clarification on terminology they did not understand. Enrollers reported that participants often asked for the simplification or translation of complex, medical terms into terms that they were familiar with. Moreover, enrollers found the simplification and explanation of terminology on the ICF to be a challenging task and wanted simpler terms as well. Participants additionally desired terms that they and the community were familiar with. This highlights the importance of enrollers understanding the community from which participants are from and participants' contextual and lifeworld issues. Knowledge on how to simplify terminology and translate terms into familiar words and explanations that participants can understand can assist in the facilitation of comprehension of the ICF.

The below entries from three different enrollers demonstrate these perspectives.

Table 2.4

Data Excerpts for Terminology

E7:	During questionnaires explaining PEP propholuxy it a challenge because it's a word that they are not familiar with it in the community and she wished if it can have another name. [entry 1]
E9:	Participant asked for an English consent form at the front desk. However the session was conducted in both English and Tswana. She was very comfortable with both languages …she paused me to get clarity on words such as "prevalence", "CD4" and "physical examination. [entry 1]
E7:	He was surprised about other words that we used when we read informed consent that they are no used to those words. And in future we should use words that they are familiar with in the area. [entry 5]

Illiteracy and informed consent.

A further reported barrier to communication and enrolment was participant illiteracy. Illiteracy is defined as the inability to read and/or write or difficulties in doing so (illiteracy, 2015). Some participants had difficulties reading whilst others found writing to be challenging. Several participants struggled to read the ICF but more frequently, had difficulties in writing their name on the consent form (journal 6, entries 11 and 14). Additionally, a mismatch between participants' speaking and language ability and their writing and reading ability was found. Participants were able to give verbal consent but some could not or struggled to give written consent. Penn and Evans (2010) found that a modified ICP facilitated participant comprehension and improved interactions. The modification of the ICF and alternative ways of acquiring informed consent (i.e. verbal consent) for participants who are illiterate can facilitate their comprehension thereof and increase enrolment.

This study has found that communication within the enroller-participant interaction is crucial to establish participants' literacy and language abilities and their comprehension of the ICF. Furthermore, communication within interactions was found to be important to help enrollers formulate participant-specific strategies to ensure participants' proper comprehension of the ICF. The enroller therefore had a vital role in ensuring comprehension, true consent, and the enrolment of participant into the study. Similar to CAT, enrollers modified their communication behaviours to meet participants' language and literacy needs. This is in alignment with the National Health Act of South Africa (2003) which stipulates that informed consent account for participants' literacy abilities. Enrollers were required to take a flexible approach to discussing and explaining the ICF to participants as well as obtaining consent.

Employing a more flexible rather than rigid approach during the ICP to obtain consent has been found in this study to effectively facilitate communication processes and ensure informed consent.

Table 2.5

Data Excerpts for Illiteracy and Informed Consent

E6:	she couldn't write her name on a separate page until she got it right so that we may avoid making more mistakes on the ICF. [entry 11]
E6:	The session didn't go well because the participant couldn't write properly and that was really making him frustrated and impatient so I assured him that if he writes slowly he will eventually write properly. [entry 14]

Issues of true consent.

As was previously mentioned, some participants had difficulties comprehending information on the ICF such as study objectives or procedures but were inclined to report to the enroller that they understood what was being explained to them even when they did not. This meant that they were consenting without having an adequate understanding of what they were consenting to. A mismatch between their comprehension of explained study procedures versus when the actual study procedures were being conducted was found. This became evident when participants had problems with procedures such as blood withdrawals after consenting (journal 8, entry 4, table 2.6).

Table 2.6

Data Excerpts for Issues of True Consent

E8:	…if he understood everything when read, explained and discussed he would not have signed. So he signed for things he did not understand. That's why when the procedure of blood was asked about it he started having problems. [entry 4]

This mismatch was further seen when participants became confused about study requirements such as follow-up visits or when experiencing side effects from the medication. In a focus group discussion, enrollers mentioned that participants experienced difficulties coming back to the site. Moreover, participants had issues with experiencing side effects even

when the side effects had been explained to them, although enrollers noted that doctors at the site did not always explain the side effects to participants. They additionally highlighted the challenge of explaining the side effects of the medication to participants. Participants were instructed to call the enroller or the site doctor if they experienced medication side effects but did not do so. Instead participants would often remain at home which would worsen their condition. Studies have found that participants/patients who are not proficient in English have difficulties comprehending and adhering to treatment and following up with practitioners which can have serious health implications (Kazzi, Bonacruz, & Cooper, 2003; Schlemmer & Mash, 2006; Meuter et al., 2015).

In the focus group discussion, enrollers noted that explaining the right to withdraw from the study was one of the most difficult concepts of the ICF to explain to participants. Enrollers further emphasised that understanding the implications of consent was crucial for participants and that participants should be willing to give consent to participate and this requires them to have a proper understanding of the ICF, study requirements and importance of their participation.

In this study, enrollers expressed their concern that participants consented when they did not understand what they were consenting to such as in the case of journal eight entry four (see above). As is seen in journal four entry two, it was important for enrollers to ask participants to verify their understanding of the ICF before allowing them to consent. This strategy became more evident after enrollers received communication training.

Language and Literacy Facilitators

This study has found that language fluency and literacy can be a major facilitator to communication within interactions during the ICP and study enrolment.

Participants who could speak and comprehend the language in which the ICF was conducted, facilitated communication between them and the enroller. Hussey (2012) suggests that healthcare practitioners should be proficient in the language of the participants. Enrollers who spoke the same language as participants had better language facilitation and communication. Language comprehension and fluency has been found to be a facilitator to communication in this study. In alignment with the findings of Jacobs et al. (2006), language-concordant pairs were found to improve enroller-participant interactions and participants' comprehension of explanations of the ICF.

When participants chose a language in which they were fluent, they better understood the information on the ICF (journal 2, entry 1, table 3.1). Furthermore, enrollers with good

introduction skills and who established participants' background information such as literacy level, facilitated better communication and comprehension of information during the session. Enrollers further reported that communication and comprehension between them and participants was better when they were fluent in the same language (journal 6, entry 6). During the communication training, enrollers noted that many of them were proficient in multiple languages and could therefore communicate with a diversity of participants. They however admitted that pre-training, they did not readily switch between the chosen language of the ICF and the spoken language of the participant. Flexibility in accommodation approaches to communication emerged post-training after enrollers were encouraged to speak more than one language during enrolment sessions to meet participants' language needs.

Table 3.1

Data Excerpts for Language and Literacy Facilitators

E2:	The session was done at the participants home in the language of her choice which was Setswana … Literate level assessed and found to be literate … The session went well. [entry 1]
E6:	The session was conducted in Setswana because he asked for Setswana ICF and he is also Setswana speaking. What stood out for me was that me and the participant had a good communication session because we were speaking the same language that we both know and understand. [entry 6]

Enrollers further reported that participant literacy was a major facilitator to communication and comprehension of the ICF. The ability to read and write was found to be an important facilitator to comprehending the study objectives and terminology in this study (journal 4, entry 4; journal 6 entry 1; journal 6 entry 16; journal 6 entry 19, table 3.2). Participants who were literate were able to comprehend information on the ICF with ease and were more likely to understand what was expected of them as participants in the study and study procedures. Moreover, participants who were literate seemed to be more interactive and asked enrollers more questions during the ICP which in turn facilitated communication and comprehension (journal 7, entry 1, table 3.2). Therefore, literacy of the participant was found to be a key factor to comprehension of the ICF, true consent and the successful enrolment of participants.

Table 3.2

E4:	The session went very smoothly because he was very literate and could understand the objectives of the study. [entry 4]
E6:	The session went well and successful because the participant was literate, she could read and write. She could easily understand the terms that were difficult to understand it the study. [entry 1]
E6:	The session went well because the participant knew how to read and write so I didn't have to look for a witness. So both went through the ICF by reading the ICF together. [entry 16]
E6:	The session well because the participant knew how to read and write. And the participant understood the ICF. [entry 19]
E7:	It went well with participant that understood what she was doing and she was interested to more research. During Informed Consent session she was able to read with confidence and ask questions. [entry 1]

Additional Facilitators to Communication and Enrolment

In addition to language and literacy, it was found that participant altruism, knowledge on research, interest in the study and previous study participation was a facilitator to communication within the ICP and enrolment. Moreover, interactive participants, clarification of information and age was found to be an additional facilitator. A summary of themes related to other perceived facilitators to communication and enrolment can be found in Table 4.

Table 4

Additional Facilitators to Communication and Enrolment

Altruism
Knowledge on research
Interest in study
Mutual, interactive communication
Clarification of information
Age

Altruism.

As previously mentioned, this study has found that participants had various reasons for participating in the trial study. The majority of participants partook to acquire reimbursement, HIV results, contraceptives, food or employment opportunities. However, some participants enrolled in the study for altruistic reasons. Altruism is defined as caring about the needs of others more than one's own (altruism, 2015). Some participants partook in the study to make a difference in the lives of others by helping researchers develop medications or vaccines that target infectious diseases such as TB (journal 2, entry 1; journal 6 entry 11, table 4.1). Moreover, some participants had lost family members or friends to TB or HIV/AIDS, therefore desired to educate family and community members (journal 2, entry 1, table 4.1).

Table 4.1

Data Excerpts for Altruism

E2:	The participant was willing to take part in the study as she said it had been her wish all along to being a difference in other people's lives by helping the researchers to come up with ways to combat infectious diseases especially TB as she already lost 2 of her siblings from it. She was also willing to share the information that she received with her friends, family and other community members. [entry 1]
E6:	The participant however agreed to participate on the study because she wanted to contribute towards helping develop a TB vaccine in the near future. [entry 11]

Other participants wanted to assist other people, the "nation", and the "coming generation" by participating in research studies (journal 8 entry 1; journal 10 entry 2; journal 10 entry 3, table 4.2) whilst others desired to assist with research (journal 9 entry 3, table 4.2). Altruism as a motivation to participate in a study has been found in other studies on clinical trials (Picillo et al., 2015).

Table 4.2

E8:	Participant was friendly and wanted to know more. He explained that he likes assisting people and if there's anything that has to do with helping the nation he's our person. [entry 1]
E10:	participant was screened because she agreed to help the new coming generation by being part of our research [entry 2]

E10:	Participant was enrolled in our study. To help the new coming generation and the nation. And also to know her status everytime she came in for her visit. [entry 3]
E9:	Participant was enrolled in the study, this was due to reason that she understood her participation in the study and wanted to help with research. [entry 3]

Knowledge on research.

Enrollers reported that participants who had past knowledge on the study or had been informed of the study by family or friends better comprehended the study objectives and procedures (journal 6, entry 4; journal 6, entry 13, journal 6, entry 20, table 4.3). Furthermore, communication and interactions during the ICP were facilitated when participants were educated on HIV/AIDS and sessions were reported to have gone well (journal 6, entry 9, table 4.3).

Table 4.3

Data Excerpts for Knowledge on Research

E6:	…she was brought by her friend who participated in the HSP study before so the friend had already told her what the study entails …The participant decided to enrol in the study because the friend had already convinced her to participate in the research study. [entry 4]
E6:	The session went well because the guy was very co-operative and knew what he came to do on our site. [entry 13]
E6:	The session went well because the participant already knew what was happening in our research study since well her family was already screened so I was informing her about the ICF, what it entails and the participant understood and she had no questions. [entry 20]
E6:	The lady was very informed about HIV, she actually knew important things about HIV testing and counselling so the session went well. [entry 9]

Interest in study.

In addition to past knowledge, an interest in the study was reported as a facilitator to participant enrolment. Participants who had an interest in what the study was about (journal 6, entry 18, table 4.4), being a part of the study (journal 4, entry 4, table 4.4) or finding out more

about TB (journal 6, entry 1, table 4.4) were more willing to participate in the study. Furthermore, some participants recognised the need to educate the community about the study and its importance (journal 7, entry 5, table 4.4).

Table 4.4

Data Excerpts for Interest in Study

E6:	The participant understood and agreed to participate in the research study because she was interested in the research study. [entry 18]
E4:	The participant had mentioned that he heard from his friend about the study and that's when he developed some interest in being part of the study. There was really nothing I could fault about the session. Everything went well. [entry 4]
E6:	…that the participant was open minded and was willing to enrol in the study because she was also interested in knowing why is she not getting infected with TB while she is staying with someone who has TB. [entry 1]
E7:	Participant was willing to participate in the study and he wanted to invite more people in the study. Since in this study we only screen people who are staying with people who has TB he was not able to invite more people. He understood and asked when are we hosting awareness events so that people can know how important it is to participate in this research. [entry 5]

Mutual, interactive communication.

This study found that interactive participants who engaged with the enroller during the ICP facilitated communication within interactions. Participants who asked the enroller many questions facilitated communication between them and the enroller by taking part in the discussion of information (journal 9, entry 8; journal 1, entry 2; journal 8, entry 3; journal 2, entry 1; journal 6, entry 11; journal 9, entry 3; journal 11, entry 3, table 4.5). Moreover, comprehension was more easily verified by enrollers when participants partook in discussions of the ICF (journal 9, entry 8, table 4.5). Amounts of talk within interactions can either facilitate or hinder communication and is a mutual and interactive process (D'Agostino & Bylund, 2014; Epstein & Street, 2007). In this study, participants and enrollers who mutually engaged in conversation in an interactive manner facilitated communication and converged dialogue toward one another. This was found in accordance with CAT which accounts for the interactive and mutual nature of communication (D'Agostino & Bylund, 2014).

Enrollers additionally reported that they wanted participants to engage in conversation by asking more questions, showing more interest in the study or partaking more in discussions on the ICF. Communication and the comprehension of information was found to be facilitated when both enrollers and participants engaged in conversation and discussions. In alignment with Nishimura et al., (2013), a focus on rich conversation between enroller and participant was found to provide opportunities for interactive communication. Even though some participants did not ask questions, communication was still facilitated when participants contributed to the discussions on the ICF (journal 11, entry 3, table 4.5). As previously mentioned, some participants were more open to talk about lifeworld issues or ask questions irrelevant to the study (journal 9, entry 3, table 4.5) rather than engage in discussions on the ICF. Even so, conversation took on a mutual, interactive nature and both enrollers and participants converged their dialogue to achieve a goal, that is the participant's understanding of the ICF.

Table 4.5

Data Excerpts for Mutual Interactive Communication

E9:	Participant was part of a group informed consent. Participant was very interactive in the session considering the fact that he was the only male in the group. He knew a lot about HIV and STI. The informed consent session went very well. [entry 8]
E1:	Everything was successful because participant was partaking in the session. [entry 2]
E6:	The session went well because the participant was talkative and asked a lot of questions. He was showing interest. [entry 6]
E8:	Participant asked lot of questions which were medical related. He was referred to the nurse. Participant agreed to be enrolled. He explained that he really enjoyed working with us. [entry 3]
E2:	The session went well as the participant was proactive and asking questions and it made the session very interesting and challenging. [entry 1]
E6:	The session was conducted in Setswana. The session went well because the participant was free and she asked a lot of questions based on the study. [entry 11]
E9:	Participant was cooperative from the moment we introduced ourselves. She was able to interact and ask questions during the session even though most of the questions were irrelevant to the study. [entry 3]
E11:	The session was an open discussion as the participant was engaging himself in all the sessions. Participant had no

	questions but continued to add on what was been said during the ICF group session. [entry 3]

Clarification of information.

This study found that participants' clarification and verification of information or terminology they do not understand additionally facilitated communication within interactions. Clarification is defined as making something "understandable or free from confusion" (clarify, 2004).

Participants who asked for clarity on words or other information on the ICF had a better understanding of the study and what they were consenting to (journal 13, entry 8, table 4.6) or were more open to talk during the session (journal 13, entry 4, table 4.6). Furthermore, enrollers found that participants who asked for clarification of information were more cooperative and knowledgeable about the study (journal 13, entry 8, table 4.6). Similar to Penn and Evan's (2009) finding, the clarification of complex language and terminology was more challenging when participants were not fluent or familiar with the language in which the ICF was written. In such a case, allowing for enrollers to modify their verbal communication behaviours to address participants' specific language and literacy abilities and needs can improve participants' understanding of information on the ICF. This in turn can ensure true consent.

In this study, participants' language fluency and literacy ability has been found multiple times to be a major facilitator to comprehension of the ICF. It is therefore important for enrollers to identify and accommodate participants' individual abilities and needs. This can then facilitate a shared understanding (D'Agostino & Bylund, 2014).

As was previously mentioned, amounts of talk within interactions facilitates communication and comprehension. Communication is a two-way process (D'Agostino & Bylund, 2014; Epstein & Street, 2007) thus both enrollers and participants were required to be interactive in order to clarify and verify information and facilitate communication and the comprehension of the ICF.

Table 4.6

Data Excerpts for Clarification of Information

E13:	Participant did not ask questions but she wanted clarity with regard to words she did not understand …When a participant ask when she can't some words, it means she does not only want to join the study, but what to have clear knowledge of what she is joining. [entry 8]

E6:	The session went well because the guy was very co-operative and knew what he came to do on our site. I just wish all participants could be like him because he was co-operative and if he did not understand something, he would ask. [entry 13]
E13:	Participant was free and opened to talk about things that he needed to be clarified for him. Things such as a healthy living, if one in living with a partner that has TB. [entry 4]

Age.

Age was found to either facilitate or restrict communication in interactions during the ICP. As previously mentioned, younger enrollers found it challenging and uncomfortable to ask elderly participants the explicit questions on the ICF and RAQ such as in the case of enroller four (journal 4, entry 5, table 4.7). Enrollers were further challenged when these participants were dishonest or uncooperative and felt disrespectful towards them by probing or being assertive.

As opposed to large age differences, being of similar age was found to facilitate communication within interactions between enrollers and participants. E6 noted that similarities in age and experience facilitated participant openness and the flow of sessions (journal 6, entry 18, table 4.7).

Table 4.7

Data Excerpts for Age

E4:	I must honestly say it was uncomfortable for me too to be asking such explicit questions to the old man. I could see that he was not answering honestly. The session was so tense [entry 5]
E4:	It was however difficult for me to call her to order because firstly she is way too older than me and secondly she is under the influence… [entry 12]
E6:	The session went well because me and the participant are the same age so I didn't have to try hard to make the participant open up but the session flowed well …being aware that age could really influence how a session flows and it can either make a session good or bad [entry 18]

Communication and Language Strategies

Throughout the journaling process, enrollers reported on the use of various strategies to facilitate communication and comprehension during the ICP. These strategies have been termed communication and language strategies in this study. Many of the communication and language strategies that enrollers reported to have used paralleled the strategies that were taught to them during the communication training. It is not clear whether these strategies were known to enrollers before or after they received communication training. Enrollers did not make this distinction in their journals; therefore, it could not be inferred. Despite this, the strategies discussed in this section were found to be crucial to the facilitation of communication within interactions, ensuring participants' understanding of the ICF, and ultimately, obtaining true consent. Moreover, these strategies were used to account for language and literacy discrepancies that emerged during the enroller-participant interaction, to adapt communication behaviour to meet participants' needs, and to converge dialogue towards participants.

Strategies included the assessment of literacy, the use of vernacular, interpretation, the verification of terms and comprehension, emphasis and repetition, and finally, articulation. Furthermore, the ICF as a discussion, simple explanations of the ICF, the use of body language and gestures, the use of pictures and probing were additional strategies used by enrollers to facilitate communication and comprehension. Such strategies paralleled the communication training enrollers received. The establishment of trust and rapport was a further and important facilitator to communication and enrolment. A summary of the identified themes relating to communication and language strategies can be found in Table 5.

Table 5

Communication and Language Strategies

Vernacular
Translation
Verification of understanding
Probing
Nonverbal communication (body language and gestures)
ICF as a discussion
Simple explanations of ICF

Repetition, emphasis, articulation, and the use of pictures
Lifeworld events and the establishment of trust and rapport

Vernacular.

The use of vernacular during explanations of the ICF was one of the most effective and frequently used strategies that enrollers employed. It was often reported that sessions were conducted in two languages, rather than one. Despite participants choosing the language of the ICF, many sessions were conducted in both the language of the ICF and the language in which participants spoke (journal 6, entry 1; journal 9, entry 3; journal 9, entry 4; journal 9, entry 5; journal 9, entry 7, table 5.1). Many participants preferred an English ICF despite it not being their speaking or first language. Enrollers therefore conducted discussions in both English and participants' first or speaking language. This use and fusion of multiple languages facilitated participants' comprehension of the ICF. In addition to the use of vernacular, sessions were reported to have gone well when participants were literate or fluent in both languages. In turn, participants were reported to have understood the ICF and difficult terms (journal 6, entry; journal 6, entry 4; journal 6, entry 16; journal 9, entry 1, table 5.1). Furthermore, participants who asked questions and interacted with enrollers were found to be more cooperative (journal 8, entry 6) and/or understood difficult terminology more easily (journal 9, entry 1, table 5.1). In this study, enrollers reported that the most successful sessions were those that had little or no language barriers.

Table 5.1

Data Excerpts for Vernacular

E6:	She preferred an English informed consent form. We discussed the informed consent form in both English and Setswana. The session went well and successful because the participant was literate, she could read and write. She could easily understand the terms that were difficult to understand it the study. [entry 1]
E6:	The session was conducted in English and Setswana as she preferred English informed consent form and she was also Setswana speaking. The session went well because the participant was literate. [entry 4]

E6:	The session was conducted in English and Setswana. The session went well because the guy was very co-operative and knew what he came to do on our site. [entry 13]
E6:	I administered an English ICF to a 31 year old guy but we communicated in both English and Setswana. The session went well because the participant knew how to read and write so I didn't have to look for a witness. So both went through the ICF by reading the ICF together. [entry 16]
E9:	Participant asked for an English consent form at the front desk. However the session was conducted in both English and Tswana. She was very comfortable with both languages. The session went well, participant understood the consent forms. She was able to ask questions. She paused me to get clarity on words such as "prevalence", "CD4" and "physical examination". She was shy however could interact because of the humor that was brought into the session. [entry 1]
E9:	She speaks Tswana, however she chose English ICF when offered different languages. The session was conducted in both English and Tswana language …Despite the amount of time we had the session was successful because there were no language barriers and participant understood the importance of the study. [entry 3]
E9:	Participant is a 47 year old male, home language is Tswana and he is from Phokeng. Participant preferred to be consented in English, however the session was held with mixed language which are Tswana and English. [entry 4]
E9:	He is Tswana he speaks both English and Tswana. He preferred an English Informed Consent. The session conducted in English and Tswana …I feel that the session was successful because there were no language barrier or difficulties during consent form session and questionnaire session [entry 5]
E9:	Home language is Tswana. She had preferred the English Informed Consent. The session was mostly done in Tswana rather English. [entry 7]
E8:	The process was conducting in both languages. Participant was co-operating. Everything went well. He seemed to know why he came to the clinic. He was responding very well …He did have much questions. The whole process went well. Questions which was asked, he responded with confident. [entry 6]

Translation.

Similar to the use of vernacular, the translation of parts of the ICF into a language that participants could understand facilitated participants' comprehension thereof. Translation is defined as turning text into another language; and/or to express something in more comprehensible terms (translate, 2004).

In some cases, enrollers were required to translate every sentence of the ICF (journal 11, entry 1, table 5.2) whilst in other cases enrollers translated certain words (journal 11, entry 5, table 5.2). The translation of words or sentences was reported to have assisted with comprehension when participants did not understand the language of the ICF. In addition, repetition of sentences was used by enrollers to further assist comprehension (journal 11, entry 5, table 5.2). Most enrollers were able to translate aspects of the ICF when required, thereby taking on the role as translator. The multilingualism of enrollers enabled them to employ language strategies, such as translating the ICF, for better understanding. In accordance with the findings, multilingualism of staff has been identified as a strategy to overcome language barriers in diverse language settings (Hussey, 2012).

Table 5.2

Data Excerpts for Translation and Interpretation

E11:	It also came to my attention that participant choose the language which she didn't understand. I tried to interpret every sentence in her language (Setswana), and it went better. [entry 1]
E11:	Language wise, there are some words which I had to interpret to the participant, so that she may be able to answer questions correctly. In some cases there were sentences which had to be repeated several times for the participant to understand what I was trying to ask, other than that the session went accordingly. [entry 5]

Verification of understanding.

Verification is defined as ascertaining "the truth, accuracy, or reality of"; or "to confirm" (verify, 2004). It was reported by enrollers that participants often did not ask any questions during the ICP. It was thus important for enrollers to probe and verify participants' comprehension of the ICF. Furthermore, as previously mentioned, it was found that many participants did not understand the ICF even when they said they did. Therefore, enrollers should not ask participants to verify comprehension with a simple "yes" or "no", head nods, or other gestures which assume confirmation of understanding. Rather, enrollers need to probe to verify participants' understanding of the ICF. A reported strategy used by enrollers to verify participants' comprehension was to ask participants to explain what they understood about the ICF. If participants did not understand the ICF, they became confused and could not explain study procedures, objectives, expectations, or terminology in comprehensible or coherent terms. Enrollers could then identify which parts of the ICF participants did not understand.

In accordance with Woodsong and Karim (2005), enrollers elicited better participant comprehension of information by use of verification methods.

Table 5.3

Data Excerpts for Verification of Understanding

E4:	At the end of the informed consent discussion, I asked the participant to tell me what she understands about this particular study. Unfortunately the participant was just all over the place without telling or not being able to tell me what I have been explaining. She basically couldn't tell me the main purpose or the objectives of the study but she has been saying that she understands what I was explaining to her. That for me was a disappointment and was wondering if it was myself who did not explain thoroughly or if it was her who was just not paying attention. [entry 2]

Probing.

Enrollers reported to have probed participants either for further background or contextual information or to encourage honest and reliable responses during the RAQ. Probing participants for further background information was found to allow for the establishment of rapport and trust between participants and enrollers (journal 1 entry 3, table 5.4). After E1 probed for additional contextual information, the participant became open to discuss her traumatic experience with the enroller. Probing was additionally used to acquire more honest responses from participants who contradicted themselves when answering the RAQ or ICF (journal 4 entry 3, table 5.4).

Table 5.4

Data Excerpts for Probing

E1:	HCT Couple Counselling was conducted pre and post counselling was done and the testing both of whom were asking questions and they were asking much on STIs only to find out when probing both participants were having STI and started to probe further because they are a couple and both females how did they ( ) or became infected with STI. So that when one told me that she was raped long time ago so that's why she had it and it comes only when they have sex with partner. [entry 3]
E4:	Although I thought she was not so honest during the Risk Assessment questionnaire because she was very inconsistent with her answers, I had to constantly probe and refer to the previous answers that she has already given. She got uncomfortable as she could see that I can notice that she was somehow not being honest with me

	…Fortunately, she understood when I highlighted the fact that the data that she gives/provides could be biased if she's not being honest and consistent. She then started to relax and gave reliable information [entry 3]

Nonverbal communication.

In alignment with the communication training that enrollers received, the use of body language was found to facilitate communication within interactions during the ICP. In this study, body language consists of hand gestures, body gestures and movement, and facial expressions. Firstly, enrollers employed body language to assist participants' comprehension of the ICF (journal 6, entry 3; journal 6, entry 10, table 5.5). In some cases, hand or body gestures were used by enrollers to assist participants' comprehension of a language which they found difficult to understand. Secondly, body language was used to establish trust and rapport and to encourage participant openness. This is in alignment with CAT which stipulates that convergence of dialogue establishes trust and strengthens relationships within interactions. Thirdly, enrollers were attentive to participants' body language to establish participants' comprehension (journal 8, entry 7, table 5.5). Although nods of the head may be taken as a sign of participants' understanding of the ICF, this alone is not adequate to establish true comprehension. E6 noted that being able to read a participant's facial expressions provided enrollers with information about the participant during the session (journal 6, entry 3, table 5.5). This indicated an attentiveness and focus to nonverbal communication behaviour. In accordance with CAT, the enroller-participant interaction was reliant on enrollers' ability to adapt their dialogue to demonstrate their understanding of participants talk and respond appropriately.

According to CAT, the use of nonverbal communicative behaviour is recognised as important within interactions and is modified to establish participants' preference for involvement therein (D'Agostino & Bylund, 2014). It is further used in addition to verbal communication to either converge or diverge dialogue (Jain & Krieger, 2011). Likewise, enrollers modified their communication behaviours and converged their dialogue towards participants by use of nonverbal communication. Enrollers further made use of nonverbal behaviour to facilitate a shared understanding of the ICP as well as an understanding of participants' language and/or social needs.

Table 5.5

Data Excerpts for Nonverbal Communication

E6:	And the session was bad because he did not know English well but we managed to carry on because I was doing hand signs and it help a lot. As the counselling was proceeding the participant started opening up and when he found out that he is HIV negative, he was very happy and stopped being rude so that showed me that the participant was scared at the beginning of the session that's why he was rude. I just wish that I could have been able to read the participant's facial physical expressions as it speaks a lot/ says a lot. [entry 3]
E6:	The session didn't go well because of the language barrier, the guy wasn't fluent with English but I use body language/signs so it really helped. [entry 10]
E8:	He was shaking his head to show that he understand what he was being told. Some of the words which were difficult he asked for further explanation and clarification. [entry 7]

ICF as a discussion.

During the communication training, enrollers were encouraged to engage participants in a discussion of the ICF in order to facilitate communication and comprehension. The inclusion of participants in a discussion has been found to facilitate two-way communication, clarify information on the ICF and alleviate participant boredom (journal 9, entry 8; journal 11, entry 3; journal 7, entry 1, table 5.6). Moreover, summarising or going through the ICF form together has been found to facilitate discussions of the ICF and in turn participants' comprehension thereof (journal 9, entry 8; journal 6, entry 16).

Interestingly, when E13 encouraged a participant to engage in a discussion of the ICF, the participant was afraid to share his views and understanding of the ICF (journal 13, entry 7, table 5.6). In a focus group discussion, enrollers mentioned that they were required to strictly follow study protocols and were not allowed to deviate from the ICF. Both enrollers and participants are reluctant to modify the ICP and share their views on the ICF. Brehaut et al. (2010) suggests that trial and site staff be included and engaged in discussions regarding the ICP to improve the adequate transfer and comprehension of information. Penn and Evans (2009) advocate for enrollers to be involved in all stages of the ICP, that is, the planning, development and reviewing of IC procedures.

Table 5.6

Data Excerpts for ICF as a Discussion

E13:	Something that stood out regarding the communication issues, participant was afraid to step in the middle of

	ICF informed consent to share his view and how he understood the ICF. [entry 7]
E7:	During Informed Consent session she was able to read with confidence and ask questions. I liked the fact that it was short she was not feeling bored because it was a discussion session. [entry 1]
E9:	During the one on one session for questions before signing participant wanted to know if he could come back the next day for his results however it was clarified to him that the study was a one day study. By summarizing the ICF together … The session was successful because we managed to engage in a two way session. [entry 8]
E11:	The session was an open discussion as the participant was engaging himself in all the sessions. Participant had no questions but continued to add on what was been said during the ICF group session …The session went well as expected. [entry 3]
E6:	The session went well because the participant knew how to read and write so I didn't have to look for a witness. So both went through the ICF by reading the ICF together. [entry 16]

Interpretation and simple explanations of the ICF.

In this study, enrollers reported that providing participants with simple explanations of and interpreting the ICF facilitated their understanding thereof. During the ICP, enrollers made use of vernacular, simple explanations, and interpretation of study procedures and terminology. Interpretation is defined as explaining the meaning of; understanding the meaning of something; and to give an oral translation of somebody's words (interpret, 2004). The modification of communication behaviour was done to account for the language discrepancies encountered during the enroller-participant interaction and adjust the dialogue style to meet the language needs of each participant.

For example, when Setswana speaking participants found the ICF difficult to read in English or Setswana, enrollers explained words in both English and Setswana (journal 9, entry 4; journal 13, entry 8, table 5.7). In this manner, enrollers adapted and converged the dialogue towards participants to ensure participants understood the meaning of the ICF.

An additional finding was that many participants had difficulties reading the complex language of the ICF even when it was written in their first or speaking language. Participants still required translations, interpretations and simplistic explanations of words, terminology, and sometimes sentences. Enrollers had the additional role of recognising the languages which participants spoke and understood and then developing a language strategy to facilitate

comprehension of the ICF. In her journal entry, E8 noted that an English ICF was used during a session but was explained in simple Setswana and Tsonga (journal 8, entry 4, table 5.7). This in turn facilitated the participant's comprehension of the study context. Likewise, E13 simplified difficult English words on the ICF for a Sotho speaking participant in addition to explaining certain words in Setswana to assist in the comprehension thereof (journal 13, entry 5, table 5.7). Here, discordance was accounted for by the adaptation of communication behaviours on behalf of enrollers. When a language discrepancy arose, enrollers modified their verbal behaviour whilst communicating to converge dialogue towards participants. This adaptation facilitated participants understanding of words that they initially did not understand.

Table 5.7

Data Excerpts for Interpretation and Simple Explanations of the ICF

E9:	home language is Tswana …participant preferred to be consented in English, however the session was held with mixed language which are Tswana and English …some English words were difficult for the participant to read as we went through the Informed Consent together. But they were explained in English and Setswana for better understanding. [entry 4]
E13:	Participant did not understand some of Setswana words, hence she is Tswana, I explain them, she eventually understood. She understood those word. [entry 8]
E8:	English ICF was read but the whole context was explain in simple Tswana. Discussion started to change from Tswana language into Tsonga. Participant explained that he is not good in Tswana since he was a Shangana from Mozambique. The process of ICF went well. Participant understood and agreed to participate. [entry 4] (vernacular)
E13:	Participant was a Sotho person and, some words in Setswana when explain, seemed to be a bit difficult but eventually understood. Participant could not also hear English, so language difficulty became a bit problem but it was resolve. Those difficult words had to be simplified. [entry 5]

Similar to these findings, White (2005) reiterates that simple comprehensible language and terminology replace technical complex language. Information should be given in a manner that is simple and easy to understand and the readability of consent forms be improved and divided into simpler sections. Enrollers who interpreted the complex language and terminology of the ICF into more comprehensible terms better met participants' language needs. In a FGD, enrollers noted that the readability of the ICF was difficult even for them to understand. They

further called for a modified ICF that was simpler to read and decipher, for both them and participants.

Repetition, emphasis, articulation, and the use of pictures.

An additional language strategy that enrollers reported to use was that of repetition and articulation of words and sentences from the ICF to facilitate participants' understanding. In one case, E9 had difficulties understanding the participant on account of the participant's accent. E9 then asked the participant to repeat the words she did not understand and encouraged the participant to do the same (journal 9, entry 6, table 5.8). Here, pronunciation facilitated the participant's understanding of certain words. This study has found that the articulation and pronunciation of words can either facilitate or hinder participants' and enrollers' comprehension of one another during conversation.

The repetition of words and verification of understanding facilitated both the enroller and participant's understanding of one another. The emphasis of certain study procedures was reported to have facilitated participants' comprehension thereof (journal 8, entry 10, table 5.8). In accordance with the communication training, E9 made use of pictures to further facilitate the participant's comprehension of the ICF. These findings support the literature on the implementation of visual aids to facilitate comprehension. The integration and use of supplementary materials such as visual aids has been found in other studies to improve participants' comprehension of the ICF and ICP as well as healthcare practitioners' confidence (Penn, Evans, Sanne, 2006). Supplementary material has been found to improve explanations of study procedures (Woodsong & Karim, 2005).

Table 5.8

Data Excerpts for Repetition, Emphasis, Articulation, and the Use of Pictures

E9:	During the questionnaire session I explained what was required from here. As I was asking her the questionnaires language began to be an issue. Some of the words she pronounced were difficult for me to hear because of her accent. In this case I asked her to repeat the words I didn't understand. The same thing for her with me, I had to repeat myself over and over. I even had to use pictures in some instant. [entry 6]
E8:	The ladies had no issue with regard to what was explained to them. The whole process and procedure were emphasised and the duration they were supposed to spend on site. [entry 10]

Lifeworld events and the establishment of trust and rapport.

The establishment of trust and rapport between the enroller and participant has been found to be important for the facilitation of communication within interactions and the subsequent enrolment of participants into the study. To facilitate rapport, some enrollers provided participants with the opportunity to introduce themselves and established background knowledge before commencing with the session (journal 2, entry 1, table 5.9). This was reported to have comforted and relaxed participants. Alternatively, enrollers who shared similar lifeworld events with participants noted that they were able to relate to the participant and this in turn established trust within the interaction. Enrollers reported that they were then able to comfort participants when they became emotional during a session and further facilitated openness (journal 6, entry 4, table 5.9). The establishment of trust and rapport within interactions was facilitated by enrollers listening to participants' lifeworld stories and allowing participants to discuss their background contexts. This study has found that when participants were encouraged to talk about their lifeworld events they became more open and interactive with the enroller (journal 4, entry 2, table 5.9). Moreover, when enrollers reassured participants that all their information would remain confidential and encouraged them to answer all the questions on the ICF honestly, participants became more open (journal 13, entry 9; journal 1, entry 3; journal 9, entry 8, table 5.9). Thus, the establishment of trust and rapport was done by enrollers in multiple ways according to the context and participant needs.

Confirming the work of Beauchamp & Childress, 1994, establishing relationships of trust allowed for enrollers to better understand participants' best interests and social structures. Enrollers were then able to support participants in decision-making and ensuring informed consent. Multiple studies reiterate the importance of the establishment of trust between participant-enroller/patient-healthcare practitioner to improve relationships, communication, and recruitment (Picillo, Kou, Barone, & Fasano, 2015, Delany-Moretlwe et al., 2011; Lovato et al., 1996).

Table 5.9

Data Excerpts for Lifeworld Events and the Establishment of Trust and Rapport

E2:	I introduced myself well and explained the reason for my visit. I gave her chance to introduce herself. After the introduction session, I made sure that the participant is comfortable and relaxed. Literate level assessed and found to be literate. [entry 1]
E6:	when I asked the participant how many pregnancies has she had and she said had a miscarriage, the participant

	started becoming emotional and confessed that she has had a miscarriage and I went through the same situation that the participant went through, so I knew how to comfort her and the participant became more comfortable and open with me. [entry 4]
E4:	The participant was very talkative to a point where she started explaining her experiences about the FACTS 001 study that she was enrolled into. I provided my ears to listen to her because she seemed to have had lovely experiences …She was very open with me but was not concentrating to what I was asking her. She was so excited that she would even elaborate on the questions I have asked. She was so loud and just too excited. Our questionnaire session took slightly over an hour because I did not want to stop her from explaining all her stories and exciting experiences. She was also answering honestly. [entry 2]
E13:	Risk Assessment Questionnaire went well but not that well, participant was not comfortable with answering other question, such as types of rounds sex he felt was personal, but I explained to him, the importance of being free and opened, because I am not there to judge and they is confidential. He eventually agreed to open up [entry 9]
E13:	What didn't go well in the session was on the Risk Assessment Questionnaire, participant felt a bit uncomfortable to answer some of the questions, especially the ones of sexual behaviour. I explained to her to feel free and assured her that everything is kept confidential. [entry 3]
E9:	The questionnaires were conducted and some of them made him uncomfortable however I reassured him that he can trust me and nothing he is saying is right or wrong. [entry 8]

The impact of training for language comfort.

In this study, enrollers employed various strategies to facilitate communication between them and participants and participants' comprehension of the ICF. Many of the strategies that were used during the ICP aligned with strategies taught during the communication training. The researcher was present during the communication training and took extensive process notes thereof.

This partly addresses the second aim of the study, that is, to determine the effect of a communication training programme aimed at improving communication processes during the obtainment of informed consent and enhancing participant comprehension of information. The communication training was aimed at providing enrollers with strategies that would facilitate language comfort and communication between enrollers and participants and ultimately

participants' complete comprehension of the ICF. As previously stated, the effectiveness of the training programme was not evaluated but enrollers' experiences of effective language strategies during the ICP were explored. Being blinded to which participants were in the control and pilot groups presented with certain difficulties. The enrollers did not explicitly state whether they had received the training or not, therefore no assumptions could be made regarding the effectiveness of the training programme. Enrollers did however report on numerous language strategies they found to be effective in facilitating understanding of the ICF and gaining IC that paralleled strategies taught in the training.

Amongst the strategies used, vernacular, interpretation, the verification of comprehension, body language, discussions of the ICF, simple explanations of the ICF, the use of pictures, and the establishment of trust and rapport by listening to lifeworld issues were strategies enrollers employed that aligned with the communication training. In most cases, these strategies were reported to have successfully facilitated communication between enrollers and participants as well as participants' comprehension of the ICF.

These strategies further provided enrollers with more flexibility during the ICP. Enrollers were encouraged to conduct sessions in more than one language, when required. As previously discussed, most participants required the ICF to be explained in more than one language. Often, enrollers translated and interpreted the information to ensure participants had a comprehensive understanding of the study procedures and protocols to obtain true consent. This modified, flexible approach was found to be effective in improving communication processes between the enroller and participant, facilitating participants' understanding of information on the ICF, and obtaining informed consent.

Perceived Procedural Barriers to Enrolment and Communication

This section of results focuses on the perceived procedural barriers to participant enrolment and/or communication during enroller-participant interactions as accounted by enrollers. These barriers occurred when potential participants were interviewed and screened for either of the two studies as part of the informed consent process. In addition, some enrollers provided accounts of procedural barriers experienced within interactions during HIV testing and counselling. HIV counselling was a service offered as part of the site's research studies.

Procedural barriers are defined as reported problems that arise within the routine processes of informed consent, enrolment and the study that hinder interactions, communication and/or enrolment. Results of the study showed that firstly specific questions on the ICF and Risk Assessment Questionnaire (RAQ) form were problematic and were viewed

as explicit or irrelevant. The process of blood withdrawals, blood storage and a fear of needles presented a further barrier to enrolment of potential participants. Further study procedures such as study duration, exclusion criteria, and length of sessions are perceived barriers to enrolment. The site's policy to not provide participants with TB treatment poses an additional barrier to enroller-participant interaction. A summary of the identified themes relating to perceived procedural barriers can be found in Table 6. Evidence for each of these themes are provided in the excerpts below and are elaborated further.

Table 6

Procedural Barriers

Explicit Questions on the Informed Consent and Risk Assessment Questionnaire
Irrelevant questions on the Informed Consent and Risk Assessment Questionnaire
Enroller strategies to facilitate openness and comfort
The process of blood withdrawals
Exclusion criteria
Study duration and length of sessions

Explicit questions on the informed consent and risk assessment questionnaire.

During the informed consent process, enrollers were required to ask participants questions from the ICF and RAQ from which they may not deviate. Despite it being mandatory for enrollers to ask all the questions on the forms, participants were not required to answer the questions that they did not want to answer (journal 13 entry 9, table 6.1).

Often, participants found the questions to be explicit in nature and became uncomfortable during the interaction. This was especially so when the questions asked referred to participants' past and present sexual behaviour. Such questions were reportedly experienced as intrusive and personal by participants, making the administering of the questionnaires a difficult and sometimes unsuccessful process for enrollers.

Participants further reported to find questions on the IC and RAQ "irritating" and "sensitive" to answer. Enroller seven attributed this to participants' preoccupation with test

results. In this case, the participant was first taken through the ICF and then sent for HIV testing. The RAQ was administered after testing but before the results were released. As a result of this process, the participant was unable to concentrate on the information being explained by the enroller and became irritated by the insensitive questions. Enroller seven subsequently felt she was wasting the participant's time because of the participant's preoccupation with "social issues" and test results (journal 7, entry 2, table 6.1). Here, the IC and testing process acted as a barrier to communication within the interaction. She further noted that the participant was not in a state to understand the ICF yet agreed to participate in the study. It is thus important for enrollers to adapt their dialogue according to participants' communication and emotional behaviour to show understanding and respond appropriately. This implies a focus and attentiveness to both verbal and nonverbal behaviour. In the event that participants do not fully understand the ICF, it is crucial that enrollers modify their communication behaviour to facilitate and ensure participants' full comprehension thereof.

Table 6.1

Data Excerpts for Explicit Questions on the IC and RAQ

E13:	What [stood] out is that when participant refuses to answer, we are allowed to not force them to answer, which I told the participant.
E13:	What didn't go well in the session was on the Risk Assessment Questionnaire, participant felt a bit uncomfortable to answer some of the questions, especially the ones of sexual behaviour. [entry 3]
E13:	Risk Assessment Questionnaire went well but not that well, participant was not comfortable with answering other question, such as types of rounds sex he felt was personal. [entry 9]
E9:	In the consent form… she was also shy to talk about sexual activities however she managed to answer all the questions. [entry 1]
E7:	…they come for questionnaire with a pre-occupied mind about result before post counselling and they feel that this questions are irritating and sensitive. [entry 2]

Explicit questions not only brought about discomfort for participants, but for some enrollers as well. In entry five, enroller four admitted to feeling "uncomfortable" to be "asking such explicit questions" to a man that was older than her (journal 4, entry 5, table 6.2). In addition to her discomfort, she further noted that the participant was experiencing discomfort

in the session. The participant refused to answer the explicit questions honestly and the enroller-participant interaction became "tense".

E4 made an additional referral to the age of the participant as being a barrier to communication within the interaction. In addition to feeling "uncomfortable", the enroller felt she was being "disrespectful" when asking a fifty-seven-year-old male the explicit questions on the RAQ (journal 4, entry 5, table 6.2). In turn, the participant became impatient and uncooperative, thus contributing to the tension within the interaction. Moreover, the participant was not interactive and was uninterested in what the enroller was saying. E4 identified that the session could possibly have gone better if an enroller of similar age to the participant had administered the questionnaire. She further described the session as "draining" for herself because of the "huge" age difference. The discomfort within the interaction was attributed to the age difference between her and the participant. In a FGD, enrollers explained that the age of the participant had an impact on the comfort of both enroller and participant within interactions. Many younger enrollers reported to experience discomfort when asking older participants explicit questions of the ICF. In such cases, enrollers would often ask an older enroller to assist with the ICP or try to match participants and enrollers by age before a session commenced. By doing so, communication within the interaction was facilitated more effectively.

Table 6.2

E4:	I must honestly say it was uncomfortable for me too to be asking such explicit questions to the old man. I could see that he was not answering honestly. The session was so tense. [entry 5]
E4:	My thoughts are probably if the questionnaire was administered by an older person like him, it could have been better. I felt like I am being disrespectful towards him and he kept on saying "this thing is taking a very long time" and he had to rush somewhere else.
E4:	…this session was very draining for me because the age difference with the participant was a very huge gap, hence the uncomfortability. Participant was not asking questions, I was the only one who's talking. He just said he wanted to know his HIV status and that was about it. [entry 5]

Irrelevant questions on the informed consent and risk assessment questionnaire.

During the administration of a RAQ, enroller thirteen noted that her participant, who identified as a homosexual, found some of the questions to be confusing and irrelevant. The

participant became especially confused when he was asked for the number of sexual partners that he had vaginal intercourse with in the past. He stressed that he had never had sexual intercourse with women, only with men (journal 13, entry 1, table 6.3). The administration of the questionnaire became a difficult process for E13 and the participant subsequently refused to answer some of the questions and to talk about his sexual behaviour. Despite this, she was still required to ask the participant all the questions even if specific questions were found to be irrelevant to him. Rather than speaking openly about his sexual behaviour, the participant elaborated on his past experiences and life story. Even though the participant spoke openly about other life experiences, E13 noted that there was no time to listen to his story due to time constraints. The issue of participants wanting to discuss lifeworld and social events with enrollers during the enrolment session became more evident but enrollers were constrained by time limits. Since enrollers cannot deviate from the questionnaire, it is important that they become aware of participants' communication behaviour within interactions, demonstrate an understanding thereof and respond accordingly.

Table 6.3

Data Excerpt for Irrelevant Questions on the IC and RAQ

E13:	…the participant was a homosexual person. Some of the question(s) were confusing for the participant to answer them. [entry 1]

Enroller strategies to facilitate openness and comfort.

Although many participants struggled to answer questions that they were uncomfortable with, enrollers employed various strategies that facilitated openness and comfort with the aim to encourage such participants to answer difficult questions, even if participants only managed to do so. In addition to participants feeling uncomfortable, it was assumed by participants that enrollers should have found the asking of explicit questions to be a challenging task. During this session, E9's participant was "shocked" by the "type of questions asked" and further queried as to how the enroller could ask such difficult questions (journal 9, entry 5, table 6.4). E9 employed a strategy to facilitate comfort within the enroller-participant interaction. She employed a simple gesture, a smile, and further explained her role as an enroller within the study after which the participant seemingly became more comfortable during the session. E9 positioned herself as a dutiful employee; doing what is expected of her,

which involved asking participants explicit questions. Furthermore, she noted the necessity and importance of the task being carried out in her referral "someone had to do it".

E9 further formed a parallel between the employment of a smile, friendliness on her part, an explanation of her role and a "successful session" (journal 9, entry 5, table 6.4). The participant was subsequently enrolled into the study.

Table 6.4

Data Excerpts for Enroller Strategies to Facilitate Openness and Comfort

E9:	During the questionnaire session participant was a bit shocked by the type of questions asked and even asked how I manage to ask such questions. I smiled at him and told him it's my job and someone had to do it. He started getting comfortable as time went. [entry 5]
E9:	I feel that it was a successful session.

In addition to the use of body gesture, enrollers assured participants of confidentiality in order to establish trust and comfort within the interaction. E13 encouraged her participant to answer all the questions freely by explaining and assuring the confidentiality of all answers (journal 13, entry 3, table 6.5). The participant was reported to have then complied by answering all questions freely. In a different session, E13 similarly guaranteed confidentiality but further assured the participant that his/her answers would be free from judgment. The participant eventually agreed to "open up" and answered all the questions (journal 13, entry 9, table 6.5). The reassurance of confidentiality and non-judgement of answers was found to be central to the establishment of trust within enroller-participant interactions which in turn often resulted in participants answering the explicit questions more freely. In a FGD with enrollers, confidentiality was seen to be one of the most crucial study protocols that participants should understand in both TB and HIV/STI studies.

Table 6.5

E13:	I explained to her to feel free and assured her that everything is kept confidential. [entry 3]
E13:	I explained to him, the importance of being free and opened, because I am not there to judge and they is confidential. He eventually agreed to open up. [entry 9]
E7:	…if she does not want to answer some of the questions it's fine. [entry 2]

The process of blood withdrawals.

Participants' lack of understanding of the blood withdrawal process and lack of knowledge on blood processes presented as a barrier to enrolment. This was found in multiple journal entries as many participants displayed a fear of the loss of too much blood and a distrust of what would happen to the blood once it was withdrawn. This presented as a novel finding in this study. Participant fears, lack of understanding of and distrust for the study's blood storage procedures posed as a further barrier to enrolment.

In entry three, E2 provided an account of her participant's fear and lack of understanding of the blood withdrawal process. After explaining from the ICF the amount of blood that was to be taken and the possible side effects, the participant became "sceptic" about agreeing to enrol in the study. The participant's sceptism was attributed to a fear of dying due to the loss of blood. Despite efforts to calm the participant, she refused to continue with enrolment. E2 articulated her frustration with the ICF which for her resulted in the discontinuation of the participant from the study.

E8 described a similar interaction in which the participant was hesitant to partake in the study due to the amount of blood required as well as his fear of needles (journal 8, entry 4). According to the enroller, the participant seemed to understand the information on the ICF. He initially agreed to participate but disagreed once the process of blood withdrawal was further explained to him. Again, issues of true consent during the ICF explanation are raised. The session was described as unsuccessful due to the participant signing the consent form without an actual understanding of the study procedures. In another entry, E8 described the session as becoming "tense" when the participant became sceptical of the site's blood storage process and feared that his blood would be sold after the study (journal 8, entry 3, table 6.6). He had further fears of his blood being tested for additional diseases without his knowledge and consent. Despite assurances of confidentiality, the participant refused to partake in the study.

In a follow-up visit, the participant signed the ICF but subsequently refused to continue in the study during the blood withdrawal procedure (journal 8, entry 15, table 6.6). Although the initial IC process had gone well, the participant lost interest in the study. Multiple participants seemed to not have fully comprehended the information on the ICF and the study procedures yet would confirm their understanding when asked by enrollers and even agreed to take part in the study. Once participants saw what the blood withdrawal procedure entailed, they become hesitant and some refused to participate. In a focus group discussion, enrollers stressed the importance of participants understanding the process of blood draws to ensure that

they did not drop out of the study. This was applicable for both TB and HIV/STI studies. E8 notes a similar session in which the participant initially agreed to participate but later refused (journal eight, entry 4, table 6.6).

A fear of needles and the amount of blood withdrawn presented as an additional barrier to enrolment. E8 argued that if the participant fully comprehended the information that was discussed during the session he would not have agreed to participate. Similarly, a participant who originally agreed to participate later refused to continue because of her fear of needles (journal 13, entry 2, table 6.6). This was further noted by enrollers in a FDG as a major barrier to study enrolment and obtaining study target enrolment figures.

Despite all the study procedures being explained, participants continued to have a problem with blood withdrawals and needles after agreeing to participate. This reiterates the issue of participants not fully comprehending the ICF yet giving their consent. Obtaining informed consent is ethically essential and requires that participants have a comprehensive understanding of all study procedures (SAGCP, 2006). To ensure such an understanding, enrollers should adjust their dialogue to accommodate participants' language, literacy and educational needs. Moreover, ICFs should be attuned to participants' language and educational background (Barry & Molyneux, 1992).

Table 6.6

Data Excerpts for the Process of Blood Withdrawals

E2:	She went through her enrolment ICF and there was a clause which explained the amount of blood that was to be drawn on this visit, and that she may experience some side effects post blood draw.
E2:	The participant was sceptic about continuing with enrolment visit. She also highlighted that she is scared that at her age she won't survive that amount of blood to be drawn from her. After several attempts were done to calm the participant down, she refused to continue with enrolment visit. [entry 3]
E8:	Process of enrolment ICF went well, the second process of storage and future testing was tense. Participant had issues with us storing his blood saying we might sell it in future after the study has been finished and that we might as well test other disease which he doesn't want to know about. Even after it was explained to him that all his details will be kept confidential only a pin ID will be used, he refused. [entry 3]
E8:	Participant came for follow-up. Pre-counselling process was done. All process went well. He agreed to sign on the ICF.

E8:	The participant explain that he was no longer interested to continue with the research because of the blood that is being collected. [entry 15]
E8:	When the participant has signed and dated on all ICF, he had problems with the collection of blood. Explained that he wants to be part but his problem is the injection and the amount of blood collected.
E8:	…if he understood everything when read, explained and discussed he would not have signed. So he signed for things he did not understand. That's why when the procedure of blood was asked about it he started having problems. [entry 4]
E13:	The contacts when she was to be picked up to be enrolled in the study, she says no I can't come anymore because the needles are painful, she is afraid of the needles …During our screening everything went well, but later, participant refused to be enrolled in the study. Although she understood everything during screening. [entry 2]
E13:	…participant said he too afraid of needles and he can't continue with all procedures. The session had to be cancelled.
E13:	…participant could have told us before we start …because all procedures were explained before. [entry 10]

Exclusion criteria.

Exclusion criteria was mentioned in a FGD to be one of the most important factors of the TB study that participants needed to understand. A participant was excluded from the study if he/she was HIV positive, had asymptomatic or symptomatic/active tuberculosis, was under the age of eighteen or had previously contracted TB.

Some participants were reported to have lied about their HIV status to enrollers during the ICF process even though exclusion and inclusion criteria were explained to them. Participants were still screened for confirmation of results. Reasons for participants' nondisclosure of their HIV status were not mentioned by enrollers but could relate to the possible stigmatisation of disclosure or the exclusion from the study.

Enrollers additionally noted that there was no cut off age for participants. Despite this, they reported age to have been a challenge as they found that older participants often became tired and frustrated.

Table 6.7

Data Excerpt for Exclusion Criteria

E10:	In T-Cell study if the participant is HIV positive we don't enrol them we called them screening failures. We do explain the inclusion and exclusion criteria in the begin but if the participant is not honest from the start we do HIV Test Counselling to be sure. [entry 1]

Study duration and length of sessions.

The long duration of the study posed as a barrier to enrolment. In a focus group discussion, enrollers noted that it was important to clarify the study duration and procedures for the TB study. Participants needed to understand that they were participating in a twelve-month study which involved follow-up visits. In entry six, enroller six provided the participant with an explanation on the length of the study (journal 6, entry 6, table 6.8). Enrollers further found that the scheduling of follow-up visits for participants that work was a difficult task and often follow-ups needed to be scheduled on a weekend. Due to the long study duration and commitment to follow-up visits, some participants dropped out of the TB study.

Table 6.8

Data Excerpt for Study Duration and Length of Sessions

E6:	The only concern that the participant had was that the study was taking long time (duration) but I explained to him and told him that it is because of the procedures that are involved in the study. [entry 6]

Enrollers often reported on long enrolment sessions in their journals and were constrained by various challenges that occurred within the session.

Most often, enrollers spent long periods of time explaining the ICF to participants to insure comprehension. E4 noticed that the participant was not paying attention to her explanations of the ICF (journal 4, entry 2, table 6.9). The participant became frustrated and hurriedly signed the consent form. Sessions additionally became long in length when participants became emotional. Enrollers were then required to calm participants down before they could proceed with the session. In entry three, the participant became emotional because of her fear of being HIV positive and the impact it would have on her life (journal 4, entry 3, table 6.9). Similarly, a different enroller reported a long session as the result of having to counsel a participant who reported to have been in an abusive relationship (journal 7, entry 4, table 6.9). It was found that enrollers took on additional roles within the IFC session which

involved the counselling of participants who had experienced trauma. These additional roles, as well as and dealing with emotional issues and life-world complexities often took time. These roles were not always considered during the rigid time-restrictions given to ICF and study enrolment protocols. Such extended roles added to the session duration and this was found to be a challenge for enrollers as time constraints were placed on the session.

Table 6.9

E4:	If there is anything that I wish could have happened differently is the fact that we should not have spent so much time for the informed consent process because participant was not paying her full attention. At some point she said "Agg. Let's just sign, as long as I'm going to get my contraception and reimbursement. [entry 2]
E4:	Participant could not contain herself to a point where she burst into tears and she couldn't stop crying. She was saying words like, "her life is over if she's really HIV positive". I tried to calm her down which worked and we started talking openly. [entry 3]
E7:	It has been a long session with young lady who reported that she is in an abusive relationship with a young boy. [entry 4]

Lifeworld Events

Lifeworld events are defined as personal experiences and contextual influences (Penn, Watermeyer & Evans, 2011) that influence the enroller-participant interaction within the IC process. Past and current trauma, illness, preconceived notions of the study, ulterior motives for participating (agenda mismatch), unemployment, and poverty are participant lifeworld events identified by enrollers to be barriers to enrolment and communication. Themes for this section are summarised in Table 7. Each theme, together with evidential quotes, are presented below.

Table 7

Lifeworld Events

Impact on length of sessions
Agenda mismatch between enroller and participant
Possibility of employment or financial/food support

Possibility of free and convenient health management
Clinical research site mistrust
Participant illness
Counselling skills and dealing with trauma

Lifeworld's impact on length of sessions.

Lifeworld issues were reported to have come in conflict with study aims and procedures. Many participants were unfamiliar with the medical procedures, study expectations, and ICF and RAQ and saw the ICP as an opportunity to share life stories, rather than a strict questionnaire that needed to be answered or completed in a timely-fashion. Enrollers often provided accounts of sessions in which participants elaborated on their past and current experiences rather than answering the questions on the IC and RA forms. Although participants attempted to, they were often unable to discuss their life story with enrollers due to sessional time constraints which the enrollers tried to adhere to. Enrollers were thus not always able to fully listen to participants talk about lifeworld issues.

Enroller thirteen commented that there was no time for her to listen to the participant's story (journal 13, entry 1, table 7.1). The participant elaborated on his answers to the RAQ by explaining his experiences beyond what was required to answer the question. In such cases, enrollers facilitated participant openness and interaction by listening to their stories. Time constraints on the ICF session acted as a barrier to this facilitation of dialogue. In contrast, some enrollers found participants' explanations of personal experiences to be irrelevant to the study and IC process aims and subsequently became frustrated. In accordance with CAT, personal and social factors were found to emerge during the enroller-participant interaction. Enrollers who recognised these factors and converged their dialogue towards participants established a relationship of trust and were better able to facilitate communication.

Table 7.1

Data Excerpts for Lifeworld's Impact on Length of Sessions

E13:	…when I ask questions (Risk Assessment Questionnaire) participant instead of answering a question, participant would be wanting to open up about what happened, let say I ask a question on our questionnaire such, have you used a post exposure prophylaxis? Instead of choosing

	from given option such as code 0=No, code 1=forgot condom, code 3=exposed to blood, code 4=following rape, participant instead of choosing from the listed above he would start by trying to tell me the whole story, some participant want to open up during our session yet there no time to listen to full story because this job has to be done in time. [entry 1]
E7:	This was not a successful session because reading Informed Consent to participant who's occupied with social issues it's like you are wasting her time. [entry 2]

Agenda mismatch between enroller and participant.

This study found a discordance between the reasons for why participants volunteered to take part in the studies. Rather than what was thought to be altruistic motives, some participants agreed to participate in the studies due to a belief that they might receive employment, support (monetary or food-related) or receive free healthcare management. These ulterior motives were found to cause mismatches in the agenda of the enroller and participant during the ICP.

Possibility of employment or financial or food support.

Participants were reported to have various motivations for study participation. As previously discussed, altruism was a major reason for participation. In contrast, momentary and personal gain such as the possibility of employment and acquiring reimbursement and food influenced some participants' decisions to take part in the study. Enrollers frequently noted contextual factors of participants such as unemployment and poverty that became evident in sessions. Participants did receive a small sum of money as reimbursement for travel expenses to and from the site and were provided with food after study procedures.

Some participants asked questions that related to possible employment at the site (journal 9, entry 3, table 7.2). Many participants enrolled in studies with the aim to acquire employment. Some participants even inquired whether study participation would give them a chance of employment (journal 7, entry 1, table 7.2). Likewise, both E4's participants admitted that the obtainment of reimbursement was their main reason for participating in the study (journal four, entry 2 and 3, table 7.2). Enrollers were then required to explain that the site did not employ participants due to trial participation. In addition to seeking employment, some participants sought food or reimbursement for study participation (journal 7, entry 7, table 7.2). In journal seven (entry 7), the participant requested assistance with food because his brother

was sick and was required to eat before taking his medication. The alleviation of extreme poverty and unemployment was the main reason for study participation. During a house visit, E2's participant refused to participate after he learnt that he would not receive reimbursement for study participation and subsequently asked her to leave (journal 2, entry 2, table 7.2).

Table 7.2

Data Excerpts for Possibility of Employment or Financial/Food Support

E7:	she keeps asking if she can come and volunteer to more clinical trials would she be able to stand a chance of employment in future with us. When I explain that company does not employ you due to clinical trials participation, you need to apply for a position in our website. She seems disappointed as if it was one of the aims to participate. [entry 1]
E9:	…most of the questions she was asking was irrelevant to the study such as "what does one need to qualify to work for Aurum… [entry 3]
E7:	…the participant asked for assist about job or food since his brother was sick and have to eat before he can drink his pills and since his not working its difficult for him to drink them. Other days he doesn't all since the is no food for them. [entry 7]
E2:	The participant asked only one question, which was that was he going to be re-imbursed to be part of the study and if not, we were just wasting our time. We must live (leave) his house and stop wasting his time [entry 2]
E4:	At some point she said "Agg. Let's just sign, as long as I'm going to get my contraception and reimbursement [entry 2]
E4:	…he actually joined the study because his friend had told him that he's going to receive reimbursement money. So that was his main reason for participating in the study. [entry 4]
E4:	Participant complied to all the procedures without hesitation simply because she wanted to be treated for an STI. [entry 3]

Possibility of free and convenient health management.

Some participants mainly sought contraceptives and medication for HIV and STIs from the site, rather than sole interest in the study. Enrollers noted that as a result, participants attempted to fit the study inclusion criteria and were dishonest when answering questions on the RAQ and ICF, including questions related to sexual behaviour. The nondisclosure of information was reported to have caused challenges within the interaction and resulted in longer session times. This ultimately affected the overall success of the study. Enrollers frequently realised when participants did not disclose or lied about certain information. For example, participants' answers would frequently contradict during the ICF and RAQ (journal

4, entry 3). Further probing and the referral to previous questions were strategies that enrollers employed to facilitate honesty within the interaction (journal 11, entry 2; journal 4, entry 3, table 7.3). This was found to have created tension between the enroller and participant as participants became uncomfortable when contradicted by enrollers. When the participant in E4's session became uncomfortable, the enroller explained that the study's data would be biased if she was dishonest and inconsistent. This then allowed the participant to relax and provide honest answers.

Table 7.3

Data Excerpts for Possibility of Free and Convenient Health Management

E11:	Troubles began when the participant started to lie about every sexual behaviours information. We had to go back to other questions and refer so that we create honesty. [entry 2]
E11:	In most case participant seemed to lie and leading to us going back to other questions and refer to what she had told at the beginning. [entry 1]
E4:	Although I thought she was not so honest during the Risk Assessment questionnaire because she was very inconsistent with her answers, I had to constantly probe and refer to the previous answers that she has already given. She got uncomfortable as she could see that I can notice that she was somehow not being honest with me. [entry 3]

Clinical research site mistrust.

E8 offered an account of community members who refused to participate when approached because of stereotyped notions of the clinical site and the site staff. The site's staff was compared to the staff at the local clinic who were described as uncaring and manipulative. It was assumed that the staff at the study site also did not care about the social and contextual issues of participants and were only there to use the community for the site's own research gain. This highlights a need for enrollers and healthcare staff to understand the contextual influences on and lifeworld issues of participants and for the site and site staff to regularly engage with the surrounding community in order to create a mutually respectful and beneficial relationship. As mentioned previously, participants often discussed their life stories with enrollers even when irrelevant to the study. These discussions facilitated participant openness and trust within the enroller-participant interaction.

Table 7.4

Data Excerpt for Clinical Research Site Mistrust

E8:	The thing which stood out for me with her is that her face was changed within seconds, her tone was aggressive. She was talking about how we always manipulate people to come and test and after that we don't care about where the come from and what environment are their living in. Just like what people in the clinic do …I wish the girl would have understand and asked questions after. Before she could judge us without enough knowledge. [entry 5]

Participant illness.

Interactions within the ICP were reported to be affected by participants who were too ill to comprehend the information on the ICF. Some participants were incoherent or distracted during sessions which complicated the discussion of the consent form. In entry eight, the participant was not in a state of mind to truly consent to participate, yet consented and was subsequently enrolled (journal 6, entry 8, table 7.5).

In addition to incoherence resultant from illness, some participants were in pain throughout the session. A participant was reported to have had little interaction with E9 and became restless during a session because of pain experienced from his swollen legs (journal 9, entry 4, table 7.5). The enroller countered this by providing the participant with multiple breaks in the session and noted that despite having limited interaction, the participant was enrolled.

Similarly, a participant revealed that he was taking medication for schizophrenia during the second session and became confused when answering questions (journal 9, entry 2, table 7.5). This information was not provided by the participant during the administration of the ICF during the initial session, nor was it noted by the enroller. The participant was then discontinued from the study.

Table 7.5

Data Excerpts for Participant Illness

E6:	The enrolment did not go well because our participant was very sick and it was like the sickness has affected her mind… I felt that the participant was not in her right state of mind because she was too sick finally the participant did agree to participate in the study. [entry 8]
E9:	The session could have been better if the participant was in good health. However the message of the study was delivered even though there was little interaction which

	personally feel that it was caused by the pain he was going through. [entry 4]
E9:	And at some point participant mentioned that he takes medication for schizophrenia on a daily basis. [entry 2]

Enrollers were tasked with the additional role of recognising participants who were ill or in pain and the facilitation of interactions and understanding of the ICF during these sessions. These contextual issues were found to be challenging for enrollers and could become barriers to communication and enrolment. The incomprehension of information of the ICF and incoherency of participants undermines the voluntary nature of consent. Participants should not be enrolled if they do not have an adequate understanding of the ICF and are not in a mental state to give consent. Informed consent implies that participants have adequate knowledge on the study's procedures, aims, and purposes (SAGCP, 2006). Including vulnerable populations in studies leads to ethical concerns of true consent, impairment in decision-making abilities, and the exploitation of such persons (Denny & Grady, 2006). It is thus crucial for enrollers to recognise vulnerable participants who are unable to provide true consent. In this study, participants who were too ill or in too much pain to attune to or understand discussions on the ICF are seen as "vulnerable". Such participants should have been excluded from the study.

Counselling skills and dealing with trauma.

A major finding of this study was that enrollers often provided participants with basic counselling during the ICP despite having not being trained to do so. Enrollers received training to perform HIV counselling but not for basic counselling. During the ICP, participants often spoke to enrollers about traumatic past and/or current traumatic experiences unrelated to HIV testing results. Participants frequently became emotional, requiring enrollers to address the trauma and calm the participant so that the session could proceed. Often enrollers felt unequipped to handle these situations comfortably and effectively.

E6 noted that she had not received training for Basic Counselling Skills but was rather trained for HIV Counselling and Testing. She subsequently became frustrated when the participant became emotional because she was unsure of how to deal with the participant in the correct way (journal 6, entry 2, table 7.6). E4 provided an account of a participant who was distraught at the thought of testing HIV positive (journal 4, entry 3, table 7.6). In the case of HIV counselling, enrollers reported to have felt better equipped to deal with these situations. Despite their training, enrollers still found sessions in which the participant revealed multiple

traumas to be challenging. The participant in E7's session reported her partner died due to his disbelief in HIV/AIDS. The participant reported to have children to care for and feared losing employment as a result of being HIV positive (journal 7, entry 2, table 7.6). E7 commented that the participant was distant during the interaction and doubted whether she was comprehending the ICF. The need for enrollers to be trained to address broader contextual and social participant traumas outside that of only HIV counselling and testing related issues is highlighted here. This may improve enrollers' confidence when facilitating interactions, communication and ultimately proper participant comprehension of the ICF.

Table 7.6

Data Excerpts for Counselling Skills and Dealing with Trauma

E6:	I wish that the participant could have asked for counselling instead of HIV counselling and Testing because they are two different things and I was not trained for Basic Counselling Skills but I was trained for HIV Counselling and Testing so it gave me a tough time and made me frustrated because I did not know what to say or do with the participant. [entry 2]
E4:	Participant could not contain herself to a point where she burst into tears and she couldn't stop crying. She was saying words like, "her life is over if she's really HIV positive". I tried to calm her down which worked and we started talking openly. [entry 3]
E7:	this has been a difficult session with a widow that report that she has kids at home and she's HIV positive and partner died of aids because he did not believe in HIV. Currently she's not sure of what to do with her health and she's scared that she might lose employment if she's sick. [entry 2]

Enrollers' Experiences of the Communication Training Programme

The third aim of the study was to explore enrollers' reported experiences of the communication training programme. Enrollers most frequently reported that the introduction and explanation of pictograms as a communication facilitator stood out for them in the communication training. Similarly, the use of role-play during the training programme and methods of dealing with difficult participants were reported stand out features. Enrollers mostly enjoyed learning the DRIVE Model, how to use picture aids to elicit information and explain study procedures, the 4C's, and taking part in the interactive games. All enrollers said that they would be able to apply the methods and communication strategies learnt during the training programme. Enrollers were further asked to make recommendations for future training and

predominantly suggested the involvement of all site staff and departments, particularly managers, principal investigators and quality control personal, in the communication training programme. An additional recommendation was for the training to be done regularly with site staff. Conclusively, the training was reported by enrollers to be informative, practical, and interactive. Examples of the feedback forms can be found in Appendix E.

Discussion

The results of this study confirm the high complexity of enrollers' various roles during the ICP in research studies and trials. It further reveals that enrolment and the ICP is a difficult, complex process impacted by numerous variables. Due to the high burden of TB and HIV in South Africa (Mayosi & Benatar, 2014), improving local healthcare and the management of healthcare workers is important to the development and retention of quality care. Community healthcare workers, such as enrollers, are necessary to increase access to and participation in healthcare (RSA Department of Health, 2011). This study confirms that enrollers have a crucial role in the improvement of quality healthcare and research.

This study aimed to explore the reported experiences of enrollers involved in the informed consent process (ICP) in tuberculosis/HIV clinical research studies. Enrollers' accounts of communication and the enroller-participant interaction were explored, predominantly through their written journaled experiences. Multiple barriers and facilitators to communication processes during the ICP were reported. Barriers were language and/or literacy-related, procedure-related, and participant-related. Language and literacy abilities of both enrollers and participants was found to be a barrier as well as a facilitator to communication.

Throughout the journals, enrollers reported to have used language and communication strategies to facilitate communication processes within interactions, to improve participants' understanding of the ICF and ultimately to obtain true informed consent. Many of these strategies paralleled the strategies that were taught during the communication training. This addresses the second aim of the study, that is, to determine the effect of a communication training programme aimed at improving communication processes during the ICP and enhancing participant comprehension. The strategies used were found to facilitate communication within the enroller-participant interaction and improve participants' understanding of information on the ICF.

The third aim of the study was to explore enrollers experiences of the communication training programme. Enrollers provided written feedback thereon and these forms can be found in Appendix E.

Barriers to the Informed Consent Process

Enrollers reported on multiple major barriers that they found hindered communication processes within the enroller-participant interaction and participants' understanding of the ICF.

Language and literacy.

Language fluency and literacy abilities of participants was found to be a major barrier to their proper understanding of information on the ICF. Confirming Penn and Evans (2009) findings, the diversity of languages on site created further barriers in communication between enrollers and participants. Participants who were illiterate or not fluent in the language of the ICF had difficulties comprehending information, study procedures, and complex terminology. Illiterate participants were further unable to read the ICF, and in some instances, were unable to sign their name. Alternatively, participants who were fluent in the language of the chosen ICF and in which the session was conducted, were reported to have easily understood information on the ICF. Likewise, literate participants were better able to read the ICF and comprehend more complex terminology.

In line with Levin (2014) and Hussey (2012), multiple interactions were conducted in participants' second or third language and many participants were found to not be fluent in the language of the chosen ICF. Many South Africans have been found to have limited literacy skills (Coovadia et al., 2009; Hussey, 2012; Spaull, 2013) and language barriers in healthcare have often been ignored (Hussey, 2012). This study supports this finding as many participants had low literacy abilities. It is thus crucial that informed consent documentation account for participants' literacy standing (National Health Act of South Africa, 2003) and language barriers be identified and addressed in research trial settings.

In accordance with the National Health Act (Act 61 of 2003), it is the enrollers and site staff's responsibility to provide a multilingual service and all languages should be included to equitably render healthcare to all citizens of South Africa (Van den Berg, 2016). Many enrollers were able to adapt their communication behaviours to meet the language needs of participants. This supports Barry and Molyneux's (1992) recommendation that informed consent documentation and explanations thereof should be specific to participants' language, local context and educational background. It is thus crucial that enrollers are equipped with the

necessary skills to recognise and effectively address language and literacy barriers as they are encountered during the ICP. In confirmation with Falagas et al (2009), adequate participant comprehension of the ICF was found to partly depend on the manner in which information was communicated by enrollers rather than solely on what was written in the ICF. This confirms the need for communication training that not only identifies and addresses site-specific language barriers but aims to equip enrollers with strategies to facilitate communication within interactions and participants understanding of the ICF. Since many of the communication strategies enrollers employed during the ICP paralleled that of the communication training, the need for training efforts and the development and modification of the ICF as a joint venture between research site staff and language professionals is highlighted. The development and modification of the ICF as well as the adaptation of the ICP to each participant should be done in a flexible manner.

Trial protocols and procedures.

Enrollers reported that certain study protocols and procedures acted as a barrier to communication processes, interactions, and participation in the study. Procedural barriers arose during the routine processes of IC, enrolment, and the study. These mostly pertained to the explicit nature of questions on the ICF and RAF, exclusion criteria, study duration, and length of sessions. Similar to Cox's (2002) findings, there was tension between satisfying legal requirements of fully informing participants and ensuring comprehension of information. ICFs and documentation were found to be lengthy and complex and not attuned to needs of participants. This came in conflict with the need for documents and explanations to be specific to participants (Barry & Molyneux, 1992).

A novel finding of this study was that numerous participants had issues with the process of blood withdrawals. Participants were found to consent to all study procedures during the enrolment session but would refuse participation when site staff were to draw blood. Even though all study procedures were explained, participants had problems with blood withdrawals and needles despite initially consenting. This highlights a major issue of participants not fully understanding the ICF yet giving their consent. Enrollers play a vital role in ensuring that participants fully comprehend the ICF and all study requirements and procedures. Again, enrollers should be equipped with the skills to recognise when participants do not have an adequate understanding of information on the ICF and make use of strategies to facilitate comprehension and obtain true informed consent.

Issues of True Consent

The consenting of participants when they did not fully understand the ICF and the exact procedures they were consenting to highlighted issues of true consent. Enrollers are tasked with the responsibility of obtaining true informed consent but experience numerous barriers thereto. It is ethically essential to obtain informed consent of participants in clinical studies and requires that they have adequate knowledge of study procedures (SAGCP, 2006). In order to ensure participants' comprehensive understanding of all information pertaining to the study and their participation therein, barriers to the ICP and enrolment should be located, understood, and addressed (Nishimura, 2013). Furthermore, the communication needs of participants should be considered and study documentation adapted to be contextually appropriate.

Facilitators to the Informed Consent Process

Interactive sessions.

In confirmation with Woodsong and Karim (2005), the use of verification methods elicited better participant comprehension of information. Sessions in which both the participant and enroller engaged in discussions and asked more questions were reported to be successful and enabled the verification of participants' comprehension of the ICF. Amounts of talk within the session facilitated communication when both the enroller and participant contributed to the discussions. In accordance with Nishimura et al. (2013), a focus on conversation that provided opportunity for interactive communication was found to be important in facilitating adequate participant comprehension of the ICFs.

Communication and Language Strategies and Training for Language Comfort

Various communication and language strategies were reported on by enrollers throughout the journaling process. In accordance with Penn (2007) and Watermeyer and Penn (2009), these strategies were employed to facilitate communication within interactions, participants' understanding of the ICF, and true consent.

Many strategies used by enrollers paralleled those that were taught during the communication skills training. These strategies were reported to have been successful in facilitating communication. The communication skills training aimed to equip enrollers with strategies to facilitate communication between them and participants, improve participants' understanding of the ICF, and increase language comfort during the ICP. Moreover, the implementation of a communication skills training programme should involve all research site staff, especially enrollers. Participant comprehension of the ICFs may depend on the manner in which relevant information is communicated by enrollers rather than solely on what is

written on the forms (Falagas et al., 2009) and this was confirmed by enrollers' reports of communication strategies used. Thus, communication training should address the task of disseminating information in an understandable manner.

Since enrollers interacted directly with participants, they were found to have in depth knowledge on participants' contextual and local issues. In confirmation with Hussey (2012), language barriers resulted from multiple differing social backgrounds of participants. Many enrollers were able to recognise participants' specific needs during the ICP and adapt accordingly. The communication needs of participants are often not recognised in health settings (Bhutta, 2004). It is thus important that enrollers expertise and knowledge be recognised and incorporated in any communication training programme aiming to modify the ICP. Approaches to the ICP should not be dictated to enrollers but rather involve enrollers and capitalise on their knowledge of participant needs.

Communication Accommodation Theory and the ICP

In this study, enrollers reported to use various communication strategies to account for language discrepancies that arose within the enroller-participant interaction. Enrollers were further found to have adapted to the linguistic needs of participants when language and/or literacy barriers were encountered. In this manner, enrollers modified their verbal and nonverbal behaviour during conversation to converge dialogue towards the participant during the ICP.

Personal and social factors are recognised to emerge during interactions and various modes of communication are made use of to establish and manage social distance (D'Agostino & Bylund, 2014). Similarly, social and contextual factors of participants were found to emerge during enrolment sessions and were often reported as a barrier to communication. Enrollers who acknowledged and addressed these factors in conversation were found to more readily establish a relationship of trust with participants, which in turn facilitated communication.

Mutual, interactive conversation between the enroller and participant was reported to be a major facilitator to effective communication and participants' comprehension of the ICF and ICP. In confirmation with CAT, accommodation behaviour within interactions involved a focus on two-way, mutual interactions and the deliberate adaptation of communication to meet participants' needs.

Enrollers frequently made use of vernacular and translated words on the ICF into more comprehensible terms to facilitate participants' understanding thereof. In this manner, enrollers accommodated participants' language needs and adapted communication accordingly. This

study highlights the various communication strategies enrollers employed during the ICP to adapt to and accommodate participants' needs, to address language and literacy barriers, to establish rapport and trust, and to, ultimately, facilitate participants' understanding of the ICF.

Mutual accommodation in communication was further found to establish rapport and strengthen relationships. This was seen when enrollers adapted their communication behaviour to be more responsive to the emergent social and language needs of participants. Rapport and trust was established between enrollers and participants when enrollers allowed participants to talk about social and personal issues during the enrolment session.

Communication strategies used by enrollers in this study integrated both verbal and nonverbal communication. The importance of both verbal and nonverbal communication and the interplay thereof is emphasised in CAT. This study aimed to identify language barriers and explore the impact that both verbal and nonverbal communication behaviours have on the enroller-participant interaction and enrolment session outcomes. The definition and importance of nonverbal communication behaviours outlined in CAT is in alignment with the communication training that enrollers received. The use and influence of nonverbal behaviour within interactions during the ICP was reported by enrollers and is discussed in the Results and Discussion section.

Lifeworld Complexities and the Establishment of Trust

During the ICP, lifeworld issues were found to influence the enroller-participant interaction. Most notably, discussions on past and current trauma, poverty, unemployment, and ulterior motives for participation were reported to have hindered communication, interactions, and enrolment. Past research has reiterated that recruitment is dependent of establishing relationships of trust and rapport between trial staff, participants, and community members (Picillo, Kou, Barone, & Fasano, 2015, Delany-Moretlwe et al., 2011; Lovato et al., 1996) which implies a focus on communication from the beginning of the study (Delany-Moretlwe et al., 2011). In this study, enrollers facilitated openness and interaction by listening to and allowing participants to discuss their life stories. These findings confirm the need for a focus on communication processes from the beginning of the study to build trust and ensure participants' comprehensive understanding of the research they are involved in (Delany-Moretlwe et al., 2011).

Systems in which Enrollers Work

Since the enroller works within multiple systems, it is necessary to understand all these systems and levels of interaction to understand the ICP and locate barriers and facilitators thereto. The enroller-participant interaction forms part of enrollers' microsystem. This study identified and discussed the perceived barriers and facilitators to communication processes within this interaction. Although this study focused on the enroller-participant interaction, other immediate social interactions should be taken into account and it is critical to understand all the levels of interaction in which enrollers are involved to understand enrolment processes and identify the barriers thereof. These include work colleagues and direct site networks. Enrollers are further impacted by the larger institution which informs the policies and procedures that govern the ICP.

This study has identified multiple barriers to enrolment and the enroller-participant interaction which include language and literacy barriers as well as procedural barriers. Procedural barriers relate to the trial protocols to which enrollers and participants must adhere such as the protocol governing the ICF and ICP. Consequences of these barriers included low enrolment figures and barriers to effective TB and HIV care. Language and literacy barriers encountered during the ICP relate partly to the strict protocols surrounding the ICF and partly to both the enroller and participant's ability to communicate effectively with one another. Interactions within the microsystem, i.e. enroller-participant interactions within the ICP, are influenced by parts of the macrosystem, i.e. trial protocol and procedures. Tension was found to exist between adhering to the strict study protocols and procedures and adapting the ICP to participants' language and contextual needs. In this way, the enroller-participant interaction (microsystem) was influenced by protocols and procedures governing the study (macrosystem).

Support and communication within the organisation involved has been found to be necessary to successfully recruit participants (Peters-Lawrence et al., 2012). It is further stipulated that trial monitoring involve the examination of process and procedural issues. To improve communication processes, interactions and participants' comprehensive understanding of the ICF at the microlevel, study protocols and procedures need to be adapted to meet the contextual needs of participants. Study documents and processes should be contextually appropriate to local settings (Bhutta, 2004). This implies changes at the macrolevel. Since changes in one subsystem affect the system as a whole (Visser, 2012), the modification of study protocols and procedures will impact the enroller-participant interaction.

The Additional Role of Enrollers

This study has found that the role of the enroller was central to the facilitation of communication within the enroller-participant interaction, as well as the successful enrolment of participants into the research study. During the ICP, enrollers took on multiple complex roles within a diverse language setting, some which extended beyond the ICP. These roles were interpreter, translator, language broker, counsellor, educator and informer. Enrollers were required to interpret the meaning of words, sentences and paragraphs of the ICF in an easily understandable manner for participants. Likewise, words and sentences were translated by enrollers when participants could not understand the language of the chosen ICF. Enrollers positioned themselves as language brokers, in that they negotiated and modified the meaning, terminology, language and delivering of the ICF and ICP to meet each participant's needs. The multilingual capabilities of most enrollers were major facilitators to communication within interactions, participants' adequate comprehension of the ICF and true consent. Most enrollers did not receive prior clinical training, therefore the task of interpreting and explaining complex medical terminology and concepts was found to be challenging.

Enrollers were further positioned as counsellors, yet only received training in HIV counselling. Several participants needed counselling due to traumatic life events, poverty and sickness and many enrollers felt unequipped to handle these situations. Regardless of being inadequately trained, enrollers found it was necessary to counsel emotional participants before informed consent could be obtained.

Enrollers were tasked with the additional role of educating participants on the prevention, spread and treatment of TB and HIV. Raising awareness on TB and HIV spread and prevention within the communities from which participants came was regarded as important by both enrollers and participants. The education of site staff and community members is seen as paramount to addressing the TB and HIV burden in South Africa (Petersen et al., 2017; Shah et al., 2017). In addition to the education of participants, enrollers had to sufficiently inform them of all study aims, procedures, and expectations.

Such a myriad of roles implies enrollers had high responsibility for the enrolment of participants into the study. Because enrollers had regular and extensive interactions with participants, they became familiar with the lifeworld events and context, culture, language, and preconceived notions of participants and the surrounding community. Such knowledge and understanding of the context from which participants came was central to the adaptation of the ICP to meet individual needs. This knowledge and the attunement to participant needs should be taken into account and utilised the planning, development, and implementation of study protocols and ICF, yet the enrollers were and currently are not involved. Enrollers were

underutilised and their knowledge on participants' language abilities and needs were not recognised, considered or incorporated in the development and implementation of study protocols. Instead, study protocol was delegated to them and they were not allowed to deviate from the complicated structure of the ICF. The requirement for enrollers to strictly adhere to protocols and the ICF had an influence on the flexibility within enrolment sessions and communication within the participant-enroller interaction. This made it challenging for enrollers to disseminate information to participants in an easily understandable manner.

In accordance with Penn and Evans (2010), an effective ICP was found to be reliant on examination and feedback of those invested in participant interactions, in this case enrollers. Brehaut et al. (2010) recommended that site staff be engaged in discussions regarding the ICP to ensure the effective transfer of complex information to participants and true consent.

Journaling as a Method

The use of journals as the predominant method of data collection did help achieve the research aims. It was especially effective in locating and understanding perceived barriers and facilitators to communication during the enroller-participant interaction. It further allowed for enrollers to document the communication strategies they employed in each enrolment session. This provided an understanding of the communication processes that occurred during the ICP. However, determining the effect of the communication training programme would have been better achieved by studying the enroller-participant interactions directly. Such a method would provide a more in-depth account of communication processes. This would involve audio and video recording interactions during enrolment sessions.

Enrollers did not report on their experiences of the communication training in their journals but gave feedback in the form of a written report.

Study Limitations

Several study limitations have been identified and pertain mostly to the use of journaling as method and the use of FGDs. These limitations have been discussed in the Methodology section. As previously mentioned, the study of audio and video recorded enroller-participant interactions would have better determined the effect of the communication training programme. This would further allow for the study of communication processes and linguistic constituents of interactions. Since enrollers reported on their experiences of the ICP, communication languages employed, and barriers and facilitators to the ICP, researchers were

unable to determine whether enrolment figures changed based on the communication training programme. A mixed methods study would address this limitation.

An additional study limitation was the challenge of analysing separate responses from the control and pilot groups, thus the effectiveness of the communication training programme could not be assessed. Being blinded to the control and pilot groups exacerbated the difficulty of analysing responses from each group. Since enrollers did not explicitly refer to the training in their responses, no assumptions could be made regarding the programme's effectiveness. A quantitative experimental design would be better suited to evaluate the programme's effectiveness. There were however, many language strategies reported by enrollers to be effective in facilitating communication during the ICP that mirrored strategies taught in the training. Communication training programmes should take these strategies into account when conducted and implemented with enrollers and site staff.

Recommendations for Future Research, Policy and Practice

The effective facilitation of communication within the participant-enroller interaction and participants' understanding of the ICF was largely impacted by the language strategies enrollers employed during the ICP. Thus, a communication training programme that addresses issues of true consent and equips enrollers with communication and language strategies should be conducted with all site staff and language strategies be incorporated into the ICP. The communication training should be site-specific and illness-specific and aim to improve communication in healthcare. Such an intervention should locate and reduce barriers to communication within interactions and informed consent in healthcare. The specificities of language barriers should be addressed in a manner that informs the communication training. It is further recommended that language practitioners collaborate with healthcare practitioners to develop and implement practical solutions to cross-linguistic barriers. In agreement with Hussey (2012), multilingual healthcare practitioners who are linguistically proficient in the language of participants should be employed and site staff should be trained in the indigenous languages of participants. The promotion of the use of indigenous languages and the development of a multilingualism setting should be prioritised. Enrollers need an understanding of medical terminology and concepts and should be able to disseminate information in a language that participants can adequately understand. The predominant use of English marginalises participants with limited access to learn English (Hussey, 2012), thus the ICP should be central to participants' language and literacy proficiency.

This study found that enrollers had the additional role of counselling participants during enrolment sessions. Enrollers should receive further counselling training apart from basic HIV/AIDS counselling that aims to equip them with skills to better counsel participants and improve confidence in doing so.

In this study, the use of a flexible approach to obtaining consent during the ICP was found to effectively facilitate communication processes and improve participants' understanding of the ICF. Besides, modifying the manner in which the ICP is conducted and information transferred from enroller to participant can ensure better communication, improve understandings of the ICF, and obtain true informed consent. This implies a focus on equipping enrollers with communication skills. The modification of the way in which the ICF is presented and communicated would be beneficial for enrollers.

Informed consent documents should be adapted and specific to participants' contextual and language needs and include all languages. Effort should be taken to understand the contextual and language needs of participants. Since enrollers were found to have in-depth knowledge on participants' local context and language needs, they should be involved in the planning, development and review of informed consent procedures and documentation. Enrollers' knowledge and expertise are currently underutilised and their crucial role in obtaining informed consent goes widely unacknowledged.

Additional research should be conducted nation-wide to further explore enrollers experiences of the ICP with a focus on understanding communication processes and the linguistic constituents of interactions. Research should go beyond the enroller-participant interaction and examine the broader systems of healthcare settings in which enrollers work.

Conclusion

Enrollers have a crucial role in obtaining informed consent and facilitating participants' understanding of the ICFs, thus their experiences of the ICP and reports of communication processes within interactions between them and participants should be accounted for. This study confirms that tension exists between the satisfaction of legal requirements and fully informing participants and ensuring comprehension of the ICFs. Obtaining informed consent is ethically essential and participants should have an adequate understanding of all study procedures and purposes. Locating factors that hinder obtaining informed consent and adapting the manner in which the ICP is conducted to meet participants' individual needs is crucial to

address barriers experienced in the ICP. Perceived barriers and facilitators to communication within the enroller-participant interaction were reported by enrollers involved in the ICP in TB/HIV clinical research studies. This study has highlighted the importance and benefit of obtaining enroller's insights when addressing complexities and challenges in IC. It also elucidates the multiple roles and systems in which enrollers have to perform and navigate. Involving enrollers during the development of research protocols and policies may assist in a greater understanding of diverse research contexts, and sensitivity to communication challenges and facilitators.

The implementation of a communication training programme that is site-specific with a focus on the identification of barriers may improve the ICP and enhance participants' comprehension of information. Enrollers' perceptions of the effect and reported experiences of the communication training programme was explored and numerous language strategies were reported to successfully facilitate communication processes, improve understandings of the ICF and obtain true consent within interactions. Thus, communication training should focus on language strategies aimed at reducing barriers to communication within interactions during the ICP. A further focus on rich, interactive conversation between enroller and participant is important to facilitate participants' understanding of the ICFs and obtaining true informed consent.

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Appendix A

Ethical Clearance Certificate from Wits HREC (Medical)

R14/49 Prof Claire Penn

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160355

NAME: (Principal Investigator)	Prof Claire Penn
DEPARTMENT:	Health Communication Research Unit Aurum Rustenburg Clinical Research Site
PROJECT TITLE:	Training for Language Comfort: Enhancing the Informed Consent Process at TB/HIV Clinical Trial Sites
DATE CONSIDERED:	01/04/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	20/04/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I **agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in March and will therefore be due in the month of March each year.

Principal Investigator Signature Date 22/4/2016

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B

An Example of How the Communication Training Programme was Conducted

FREEDOM RULES FOR A 'LIGHT' INFORMED CONSENT PROCESS

1. ***Setting:*** Before you start the consultation, keep in mind your surrounding area. Are there physical barriers between you and the participant? E.g. desk, cluttered area, cramped space? Be aware of potential noise, privacy & seating arrangements.
2. ***Establish Trust*:** Emphasise that the information disclosed is private & no personal information will be shared with anyone.
3. ***Language conversations:*** Use this at the start of a conversation to assess the participant's language comfort. You can use any language you like to keep things easy, not just the language of the form.
4. ***Life-world conversations:*** Use this at the start of a conversation as an 'ice-breaker' and to get to know your participant.
5. ***Agenda Setting:*** At the beginning of the session, explain what you are going to be doing in the session, and ask your participant if there is anything that they would particularly like to know or achieve from the session.
6. ***Start with the Basics:*** Before going into complex explanations of trial details, start from the beginning. Explain what research is, why it is important, and why the participant or the community has been invited to participate.
7. ***Humour:*** If you are feeling uncomfortable with some of the questions, acknowledge it. We are all human!
8. ***Props:*** Use tools to help you explain concepts e.g. paper & pen, pamphlets, pictures, medical equipment etc.
9. ***Talk Don't Read!*** You know what is in the form, so convey it your own way (in a comfortable language which suits you both). Provide talk that flows.
10. ***Vocabulary negotiation:*** Check whether the participant understands certain words in particular languages, or use alternative words or phrases to explain something.
11. ***Chunking/Sequencing****:* Break the information up into short manageable sections, and explain to the participant that you are moving from one section to another.
12. ***Repetition & Checking Understanding:*** Emphasise important parts of the trial and frequently stop between sections to check understanding. Use strategies such as repetition, rephrasing and slower speech. Use comparisons, analogies, or everyday 'knowledge' to help you to explain a difficult concept to a participant. Encourage the participant to explain in their own words what they have been told. Don't just do a single check at the end of the session!
13. ***Be aware of Non-Verbals*:** Keep in mind both the participant's and your own body language, facial expressions, head movements and gestures.
14. ***Let Participant know that they can take the "deep/detailed" informed consent form home***- For further reading, to show their family if necessary, etc.
15. ***Debriefing****:* Seek opportunities to discuss with your colleagues areas of the enrollment process which you are struggling with, or to provide tips/strategies to others on what works well.

Remember the 4 "Cs" on what goals the informed consent process is trying to achieve:

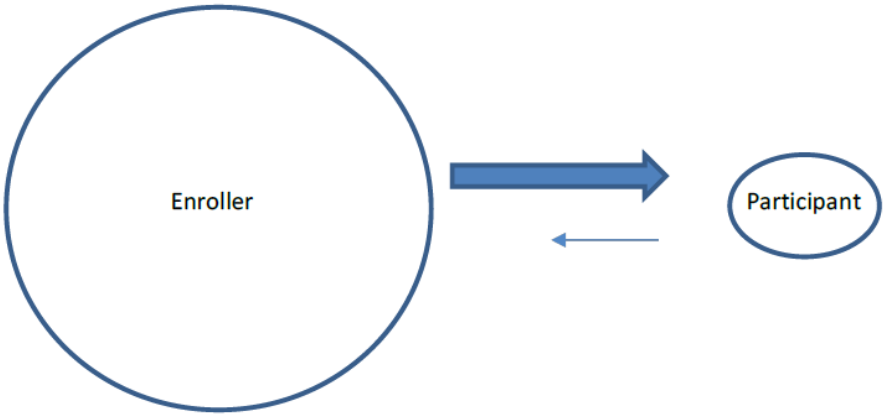
- **Comfort** (the enroller and the participant must both feel comfortable when communicating).
- **Confidence** (the enroller must feel confident when explaining information & help the participant to feel confident that they have understood the information).
- **Comprehension** (the participant must understand the information so that they can make an informed decision).
- **Confidentiality** (remember to always make the participant feel safe to be able to discuss personal information).

Be Aware of the "Amount of Talk"

We are trying to achieve an interaction where there is an equal amount of talk between both individuals.

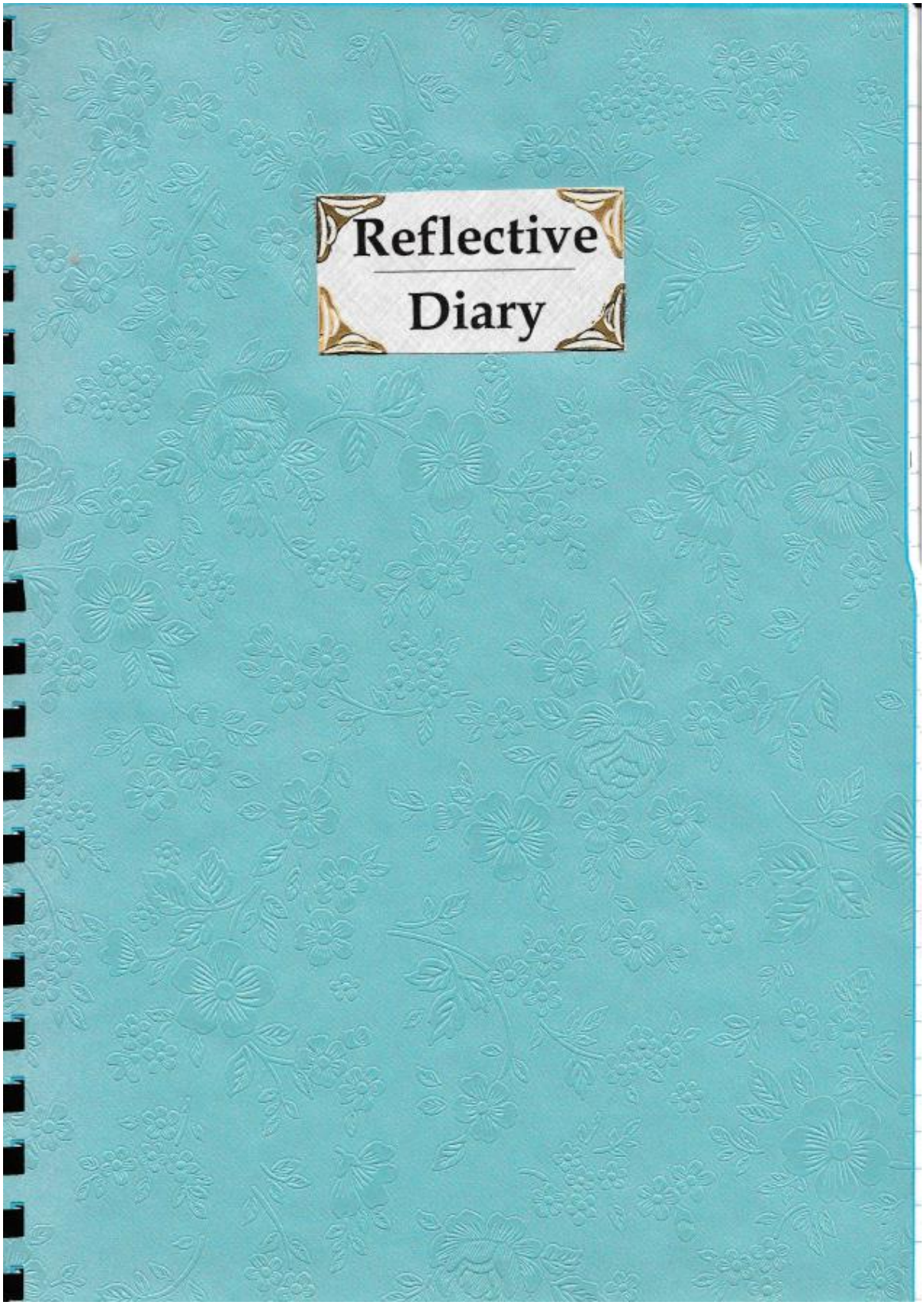


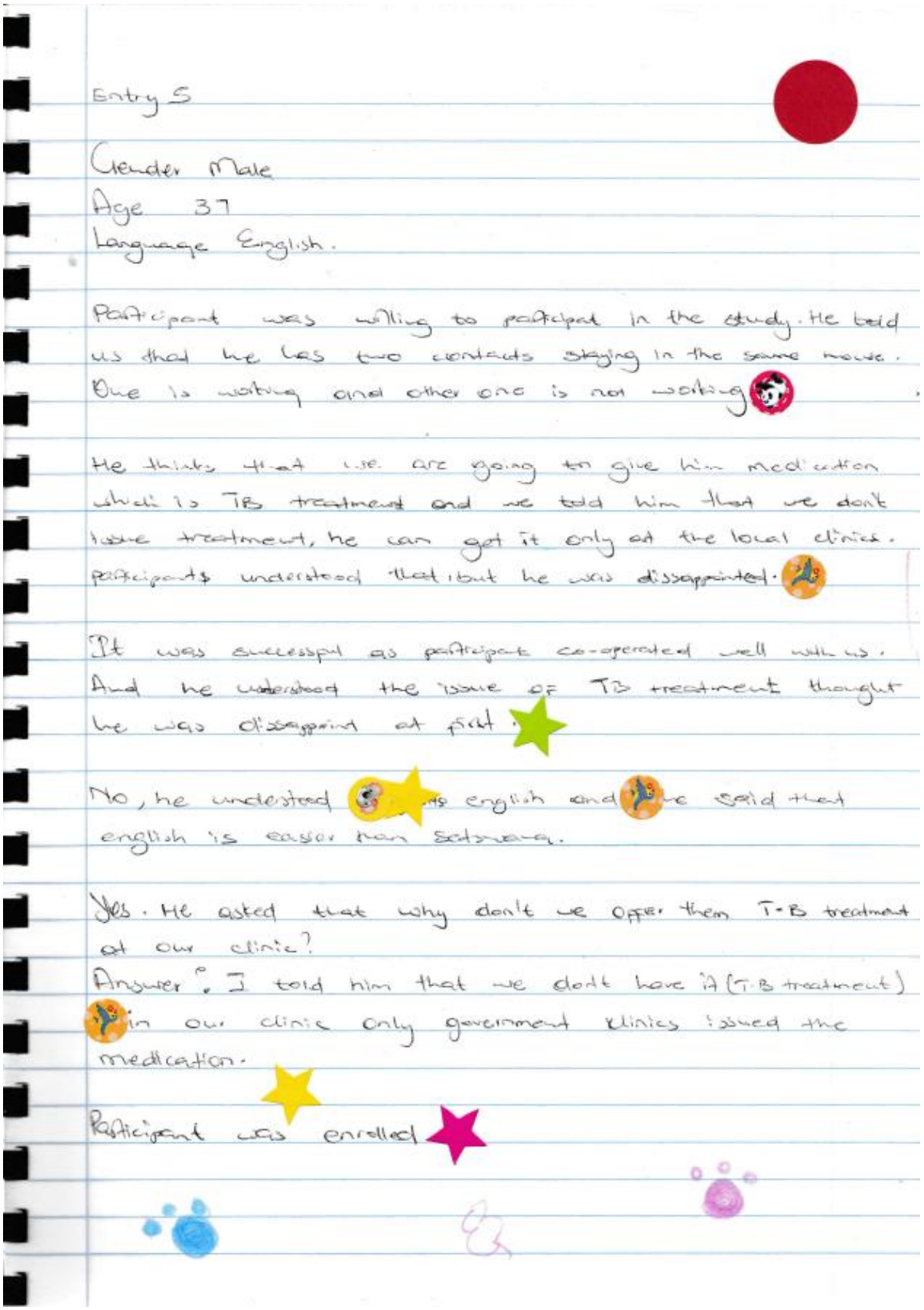
We are trying to avoid an interaction where the conversation is dominated by one individual only.



Appendix C

Example Reflective Journal





Entry 5

Gender Male
Age 37
Language English.

Participant was willing to participat in the study. He told us that he has two contacts staying in the same house. One is working and other one is not working

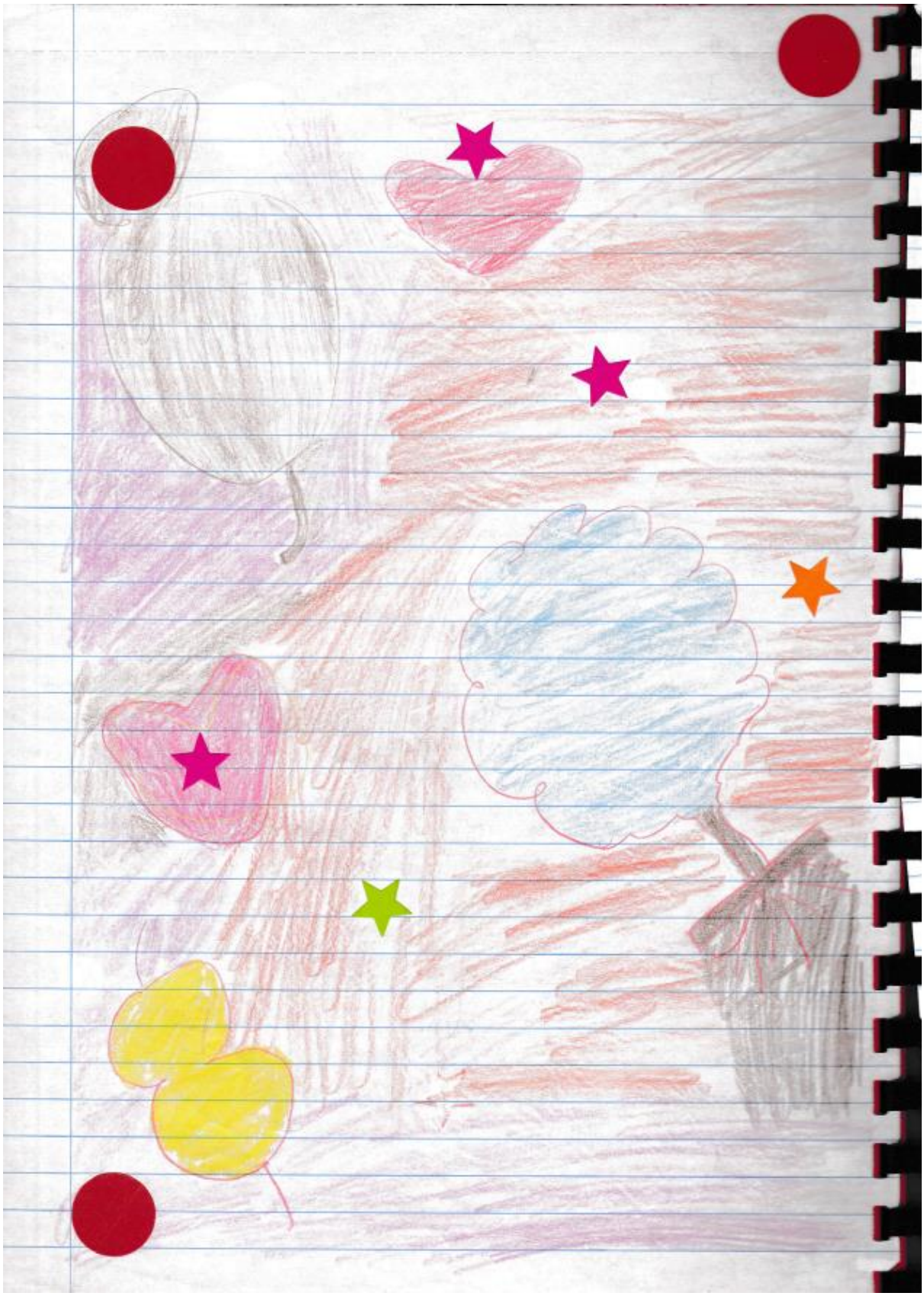
He thinks that we are going to give him medication which is TB treatment and we told him that we don't have treatment, he can get it only at the local clinics. participants understood that but he was dissappointed.

It was successful as participant co-operated well with us. And he understood the issue of TB treatment thought he was dissappoint at first.

No, he understood english and he said that english is easier than Setswana.

Yes. He asked that why don't we offer them T-B treatment at our clinic?
Answer: I told him that we don't have it (T-B treatment) in our clinic only government clinics issued the medication.

Participant was enrolled



Appendix D

Examples of Reflective Journal Questions

REFLECTIVE QUESTIONS FOR JOURNALS:

1. *Patient demographics: Gender, age of participant, and language(s) that session was conducted in.*

2. *How was this session for you?*

3. *What factors made it easy?*

4. *What factors made it difficult?*

5. *Is there something that stood out for you regarding communication issues (e.g. words, language difficulties, sections in the consent forms, etc.)*

6. *Is there something you wish you could have done differently?*

7. *Is there something that you did that you felt really assisted the patient in making an informed decision?*

Appendix E

Enroller Feedback Reports on the Communication Training Programme



09 June 2016

HCRU COMMUNICATION TRAINING FEEDBACK

Thank you for participating in our study. We would be grateful if you could give us some feedback on the communication training that you received. Please could you answer the following questions:

1. What stood out for you?

→ Discussing the five most important things on the protocol. Because it would simplify the Studies.

2. What methods did you enjoy?

→ The DRIVE method works better for me and Pictureprons. Because you can elicit alot of information from participant.

3. Was there something that you didn't enjoy?

→ Quite frankly I enjoyed everything, the enviroment of the training and the trainers were informative. Maybe next time we could do the whole day training with Managers.

4. Do you think you will be able to apply some of the things that you learnt today?

→ Yes most defanetly.

5. Do you have any suggestions for future training?

→ Involve all the other department especially quality control. And personel such as Principal Investigators so they can understand our experiences and difficulties.

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09 June 2016

HCRU COMMUNICATION TRAINING FEEDBACK

Thank you for participating in our study. We would be grateful if you could give us some feedback on the communication training that you received. Please could you answer the following questions:

1. What stood out for you?
   - Pictograms
   - Non-verbal communication games
   - Role-plays
2. What methods did you enjoy?
   - DRIVE Method makes things easier and makes the enroller to cover important information about a study.
3. Was there something that you didn't enjoy?
   - Honestly, No.
4. Do you think you will be able to apply some of the things that you learnt today?
   - Most definately. This was the most informative and assertive training. The 4 C's and the DRIVE model are going to make easier for a lot of us
5. Do you have any suggestions for future training?
   - I would suggest that we have videos (communication) to watch so that we can have a clear idea of how it should be done.



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09 June 2016

HCRU COMMUNICATION TRAINING FEEDBACK

Thank you for participating in our study. We would be grateful if you could give us some feedback on the communication training that you received. Please could you answer the following questions:

1. What stood out for you?

- Realising how difficult to meet people who are illiterate.
- And how difficult to explain some of abbreviations
- Expressing was Safe and being confident

2. What methods did you enjoy?

- Drive
- Pictures
- Virus infected cell Method

3. Was there something that you didn't enjoy?

No

4. Do you think you will be able to apply some of the things that you learnt today?

Yes of Cause

5. Do you have any suggestions for future training?

- So with it can be for all the Staff

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