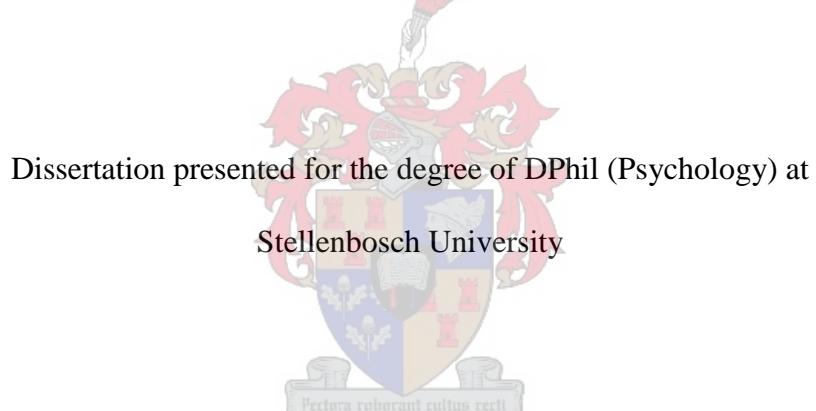


Willingness to participate in an HIV vaccine trial: Construction and initial validation of the Willingness to Participate Scale (WTPS), and an application and extension of the Theory of Planned Behavior.

Dylan Shaun Fincham



Dissertation presented for the degree of DPhil (Psychology) at
Stellenbosch University

Promoter: Professor Ashraf Kagee

Co-promoter: Professor Leslie Swartz

December 2008

DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

29/07/2008

.....
Signature

.....
Date

SUMMARY

Background

South Africa is the country with the largest number of HIV infections in the world. As behaviour change initiatives have been suboptimal in curbing the spread of the pandemic, an HIV vaccine is likely to be an important development as a biological agent may circumvent some of the challenges of initiating widespread behaviour change. The development of an HIV vaccine will require several thousands of HIV negative participants who are at high risk of HIV infection to participate in HIV vaccine clinical trials. Before recruitment for such trials may begin, various scientific, ethical, and sociobehavioural issues need to be considered. One of the key sociobehavioural issues concerns the willingness of individuals at high risk of HIV infection to participate in HIV vaccine trials. However, a psychometric measure of willingness to participate (WTP) has not been constructed, and there is a paucity of theory to guide studies of WTP.

Objectives

The first objective of this study was to construct a psychometric measure of WTP in an HIV vaccine trial, and to derive the exploratory factor structure of the measure. The second objective was to examine the extent to which the Theory of Planned Behavior (TPB) could predict variance in WTP, and to determine whether the TPB was strengthened by the inclusion of mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables.

Methodology

This study was a research survey with a cross-sectional design. A convenience sample of 399 participants was recruited from an urban-informal settlement near Cape Town. As 79 of the questionnaires were poorly completed, the final sample size was 320. To develop a measure

of WTP in an HIV vaccine trial, an item pool was developed whereby items directly reflected inhibitors and facilitators of WTP. After an iterative process of refinement, the final scale consisted of 35 items and was named the Willingness to Participate Scale (WTPS). A principal component Kaiser normalised exploratory factor analysis (EFA) was conducted on the items that constituted the WTPS. This procedure was performed to identify latent factors which were informed by the items of the scale. To test the predictive capacity of the TPB and the additional predictor variables, a two-step linear hierarchical multiple regression analysis was performed. At step 1, the TPB variables were entered simultaneously. At step 2, the TPB variables along with the additional predictor variables were entered simultaneously.

Results

The WTPS demonstrated excellent internal consistency ($\alpha = 0.90$) and initial construct validity, as evidenced by the presence of seven latent factors. The factors accounted for 53.15% of the variance in WTP and were: (i) Social approval and trust; (ii) Stigmatisation; (iii) Personal costs; (iv) Personal gains; (v) Personal risks; (vi) Convenience; and (vii) Safety. The TPB significantly accounted for 6.4% ($R^2 = 0.06$) of the variance in WTP [$F(3, 316) = 7.16, p < 0.001$], yielding a small effect size ($f^2 = 0.06$). The TPB, together with mistrust, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables significantly accounted for 10.2% ($R^2 = 0.10$) of the variance in WTP [$F(7, 312) = 5.06, p < 0.001$], yielding a small to medium effect size ($f^2 = 0.11$). Subjective norms, mistrust of researchers, altruism, and perceived risk of HIV infection were significant independent predictors of WTP.

Conclusion

Against the backdrop of the study limitations, the results of this study provide initial support for the reliability and construct validity of the WTPS among the most eligible trial participants in the Western Cape of South Africa. The findings also suggest that the TPB may

not be an appropriate theoretical framework for predicting WTP in an HIV vaccine trial in this context. Nonetheless, normative pressure by others, mistrust of researchers, altruism, and perceived risk of HIV infection may influence WTP in this population. Implications for future research are discussed.

OPSOMMING

Agtergrond

Suid Afrika is die land met die hoogste getal HIV infeksies in die wêreld. Vir die ontwikkeling van 'n HIV entstof, sal daar vereis word dat duisende HIV negatiewe deelnemers, wat 'n hoë risiko kans staan om HIV infeksie op te doen, moet deelneem aan 'n kliniese HIV vaksine proeftog. Verskeie, wetenskaplike, etiese en sosiale gedrags punte moet oorweeg word, voor die werwing van sulke proefnemings. Een van die hoof aspekte van sosiale gedrags punte is die bereidwilligheid van 'n individu om blootgestel te word aan die HIV infeksie tydens die proeftog. 'n Psigometriese skatting van bereidwilheid om deel te neem (BODTN) is egter nog nie gekonstruksioneer nie en daar is 'n skaarste/geringheid in studies om as gids te dien vir die BODTN.

Doel

Die eerste doel van hierdie studie was om 'n psigometriese skatting van BODTN in 'n HIV vaksiene proefneming te konstruksioneer, en om die ondersoekings oorsaak/faktor struktuur daarvan te meet en af te lei. Die tweede doel was om ondersoek in te stel of die omvang van die Teorie van Beplande Gedrag (TBG) verskille kan voorspel in die BODTN, en om vas te stel of die TBG versterk word deur die insluiting van wantroue in navorsers, kennis van HIV vaksienes en HIV vaksiene proefnemings, altruïsme, en die begrypbare risiko van HIV infeksie as adisionele voorspellers.

Metode

Hierdie studie is 'n navorsings ondersoek met 'n deursneeproef ontwerp. 'n Grieflike aantal van 399 deelnemers was gewerf van 'n informele nedersetting naby Kaapstad. Die finale getal was 320 omdat 79 nie die vraelys korrek on volledig ingevul het nie. Na 'n interaktiewe proses van suiwering/verfyning, het die finale skaal uit 35 items bestaan en word die skaal

benoem na die Willingness to Participate Scale (WTPS). Die prinsipale komponent Kaiser normaliseer EFA wat gedoen was op die items wat die WTPS konstitueer. Hierdie prosedure was gedoen om die latente faktore te identifiseer wat beskikbaar gestel was deur die items van die skaal. Om die voorspelbare kapasiteit van die TBG en die adisionele voorspelbare verskille te toets, het ons 'n twee stap hiërargiese veelvoudige agteruitgaan analyse gebruik. By stap 1 was die TBG veranderlikes gelyktydig ingedruk. By stap 2 is die TBG veranderlikes tesame met die adisionele voorspellers in gedruk.

Resultate

Die WTPS het uitstekende interne konsistensie en 'n aanvanklike geldigheid gedemonstreer, soos bewys deur die teenwoordigheid van die 7 latente faktore. Die faktore verantwoord 53.15% van die verskil in WTP en was: (i) Sosiale aanvaarding en vertroue; (ii) Stigma; (iii) Persoonlike koste; (iv) Persoonlike wins/profyt; (v) Persoonlike risiko's; (vi) Gerieflikheid; en (vii) Veiligheid. Die TBG verantwoord 6.4% ($R^2=0.06$) van die verskil in BODTN [$F(3.316) = 7.16$, $p<0.001$] met 'n toegewende klein groote uitwerking/uitslag. Die TBG tesame met wantroue, kennis van HIV vaksienes en HIV vaksiene proefnemings, altruïsme, en begrypbare risiko van HIV infeksie as adisionele voorspellers, verwantwoord 10.2% ($R^2=0.10$) van die verskil in BODTN [$F(7.312 = 5.06$, $p<0.001$], met 'n toegewende klein tot medium groote uitwerking/uitslag ($\beta^2=0.11$). Subjektiewe norme, wantroue in navorsers, altruïsme, en 'n beprypbare risiko van HIV infeksie was betekenisvolle, onafhanklike voorspellers van die BODTN.

Gevolgtrekking

Teen die agtergrond van die studie beperkinge, het die resultate van hierdie studie ondersteuning voorsien aan die vertroubaarheid en konstruktiewe geldigheid van die WTPS onder die mees geskikste proef deelnemers in die Wes Kaap van Suid Afrika. Die bevinding stel ook voor dat die TBG nie altyd 'n geskikte teoretiese raamwerk is vir die voorspelling van

die BODTN in 'n HIV vaksiene proefneming in hierdie konteks is nie. Des nie teen staande, normale druk van ander, wantroue in navorsers, altruïsme en die begrypbare infeksie van HIV kan die populasie deur die BODTN beïnvloed word. Implikasies vir toekomstige navorsing is bespreek.

ACKNOWLEDGEMENTS

- First and foremost, I thank Professors Ashraf Kagee and Leslie Swartz for their outstanding guidance and support.
- I thank the National Research Fund (NRF) for the funding that made this study possible.
- Thanks to my mother Angie, father Greg, brother Ryan, and sister Tamsyn for their encouragement and support.
- Thanks to my employer and mentor, Professor Soraya Seedat, for allowing me the flexibility to meet with my promoters and to complete the thesis.
- Finally, thanks to Berna Bekker for translating the summary.

Oh, and very special thanks to Nonny, Tiger, and Evel Knievel...

DEDICATION

This thesis is dedicated to the people of Masiphumelele.

TABLE OF CONTENTS

Declaration	ii
Summary	iii
Opsomming	vi
Acknowledgements	ix
Dedication	x
List of Tables	xvii
List of Figures	xviii
List of Abbreviations	xix
Chapter 1: Introduction	1
1.1 The HIV/AIDS pandemic	1
1.2 HIV/AIDS prevention	3
1.3 The South African AIDS Vaccine Initiative (SAAVI)	3
1.4 The development of an HIV vaccine	4
1.5 The importance of studying willingness to participate (WTP) in an HIV vaccine trial	5
1.6 The Sociobehavioural Working Group of SAAVI (SAAVI-SB)	7
1.7 Research problems	8
1.8 A theoretical framework for studying WTP in an HIV vaccine trial	9
1.9 Extending the TPB in the context of WTP in an HIV vaccine trial	10
1.10 Goals of the study	11
1.11 Importance of this study	12
1.12 Definition of concepts	12
1.12.1 Facilitator	12

1.12.2 Inhibitor	13
1.12.3 Altruism	13
1.13 Overview of chapters	13
Chapter 2: Literature review and theoretical framework	15
2.1 Introduction	15
2.2 Retention and attrition	15
2.3 Sexual disinhibition	16
2.4 Social harms	17
2.5 Willingness to participate (WTP) in an HIV vaccine trial	18
2.5.1 Inhibitors of WTP in an HIV vaccine trial	18
2.5.1.1 Mistrust	18
2.5.1.2 Knowledge of HIV vaccines and HIV vaccine trials	23
2.5.2 Facilitators of WTP in an HIV vaccine trial	26
2.5.2.1 Altruism	26
2.5.2.2 Perceived risk of HIV infection	29
2.5.3 Health concerns and WTP in an HIV vaccine trial	31
2.5.4 Gender and WTP in an HIV vaccine trial	32
2.5.5 Age and WTP in an HIV vaccine trial	34
2.5.6 Educational level and WTP in an HIV vaccine trial	35
2.6 Part I of this study	35
2.7 Measuring WTP in an HIV vaccine trial	37
2.8 A theoretical framework for studying WTP in an HIV vaccine trial	39
2.8.1 The Health Belief Model	40
2.8.2 The Protection Motivation Theory	41
2.8.3 The Theory of Planned Behavior	43

2.8.4 The Theory of Planned Behavior and WTP in an HIV vaccine trial	47
2.9 Overview of the chapter	50
Chapter 3: Research methodology	51
3.1 Introduction	51
3.2 Participants	52
3.3 Research design	53
3.4 Measuring instruments	53
3.4.1 The Willingness to Participate Scale (WTPS)	53
3.4.1.1 Item development	53
3.4.1.2 Item refinement	54
3.4.2 Measuring the TPB variables	54
3.4.2.1 Attitudes	55
3.4.2.2 Subjective norms	56
3.4.2.3 Perceived behavioural control	57
3.4.3 Scales for the additional variables	58
3.4.3.1 Mistrust of researchers	58
3.4.3.2 Knowledge of HIV vaccines and HIV vaccine trials	58
3.4.3.3 Altruism	59
3.4.3.4 Perceived risk of HIV infection	59
3.4.3.5 Demographic variables	59
3.5 Translation of measuring instruments	60
3.6 Procedure	61
3.7 Data analysis	62
3.7.1 Data screening	62

3.7.2 Exploratory factor analysis	63
3.7.2.1 Sample size for exploratory factor analysis	64
3.7.3 Two-step linear hierarchical multiple regression analysis	64
3.7.3.1 Model specification	65
3.7.3.2 Sample size for multiple linear regression analysis	65
Chapter 4: Results	66
4.1 Demographic characteristics of the sample	66
4.2 Internal reliability of the measures	68
4.2.1 Attitudes	68
4.2.2 Subjective norms	68
4.2.3 Perceived behavioural control	68
4.2.4 Mistrust	68
4.2.5 Knowledge of HIV vaccines and HIV vaccine trials	69
4.2.6 Altruism	69
4.3 Bivariate correlations between variables	70
4.4 Between-groups effects	72
4.5 The Willingness to Participate Scale (WTPS)	74
4.5.1 Factor structure of the WTPS	78
4.5.2 Exploratory factor analysis diagnostics	81
4.6 Application and extension of the Theory of Planned Behavior	81
4.6.1 Two-step linear hierarchical multiple regression analysis	81
4.6.2 Regression diagnostics	84
4.7 Summary of findings	85
Chapter 5: Discussion and conclusion	87
5.1 Introduction	87

5.2	Limitations of the study	89
5.3	The representativeness of the sample	91
5.4	Factor structure of the WTPS	94
5.4.1	Social approval and trust	94
5.4.2	Stigmatisation	96
5.4.3	Personal costs	97
5.4.4	Personal gains	99
5.4.5	Personal risks	100
5.4.6	Convenience	102
5.4.7	Safety	103
5.5	Application of the Theory of Planned Behavior	104
5.5.1	Attitudes	104
5.5.2	Subjective norms	105
5.5.3	Perceived behavioural control	106
5.6	Extension of the Theory of Planned Behavior	107
5.6.1	Mistrust of researchers	108
5.6.2	Knowledge of HIV vaccines and HIV vaccine trials	109
5.6.3	Altruism	110
5.6.4	Perceived risk of HIV infection	110
5.7	Conclusions	112
	Reference list	114
	Appendices	
	Appendix A	141
	Appendix B	159
	Appendix C	161

	xvi
Appendix D	164
Appendix E	167
Appendix F	171
Appendix G	179
Appendix H	183
Appendix I	189

LIST OF TABLES

Table 1:	Demographic Characteristics of the Sample	66
Table 2:	Internal Consistency of Measures Before and After Deleting Poorly Performing Items	70
Table 3:	Bivariate Pearson Product-moment Correlations between Continuous Variables	71
Table 4:	Tests of Between-groups Effects	73
Table 5:	Item-by-item Descriptive Analyses for the WTPS	75
Table 6:	Principal Components Exploratory Factor Analysis of the WTPS	80
Table 7:	Summary of Two-step Linear Hierarchical Multiple Regression Analysis for Variables Predicting WTP	83

LIST OF FIGURES

Figure 1:	Enabler-Inhibitor quadrant model (Swartz et al., 2006)	36
Figure 2:	The Theory of Reasoned Action	44
Figure 3:	The Theory of Planned Behavior	45
Figure 4:	Application and extension of the Theory of Planned Behavior in this study	49
Figure 5:	Scree plot of factors to be extracted (Eigenvalues ≥ 1)	79
Figure 6:	Histogram and normal probability plot of the standardised residuals	84
Figure 7:	Standardised residuals/standardised predicted values plot	85

LIST OF ABBREVIATIONS

AAVI:	African AIDS Vaccine Initiative
AIDS:	Acquired Immunodeficiency Syndrome
BHAI:	Botswana Harvard AIDS Institute
CAB:	Community Advisory Board
CSW:	Casual Sex Worker
DoH:	Department of Health
DPMSA:	Detroit Primary Metropolitan Statistical Area
DST:	Department of Science and Technology
EAVI:	Ethiopian AIDS Vaccine Initiative
EFA:	Exploratory Factor Analysis
EU:	European Union
HAART:	Highly active anti-retroviral therapy
HBM:	Health Belief Model
HIV:	Human Immunodeficiency Virus
HVTN:	HIV Vaccine Trials Network
IAVI:	International AIDS Vaccine Initiative
IDU:	Injection Drug User
IRB:	Internal Review Board
KOSH:	The Klerksdorp, Orkney, Stilfontein and Hartbeesfontein district
LSD:	Lysergic acid diethylamide
MSM:	Men who have sex with men
MVA:	Missing Value Analysis
NAVP:	Nigerian AIDS Vaccine Programme

NIH:	The US National Institute of Health
PMT:	Protection Motivation Theory
SAAVI:	South African AIDS Vaccine Initiative
SEM:	Structural Equation Modelling
SPSS:	Statistical Package for the Social Sciences
STD:	Sexually Transmitted Disease
TPB:	Theory of Planned Behavior
TRA:	Theory of Reasoned Action
UAI:	Unprotected Anal Intercourse
UNAIDS:	The joint United Nations program on HIV/AIDS
US:	United States
VIF:	Variance Inflation Factor
WTP:	Willingness to Participate
WTPS:	Willingness to Participate Scale

CHAPTER 1

INTRODUCTION

1.1. The HIV/AIDS pandemic

The most recent report by the joint United Nations program on HIV/AIDS (UNAIDS, 2007) estimates that by December of 2007, 33.2 million people (95% CI: 30.6 million - 36.1 million) were infected with HIV worldwide. In 2007 alone, 2.5 million people (95% CI: 1.8 million - 4.1 million) became newly infected with HIV and 2.1 million people (95% CI: 1.9 million - 2.4 million) died from AIDS related causes. Sub-Saharan Africa remains the most seriously affected region in the world, with 22.5 million people (95% CI: 20.9 million - 24.3 million) infected with HIV by December of 2007.

South Africa is the country with the largest number of HIV infections in the world (UNAIDS, 2007). A national HIV prevalence and incidence study by Shisana et al. (2005) showed that the prevalence rate of HIV among persons aged 15 to 49 years in 2005 was 16.2% (95% CI: 14.9% - 17.7%). The prevalence of HIV among females (20.2%) was nearly twice that of males (11.7%), and the prevalence rate among Blacks¹ (19.9%) was substantially greater than in any other racial group (Whites: 0.5%; Coloureds: 3.2%; and Indians: 1.0%). Persons living in urban informal settlements demonstrated a substantially higher HIV prevalence rate (25.8%) than those in urban formal (13.9%), rural formal (13.9%), or rural informal settlements (17.3%). In sum, it seems that Black individuals (especially Black women)

¹ Given South Africa's history of political oppression and racial segregation, the terms 'Black', 'White', and 'Coloured' may be considered offensive. This study, however, used the terms for the exclusive purpose of describing differences between members of different groups which occur in the context of the consequences of a history of discrimination on the basis of politically used categories. No inherent "racial" differences are implied

between the ages of 15 and 49 years who reside in urban informal settlements are at highest risk of HIV infection in South Africa.

Black women are also the poorest individuals in South Africa. According to the most recent South African census data (Statistics South Africa [SSA], 2001), 31.4% of Black females between the ages of 15 and 65 years had no formal source of income compared to 23.5% of both sexes from all population groups. Furthermore, 55.6% of employed Black females between the ages of 15 and 65 years were in elementary occupations, compared to 2.6% of both sexes from all population groups. The disproportionate burden of disease among the poor is a global trend (Gilbert & Walker, 2002) and suggests that socioeconomic risk factors may predict HIV seropositivity in developing and developed country settings alike.

Given the high levels of economic, gender, and health inequality in South Africa, it seems that social risk factors play an exceedingly important role in the transmission of HIV in this context. It may even be the case that “social inequality is the greatest transmitter of HIV/AIDS” (Gilbert & Walker, 2002, p. 1094). Unless both biological and social risk factors are addressed, it is likely that there will be an exacerbation of the very inequalities that contributed to the spread of the epidemic in the first place (Campbell, 2003). Also, the loss of human capital associated with the unchecked spread of HIV will seriously impede economic growth and inhibit social development (Arndt & Lewis, 2000; Bachmann & Boysen, 2003; Piot, Bartos, Ghys, Walker, & Schwartlander, 2001). Various efforts have therefore been made to prevent the transmission of HIV.

1.2 HIV/AIDS prevention

Multilateral efforts have been made to ameliorate structural risk factors such as unemployment, poverty, gender inequality, inadequate healthcare facilities, high costs of antiretroviral drugs, and low levels of education (Myer, Morroni, & Susser, 2003; Smit et al., 2005). In sub-Saharan Africa however, most intervention strategies have focused on sociobehavioural risk factors. For example, behaviour change initiatives such as the promotion of barrier contraceptives, abstinence, a reduction in number of sexual partners, and delayed sexual debut have been widely implemented, with some success in Kenya and Zimbabwe (UNAIDS, 2007).

In South Africa however, as elsewhere, the effectiveness of such interventions has been suboptimal as the pandemic shows no sign of abating (Sahay et al., 2005). An HIV vaccine may therefore be an important development as a biological agent may circumvent some of the challenges of initiating widespread behaviour change (McCluskey, Alexander, Larkin, Murguia, & Wakefield, 2005). To this end, the South African AIDS Vaccine Initiative (SAAVI) was formed.

1.3 The South African AIDS Vaccine Initiative (SAAVI)

SAAVI, established in 1999 by the Medical Research Council (MRC) of South Africa, is a collaborative partner in the broader international effort to develop an efficacious HIV vaccine (South African AIDS Vaccine Initiative [SAAVI], 2008). African partners include the African AIDS Vaccine Programme (AAVP), the Ethiopian AIDS Vaccine Initiative (EAVI), the Nigerian AIDS Vaccine Programme (NAVP) and the Botswana Harvard AIDS Institute

(BHAI). Further abroad, SAAVI collaborate with the International AIDS Vaccine Initiative (IAVI), the US National Institutes of Health (NIH), the NIH-funded HIV Vaccine Trials Network (HVTN), and the European Union (EU). SAAVI receives funding from both the public and the private sectors of South Africa, as well as funding from abroad. Public funders include the Department of Health (DoH) and the Department of Science and Technology (DST). The majority of private sector funding comes from Eskom (the national energy supplier) and Impala Platinum (the leading producer of platinum in the world). Internationally, SAAVI receives funding from the European Union (EU) and several biotechnology companies.

Despite being highly connected with global players, the foremost goal of SAAVI is to address the needs of South Africa and the southern African region as a whole (SAAVI, 2008). There were five research sites in South Africa at the time of this study. These sites were located in Soweto, Cape Town, Durban, and the Klerksdorp, Orkney, Stilfontein and Hartbeesfontein (KOSH) district. The site in the Durban has since been closed.

1.4 The development of an HIV vaccine

The development of an HIV vaccine - indeed, of any pharmaceutical agent of this kind - involves three Phases (Slack et al., 2005). Phase I tests vaccine safety, vaccination schedule, and immune responses in small numbers of HIV negative participants. If the candidate vaccine is determined to be safe and stimulates an immune response, immunologists proceed to Phase II which tests the candidate vaccine's safety and immunogenicity in larger numbers of HIV negative participants. If successful, immunologists proceed to Phase III which tests vaccine efficacy in several thousands of HIV negative participants who are at high risk of

HIV infection. Considering that such a large number of individuals will be required to risk exposure to an experimental vaccine that has not been widely tested on human subjects, various scientific (Slack et al., 2005), ethical (Kerns, 1997; Lindegger & Richter, 2000; Lindegger, Slack, & Vardas, 2000), and sociobehavioural (Smit et al., 2005) issues need to be considered. One of the key sociobehavioural issues concerns the willingness of individuals at high risk of HIV infection to participate in HIV vaccine trials.

1.5 The importance of studying willingness to participate (WTP) in an HIV vaccine trial

Understanding the psychosocial factors that may inhibit or facilitate WTP is important to ensure that a sufficiently large number of eligible individuals enrol in an HIV vaccine trial, and to promote the ethical treatment of trial participants. A large sample size is crucial to yield sufficient power to detect significant differences in rates of HIV seroconversion between the experimental group that receives the candidate vaccine, and the placebo control group. While recruiting a sample large enough to ensure adequate statistical power is a common hurdle in clinical trials (DerSimonian, Charette, McPeek, & Mosteller, 1982), there are unique challenges in the case of HIV vaccine trials. These include the existence of different HIV clades, variability in viral susceptibility between individuals, and a poor understanding of the mode of action of an HIV vaccine before the start of a clinical trial (Boily, Masse, Desai, Alary, & Anderson, 1999). These unusual confounds bias statistical power calculations which aim to estimate appropriate sample size.

In addition to unusual confounds, trial participants willingly accept the burden of receiving a potentially harmful candidate vaccine with the belief that their participation will result in a

greater social good (Jenkins et al., 2000; Swartz et al., 2006). Exposing trial participants to an experimental vaccine in an underpowered trial which is likely to yield invalid results is therefore unethical (Halpern, Karlawish, & Berlin, 2002). Participants may also experience stigma and discrimination by participating in an HIV vaccine trial (Jenkins et al., 2000; McCluskey et al., 2005), adding to the unethical nature of poorly-powered clinical trials. It is therefore also an ethical imperative that the psychosocial factors that inhibit or facilitate WTP be understood.

Aside from concerns over sample size and power, knowledge of inhibitors and facilitators of WTP that are unique to each population group may reduce disproportionate enrolment of subgroups of the eligible population (Moodley, 2005). Inequitable enrolment is likely to limit the external validity of the trial results, and will violate *justice*: the fourth principle of ethical research according to the Belmont Report of 1979 (Loue, Okello, & Kawuma, 1996).

According to the principle of justice, the risks and rewards of research should be evenly distributed, whereby no single group carries a disproportionate share of the burden or the benefits (Moodley, 2005).

In sum, recruitment difficulties are likely to hinder the development of an efficacious HIV vaccine. It is therefore both scientifically and ethically important that researchers understand the psychosocial factors that may inhibit or facilitate WTP among potential trial participants. Despite this need however, there was no sociobehavioural research agenda in the larger SAAVI group until 2003 (SAAVI, 2008). In that year, SAAVI asked Stellenbosch University to form a sociobehavioural working group with the goal of developing social science research capacity for the four national SAAVI sites mentioned above.

1.6 The Sociobehavioural Working Group of SAAVI (SAAVI-SB)

Five objectives were set for SAAVI-SB. These objectives, taken directly from the SAAVI website (SAAVI, 2008), were:

- National co-ordination of all SAAVI-funded sociobehavioural activities.
- To provide a methodologically sound framework for sociobehavioural research as part of HIV vaccine trials in South Africa.
- To become a national resource for SAAVI-funded sites: strengthening capacity building; providing input into staff needs and recruitment; providing assistance with protocol development, funding requirements and training of staff; facilitating co-ordination between existing research; and, managing data among sites.
- To facilitate communication among national and regional SB researchers, trial-site PIs and CAB members on sociobehavioural issues.
- To liaise, inform and educate researchers, CAB members and fieldworkers on sociobehavioural research.

In 2006, the SAAVI-SB group began a two-part mixed-method investigation that aimed to determine the factors associated with WTP in a South African sample. Part I was a qualitative study that aimed to elicit thick descriptions of the psychological, behavioural, and social concerns of South Africans who will be eligible to participate in a future HIV vaccine trial (Swartz et al., 2006). The results of that study are reported in Chapter 2. The research problems that Part II of the investigation aimed to address constituted the basis of this thesis and are stated below.

1.7 Research problems

Based on the results of Part I of the two-part investigation and a review of the literature, the following research problems were identified:

1. A psychometric measure of WTP in an HIV vaccine trial has not been developed.

As a reliable and valid measure of WTP has not yet been developed, researchers have had to rely on visual analogue scales (Giocos, Kagee, & Swartz, 2007) and single-item scales (Bartholow et al., 1997; Jenkins et al., 2000; O'Connell et al., 2002; Vieira de Souza, Lowndes, Szwarcwald, Sutmöller, & Bastos, 2003; Yang et al., 2004) to measure WTP. There are at least two shortcomings to such approaches. Firstly, an assortment of response options used by different researchers makes comparisons across studies problematic. Secondly, the use of a single item to measure a potentially multidimensional construct such as WTP is likely to yield a shallow, one-dimensional measurement leading to high levels of measurement error (Neuman, 2000). It is therefore important that a psychometrically sound measure of WTP be developed.

2. There is a paucity of theory to guide studies of WTP in an HIV vaccine trial.

Studies that have examined inhibitors and facilitators of WTP have not commonly been informed by behavioural theory (Giocos et al., 2007; Priddy, Cheng, Salazar, & Frew, 2006). The result has been a lack of synthesis of research findings. The development of an appropriate theoretical framework may organize knowledge and guide future research by

specifying the types of facts to be observed, as well as how the facts relate to each other (Bless, Higson-Smith, & Kagee, 2006).

1.8 A theoretical framework for studying WTP in an HIV vaccine trial.

While searching for an appropriate theoretical framework for studying WTP, an important question arose: “to what extent is participating in an HIV vaccine trial a health-promoting behaviour?” Kafaar, Kagee, Lesch, and Swartz (2007) argue that from the perspective of the researcher, WTP in an HIV vaccine trial may not be regarded as a health-promoting behaviour since the primary aim of developing an effective HIV vaccine is to improve public health, and not necessarily the health of the research participants. From the perspective of a participant however, participating in an HIV vaccine might offer increased protection from HIV and, as a result, may be regarded as a health-promoting behaviour. In addition, participation in such trials and regular visits to trial site clinics remind individuals repeatedly of their risk for HIV infection (Kafaar et al., 2007). Such reminders may discourage behaviours that increase the likelihood of HIV infection. In this sense, participating in an HIV vaccine trial can be considered to be a health-promoting behaviour.

Three theories of health-promoting behaviour were reviewed. These were the Health Belief Model (HBM) (Rosenstock, 1966), the Protection Motivation Theory (PMT) (Rogers, 1975, 1983, 1985), and the Theory of Planned Behavior² (TPB) (Ajzen, 1985, 1988, 1991). Meta-analyses of studies that used the HBM (Harrison, Mullen, & Green, 1992; Janz & Becker, 1984) and the PMT (Floyd, Prentice-Dunn, & Rogers, 2000) showed that these theories have been only partially successful in predicting health behaviours. Ogden (2004) argues that a

² While ‘behavior’ is the American style of spelling ‘behaviour’, the TPB was developed in the US and therefore I refer to the original spelling throughout.

major reason for the limited success of the PMT and HBM has been their failure to incorporate social and environmental factors. A further problem with the HBM in the context of WTP in an HIV vaccine trial is that the theory examines the relationship between cognitive predictors and actual behaviour. As no Phase III HIV vaccine trials were yet underway in South Africa at the time of this study, actual enrolment could not be measured.

Unlike the PMT and the HBM, meta-analyses of studies that have employed the TPB recurrently show that the theory predicts significant amounts of variance in a wide range of health-promoting behaviours (Armitage & Conner, 1999b, 2001; Albarracín, Johnson, Fishbein, & Muellerleile, 2001). In addition to the fact that the TPB is well researched, a benefit to using the theory in the context of WTP is that it makes provision for the role of social and environmental factors. Given the important role that social factors play in the transmission of HIV, an assessment of these factors is paramount. Another benefit to using the TPB in this context is the theory's inclusion of behavioural intention, a robust predictor of actual behaviour (Ajzen, 1985, 1988). It follows that in the absence of actual enrolling behaviour, measuring an individual's intention or *willingness* to participate may be the most appropriate proxy for future participation in an HIV vaccine trial.

1.9 Extending the TPB in the context of WTP in an HIV vaccine trial

While it seems that the TPB may account for variance in WTP, it might nonetheless be useful to include additional predictor variables shown to be robustly associated with WTP. We hypothesised that extending the TPB with such variables would tailor the theory to the unique context of WTP in an HIV vaccine trial, as evidence by incremental change in variance explained by the additional predictor variables over the TPB variables. The TPB has been

successfully adapted for various behaviours previously, including exercise (Bozionelos & Bennett, 1999), healthy eating (Povey, Conner, Sparks, James, & Shepherd, 2000), elicit drug use (McMillan & Conner, 2003), condom use (Conner, Graham, & Moore, 1999), and dietary and fluid adherence among a sample of haemodialysis patients (Fincham, Moosa, & Kagee, 2008).

To identify robust correlates of WTP in an HIV vaccine trial that would be added to the TPB variables, a comprehensive literature review was conducted and is discussed in Chapter 2. Briefly, mistrust of researchers, drug companies, and governmental organisations (Hays, & Kegeles, 1999; Parker, 2005; Sengupta et al., 2000), and poor knowledge of HIV vaccines and HIV vaccine trials (Hennessy et al., 1996; Nyamathi, et al., 2004) have been commonly reported to be inhibitors of WTP. Perceived risk of HIV infection (Jenkins et al., 2000; Parker, 2005) and altruism (Jenkins et al., 1998; Swartz et al., 2006) have been commonly reported to be facilitators of WTP. Therefore, these four variables were included as additional predictor variables with the aim of improving the predictive power of the TPB in the context of WTP.

1.10 Goals of this study

A consideration of the two research problems outlined above led to the development of four goals for this study. These were:

1. Construct a psychometric measure of WTP in an HIV vaccine trial.
2. Derive, in an exploratory fashion, the factor structure of the new instrument.
3. Examine the extent to which the TPB predicts variance in WTP in an HIV vaccine trial.
4. Determine whether the TPB is strengthened by the inclusion of mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables.

1.11 Importance of this study

Addressing the objectives of this study may result in two significant contributions to the field of WTP in an HIV vaccine trial. Firstly, this study may provide a psychometrically sound measure of WTP that will enable researchers to make reliable and valid measurements of WTP. Secondly, the development of an appropriate theoretical framework may serve to organize and structure future research.

1.12 Definition of concepts

1.12.1 Facilitator

A facilitator was defined as any factor that enhances the likelihood that community members would participate in an HIV vaccine trial (Swartz et al., 2006).

1.12.2 Inhibitor

An inhibitor was defined as any factor which reduces the likelihood that community members would participate in an HIV vaccine trial (Swartz et al., 2006).

1.12.3 Altruism

Despite general agreement that the notion of ‘altruism’ refers to the unselfish concern for the welfare of others (Baron & Byrne, 2000), there are subtle variations in the conceptualisation and operationalisation of this construct among researchers. Variations in definitions of altruism seem to be, in part, a function of differing opinions regarding the motivation behind altruistic behaviour (Batson, 1991), the amount of benefits or costs to the altruist (Krebs, 1987), and the extent to which altruistic behaviour is a conscious decision (Hill, 1984).

Within the context of WTP in an HIV vaccine trial, this study defined altruism as “behavior [sic] intended to benefit another, even when doing so may risk or entail some sacrifice to the welfare of the actor” (Monroe, 1994, p. 862).

1.13 Overview of chapters

Chapter 2 provides a critical review of both international and South African literature pertaining to the variables identified for inclusion in this study. In addition, the results of Part I of the study are reported, and methods employed by researchers to measure WTP are evaluated. Finally, the application and extension of the TPB in this study is described in detail. Chapter 3 describes the methodology used in this study, and includes a description of the participants, the development of an instrument to measure WTP in an HIV vaccine trial

and other measures, the research design, and the statistical procedures used to analyse the data. Chapter 4 presents the demographic characteristics of the sample and the results of the statistical analyses. Chapter 5 attempts to interpret the results within the context of the study population and sample, and against the backdrop of the limitations of the study. Conclusions and implications for future research are also discussed.

CHAPTER 2

LITERATURE REVIEW AND THEORETICAL FRAMEWORK

2.1 Introduction

This chapter begins with an overview of four key sociobehavioural issues relating to HIV vaccine trials. These are retention and attrition, sexual disinhibition, social harms, and willingness to participate (WTP). Thereafter, international and South African literature pertaining to inhibitors and facilitators of WTP identified for inclusion in this study are critically reviewed. Inhibitors include mistrust of researchers and poor knowledge of HIV vaccines and HIV vaccine trials. Facilitators include altruism and a high perceived risk of HIV infection. Each will be discussed in turn. The results of Swartz et al. (2006) (Part I of this study) are then discussed, and methods employed by researchers to measure WTP are evaluated. Finally, the application and extension of the Theory of Planned Behavior (TPB) in this study is described detail.

2.2 Retention and attrition

A major sociobehavioural concern in HIV vaccine trials is the recruitment and retention of large numbers of trial participants (Grinstead, 1995; Smit et al., 2005). While some studies have shown that levels of retention may be high among certain populations (e.g.: Seage et al., 2001), other studies report that attrition may be a serious concern. For example, a study that examined the retention of 4979 trial participants in New York found that only 36% of participants were retained after 12 months (Des Jarlais et al., 2000). Poor levels of retention were also reported by Baeten et al. (2000) in a study that examined HIV incidence in a cohort

of casual sex workers (CSW) in Kenya. Among the many possible reasons for attrition, migration of trial participants away from trial sites poses a considerable problem (Smit et al., 2005; Suligoi, Wagner, Ciccozzi, & Rezza, 2005). Migration may be especially problematic in the South African context as many thousands of labourers travel between their homes in rural parts of the country, and urban and mining areas of the country where they work (Bank, 2001; Lurie et al., 2003). Migration therefore inhibits the retention of HIV vaccine trial participants as many participants may move away from HIV vaccine trial sites (Smit et al., 2005). In sum, retention and attrition of HIV vaccine trial participants is a major sociobehavioural challenge.

2.3 Sexual disinhibition

There is evidence to suggest that HIV vaccine trial participants may increase their sexual risk behaviour due to the belief that a candidate HIV vaccine will protect them against HIV infection. For example, Chesney, Chambers, and Kahn (1997) examined changes in sexual risk behaviour among 48 participants enrolled in Phase I and II HIV vaccine trials conducted in San Francisco. The researchers found a significant increase in insertive unprotected anal intercourse (UAI) among men who have sex with men (MSM) over time. At baseline, 9% reported UAI. The proportion increased to 13% at the sixth month assessment, and to 20% at the twelfth month assessment. Similar results were reported by Van de Ven, Kippax, Knox, Prestage, and Crawford (1999), who examined associations between optimism of new treatments for HIV and sexual behaviour among 4091 Australian MSM. Considering that a candidate HIV vaccine may not necessarily demonstrate efficacy (Slack et al., 2000, 2005), sexual disinhibition among HIV vaccine trial participants may lead to a perverse outcome where HIV vaccine trials result, paradoxically, in more HIV infections rather than less. The

possibility of sexual disinhibition, or increased sexual risk behaviour, is therefore a major challenge for researchers.

2.4 Social harms

Another socio behavioural concern associated with HIV vaccine trials is the possibility that trial participants may experience stigma and discrimination from friends, family members, and the community at large as a result of their participation (Allen et al., 2001). A major source of negative social reactions is reported to stem from the perception that HIV vaccine trial participants are infected with HIV, or may at least be at high risk of HIV infection (Lesch, Kafaar, & Kagee, 2006). In addition, research suggests that many people are unaware that testing positive for HIV antibodies during an HIV vaccine trial is a result of the body's response to the candidate HIV vaccine and not necessarily to HIV (Jenkins et al., 2000; Sahay et al., 2005; Sheon, Wagner, McElrath, Keefer, & Zimmerman, 1998). Problems experienced in this regard relate to difficulty obtaining health or life insurance, restrictions on trial participants' ability to travel abroad, being refused to donate blood, being overlooked by potential employers, and being disallowed to serve in the military (McCluskey et al., 2005). In contexts such as South Africa where there are high levels of gender inequality, social harms may even manifest in domestic violence (Milford, Barsdorf, & Kafaar, 2007). Possible social harms associated with participation in South African HIV vaccine trials therefore represent a unique challenge to vaccine researchers.

2.5 Willingness to participate (WTP) in an HIV vaccine trial

A further socio behavioural concern in HIV vaccine trials is the willingness of many thousands of HIV negative participants at high risk of HIV infection to participate in HIV vaccine trials. Understanding the psychosocial factors that may inhibit or facilitate WTP is important to ensure that sufficient numbers of eligible individuals enrol, and that the participants are treated in an ethical manner (DerSimonian et al., 1982; Halpern et al., 2002). Previous research suggests that the factors associated with WTP in HIV vaccine trials may be understood in terms of inhibitors and facilitators of WTP (Bartholow et al., 1997; Buchbinder et al., 2004; Golub et al., 2005; Hennessy et al., 1996; Jenkins et al., 1998, 2000; McCluskey et al., 2005; Moodley, Barnes, van Rensburg, & Myer, 2002; Nyamathi, et al., 2004). The results of these studies show that mistrust of researchers (Hays, & Kegeles, 1999; Parker, 2005; Sengupta et al., 2000) and poor knowledge of HIV vaccines and HIV vaccine trials (Hennessy et al., 1996; Nyamathi, et al., 2004) may be robust inhibitors of WTP. In addition, perceived risk of HIV infection (Jenkins et al., 2000; Parker, 2005) and altruism (Jenkins et al., 1998; Swartz et al., 2006) may be robust facilitators of WTP. Each is discussed in turn.

2.5.1 Inhibitors of WTP in an HIV vaccine trial

2.5.1.1 Mistrust

Mistrust of medical researchers, drug companies, and governmental organisations has been frequently reported to be an inhibitor of WTP in an HIV vaccine trial among both Whites and Blacks from developing and developed countries alike. However, levels of mistrust seem to be higher among Blacks, regardless of geographical, sociopolitical, and economic differences.

In the US, Sengupta et al. (2000) examined mistrust and other correlates of WTP in AIDS research among 301 Black Americans aged 18 years or older residing in Durham, North Carolina. Structural equation modelling (SEM) was used to test models of relationships between factors that inform WTP. Analyses revealed that mistrust of research and research institutions was the strongest inverse predictor of WTP. It is important to note, however, that the overall fit indices were only just acceptable. As such, the model needs to be tested again in future research.

Notwithstanding the limitations of the study by Sengupta et al. (2000), similar results were reported by Braunstein, Sherber, Schulman, Ding, and Powe (2008). The researchers assessed WTP in clinical trials in a sample of 717 participants from 13 cardiology and general medical clinics in Maryland. Compared to the 460 White participants, the 257 Black participants more frequently reported that: (i) researchers would not adequately explain what participating in a clinical trial will entail (24% vs. 13%); (ii) researchers use participants as ‘guinea pigs’ without their consent (72% vs. 49%); (iii) researchers prescribe drugs as a way of experimenting on people without their knowledge (35% vs. 16%); and (iv) researchers as individuals to participate in clinical trials knowing that the drug under investigation may be unsafe (24% vs. 15%). While levels of mistrust were high for both Whites and Blacks, Blacks demonstrated significantly higher levels of mistrust, and lower levels of WTP. These differences remained significant even after controlling for racial variability in gender, age, cardiovascular risk profiles, and socioeconomic status.

A study that explored racial differences in inhibitors of WTP in medical research studies among 198 residents of the Detroit Primary Metropolitan Statistical Area (DPMSA) yielded comparable results (Shavers, Lynch, & Burmeister, 2002). The researchers found that

compared to White participants, Black participants believed that minority groups bear most of the risks in medical research (25.2% vs. 5.2%). While both Blacks and Whites believed that the poor bear more of the risks in medical research than the rich, Black participants endorsed this belief more often than Whites (65.6% vs. 42.2%). The researchers note that a limitation of the study was that the census data, which constituted the sampling frame, were 10 years old at the time of the study. In the previous decade, the population of richer people living in suburban areas (predominantly White individuals) of Detroit had increased by 20%, and the population of poorer people living in housing units within the city (predominantly Black individuals) had decreased by 5.7%. Although the researchers weighted the data to account for possible non-coverage bias, it is possible that the Black participants in the study were overrepresented, perhaps overstating the reported racial differential.

In another US study, Buchbinder et al. (2004) compared hypothetical and actual WTP in a preventive HIV vaccine trial among 2531 participants previously enrolled in an HIV vaccine preparedness study (VPS). The researchers found that among participants who expressed low levels of WTP, 55% of Black participants cited mistrust of government as an inhibitor of WTP compared to 21% of White participants. Furthermore, 24% of Black participants cited mistrust of drug companies as an inhibitor of WTP compared to 16% of White participants. A study of 58 participants from the broader area of Los Angeles found that of the nine themes elicited from the data, mistrust of HIV vaccine researchers was the fifth most frequently cited inhibitor of WTP (Newman et al., 2006).

Comparable findings have been reported by South African researchers. Parker (2005) conducted in-depth qualitative interviews with 10 participants between the ages of 19 and 30 years from a lower socioeconomic, peri-urban settlement in the Western Cape. She found that

alongside not wanting injections and fears relating to stigma and discrimination, mistrust of researchers was an important barrier to WTP. Comparable findings were reported by Barsdorf and Wassenaar (2005) who examined racial differences in public perceptions of voluntariness of medical research participants among 111 participants from two commercial South African companies. Black respondents were significantly less likely to volunteer as participants in medical research than both White and Indian respondents. Furthermore, these racial differences were independent of level of knowledge of medical research procedures and personal experience of medical research.

Various explanations for the high levels of mistrust of medical researchers, pharmaceutical companies, and governmental organisations among Blacks have been put forth. In the US, medical researchers continue to conduct experiments in the shadow of the infamous Tuskegee syphilis study, in which 399 Black men from Alabama were purposely denied efficacious treatment for syphilis (Gamble, 1997; Shavers et al., 2002). Such exploitation of Blacks due to their obvious vulnerability has understandably created a general sentiment of mistrust of researchers and powerful, White-controlled pharmaceutical companies (Baldwin–Ragaven, de Gruchy, & London, 1999). Similar mistrustfulness is seen in post-colonial Africa, where the testing and implementation of Western drugs has been met by some with suspicion, opposition, and resistance (Boone & Batsell, 2001; Leach & Fairhead, 2007). Mistrust of researchers and pharmaceutical companies by Black Africans seems to have its roots firmly planted in Africa's experience of oppression and exploitation by Whites during the years of colonialisation (Nichter, 1995). In that period, the area of public health was one of the key “vehicles of ideology” (Lindegger, Quayle, & Ndlovu, 2007, p. 110) used to propagate Western dominance and White oppression. For example, the bubonic plague in Cape Town at the turn of the twentieth century was used to justify the forced removal of Black Africans

from their homes (Swanson, 1977). During the apartheid years, disregard for the human rights of Blacks created a fertile breeding ground for unethical research; the legacy of which still stands today. According to Barsdorf and Wassenaar (2005, p. 2):

Violations of human rights during apartheid no doubt impacted negatively on health practice and research in South Africa. Unethical research before South Africa's democracy in 1994, some targeted at previously disadvantaged segments of the population, could serve to reinforce an already tainted public perception of the voluntariness of medical research participants.

Mistrust of HIV vaccine researchers by Black Africans has steered the belief that HIV prevention efforts are a hidden political conspiracy to control the birth rates of Blacks, thereby allowing Whites to regain political control (Klonoff & Landrine, 1999; Nichter, 1995; Ross, Essien, & Torres, 2006). There is also the belief that HIV vaccine campaigns are a Western initiative to undermine African autonomy, traditional values, and cultural practice (Lindegger et al., 2007). Proponents of the latter suggest that Africa's participation in HIV vaccine research represents a 'selling-out' to pharmaceutical companies at the expense of Black Africans who will be exploited by researchers (Nattrass, 2007). This was the sentiment of the South African president Thabo Mbeki, who publicly stated in 2000 that he was unconvinced that HIV was the sole cause of AIDS. He also expressed concern over the safety of highly-active antiretroviral therapy (HAART) which resulted in a slow roll-out of these drugs to pregnant HIV positive women (Fassin & Schneider, 2003; Nattrass, 2007).

Research also suggests that many individuals believe that an efficacious vaccine has already been developed but is being kept from them. For example, Allen et al. (2005) conducted 3509

telephonic interviews with Blacks, Hispanics, MSM, and members of the general US population to assess HIV vaccine research attitudes, awareness, and knowledge. Compared to 18.2% of the general population, 47.1% of the Black participants believed that an HIV vaccine has already been developed but is being kept secret. Finally, Nyamathi et al. (2004) suggest that the failure of HIV vaccine researchers to allow community members an opportunity to be actively involved in the planning of HIV vaccine trials has also contributed to the high levels of mistrust. Taken together, it seems that mistrust of HIV vaccine researchers is a robust inhibitor of WTP.

2.5.1.2 Knowledge of HIV vaccines and HIV vaccine trials

Several studies have shown that potential HIV vaccine trial participants demonstrate a lack of knowledge of HIV vaccines and HIV vaccine trials. Furthermore, poor understanding of HIV vaccine trial methodology seems to be associated with lower WTP. The association between knowledge and WTP has been found in Western and non-Western settings alike, and seems to be independent of the effects of education and socioeconomic status. In the US, Strauss et al. (2001) examined factors associated with WTP among injecting drug users (IDUs) from Philadelphia, MSM from San Francisco, and Black Americans from Durham. Participants indicated that they would not be willing to participate in an HIV vaccine trial unless they became more knowledgeable in certain areas of vaccine trial methodology. The areas of knowledge included: (i) health complications that may be experienced, and assistance offered in dealing with complications; (ii) incentives that would be offered to compensate them for their participation; (iii) the effectiveness of the vaccine and future availability of the vaccine; and (iv) issues surrounding trust and confidentiality.

Similar results were reported by a study that examined correlates of WTP in HIV/STD prevention intervention activities among 4,208 migrants aged 18-30 years old in Beijing and Nanjing (Yang et al., 2004). The researchers found that a large proportion of the participants demonstrated a lack of HIV/AIDS awareness and knowledge surrounding the transmission of HIV. Furthermore, a lower level of knowledge was associated with a lower level of WTP. A limitation of the study was that the outcome variable ‘WTP in an HIV/STD prevention intervention program’ was vague and may have been too general for some participants. As such, the results might well have been tainted by participants’ perceptions of what constituted an HIV/STD prevention intervention programme.

In Italy, a study that examined knowledge and attitudes regarding prophylactic HIV vaccine trials among a national sample yielded similar results to Strauss et al. (2001) and Yang et al. (2004) (Starace et al., 2006). Results indicated that only 57.1% of the respondents demonstrated a level of knowledge that was ‘sufficient’ for informed consent (knowledge level was considered ‘sufficient’ if respondents correctly answered at least four of the six questions relating to prophylactic HIV vaccine trials). Areas of knowledge assessed included an understanding of prophylactic versus therapeutic vaccines, and potential side effects. A multivariate analysis showed that participants with insufficient knowledge were significantly less likely to express WTP than participants demonstrating sufficient knowledge.

The most common misconception among potential trial participants seems to be the belief that the presence of HIV antibodies after receiving a candidate HIV vaccine means that the vaccine has inadvertently infected one with HIV. For example, a study that examined WTP among 349 Indian participants at high risk of HIV infection found that post-vaccination HIV seropositivity was an important inhibitor of WTP (Sahay et al., 2005). Similar results were

reported by a study that evaluated specific features of vaccine trial designs that would encourage participation among 73 participants at high risk of HIV infection from Denver, Chicago, and San Francisco (Hennessy et al., 1996). Moreover, Newman et al. (2007) found that lower WTP was associated with the fear of vaccine-induced infection, and testing positive for HIV antibodies among 123 participants from Los Angeles.

While the aforementioned studies suggest that a low level of knowledge is associated with a low level of WTP, some studies have reported a null relationship between knowledge and WTP (Giocos et al., 2007; Halpern, Metzger, Berlin, & Ubel, 2001; Priddy et al., 2006). Moreover, a study that examined changes in WTP and knowledge of vaccine trial concepts among 4892 participants from several US populations at high risk of HIV infection yielded conflicting results (Koblin, Holte, Lenderking, & Heagerty, 2000). The researchers found that WTP declined significantly over time despite significant increases in knowledge of concepts such as vaccine-induced seropositivity, placebos, and randomization. The conflicting findings suggest that the relationship between knowledge of HIV vaccines and HIV vaccine trial concepts and WTP may be parabolic, where relatively low and high levels of knowledge are associated with lower WTP. However, further research is required to provide evidence for such a hypothesis. Notwithstanding the complexity of the relationship, knowledge of HIV vaccines and HIV vaccine trials seems to be a robust inhibitor of WTP.

2.5.2 Facilitators of WTP in an HIV vaccine trial

2.5.2.1 Altruism

Evidence suggests that altruism may be a robust facilitator of WTP in an HIV vaccine trial in both developing and developed country settings alike. A study that assessed WTP among 2670 Royal Thai army conscripted recruits found that 43.2% cited altruism as primary motivation for WTP (Jenkins et al., 2000). A multivariate logistic regression analysis revealed that participants who expressed the wish to help Thai society were significantly more likely to express WTP than those who did not. Another study that employed a Thai sample yielded similar results (MacQueen et al., 1999). The researchers found that out of the 193 IDUs attending drug treatment clinics in Bangkok, 78.6% of the participants expressed the altruistic desire to help stop the spread of AIDS.

Comparable findings have been reported by studies in the US. Sengupta et al. (2000) found that 80% of their sample of 301 Black Americans cited altruistic reasons for WTP. Examples of altruistic reasons were: (i) assisting researchers in their attempt to find a cure for HIV/AIDS; (ii) helping those who are HIV-infected or have AIDS; and (iii) wanting to participate in HIV vaccine research. Multivariate analyses showed that altruism was the only factor that was significantly associated with WTP in AIDS surveys and educational interventions. Comparable results were reported by Hays and Kegeles (1999) in a study that examined factors associated with WTP among 390 US MSM aged 18 to 29 years. The researchers found that the most common reasons for WTP were the desires to contribute to ending the AIDS epidemic and to helping others.

In another US sample, Nyamathi et al. (2004) conducted qualitative focus groups with 40 homeless and low-income adults from subsidized apartments and homeless shelters in Los Angeles. Participants recurrently reported an altruistic desire to help combat the HIV pandemic. Not only is altruism reported to be an important correlate of WTP, but some studies show that altruism may be a primary motivation. For example, a study by Buchbinder et al. (2004) found that 94% of the participants in their study reported altruism as the main reason for WTP.

Studies examining WTP in Brazilian and Indian samples have yielded results similar to those found in Thai and US samples. A study that examined WTP among 569 MSM from Rio de Janeiro found that 499 (87.7%) considered it very important to help the community at large (Périssé et al., 2000). In India, Sahay et al. (2005) conducted a study that examined WTP among 349 participants attending three sexually transmitted infections clinics and one reproductive tract infections clinic. Approximately 34.1% of all participants and 40.7% of male participants at high risk of HIV infection indicated an altruistic desire to participate in a future HIV vaccine trial. A multivariate logistic regression analysis showed that altruism increased the predictive power of the model significantly by 3.9 units (adjusted OR = 3.9; 95% CI 1.8 – 8.1). In South Africa, qualitative studies by Parker (2005) and Swartz et al. (2006) found that altruism was one of the most important themes to be elicited from the data.

It is not yet clear why individuals express an altruistic desire to participate in an HIV vaccine trial. Swartz et al. (2006) suggest that altruism as a reason for WTP may be related to a high level of exposure to the deleterious effects of HIV. While that may be so, the researchers do not speculate on the possible mechanism by which HIV exposure predicts the altruistic desire to participate in a trial. For example, social psychologists have been debating for years the

question of whether helping behaviour is egoistically motivated, or whether such behaviour is motivated by truly selfless reasons (Hogg & Cooper, 2003). According to Batson (1995), helping behaviour is egoistically motivated since the helper may experience many possible self-benefits from helping. For example, the helper may receive material rewards (e.g. reimbursement or financial reward for participating in an HIV vaccine trial), social rewards (e.g. praise and approval by community members), or self-rewards (e.g. enhanced self-esteem from participating). The helper may also avoid social punishments (e.g. negative community reactions), and self-punishments (e.g. guilt and/ or shame associated with not participating). Finally, the helper may reduce aversive arousal evoked by seeing others dying from AIDS. In converse however, an altruistic behaviour is seen by some as a truly selfless act motivated by empathic concern for another (Dovidio, Allen, & Schroeder, 1990; Smith, Keating, & Stotland, 1989). According to Sibicky, Schroeder, and Dovidio (1995, p. 436), empathic concern is defined as “an other-oriented emotional response characterized by such feelings as compassion, tenderness, soft-heartedness, sympathy, warmth, and feeling moved”. As per this school of thought, participating in an HIV vaccine trial is the result of empathetic concern for the well-being of others, with self-benefits of participating being unintended consequences.

Related to the debate over the motivation behind helping behaviour is the tension between Western and non-Western conceptions of self and other. According to Moodley (2005), the ‘self’ in Western cultures is considered synonymous with the ‘individual’. As such, the self is rigidly contained within the defined boundary of the individual’s body. In non-Western cultures such as in South Africa however, the definition of ‘self’ is more fluid and transcends the boundaries of the individual body. Therefore, when one experiences empathetic concern for another and takes the other’s perspective, one vicariously experiences what the other is experiencing because one comes to incorporate oneself within the boundaries of the other

(Cialdini, Brown, Lewis, Luce, & Neuberg, 1997). As the distinction between ‘self’ and ‘other’ becomes more obscure, it may be useful to understand altruism within the milieu of ‘Ubuntu’ (Moodley, 2005). According to Louw (1998) the notion of Ubuntu may be conceptualised by the Zulu axiom ‘umuntu ngumuntu ngabantu’, meaning ‘a person is a person through (other) persons’. A definition of Ubuntu is offered by Venter (2004, p. 149):

Ubuntu is a philosophy that promotes the common good of society and includes humanness as an essential element of human growth. In African culture the community always comes first. The individual is born out of and into the community, [and] therefore will always be part of the community. Interdependence, communalism, sensitivity towards others and caring for others are all aspects of Ubuntu.

To sum up, altruism seems to be a robust predictor of WTP in both Western and non-Western setting alike despite a poor understanding of the mechanism by which altruism predicts WTP. Against the backdrop of Ubuntu, an altruistic desire to participate in an HIV vaccine trial may be a particularly robust facilitator of WTP among eligible Black South Africans.

2.5.2.2 Perceived risk of HIV infection

Several studies have shown that persons who perceive themselves to be at high risk of HIV infection are more likely to express WTP in an HIV vaccine trial. In the US, a longitudinal study by Bartholow et al. (1997) assessed changing WTP over an 18 month period among 1267 MSM. A perception of being highly susceptible to HIV infection was robustly associated with WTP at each assessment over the 18 month period of the study. In another US study mentioned previously, researchers compared hypothetical and actual willingness to

enroll in a prophylactic HIV vaccine trial among participants previously enrolled in an HIV vaccine preparedness study (Buchbinder et al., 2004). Participants who reported having at least five sexual partners in the previous six months expressed greater WTP in a future HIV vaccine trial.

In China, Yang et al. (2004) found that among other correlates, perceived severity of risk behaviours was a robust predictor of WTP. A high perceived risk of HIV infection has also been shown to be significantly correlated with WTP among 401 Chinese IDUs from Urumqi City (Yin et al., 2008). A multivariate logistic regression analysis showed that WTP was positively associated with having ever had sex with a drug use partner, needle sharing with a new drug use partner in the past 3 months, and seven or more injections per week in the past three months.

A positive relationship between perceived risk of HIV infection and WTP has also been reported by researchers investigating WTP in Canadian, Italian, and Ugandan samples. In Canada, O'Connell et al. (2002) examined WTP in a sample of 440 MSM and bisexual men in the greater Vancouver region. The researchers found that participants who expressed a high level of perceived HIV risk were significantly more likely to express WTP than participants who expressed a low level of perceived risk. In another sample from a Vancouver community, Strathdee et al. (2000) investigated WTP among 435 IDU and 330 MSM. In both sub-samples, WTP was significantly associated with a high perceived risk of HIV infection. In Uganda, McGrath et al. (2001) assessed knowledge of vaccine trials and WTP among 1182 military men between the ages of 18 and 30 years stationed near Kampala. Bivariate analyses showed that number of sex partners (other than a wife or regular girlfriend) and perceived likelihood of contracting HIV were significantly associated with WTP.

In Italy, Starace et al. (2006) found that compared with participants who did not consider themselves to be at risk of HIV infection, those with high perceived risk were significantly more likely to express WTP. While the study was limited insofar as the sample was not representative of the general population of Italy, the participants were sampled from a self-selected population of individuals that are likely to be identified for participation in a future HIV vaccine trial.

In South Africa, Smit et al. (2005) examined WTP among 198 individuals from an urban-informal community directly after their enrolment into an HIV vaccine preparedness study. A bivariate analysis showed that WTP was significantly associated with self-perceived HIV risk. Qualitative studies employing South African samples have yielded similar results, whereby participants with a high self-perceived risk of HIV infection expressed the desire to participate in a future HIV vaccine trial (Parker, 2005). Bartholow et al. (1997) and Nyamathi et al. (2004) suggest that individuals who perceive themselves to be at high risk of HIV infection express greater WTP in order to be protected against HIV infection. Considering that candidate HIV vaccines may not necessarily offer protection from HIV infection, an assessment of perceived risk may serve as a proxy variable for level of knowledge of HIV vaccines and HIV vaccine trials.

2.5.3 Health concerns and WTP in an HIV vaccine trial

Health concerns have been commonly reported to be an issue for potential trial participants. These concerns include the fear of possible short and long term vaccine side-effects, disability, or death. For example, Celentano et al. (1995) examined barriers and facilitators of WTP among a large sample of female commercial sex workers, men attending sexually

transmitted disease clinics, conscripts in the Royal Thai Army, and men discharged from the army. The researchers found that 37.6% of the sample expressed a fear of short-term side-effects, and 30.5% feared possible long-term side-effects. Furthermore, 36.5% reported fearing disability or death as a result of receiving a candidate HIV vaccine. Similar results were reported by McGrath et al. (2001) in a study that assessed WTP among 1182 Ugandan military men between the ages of 18 and 30 years stationed near Kampala. With regard to reproductive health concerns, Rudy et al. (2005) reported that the women in their sample were fearful that receiving a candidate HIV vaccine may result in difficulties conceiving children, effects of the HIV vaccine on the foetus, infection of breast milk and the possibility that the vaccine may interfere with long-term fertility.

In South Africa, comparable results were reported by Parker (2005) and Swartz et al. (2006). In both studies, participants reported being afraid that the vaccine might cause ill health; a serious concern in a setting where many families rely on a single bread-winner. Should a participant experience vaccine side-effects and die or feel too ill to work, the economic repercussions for the dependents of that participant could be severe. As such, several participants reported that they would expect to receive health insurance if they participated. That way, their dependents would be taken care of in the event of their ill health or death.

2.5.4 Gender and WTP in an HIV vaccine trial

Of the 30.8 million (95% CI: 30.6 million – 36.1 million) infected adults around the world at the end of 2007, 15.4 million (95% CI: 13.9 million – 16.6 million) are women (UNAIDS, 2007). These statistics indicate that men and women demonstrate equal numbers of HIV infections globally. In sub-Saharan Africa however, women carry a disproportionately large

burden of the disease as almost 61% of infected adults in this region at the end of 2007 were women (UNAIDS, 2007). Given the high levels of HIV seropositivity among women in sub-Saharan Africa, large numbers of these women will be required to participate in a trial if they stand to benefit from an HIV vaccine. Nonetheless, women have had little participation in HIV vaccine trials to date (Kapoor, 2004). It is therefore important that researchers focus on understanding the barriers and facilitators of WTP among women more specifically.

There seem to be both biological and socioeconomic reasons for the higher prevalence of HIV infection among women in sub-Saharan Africa. Biologically, the susceptibility of the vaginal tract makes women up to seven times more likely than men to contract HIV during unprotected sexual intercourse with an HIV-infected partner (Wassenaar, Barsdorf, & Richter, 2005). Furthermore, STDs are more likely to be asymptomatic in women than in men, increasing the risk of HIV infection (Wilkinson, Connolly, & Rotchford, 1999). In addition, some African men are reported to favour ‘dry sex’, or sex where vaginal lubrication is impeded (Bass & Jefferys, 2001, as cited in Wassenaar et al., 2005). This practice leads to increased tearing of the vaginal membranes resulting in an increased risk of HIV infection.

Socioeconomically, women living in developing country regions such as South Africa experience high levels of intimate partner violence and gender inequality; both of which have been shown to be important determinants of women’s HIV risk (Mills et al., 2006a; Piot et al, 2001). In a study that examined the relationship between gender-based violence, gender inequality, and women’s HIV risk among 1366 women attending four antenatal health centres in Soweto, intimate partner violence and high levels of male control were significantly associated with HIV infection (Dunkle et al., 2004). These effects remained even after controlling for age, current relationship status, and woman’s HIV-risk behaviour. Stemming

from gender inequality, women are often unable to negotiate condom use as contraception is thought by many men to be a sign of infidelity (Kapoor, 2004; Mills et al., 2006a; Wassenaar et al., 2005). Financially, woman's reliance on men for economic subsistence often results in what Fassin and Schneider (2003) term 'survival sex', where women have no choice but to agree to unprotected intercourse. Even when women are able to negotiate condom use, their dire economic circumstances may prevent them from doing so. For example, studies of female sex workers have shown that many do not use condoms as some clients are willing to pay more for unprotected sex (e.g.: Basuki et al., 2002). Taken together, studies of WTP should focus on understanding the barriers and facilitators of WTP among women more specifically if they are to benefit from the development of an HIV vaccine.

2.5.5 Age and WTP in an HIV vaccine trial

Age was reported to be unrelated to WTP in an HIV vaccine trial among a sample of Italians (Starace et al., 2006); a sample of populations at high risk of HIV infection in the US (Koblin et al., 2000); and a sample of Chinese migrants (Yang et al., 2004). However, a study of gay and bisexual men in the greater Vancouver region found that participants aged 24 to 31 years were significantly more likely to express WTP than participants aged 26 to 31 years (O'Connell et al., 2002). A divergent finding was reported by Buchbinder et al. (2004), who found that refusal to participate was lower in participants over the age of 40 years. These findings suggest that the relationship between age and WTP may vary from population to population. To date, few studies have examined the relationship between age and WTP in South African samples.

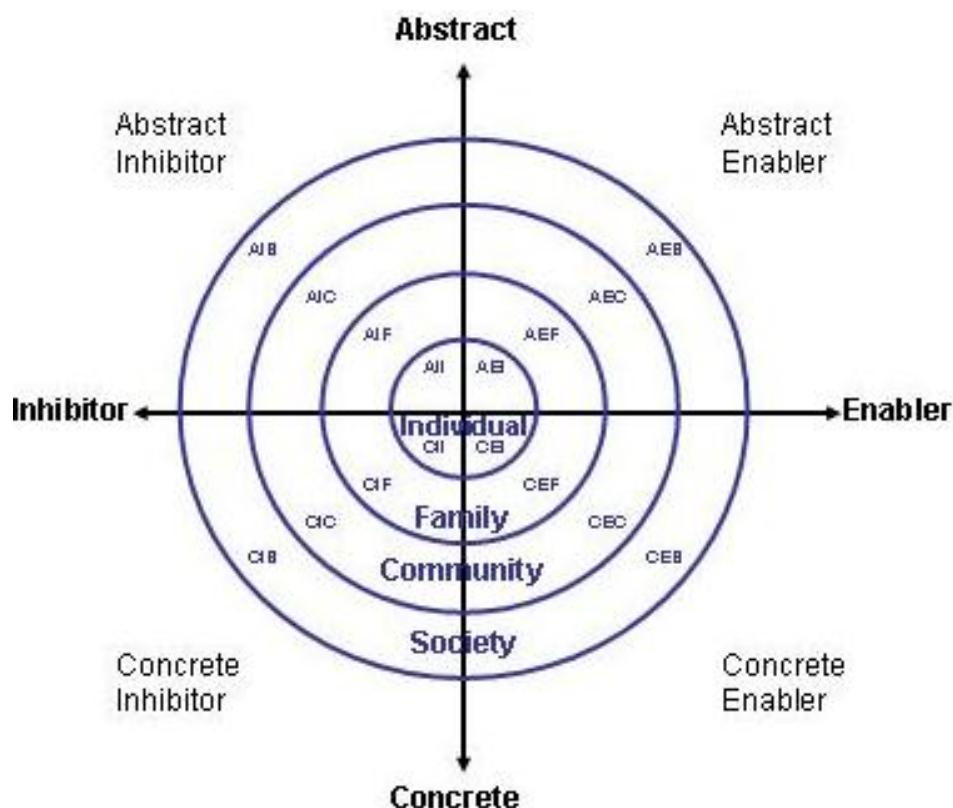
2.5.6 Educational level and WTP in an HIV vaccine trial

A low educational level has been shown to be associated with WTP. A study that assessed WTP in Phase I HIV vaccine trials among Royal Thai army conscripted recruits found that participants with primary school education or less were significantly more likely to express WTP than participants with secondary or vocational schooling (Jenkins et al., 2000). A study that examined changes in WTP and knowledge of vaccine trial concepts among high risk populations in the US yielded similar results (Koblin et al., 2000). The researchers found that participants with college education were significantly less likely to express WTP than participants with less than high school education.

2.6 Part I of this study

As mentioned in Chapter 1, this study constituted the second part of a two-part mixed-method investigation that aimed to determine the factors associated with WTP in a South African sample. Part I was a qualitative study that aimed to elicit thick descriptions of the psychological, behavioural, and social concerns of individuals who will be eligible to participate in a future HIV vaccine trial (Swartz et al., 2006). To obtain rich narratives from such individuals, Swartz et al. conducted 37 semi-structured interviews and 2 focus groups with trial site community members who had attended HIV vaccine education workshops conducted by Masikhulisane, the community involvement wing of SAAVI. These sites were located in Cape Town, Durban, and the Klerksdorp, Orkney, Stilfontein and Hartbeesfontein (KOSH) district (the methodology employed is discussed in more detail in Chapter 3). The themes related to whether a sub-theme was an inhibitor or enabler, whether a sub-theme was

abstract or concrete, and whether a sub-theme concerned only the individual, the individual's family, the individual's community, or society at large (see Figure 1).



AII	=Abstract Inhibitor at the Individual Level	AEI	=Abstract Enabler at the Individual Level
AIF	=Abstract Inhibitor at the Family Level	AEF	=Abstract Enabler at the Family Level
AIC	=Abstract Inhibitor at the Community Level	AEC	=Abstract Enabler at the Community Level
AIS	=Abstract Inhibitor at the Societal Level	AES	=Abstract Enabler at the Societal Level
CII	=Concrete Inhibitor at the Individual Level	CEI	=Concrete Enabler at the Individual Level
CIF	=Concrete Inhibitor at the Family Level	CEF	=Concrete Enabler at the Family Level
CIC	=Concrete Inhibitor at the Community Level	CEC	=Concrete Enabler at the Community Level
CIS	=Concrete Inhibitor at the Societal Level	CES	=Concrete Enabler at the Societal Level

Figure 1. Enabler-Inhibitor quadrant model (Swartz et al., 2006).

Abstract inhibitors were identified at the individual, community, and societal levels and included: (i) a negative association between an HIV vaccine trial and HIV/AIDS; (ii) fear of illness or death as a result of participating in an HIV vaccine trial; and (iii) a lack of

knowledge of HIV vaccines and HIV vaccine trials. Abstract enablers were only identified at the individual level and included participant's reported sense of altruism. Concrete inhibitors were identified at the individual, family, and community levels and included: (i) monetary costs associated with participation; (ii) fear of being tested for HIV and receiving test results; (iii) negative reactions from family and community members; (iv) time delays between receiving trial participation information and actual enrolment; and (v) a general mistrust of researchers. Concrete enablers were identified at the individual, family, community, and societal levels and included (i) practicalities and convenience; (ii) financial rewards; (iii) a safe testing environment; (iv) positive family reactions to trial participation; (v) the different levels of participation available to different members of the community; (vi) the salience of HIV in the community; (vii) positive community reactions to vaccine trials; (viii) the need for protection from HIV infection; and (ix) the presence of role models.

These findings are largely in keeping with those of the studies discussed above. This suggests that despite the unique socioepidemiological factors associated with the spread of HIV in South Africa, eligible participants may to some extent experience similar psychosocial concerns about participating in an HIV vaccine trial.

2.7 Measuring WTP in an HIV vaccine trial

A review of the literature revealed that a psychometric measure of WTP in an HIV vaccine trial has not been developed. Researchers have relied on visual analogue scales (e.g.: Giocos et al., 2007) and single-item scales asking participants to indicate their WTP according to response options such as:

- “yes” or “no” (Bartholow et al., 1997; Yang et al., 2004);
- “yes”, “no”, “it depends”, or “do not know” (Vieira de Souza et al., 2003);
- “definitely join”, “very likely join”, “might join”, “very likely not join”, or “definitely not join” (Jenkins et al., 2000);
- “absolutely”, “probably”, “don’t know”, “probably not”, “no”, or “not eligible” (O’Connell et al., 2002);
- “definitely”, “probably”, “probably not”, or “definitely not willing” (Koblin et al., 2000).
- “I am definitely willing to participate”, “I want to participate but let me think about it”, “I do not want to participate but would think about it”, “I am not at all willing to participate” (Ying et al., 2008).

There are several shortcomings to such an approach. Firstly, an assortment of response options makes comparisons between studies problematic as different criteria are used to establish WTP. In addition, different response formats yield different levels of measurement. For example, whereas scales with response options such as “yes” or “no” produce nominal data, scales with response options such as “definitely”, “probably”, “probably not”, or “definitely not willing” produce ordinal data. As a result, comparisons between data from different studies become complicated.

A second shortcoming is the use of a single item to measure a potentially multidimensional construct such as WTP in an HIV vaccine trial. According to Sullivan and Feldman (1979), it is doubtful whether a scale with one item can comprehensively assess a wide conception domain indicative of a multidimensional construct. A single item is therefore likely to yield a

shallow, one-dimensional measurement leading to high levels of systematic error (Neuman, 2000).

Reliability of single-item scales has also been reported to be problematic. For example, Loo (2002, p. 68) states that “while a single-item measure allows for the estimation of test-retest reliability, such a measure does not allow for the estimation of the more psychometrically important internal consistency reliability of the measure”. One advantage of being able to determine internal consistency, usually indexed by Cronbach’s alpha (α), is that poorly-performing items can be identified and deleted to improve the consistency and accuracy of a measure. With a single-item measure, however, no such improvements are possible.

With regard to validity, Herting and Costner (1985) argue that content validity and construct validity of scales with one item are rarely upheld, since a single item produces a one-dimensional measurement. Therefore, the extent to which a single-item measures what it purports to measure is questionable. In sum then, valid and reliable measurements of WTP require the development of a multi-item, multidimensional measure.

2.8 A theoretical framework for studying WTP in an HIV vaccine trial

As mentioned in Chapter 1, WTP in an HIV vaccine trial can be considered to be a health-promoting behaviour from the perspective of trial participants (Kafaar et al., 2007). Thus, three theories of health-promoting behaviour were reviewed in the search for one that may be suitable in the context of WTP. These were the Health Belief Model (HBM) (Rosenstock, 1966), the Protection Motivation Theory (PMT) (Rogers, 1975, 1983, 1985), and the Theory of Planned Behavior (TPB) (Ajzen, 1985, 1988, 1991). The HBM and the PMT are briefly

described and the reasons for their exclusion will be reiterated. Thereafter, TPB will be described in detail and the extension of the theory by the inclusion of additional predictor variables will be motivated and discussed.

2.8.1 The Health Belief Model

According to the Rosenstock's (1966) HBM, the likelihood of an individual performing a health behaviour is determined by a consideration of four cognitive factors. These are, using condom use as a means of preventing HIV infection as an example:

1. Perceived susceptibility (an individual's assessment of their risk of contracting HIV);
2. Perceived severity (an individual's assessment of the seriousness of HIV, and its potential consequences);
3. Perceived costs (an individual's assessment of the costs and barriers to using condoms); and
4. Perceived benefits (an individual's assessment of the positive consequences of using condom).

Since 1966 when Rosenstock first developed the HBM, several additional factors were added to the model. These include:

1. Cues to action (external influences promoting condom use, such as media campaigns and personal experiences);
2. Health motivation (the extent to which an individual is motivated to use condoms); and
3. Perceived control (the extent to which an individual perceives to have control over using condoms).

The HBM has been successful at predicting some health behaviours such as condom use (Mahoney, Thumbs, & Ford, 1995); compliance and attrition in cardiac rehabilitation (Oldridge & Streiner, 1990), and the early detection of breast cancer (Calnan, 1984).

However, meta-analyses of studies that used the HBM (Harrison et al., 1992; Janz & Becker, 1984) showed that the HBM has only partially successful in predicting health behaviours.

Ogden (2004) argues that a major reason for the limited success of the HBM has been its failure to incorporate social and environmental factors. There is also no provision for the role of past behaviour or for fear appeals. A further problem with the HBM in the context of WTP in an HIV vaccine trial is that the theory examines the relationship between cognitive predictors and the likelihood of actual behaviour. As no Phase III HIV vaccine trials were yet underway in South Africa at the time of this study, actual enrolment could not be measured.

For these reasons, the HBM was ruled out as a theory that may be appropriate within the context of WTP in HIV vaccine trials.

2.8.2 The Protection Motivation Theory

The PMT expanded the HBM to include a role for fear appeals (Ogden, 2004). The PMT postulates that the likelihood of an individual performing a health behaviour is determined by

a consideration of five cognitive factors. These are, again using condom use as a means of preventing HIV infection as an example:

1. Perceived susceptibility (an individual's assessment of their risk of contracting HIV);
2. Perceived severity (an individual's assessment of the seriousness of HIV, and its potential consequences);
3. Response effectiveness (an individual's assessment of the effect that using condoms would have on lowering their risk of HIV infection);
4. Self-efficacy (an individual's appraisal of their ability to use condoms); and
5. Fear (the emotional response to the threat of contracting HIV should condoms not be used).

The PMT has been less widely criticized than the HBM (Ogden, 2004). Nevertheless, many of the criticisms of the HBM also relate to the PMT. For example, the PMT also fails to incorporate social and environmental factors that may impact on an individuals' performing a health behaviour. In the context of HIV vaccines trials, socioeconomic factors have been frequently shown to be associated with WTP (Smit et al., 2005). As such, the exclusion of social and environmental factors by the PMT and HBM poses a serious problem. In addition, meta-analyses of studies that used the PMT (e.g. Floyd et al., 2000) have shown that the PMT has also been sub-optimal in predicting health behaviours. Taken together, the PMT might also be inappropriate for the context of WTP in South African HIV vaccine trials and was therefore ruled out.

2.8.3 The Theory of Planned behavior

The TPB (Ajzen, 1985, 1988, 1991) is an extension of an earlier theory, the Theory of Reasoned Action (TRA) (Ajzen & Fishbein, 1980). The TRA posits that an individual's intention to perform a behaviour is a robust predictor of the individual actually performing the behaviour. A behavioural intention is the outcome of a combination of two variables:

1. An individual's attitude towards the behaviour; and
2. An individual's perception of existing subjective norms concerning the behaviour.

An individual's attitude towards a behaviour is informed by the individual's beliefs about the outcomes of the behaviour, and the individual's evaluation of these outcomes. An individual's perceived subjective norms is informed by the individual's perception of the attitude of others towards the behaviour, and the individual's motivation to comply with others. Taken together, the TRA predicts that that a positive attitude toward the behaviour and strong normative pressure to perform (or not perform) the behaviour will accurately predict an intention to perform the behaviour. Furthermore, a strong intention to perform the behaviour will robustly predict actual behaviour (Ajzen, 1985, 1988, 1991). The TRA is displayed in Figure 2.

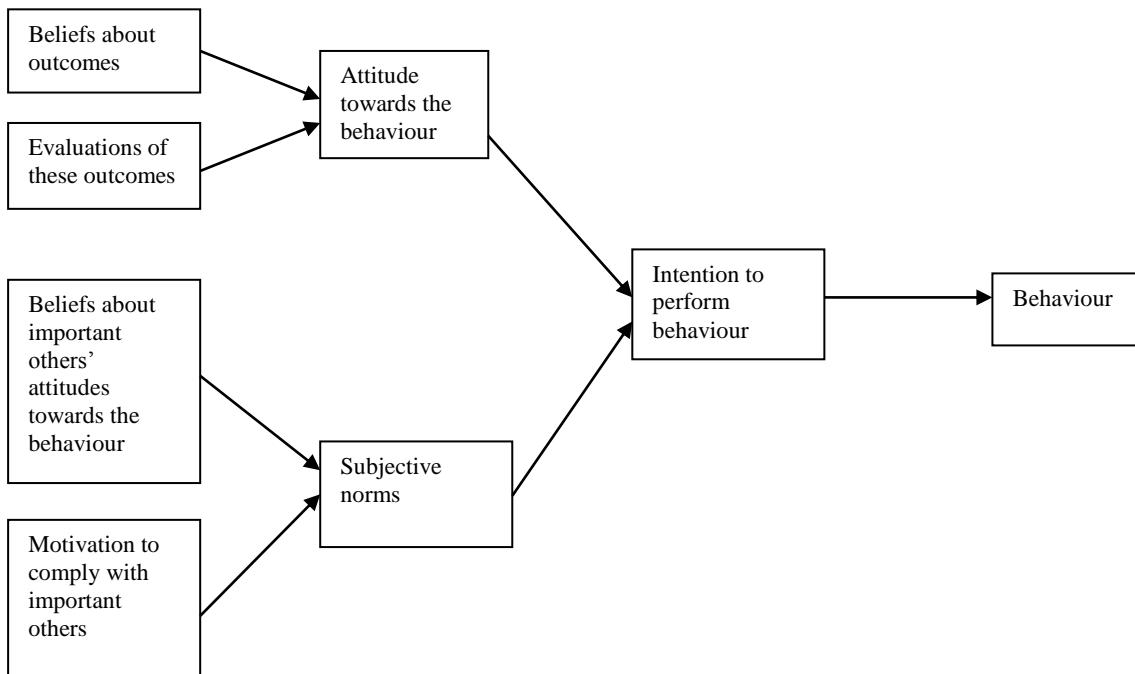


Figure 2. The Theory of Reasoned Action.

The TRA can be expressed as the following mathematical function: Behavioural intention = $\beta_0 + (\beta_1)$ Attitudes [(beliefs about the outcomes of the behaviour) + (the individual's evaluation of these outcomes)] + (β_2) Subjective norms [(the individual's perception of the attitude of others towards the behaviour) + (the individual's motivation to comply with others)].

The TPB is an extension of the TRA by the inclusion of an additional variable, the individual's perceived behavioural control. An individual's perception of control over a behaviour is informed by the individual's evaluation of internal factors such prior experience, and external factors such as social learning. The TPB also states that perceived behavioural control can predict behaviour without the mediating effect of attitudes towards the behaviour

and subjective norms. Taken together, the TPB predicts that that a positive attitude toward the behaviour, strong normative pressure to perform (or not perform) the behaviour, and a strong perception of control over the behaviour will accurately predict an intention to perform the behaviour. A strong intention to perform the behaviour will in turn robustly predict actual behaviour. Finally, a strong perception of control over the behaviour may predict actual behaviour despite one's attitude towards the behaviour or one's perception of normative pressure. The TPB is displayed in Figure 3.

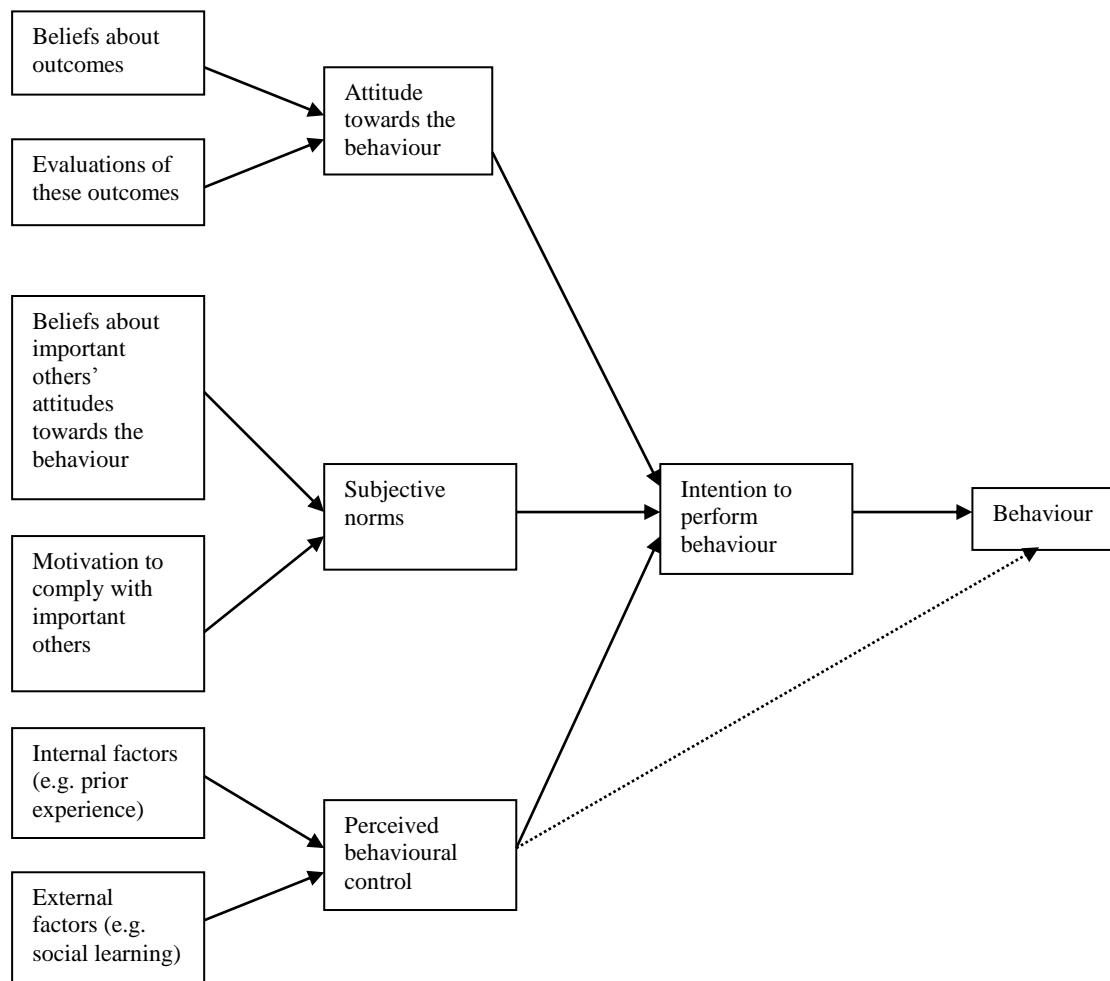


Figure 3. The Theory of Planned Behavior.

The TPB can be expressed as the following mathematical function: Behavioural intention = $\beta_0 + (\beta_1) \text{ Attitudes } [(\text{beliefs about the outcomes of the behaviour}) + (\text{the individual's evaluation of these outcomes})] + (\beta_2) \text{ Subjective norms } [(\text{the individual's perception of the attitude of others towards the behaviour}) + (\text{the individual's motivation to comply with others})] + (\beta_3) \text{ Perceived behavioural control } [(\text{the individual's evaluation of internal factors}) + (\text{the individual's evaluation of external factors})]$.

Unlike the PMT and the HBM, meta-analyses of studies that have employed the TPB recurrently show that the theory has successfully predicted a wide range of health-promoting behaviours (Armitage & Conner, 1999b; Armitage & Conner, 2001; Albarracín et al., 2001). Behaviours predicted include medication adherence (Conner, Black, & Stratton, 1998), condom use (Albarracín et al., 2001; Bryan, Kagee, & Broaddus, 2006; Sheeran & Orbell, 1998), exercise (Hagger, Chatzisarantis, & Biddle, 2002b), clinical glove use (Watson & Myers, 2001); and dietary and fluid adherence in haemodialysis (Fincham et al., 2008). In addition, the theory makes provision for the role of social and environmental factors. Given the important role that social factors play in the transmission of HIV, an assessment of these factors is paramount. Another benefit to using the TPB in this context is the theory's inclusion of behavioural intention, a reliable proxy for actual behaviour (Armitage & Conner, 2001; Ajzen, 1985, 1988, 1991; Francis et al., 2004). It follows that in the absence of actual enrolling behaviour, measuring an individual's intention or *willingness* to participate may be the most appropriate proxy for future participation in an HIV vaccine trial.

2.8.4 The Theory of Planned Behavior and WTP in an HIV vaccine trial

Regarding WTP in future HIV vaccine trials, only two studies (to my knowledge) have used the TPB as a predictive model. The first study evaluated the acceptability of a hypothetical future HIV vaccine among 136 Canadian adolescents (Gagnon & Godin, 2000). The second study evaluated the extent to which the TPB predicted variance in WTP among 224 South African adolescents (Giocos et al., 2007). Multivariate analyses showed that the TPB variables were significant predictors of WTP in both samples. These early findings provide support for the hypothesis that the TPB may be a useful theoretical framework for understanding and predicting WTP in an HIV vaccine trial.

While behavioural intentions are strong predictors of actual behaviour (Ajzen, 1988), they do not however account for all of the variance in actual behaviour. Similarly, attitude, subjective norms, and perceived behavioural control do not account for all of the variance in behavioural intention. The residual variance may therefore be explained by variables beyond the scope of the TPB. To account for unexplained variance, researchers have expanded the TPB by including additional predictor variables. For example, Bozionelos and Bennett (1999) investigated the predictive strength of the TPB in relation to exercise behaviour among 114 British students. Past behaviour, personal normative beliefs, role beliefs, level of self-monitoring, and sex role identity were added as additional predictor variables. Results indicated that the added variables significantly improved the predictive power of the TPB.

In another sample of British students, McMillan and Conner (2003) used the TPB to predict the use of lysergic acid diethylamide (LSD), amphetamine, cannabis, and ecstasy over 6 months in a sample of 461 British students. Descriptive and moral norms were additional

predictor variables. The extended version of the TPB significantly accounted for 49% of the variance in intentions, and 45% of the variance in actual behaviour. Furthermore, descriptive norms explained additional variance in intentions for all the drugs, and moral norms explained additional variance in the intention to use cannabis.

While these research findings are limited to British student samples, they nonetheless illustrate that the inclusion of theoretically-driven predictor variables may increase the amount of variance explained. To this end, this study included mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection (see Figure 4). As no Phase III HIV vaccine trials were yet underway in South Africa at the time of this writing, we only measured participants' intention, or willingness, to participate in a future Phase III HIV vaccine trial.

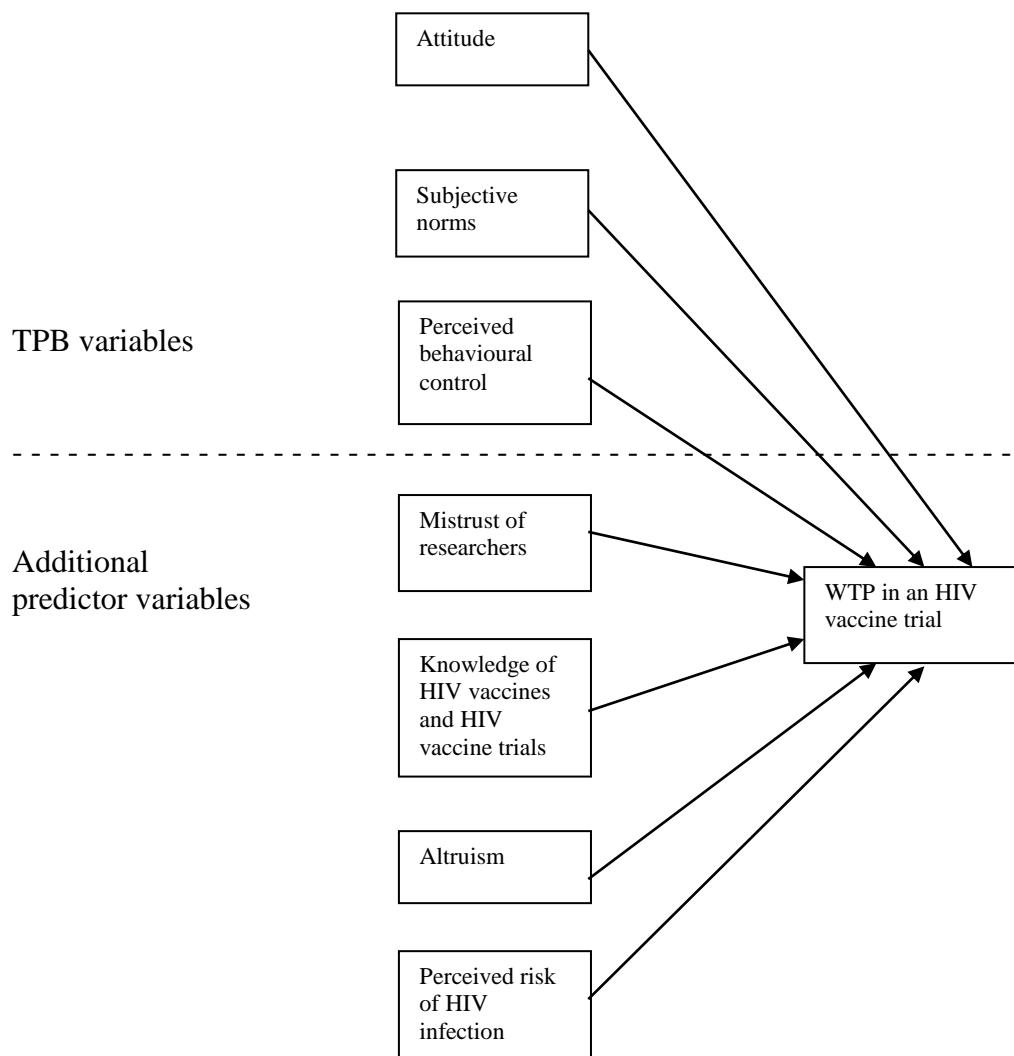


Figure 4. Application and extension of the Theory of Planned Behavior in this study.

The extended TPB used in this study can be expressed as the following mathematical function: $\text{WTP in an HIV vaccine trial} = \beta_0 + (\beta_1) \text{ Attitudes} + (\beta_2) \text{ Subjective norms} + (\beta_3) \text{ Perceived behavioural control} + (\beta_4) \text{ Mistrust of researchers} + (\beta_5) \text{ Knowledge of HIV vaccines and HIV vaccine trials} + (\beta_6) \text{ Altruism} + (\beta_7) \text{ Perceived risk of HIV infection.}$

2.9 Overview of the chapter

This chapter provided a critical review of both international and South African literature surrounding factors that may inhibit or facilitate WTP in an HIV vaccine trial. The literature review identified variables that may be robust predictors of WTP in the South African context. These include mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection. This chapter also outlined the application and extension of the TPB to the prediction of WTP in this study, and underscored the need for the construction of a reliable and valid measure of WTP. The next chapter describes the methodology that was used in this study, and includes a description of the research design, the selection of the sample, the construction of a psychometric measure of WTP, and the statistical procedures used to analyse the data.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction

As mentioned previously, this study constituted the second part of a two-part mixed-method investigation that aimed to determine the factors associated with WTP in a South African sample. Part I was a qualitative study that aimed to elicit thick descriptions of the psychological, behavioural, and social concerns of South Africans who will be eligible to participate in a future HIV vaccine trial (Swartz et al., 2006). The researchers conducted 37 semi-structured interviews and 2 focus groups with trial site community members who had attended HIV vaccine education workshops conducted by Masikhulisane, the community involvement wing of SAAVI. The interviews were recorded verbatim using a dictaphone and later transcribed. The transcriptions were entered into the Atlas.ti. software program to assist in the identification of themes within the tradition of Grounded Theory (Strauss & Corbin, 1998). After the interviewers had completed an initial analysis of the transcriptions, the research team met to discuss common themes that had emerged from the data. The themes related to whether a sub-theme was an inhibitor or enabler, whether a sub-theme was abstract or concrete, and whether a sub-theme concerned only the individual, the individual's family, the individual's community, or society at large. The results of the study were reported in Chapter 2.

The objectives for this study (Part II of the investigation) were: 1) to construct a psychometric measure of WTP in an HIV vaccine trial; 2) to derive, in an exploratory fashion, the factor structure of the new instrument; 3) to examine the extent to which the TPB predicts variance

in WTP in an HIV vaccine trial; and 4) to determine whether the TPB is strengthened by the inclusion of mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables. This study built on the results of Part I in two ways. Firstly, Part I facilitated the development of an item pool for the construction of a WTP measure. Secondly, Part I contributed towards the identification of important variables that were included as additional predictor variables in the TPB model.

3.2 Participants

A convenience sample of 399 participants was drawn from Masiphumelele, an urban-informal settlement near Cape Town. A great concern was whether participants would be sufficiently literate to complete the self-report questionnaires, given the high rates of illiteracy in the area (Masiphumelele Annual Report, 2008). Careful analysis of the completed questionnaires revealed that 79 of the 399 questionnaires (19.8%) were poorly completed, leaving a sample size of 320. The large proportion of discarded questionnaires was understandable considering that only 60.6% of the participants reported at least a high school level of education. The bias introduced by the under-representation of less literate individuals, coupled with the non-randomness of the sample, indicates that the results of this study are not representative of the population at large. Therefore, the results reported in Chapter 4 need to be interpreted against the backdrop of the sample limitations.

3.3 Research design

This study was a research survey with a cross-sectional design. Participants were asked to complete a battery of psychometric instruments on a single occasion during the period of 1 April 2007 to 14 April 2007.

3.4 Measuring instruments

3.4.1 The Willingness to Participate Scale (WTPS) (Appendix A)

3.4.1.1 Item development

According to Clark and Watson (1995), the first priority in scale construction is to formulate a clear conceptualisation of the target construct. The process of conceptualising, articulating, and circumscribing the construct of WTP was aided by examining the results of Part I of this investigation, and by conducting a comprehensive literature review of both South African and international literature on WTP. Once the scope and content domain of the construct was identified, the process of developing an item pool began. The primary goal of creating an item pool is to derive as many potentially relevant scale items as is necessary to achieve saturation of the all facets of the target construct (Comrey, 1988; Comrey & Lee, 1992). Items were developed so that they directly reflected inhibitors and facilitators of WTP.

3.4.1.2 Item refinement

Once enough items were developed to sufficiently cover all aspects and domains of the construct WTP, items were closely examined for ambiguity and redundancy. The process of item-refinement continued in an iterative fashion until no further improvements could be made. Thereafter, a panel of social scientists working in the area of HIV vaccines that had been trained in scale development were asked to review the items for clarity, conciseness, relevance, and possible omissions. Once the recommendations made by the panel were integrated, focus groups were held with two separate groups of postgraduate psychology students undergoing training in psychometric scale construction. The participants were invited to comment on the items and made suggestions which improved the readability and interpretability of the items. The revised items were once again reviewed by the panel of social scientists.

The final scale consisted of 35 items and was named the Willingness to Participate Scale (WTPS). The WTPS used a five-point Likert scale response format ranging from “very unwilling” to “very willing”. “Very unwilling” was coded 1 and “very willing” was coded 5, yielding total scores that ranged between 35 and 175. Higher scores indicated greater WTP. Item-by-item descriptive analyses, Cronbach alpha (α) internal reliability coefficients, and item-total correlation coefficients were computed and are presented in Chapter 4.

3.4.2 Measuring the TPB variables

A comprehensive review of the literature showed that, at the time of this study, there were no standard measures for the TPB constructs in the context of WTP in an HIV vaccine trial. The

constructs were attitudes towards participating in an HIV vaccine trial, subjective norms about participating in an HIV vaccine trial, and perceived behavioural control of participating in an HIV vaccine trial. In the absence of appropriate instruments, scales for the variables were constructed according to a scale development manual developed by Francis et al. (2004). The manual provides procedural guidelines for the construction of scales to measure TPB variables specifically, and integrates literature ranging from the original TPB manuscripts (Ajzen, 1985, 1988, 1991) to meta-analyses of studies that have employed the TPB (Armitage & Conner, 1999b, 2001; Godin & Kok, 1996). The result is a guide to scale development that is not only theoretically accurate, but is based on current practice among TPB researchers. Scales were constructed according to the construction guidelines used to develop the WTPS. Psychometric properties of the resulting scales are reported in Chapter 4.

3.4.2.1 Attitudes (Appendix B)

To measure attitudes, Francis et al. (2004) suggest the use of several evaluative bipolar adjectives which are anchored by a single stem. The bipolar adjectives should be arranged in a manner that may yield a mix of positive and negative endpoints. Negatively-worded items need to be recoded such that higher numbers reflect a positive attitude towards the target behaviour. The item scores are then added to give a total attitude score.

Following these guidelines, a scale with 9 items was developed. Each item was anchored by the phrase “participating in an HIV vaccine would be” followed by the use of evaluative bipolar adjectives on a seven point scale. Items with positive endpoints, such as “participating in an HIV vaccine trial would be worthless/worthwhile”, were scored from 1 to 7 while items with negative endpoints, such as “participating in an HIV vaccine trial would be

pleasant/unpleasant” were scored from 7 to 1. As such, total scores ranged from 9 to 63 where higher scores reflected a more positive attitude toward participating in an HIV vaccine trial.

3.4.2.2 Subjective norms (Appendix C)

Francis et al. (2004) suggest that to measure subjective norms, three standard items should be used and adapted to the context of the study (additional items may be included). The standard items are: 1) “most people who are important to me think that...”; 2) “it is expected of me...”; and 3) “I feel under social pressure to...” The items should be followed by a Likert scale response format ranging from “strongly agree” to “strongly disagree”, and should be arranged so that there is a mix of positive and negative endpoints. Negatively-worded items need to be recoded such that higher numbers reflect a greater social pressure to perform the target behaviour. The item scores are then added to give a total score for subjective norms.

Following these guidelines, a measure consisting of 6 items was developed. The scale consisted of items such as “I feel pressured by people around me to participate in an HIV vaccine trial” and “most people who are important to me think that I should participate in an HIV vaccine trial”. The items were scored according to a four-point Likert scale where responses ranged from “strongly disagree” to “strongly agree”. “Strongly disagree” was coded 1 and “strongly agree” was coded 4 yielding total scores that ranged from 6 to 24. Higher scores indicated a stronger perception of participation in an HIV vaccine trial being the norm.

3.4.2.3 Perceived behavioural control (Appendix D).

According to Francis et al. (2004), items in a scale measuring perceived behavioural control should assess two factors: 1) self-efficacy performing the target behaviour; and (2) controllability over performing the target behaviour. Self-efficacy is assessed by asking participants to report the perceived difficulty of performing the behaviour and their confidence in performing the behaviour. Controllability is assessed by asking participants to report whether performing the behaviour is up to them, and whether factors beyond their control determine their behaviour. As with scales measuring subjective norms, items should be followed by a Likert scale response format ranging from “strongly agree” to “strongly disagree”. The items should be arranged so that there is a mix of positive and negative endpoints. Negatively-worded items need to be recoded such that higher numbers reflect a greater perception of control of the target behaviour. Item scores are added to give a total score for perceived behavioural control.

According to these guidelines, a scale consisting of 6 items was constructed. A four-point Likert response format ranging from “strongly disagree” to “strongly agree” was used. For items such as “I am confident that I could participate in an HIV vaccine trial if I wanted to”, “strongly disagree” was coded 1 and “strongly agree” was coded 4. For reversed items such as “the decision to participate in an HIV vaccine trial is beyond my control”, “strongly disagree” was coded 4 and “strongly agree” was coded 1. As such, total scores ranged from 6 to 24 where higher scores indicated a stronger perception of behavioural control over participating in an HIV vaccine trial.

3.4.3 Scales for the additional variables

There were no standard instruments available for measuring mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, or altruism in the context of WTP in an HIV vaccine trial. As such, brief self-report scales were constructed according to the scale construction guidelines used to construct the WTPS. Psychometric properties of the scales are reported in Chapter 4.

3.4.3.1 Mistrust of researchers (Appendix E)

A measure consisting of 9 items was developed to measure mistrust of researchers. The scale used a four-point Likert response format ranging from “strongly disagree” to “strongly agree”. For items such as “the public should be wary of researchers”, “strongly disagree” was coded 1 and “strongly agree” was coded 4. For reversed items such as “when a researcher gives me information I would accept it as true”, “strongly disagree” was coded 4 and “strongly agree” was coded 1. As such, total scores ranged from 9 to 36 where higher scores indicated higher levels of mistrust of researchers.

3.4.3.2 Knowledge of HIV vaccines and HIV vaccine trials (Appendix F)

To measure knowledge of HIV vaccines and HIV vaccine trials, a scale consisting of 23 items was developed. The instrument utilised a two-option response format consisting of “true” and “false”. Items included “a placebo is a fake treatment that is similar to the real vaccine or drug”, and “HIV vaccines are given to help prevent someone from becoming infected with HIV”. Correct responses were coded 2 and incorrect responses were coded 1. As

such, total scores ranged from 23 to 46 where higher scores indicated higher levels of knowledge of HIV vaccines and HIV vaccine trials.

3.4.3.3 Altruism (Appendix G)

A measure consisting of 11 items was constructed to measure altruism in the context of WTP in an HIV vaccine trial. The scale used a four-point Likert response format ranging from “strongly disagree” to “strongly agree”. For items such as “I try to help those in need”, “strongly disagree” was coded 1 and “strongly agree” was coded 4. For reversed items such as “if I cared for others I would be wasting my time”, “strongly disagree” was coded 4 and “strongly agree” was coded 1. As such, total scores ranged from 11 to 44 where higher scores indicated higher levels of altruism.

3.4.3.4 Perceived risk of HIV infection

To measure perceived risk of HIV infection, participants were requested to indicate their perception of self-risk on a ten point scale ranging from “very low risk” to “very high risk”. Total scores ranged from 1 to 10 where higher scores indicated a higher perceived risk of HIV infection.

3.4.3.5 Demographic variables (Appendix H)

Gender, age, marital status, ethnicity, first language, educational level, and annual family income before taxes were assessed using a standard demographic questionnaire.

3.5 Translation of measuring instruments

As Xhosa is the predominant language spoken in Masiphumelele (Masiphumelele Annual Report, 2008), the scales needed to be translated. The cross-cultural translation and adaptation of psychometric instruments is fraught with methodological, conceptual, and linguistic difficulties (Beaton, Bombardier, Guillemin, & Ferraz, 2000; Kulich et al., 2008; Van de Vijver & Hambleton, 1996). For example, there may be differences in the level of literacy, taboo subjects, and social desirability between cultures (Ren, Amick, Zhou, & Gandek, 1998). There may also be a lack of appropriate terms or idioms in the target language, preventing literal translation. In addition to linguistic differences, there may be contrasting cultural beliefs and practices about the body, illness, and health behaviours (Ren et al., 1998). The translation of a psychometric instrument therefore involves more than just linguistic adaptation of the original language into the target language; it is an iterative process that aims to achieve *conceptual* equivalence within the cultural context of the target language (Beaton et al., 2000; Kulich et al., 2008). As such, we aimed to replicate the English measures as closely as possible while being sensitive to cultural and linguistic differences between English and Xhosa.

A Xhosa-speaking clinical psychologist with training in psychometric scale construction was employed to translate the measures from English into Xhosa. The Xhosa instruments were then back-translated into English by a Xhosa-speaking post-graduate psychology student with training in psychometric scale construction. The student was very experienced in translating questionnaires and did not have access to the original English versions of the instruments. A panel of five social scientists with training in psychometric scale construction then assessed the conceptual equivalence of the items from the two English versions of the measures. The

panel concluded that the two sets of English measures demonstrated very good correspondence, providing confidence in the Xhosa version of the measures. While significant correlations between original and translated items provide support for the validity of the translated items (Ren et al., 1998), such analyses could not be performed in this study as there were too few completed English questionnaire packets.

3.6 Procedure

A partnership was established with the Desmond Tutu HIV Centre (DTHC) in Cape Town, as the centre has a good rapport with Community Advisory Board (CAB) members at Masiphumelele. A meeting was held with the CAB members and other interested parties of the Masiphumelele community where details of the study were presented and permission to conduct the study was requested. After obtaining permission from the CAB and ethical clearance was granted by the Internal Review Boards (IRB) of both Stellenbosch University and the University of Cape Town, the administration of questionnaires ensued. Community educators and recruiters carefully explained the details of the study to potential participants who were required to read, understand, and sign consent forms prior to participating in the study (Appendix I). A hall was rented at the Masiphumelele clinic to provide a location for participants to complete their questionnaires. After completing the questionnaires, participants were thanked for their time and each received a R50 gift voucher for a local supermarket as a show of gratitude for their participation.

3.7 Data analysis

All statistical procedures were performed using the SPSS 15.0 software package. Analyses were two-tailed and alpha (α) was set at 0.05.

3.7.1 Data screening

Firstly, case summaries for all variables were requested in order to identify data-capturing errors. Secondly, a missing value analysis (MVA) was performed for each variable to identify systematic trends in missing data. While listwise deletion of cases with missing data is the procedure most likely to produce unbiased parameter estimates (Howell, 2008), doing so would have substantially reduced the sample size and power of the study. According to Little (1998), the use of least squares has also been shown to be a very good approach to missing data. Therefore, missing data were imputed via regression estimation. Variable means and percentages before and after missing data imputation were compared to assess the validity of the imputed data. Frequencies, percentages, means, and standard deviations were computed to describe the sample. Cronbach alpha (α) reliability coefficients were computed to assess the internal consistency of the scales. A Pearson product-moment correlation matrix was computed to examine bivariate associations between continuous variables. Independent samples t-tests and one-way ANOVA tests were performed to examine differences between groups.

3.7.2 Exploratory factor analysis

A principal component Kaiser normalised exploratory factor analysis (EFA) was conducted on the items that constituted the WTPS. This procedure was performed to identify latent factors which were informed by the items of the scale. Firstly, the Kaiser-Meyer-Olkin statistic (which represents the ratio of the squared correlation between items to the squared partial correlation between items) was computed to determine whether or not the data were likely to factor well. Thereafter, inter-item Pearson product-moment correlation coefficients (r) were derived to examine associations between the items. Items that were not significantly correlated with other items were removed from the analysis. Bartlett's test of sphericity was computed to ensure that the inter-item correlation matrix did not approach an identity matrix. The converse problem of multicollinearity was assessed by analyzing the determinant of the inter-item correlation matrix. Items that correlated very highly with other items ($r > 0.8$) were removed from the analysis. Finally, item-by-item descriptive analyses, Cronbach's alpha internal reliability coefficients, and item-total Pearson product-moment correlation coefficients were computed. Factors with eigenvalues greater than 1 were retained (Kaiser, 1960, 1974). A scree plot was computed to graphically display the number of factors to be extracted. A factor loading of 0.40 or greater was used to identify the primary factor on which the items loaded. A factor correlation matrix revealed that the factors were significantly correlated. As such, oblique rotation (direct oblimin) was performed instead of orthogonal rotation (factor score coefficients were computed according to the regression method, where scores have a mean of 0 and a variance equal to the squared multiple correlation between the estimated factor scores and the true factor values).

3.7.2.1 Sample size for exploratory factor analysis

Various and conflicting suggestions have been put forth regarding appropriate sample size for EFA. While some recommend having at least 10 observations per variable (Nunnally & Bernstein, 1994), others suggest that as few as 5 observations per variable would be sufficient (Bryant & Yarnold, 1995; Kass & Tinsley, 1979). Despite the contradictory guidelines provided in the literature, a sample size of 300 or more tends to produce stable factor solutions regardless of the observation to variable ratio (Comrey & Lee, 1992; Norušis, 2005; Tabachnick & Fidell, 2001). For this reason, this study's sample size of 320 was considered to be large enough to ensure stable and reliable parameter estimates.

3.7.3 Two-step linear hierarchical multiple regression analysis

A two-step linear hierarchical multiple regression analysis was performed to: (i) determine the amount of variance in WTP explained by the linear combination of TPB variables; and (ii) to determine whether or not the inclusion of mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables significant improved the amount of variance explained in WTP. Multicollinearity between predictor variables was assessed using the Variance Inflation Factor (VIF) statistic. According to Myers (1990), values exceeding 10 are cause for concern. The assumption of independence of standardised residuals was assessed using the Durbin-Watson statistic. According to Field (2000, 2005), values should be greater than or equal to 1 and less than or equal to 3 ($1 \leq x \leq 3$). Boxplots were computed to reveal the presence of outliers. Cook's distances were calculated for each outlier to determine whether or not the outlier exerted a significant influence on the regression model as a whole. Cook and Weisberg (1982) suggest

that values greater than 1 may be a cause for concern. The assumptions of homoscedasticity and linearity were assessed by analysing the standardised residuals/ standardised predicted values graph. Finally, the assumption of normally distributed standardised residuals was assessed using the Kolmogorov-Smirnov test.

3.7.3.1 Model specification

At step 1, attitude, subjective norms, and perceived behavioural control were entered simultaneously to determine the amount of variance in WTP that could be explained by the TPB. At step 2, the additional predictor variables were entered simultaneously with TPB variables to determine whether or not the additional predictor variables could account for additional variance in WTP.

3.7.3.2 Sample size for multiple linear regression analysis

Tabachnick and Fidell (2001) suggest that $n \geq 104 + k$ (where n refers to sample size and k refers to the number of predictor variables) should yield sufficient power to test individual predictors. Furthermore, $n \geq 50 + 8(k)$ should yield enough power to test the squared multiple correlation coefficient. According to these guidelines, this study's sample size of 320 was able to yield enough power.

CHAPTER 4**RESULTS****4.1 Demographic characteristics of the sample (Table 1)**

The sample consisted exclusively of Black participants who were mostly unemployed (76.3%). The large majority were female (89.7%) and the mean age was 30.29 years ($SD = 10.57$). Almost all spoke Xhosa as a first language (98.1%) and most were single (71.6%). While most indicated that they were unsure of their annual household income before taxes (72.8%), a large proportion indicated that their annual household income before taxes was less than R10 000 (21.9%). A third of the participants (33.1%) had completed primary school and 42.2% had attended high school, but had not completed matric.

Table 1

Demographic Characteristics of the Sample

	n	f	(%)	M	SD	Range
Age (years)	320		(100)	30.29	10.57	16-49
Race	320		(100)			
Black		320	(100)			
Sex	320		(100)			
Male		33	(10.3)			
Female		287	(89.7)			

(Table continues)

(Continued)

	n	f	(%)	M	SD	Range
Annual household income before taxes	320		(100)			
Less than R10 000		70	(21.9)			
R10 001-R40 000		7	(2.2)			
R40 001-R80 000		2	(0.6)			
R80 001-R110 000		3	(0.9)			
R110 001-R170 000		2	(0.6)			
R170 001-R240 000		1	(0.3)			
R240 001 and above		2	(0.6)			
Unsure		233	(72.8)			
Educational status	320		(100)			
No formal education		20	(6.3)			
Completed primary school		106	(33.1)			
Attended high school but did not complete matric		135	(42.2)			
Completed matric		52	(16.3)			
Attended college, university, or technikon but did graduate		5	(1.6)			
Graduated from college, university, or technikon		2	(0.6)			
Employment status	320		(100)			
Employed full time		18	(5.6)			
Employed part time		34	(10.6)			
Student		21	(6.6)			
Unemployed		244	(76.3)			
Retired		3	(0.9)			
First language	320		(100)			
Xhosa		314	(98.1)			
Southern Sotho		2	(0.6)			
Zulu		1	(0.3)			
English		2	(0.6)			
Venda		1	(0.3)			
Marital status	320		(100)			
Single		229	(71.6)			
Co-habiting		22	(6.9)			
Married		66	(20.6)			
Divorced		1	(0.3)			
Other		2	(0.6)			

4.2 Internal reliability of the measures (Table 2)

4.2.1 Attitudes

The first version of the measure demonstrated poor to modest internal consistency ($\alpha = 0.59$). However, after deleting item 1 (“participating in an HIV vaccine trial would be harmful/beneficial”); item 4 (“participating in an HIV vaccine trial would be worthless/worthwhile”); and item 9 (“participating in an HIV vaccine trial would be silly/clever”), the internal consistency of the scale demonstrated excellent internal consistency ($\alpha = 0.87$). The refined instrument consisted of 6 items.

4.2.2 Subjective norms

The measure demonstrated excellent internal consistency ($\alpha = 0.84$).

4.2.3 Perceived behavioural control

The measure demonstrated modest internal consistency ($\alpha = 0.65$). As no items performed particularly poorly, the internal consistency of the measure could not be improved.

4.2.4 Mistrust of researchers

The first version of the scale demonstrated modest internal consistency ($\alpha = 0.63$). However, when item 1 (“if I were asked to participate in a research study and the study procedures were explained to me by the researcher, I would believe what he or she told me”) was removed

from the analysis, the scale demonstrated excellent internal consistency ($\alpha = 0.79$). The refined instrument consisted of 8 items.

4.2.5 Knowledge of HIV vaccines and HIV vaccine trials

The first version of the measure demonstrated modest internal consistency ($\alpha = 0.64$). However, when item 3 (“it is important that the individuals placed in each group in a clinical trial are different to each other in as many ways as possible”); item 4 (“in a clinical trial, the participants know whether they have received the real vaccine or drug or whether they have received the fake vaccine or drug”); item 8 (“a vaccine is given to children, never to adults”); item 18 (“if you enroll in an HIV vaccine trial, you will not be asked questions about your health and sexual behaviour”); and item 19 (“people who take part in an HIV vaccine trial will not be allowed to stop their involvement in the trial”) were deleted, the scale yielded good internal consistency ($\alpha = 0.71$). The refined instrument consisted of 18 items.

4.2.6 Altruism

The original scale demonstrated good internal consistency ($\alpha = 0.71$). Nonetheless, when item 1 (“if I help others too much, they may take advantage of me”); item 3 (“I must take care of myself before taking care of others”); item 6 (“if I cared for others I would be wasting my time”); item 8 (“I will lose out if I worry about other people’s problems or needs”); and item 10 (“I think the most important thing in life is to look after my own interests first”) were deleted, the scale displayed excellent internal consistency ($\alpha = 0.87$). The refined instrument consisted of 6 items.

Table 2

Internal Consistency of Measures Before and After Deleting Poorly Performing Items

Scale	α -bid [†]	No. of items before deletion	Items deleted	No. of items after deletion	α -aid [‡]
Attitude	0.59	9	1, 4, 9	6	0.87
Subjective norms	0.84	6	None	6	0.84
PBC	0.65	6	None	6	0.65
Mistrust	0.63	9	1	8	0.79
Knowledge	0.64	23	3, 4, 8, 18, 19	18	0.71
Altruism	0.71	11	1, 3, 6, 8, 10	6	0.87

[†] Cronbach's alpha (α) before item deletion; [‡] Cronbach's alpha (α) after item deletion

4.3 Bivariate correlations between variables (Table 3)

Results indicated that a high level of WTP was associated with a low level of normative pressure ($r = -0.24$, $p < 0.01$), a high level of altruism ($r = 0.24$, $p < 0.01$), a low level of mistrust of researchers ($r = -0.21$, $p < 0.05$), and a high level of perceived risk of HIV infection ($r = 0.12$, $p < 0.05$) (Table 3 is presented on the next page).

Table 3

Bivariate Pearson Product-moment Correlations between Variables

	WTP	Age	Attitude	Subjective norms	PBC [†]	Mistrust	Knowledge	Altruism	Perceived risk
WTP	1.00								
Age	0.01	1.00							
Attitude	0.00	-0.12*	1.00						
Subjective norms	-0.24**	-0.00	0.11*	1.00					
PBC [†]	-0.08	0.09	0.04	0.13*	1.00				
Mistrust	-0.21*	-0.00	0.09	0.46**	-0.12*	1.00			
Knowledge	0.10	0.08	0.07	-0.00	-0.02	0.08	1.00		
Altruism	0.24**	-0.01	0.19**	-0.56**	-0.27**	-0.41**	0.06	1.00	
Perceived risk	0.12*	0.05	0.20**	0.03	-0.12*	-0.02	0.12*	0.11*	1.00

[†] Perceived behavioural control; *p < 0.05; **p < 0.01

4.4 Between-groups effects (Table 4)

Owing to the homogeneity of the sample, the majority of independent variable cell frequencies were very low (see Table 1). To permit tests of between-groups effects, the independent variables were dichotomised so that each category had enough observations to make meaningful comparisons possible. Categories that could not be collapsed were removed from the analyses. Annual household income before taxes was dichotomised as ‘less than R10 000 versus R10 000 or more’. There were 87 cases that could be analysed after dichotomising the variable. Educational status was dichotomised into ‘have not completed matric versus completed matric or higher education’. All the cases (320) could be analysed after dichotomising the variable. Employment status was categorised into ‘unemployed versus employed full or part time’. There were 296 cases that could be analysed after dichotomising the variable. Finally, marital status was categorised into ‘single versus married’. There were 295 cases that could be analysed after dichotomising the variable. Comparisons could not be made between males and females as there were too few males in the sample. Results indicated that participants who had completed matric or higher education demonstrated a higher level of altruism [$t(319) = 8.23, p < 0.05$], and more positive attitudes towards trial participation [$t(319) = 6.36, p < 0.05$] than participants who had not completed matric. (Table 4 begins on the next page).

Table 4

Tests of Between-groups Effects

Variable	t	df	p
Annual household income		86	
WTP	0.68		0.41
Attitude	0.73		0.39
Subjective norms	0.84		0.36
PBC	1.92		0.16
Mistrust	0.06		0.80
Knowledge	3.45		0.06
Altruism	0.51		0.47
Perceived risk	0.17		0.67
Educational status		319	
WTP	0.33		0.56
Attitude	6.36		0.01*
Subjective norms	0.02		0.88
PBC	2.65		0.10
Mistrust	2.36		0.12
Knowledge	0.55		0.45
Altruism	8.23		0.01*
Perceived risk	0.58		0.58
Employment status		295	
WTP	2.33		0.12
Attitude	0.13		0.71
Subjective norms	2.12		0.14
PBC	0.09		0.23
Mistrust	0.07		0.78
Knowledge	1.56		0.21
Altruism	0.35		0.55
Perceived risk	0.45		0.50

(Table continues); *p < 0.05

(Continued)

Variable	t	df	p
Marital status		294	
WTP	0.08		0.77
Attitude	1.95		0.16
Subjective norms	0.11		0.70
PBC	1.63		0.20
Mistrust	0.37		0.54
Knowledge	0.01		0.92
Altruism	1.04		0.30
Perceived risk	2.47		0.11

4.5 The Willingness to Participate Scale (WTPS) (Table 5)

The WTPS demonstrated excellent internal reliability ($\alpha = 0.90$). Item-by-item descriptive analyses and item-total correlation coefficients provided additional evidence for the internal consistency of the measure (Table 5 begins on the next page).

Table 5

Item-by-item Descriptive Analyses for the WTPS

Item	Item-total r	α -iid [†]	M	SD
1. Knowing more about the possible benefits of an HIV vaccine would make me...	0.43**	0.90	4.30	1.23
2. Having more information about how to cope with possible side effects of an HIV vaccine would make me...	0.47**	0.90	4.20	1.25
3. Knowing that participating in an HIV vaccine trial would help stop the AIDS pandemic would make me...	0.43**	0.90	4.10	1.22
4. Receiving free medical care for trial-related illnesses would make me...	0.43**	0.90	4.27	1.16
5. The fact that participating in an HIV vaccine trial would be a new experience for me would make me...	0.49**	0.90	4.25	1.14
6. If I were regarded as a role model because of my participation in an HIV vaccine trial would be...	0.56**	0.89	4.12	1.29
7. Receiving money in return for enrolling in an HIV vaccine trial would make me...	0.51**	0.90	3.97	1.39
8. The possibility of falsely testing HIV positive would make me...	0.46**	0.90	3.38	1.48
9. If my friends approved of my participation in an HIV vaccine trial I would be...	0.46**	0.90	3.72	1.35
10. If I were certain that HIV vaccine researchers have my best interests at heart I would be...	0.48**	0.90	4.18	1.26
11. Knowing more about the possible shortcomings of HIV vaccines would make me...	0.55**	0.90	3.91	1.39

(Table continues); † Cronbach's alpha (α) if item deleted; **p < 0.01

(Continued)

Item	Item-total r	α -iid†	M	SD
12. If there was a risk of being infected with HIV from the HIV vaccine being tested I would be...	0.41**	0.90	4.02	1.62
13. If participating in an HIV vaccine trial were to take up a lot of my time I would be...	0.58**	0.89	4.26	1.39
14. The possibility that I would receive injections in an HIV vaccine trial would make me...	0.53**	0.90	3.35	1.40
15. If my partner were to refuse to have sex with me because of my participation in an HIV vaccine trial I would be...	0.39**	0.90	3.80	1.48
16. The possibility of being discriminated against by others because of my participation in an HIV vaccine trial would make me...	0.54**	0.90	4.24	1.37
17. The possibility of experiencing mild side effects from the HIV vaccine being tested would make me...	0.47**	0.90	4.11	1.43
18. If transportation to and from the HIV vaccine trial site is expensive I would be...	0.49**	0.90	3.45	1.47
19. HIV vaccine researchers who are clearly trustworthy would make me...	0.36**	0.90	3.85	1.33
20. If I were to lose my job as a result of participating in an HIV vaccine trial I would be...	0.49**	0.90	3.17	1.39
21. Being tested for HIV by medically trained HIV vaccine researchers would make me...	0.47**	0.90	3.54	1.03
22. The possibility that my partner might leave me because of my participation in an HIV vaccine trial would make me...	0.58**	0.89	3.51	1.33

(Table continues); † Cronbach's alpha (α) if item deleted; **p < 0.01

(Continued)

Item	Item-total r	α -iid†	M	SD
23. The possibility that members of my church might react negatively to my participation in an HIV vaccine trial would make me...	0.54**	0.90	4.02	1.36
24. If other people thought I was HIV positive because of my participation in an HIV vaccine trial I would be...	0.59**	0.89	3.07	1.28
25. If my partner approved of my participation in an HIV vaccine trial I would be...	0.48**	0.90	3.79	1.34
26. Free transportation to and from the HIV vaccine trial site would make me...	0.39**	0.90	3.85	1.20
27. The possibility of becoming slightly ill from the HIV vaccine being tested would make me...	0.45**	0.90	3.37	1.48
28. If participating in an HIV vaccine trial fitted into my daily routine I would be...	0.46**	0.90	4.43	1.36
29. If HIV vaccine researchers participated in HIV vaccine trials themselves I would be...	0.50**	0.90	3.40	1.19
30. If I had a guarantee from HIV vaccine researchers that the HIV vaccine being tested is safe I would be...	0.51**	0.90	3.62	1.23
31. If my family reacted negatively to me because of my participation in an HIV vaccine trial I would be...	0.42**	0.90	4.08	1.32
32. Being questioned by HIV vaccine researchers about my sexual behaviour would make me...	0.43**	0.90	3.19	1.30
33. The possibility of receiving a placebo and not the HIV vaccine being tested makes me...	0.50**	0.90	4.43	1.57
34. If my community reacted negatively to me because of my participation in an HIV vaccine trial I would be...	0.51**	0.90	3.43	1.27

(Table continues); † Cronbach's alpha (α) if item deleted; **p < 0.01

(Continued)

Item	Item-total r	α -iid†	M	SD
35. The possibility that I may not benefit personally from participating in an HIV vaccine trial would make me...	0.45**	0.90	3.48	1.35

† Cronbach's alpha (α) if item deleted; **p < 0.01

4.5.1 Factor structure of the WTPS (Figure 5 and Table 6)

Based on an analysis of the scree plot (Figure 5 is presented on the next page) and Kaiser's (1960, 1974) criteria of eigenvalues greater than 1, seven factors were extracted accounting for 53.15% of the variance. The first factor, Social approval and trust, included four items and accounted for 23.87% of the variance in the model (eigenvalue = 8.35). The second factor, Stigmatisation, included five items and accounted for 10.21% of the variance in the model (eigenvalue = 3.57). The third factor, Personal costs, included four items and accounted for 4.80% of the variance in the model (eigenvalue = 1.68). The fourth factor, Personal gains, included five items and accounted for 4.08% of the variance in the model (eigenvalue = 1.42). The fifth factor, Personal risks, included four items and accounted for 3.51% of the variance in the model (eigenvalue = 1.23). The sixth factor, Convenience, included three items and accounted for 3.39% of the variance in the model (eigenvalue = 1.18). The seventh factor, Safety, included four items and accounted for 3.09% of the variance in the model (eigenvalue = 1.08) (Table 6 is presented on page 80).

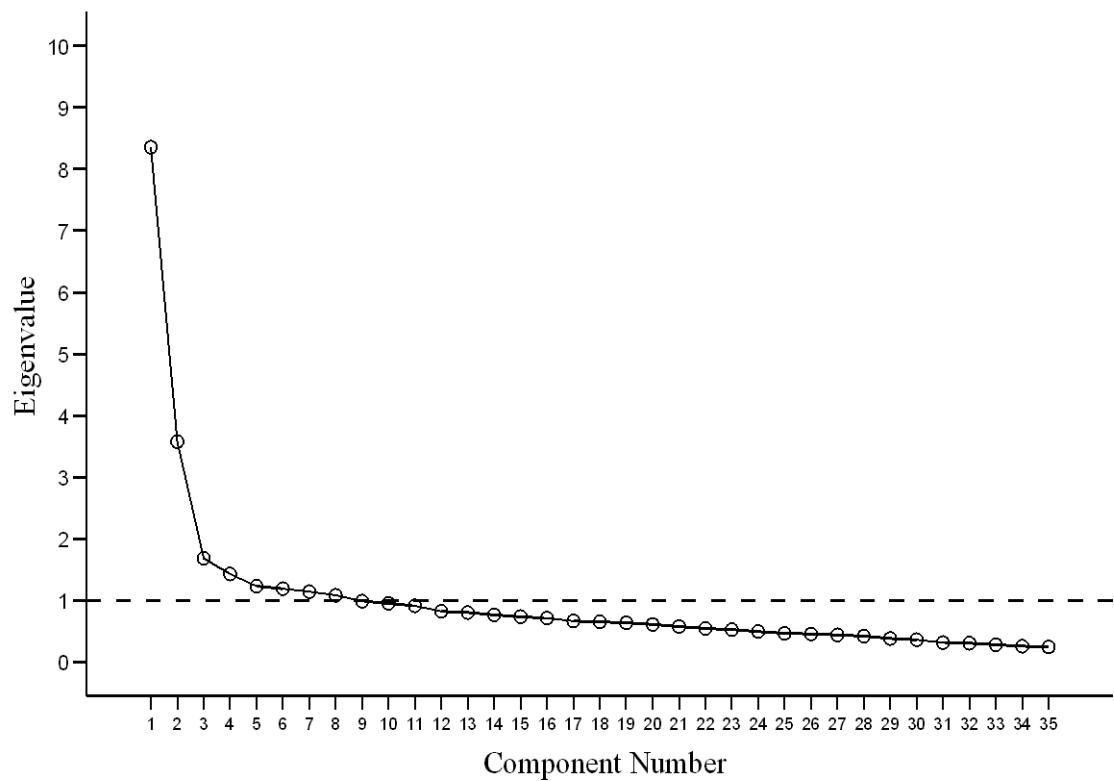


Figure 5. Scree plot of factors to be extracted (Eigenvalue ≥ 1)

Table 6

Principal Components Exploratory Factor Analysis of the WTPS

Item	Description	F1	F2	F3	F4	F5	F6	F7
9	Friends approval	0.79	0.04	-0.08	-0.00	0.01	0.08	-0.14
6	Seen as role model	0.58	-0.00	0.00	0.26	-0.08	0.02	0.08
10	My interests at heart	0.56	-0.08	0.07	0.07	-0.12	-0.02	0.25
11	Knowledge of vaccine shortcomings	0.48	-0.02	0.11	0.26	0.09	-0.05	0.06
13	Having time to participate	0.32	0.08	0.27	-0.07	0.20	0.16	0.23
34	Negative community reactions	0.18	0.76	-0.11	0.05	0.03	-0.10	-0.01
31	Negative family reactions	-0.05	0.73	-0.00	0.11	0.04	0.12	-0.28
23	Negative church reactions	-0.08	0.68	0.08	-0.02	0.03	0.05	0.16
24	Perception of being HIV positive	-0.00	0.67	0.10	0.07	-0.10	0.03	0.12
27	Becoming slightly ill	-0.11	0.51	0.20	-0.02	0.09	0.24	0.12
18	Transportation expenses	-0.09	-0.00	0.75	0.08	-0.06	0.12	-0.06
20	Lose job	0.01	0.13	0.71	-0.03	0.00	-0.04	-0.09
17	Mild side effects	0.07	0.00	0.63	0.10	0.12	-0.08	0.12
22	Partner might leave	0.09	0.38	0.48	-0.06	-0.16	-0.05	0.08
2	Side effects information	-0.00	0.11	0.04	0.78	-0.08	-0.11	0.00
3	Help stop AIDS	0.09	0.11	-0.06	0.73	0.01	0.12	-0.11
4	Free medical care	0.13	0.00	0.03	0.68	-0.04	0.02	-0.08
1	Knowing the benefits of vaccine	-0.01	-0.07	-0.12	0.64	0.07	-0.06	0.22
5	New experience	-0.05	-0.04	0.19	0.55	0.03	0.13	0.02
19	Trustworthy researchers	0.22	-0.00	0.21	0.16	-0.60	-0.03	0.16
12	Risk of HIV infection	0.15	0.10	0.25	0.08	0.58	-0.13	0.13
32	Questions about sexual behaviour	0.27	0.07	0.14	-0.03	-0.44	0.01	0.10
8	Falsely testing HIV positive	0.33	-0.01	0.35	-0.01	0.40	0.18	-0.07
15	Partner refuses sex	0.04	0.22	0.07	-0.13	0.39	-0.13	0.35
28	Fit into daily routine	-0.03	-0.00	0.15	-0.01	-0.01	0.72	0.05
26	Free transportation	0.08	0.10	-0.25	0.21	0.09	0.64	0.14
25	Partner approval	0.35	0.09	0.01	-0.07	-0.17	0.49	-0.02
35	May not benefit personally	-0.02	0.25	0.04	0.05	-0.01	0.03	0.00
33	Receiving a placebo	0.09	0.29	0.21	0.03	0.13	0.13	-0.16
7	Receiving monetary compensation	0.28	0.10	-0.10	0.16	-0.11	0.09	0.17
29	Participation by researchers	0.12	0.13	-0.14	0.01	-0.05	0.24	0.59
30	Vaccine guaranteed to be safe	0.11	0.11	-0.00	0.15	-0.23	0.20	0.51
21	Medically trained researchers	-0.15	-0.12	0.18	0.22	-0.13	0.23	0.46
16	Discrimination by others	0.08	0.39	0.15	-0.00	0.12	-0.26	0.45
14	Receiving injections	0.16	-0.19	0.12	0.13	0.14	0.13	0.35
Eigenvalue		8.35	3.57	1.68	1.42	1.23	1.18	1.14
Cumulative %		23.8	7	34.08	38.89	42.97	46.48	49.88
								53.15

F1 = Social approval and trust; F2 = Stigmatisation; F3 = Personal costs; F4 = Personal gains; F5 = Personal risks;
F6 = Convenience; F7 = Safety.

4.5.2 Exploratory factor analysis diagnostics

The Kaiser-Meyer-Olkin statistic, which provides an indication of the appropriateness of factor analysis, yielded a value of 0.86. According to Kaiser (1974), values greater than 0.5 are acceptable, values between 0.7 and 0.8 are good, and values exceeding 0.8 are excellent. As such, factor analysis was deemed to be appropriate. An examination of the inter-item correlation matrix showed that all the items were significantly correlated with one another indicating that no items were required to be deleted. Bartlett's test of sphericity was significant ($p < 0.001$) indicating that the inter-item correlation matrix was significantly different from an identity matrix. Regarding multicollinearity, an analysis of the determinant of the inter-item correlation matrix revealed that none of the items correlated excessively with one another ($r > 0.8$), again indicating that no items were required to be deleted.

4.6 Application and extension of the Theory of Planned Behavior

4.6.1 Two-step linear hierarchical multiple regression analysis (Table 7)

At step 1 of the analysis, attitudes, subjective norms, and perceived behavioural control, were entered simultaneously and significantly accounted for 6.4% ($R^2 = 0.06$, 95% CI 0.01-0.10) of the variance in WTP [$F(3, 316) = 7.16$, $p < 0.001$]. According to guidelines by Cohen (1988), the squared multiple correlation coefficient yielded a small effect size ($f^2 = 0.06$)³. At step 2 of the analysis, attitudes, subjective norms, perceived behavioural control, mistrust,

³ f^2 values of 0.02, 0.18, and 0.40 are considered small, medium, and large, respectively (Cohen, 1988).

knowledge, altruism, and perceived risk of HIV infection were entered simultaneously and significantly accounted for 10.2% ($R^2 = 0.10$, 95% CI: 0.06-0.13) of the variance in WTP [$F(7, 312) = 5.06$, $p < 0.001$]. According to guidelines by Cohen (1988), the squared multiple correlation coefficient yielded a small to medium effect size ($f^2 = 0.11$). At step one, subjective norms was the only significant predictor ($\beta = -0.23$, $t = -4.32$, $p < 0.01$). At step 2, significant predictors were subjective norms ($\beta = -0.19$, $t = -2.88$, $p < 0.01$), mistrust of researchers ($\beta = -0.14$, $t = 2.07$, $p < 0.05$), altruism ($\beta = 0.15$, $t = 2.14$, $p < 0.05$), and perceived risk of HIV infection ($\beta = 0.12$, $t = 2.17$, $p < 0.05$) (Table 7 is presented on the next page).

Table 7

Summary of Two-step Linear Hierarchical Multiple Regression Analysis for Variables Predicting WTP

Step and predictor variable	R ²	ΔR ²	B	SE	β	p	f ²
Step 1		0.06				0.00**	0.06
Attitude			0.09	0.13	0.04	0.45	
Subjective norms			-1.19	0.27	-0.23	0.00**	
Perceived behavioural control			-0.53	0.50	-0.05	0.28	
Step 2	0.10	0.03				0.00**	0.11
Attitude			0.18	0.13	0.07	0.16	
Subjective norms			-0.99	0.34	-0.19	0.00**	
Perceived behavioural control			-0.02	0.53	0.00	0.99	
Mistrust			-0.38	0.38	-0.14	0.04*	
Knowledge			0.45	0.38	0.06	0.24	
Altruism			0.61	0.42	0.15	0.03*	
Perceived risk			0.78	0.36	0.12	0.03*	

*p < 0.05; **p < 0.01; R² = Variance explained; ΔR² = Change in variance explained; B = Unstandardised beta coefficient; SE = Standard error for unstandardised beta coefficient; β = Standardised beta coefficient; f² = Cohen's effect size measure for the squared multiple correlation coefficient.

4.6.2 Regression diagnostics (Figure 6 and Figure 7)

The Kolmogorov-Smirnov test of normality revealed that the distribution of standardised residuals was normally distributed [$D(319) = 0.47, p = 0.07$] (Figure 6 is presented below).

The Durbin-Watson statistic yielded a value of 2.05. The standardised residuals were therefore considered to be independent. Although boxplots revealed the presence of several outliers, no Cook's distances exceeded 1. As such, none of the outliers exerted undue influence over the regression model. Examination of the standardised residuals/ standardised predicted values plot showed that the assumptions of homoscedasticity and linearity were met (Figure 7 is presented on the next page). Finally, the VIF statistic yielded values well below 10 indicating that no significant multicollinearity between predictor variables was present.

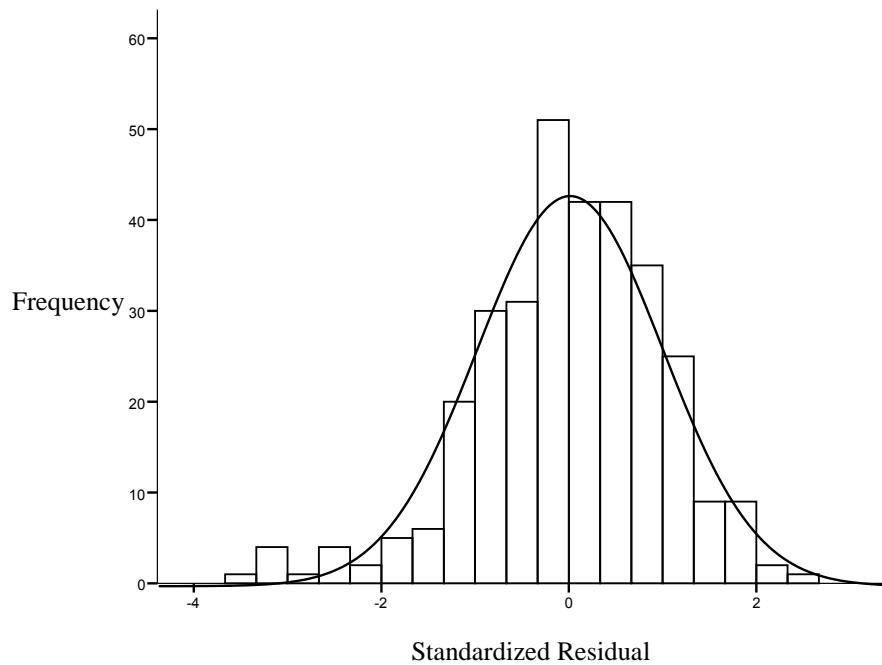


Figure 6. Histogram and normal probability plot of the standardised residuals.

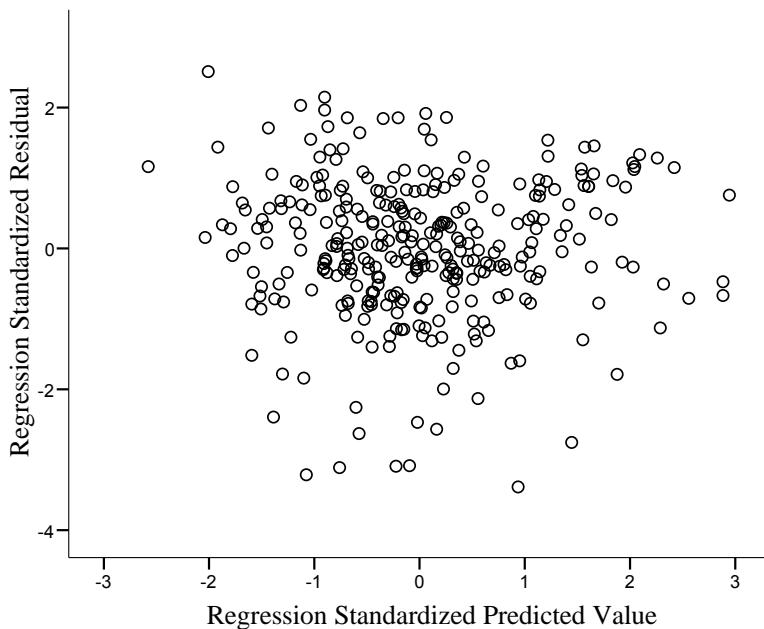


Figure 7. Standardised residuals/standardised predicted values plot

4.7 Summary of findings

The sample consisted mainly of disadvantaged Black females between the ages of 16 to 49 years. Independent samples t-tests revealed that participants who were more educated demonstrated a higher level of altruism and more positive attitudes towards trial participation than less educated participants. The WTPS demonstrated excellent internal consistency and an EFA revealed the presence of seven latent factors. The factors accounted for 53.15% of the variance in WTP and were: (i) Social approval and trust; (ii) Stigmatisation; (iii) Personal costs; (iv) Personal gains; (v) Personal risks; (vi) Convenience; and (vii) Safety. A two-step linear hierarchical multiple regression analysis showed that the linear combination of attitudes, subjective norms, and perceived behavioural control significantly accounted for

6.4% of the variance in WTP, yielding a small effect size. Moreover, the linear combination of attitudes, subjective norms, perceived behavioural control, mistrust, knowledge, altruism, and perceived risk of HIV infection significantly accounted for 10.2% of the variance in WTP, yielding a small to medium effect size. Subjective norms, mistrust of researchers, altruism, and perceived risk of HIV infection were significant independent predictors of WTP. A reduction in normative pressure and mistrust of researchers, and an increase in altruism and perceived risk of HIV infection were significantly associated with an increase in WTP.

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Introduction

According to the most recent data available on the prevalence and incidence of HIV (UNAIDS, 2007), South Africa continues to be the country with the largest number of HIV infections in the world. While various behaviour change initiatives have been implemented with the goal of reducing the spread of HIV/AIDS, these initiatives have been suboptimal as the pandemic shows no sign of abating (Sahay et al., 2005). As such, an HIV vaccine is likely to be an important development as a biological agent may circumvent some of the challenges of initiating widespread behaviour change. A challenge to the development of an efficacious vaccine, however, is the recruitment of several thousands of participants who need to be HIV negative but at high risk of HIV infection (Slack et al., 2005). There are therefore important ethical (Kerns, 1997; Lindegger & Richter, 2000; Lindegger et al., 2000) and sociobehavioural (Smit et al., 2005) issues need to be considered before large scale HIV vaccine trials can commence.

One of the key sociobehavioural issues concerns the willingness of individuals at high risk of HIV infection to participate in HIV vaccine trials. A review of the WTP literature revealed two important research needs. Firstly, a reliable and valid psychometric measure of WTP has not yet been developed. Secondly, there is a paucity of theory to guide studies of WTP. Accordingly, the first objective of this thesis was to construct a psychometric measure of

WTP, and to derive the exploratory factor structure of the measure. The second objective was to examine the extent to which the Theory of Planned Behavior (TPB) could predict variance in WTP, and to determine whether the TPB was strengthened by the inclusion of mistrust of researchers, knowledge of HIV vaccines and HIV vaccine trials, altruism, and perceived risk of HIV infection as additional predictor variables.

Results indicated that the Willingness to Participate Scale (WTPS) is a reliable measure of WTP among the most eligible Black individuals in the Western Cape of South Africa. The WTPS also displayed initial construct validity, as evidenced by the presence of seven latent factors that reflected various inhibitors and facilitators of WTP that have been identified in the literature. The factors accounted for 53.15% of the variance in WTP, and were: (i) Social approval and trust; (ii) Stigmatisation; (iii) Personal costs; (iv) Personal gains; (v) Personal risks; (vi) Convenience; and (vii) Safety.

Regarding the second objective, the linear combination of the TPB variables (attitudes, subjective norms, and perceived behavioural control) significantly accounted for 6.4% of the variance in WTP, yielding a small effect size. Furthermore, the linear combination of the TPB variables, together with mistrust of researchers, knowledge, altruism, and perceived risk of HIV infection significantly accounted for 10.2% of the variance in WTP, yielding a small to medium effect size. A reduction in normative pressure and mistrust of researchers, and an increase in altruism and perceived risk of HIV infection were significantly associated with an increase in WTP.

This chapter begins with a discussion of the study limitations, and an evaluation of the extent to which the sample represented the population of Masiphumelele residents. Thereafter, the factor structure of the WTPS is discussed and the applicability of the TPB in this context is examined. Finally, the conclusions drawn from this study are presented and implications for further research are considered.

5.2 Limitations of the study

The results of this study should be interpreted against the backdrop of several limitations. Firstly, the level of literacy among the participants was low. As such, there is doubt as to whether the participants completed the measures accurately. Low levels of literacy in developing country setting such as South Africa is a common hurdle for quantitative research projects which employ psychometric instruments (Foxcroft, 1997). Furthermore, cross-cultural translation and adaptation of psychometric instruments is fraught with methodological, conceptual, and linguistic difficulties (Beaton et al., 2000; Kulich et al., 2008; Van de Vijver & Hambleton, 1996). While every effort was made to ensure the validity of the translated questionnaires, it is possible that there may have been conceptual incongruence between some items.

In addition to issues of literacy and cross-cultural adaptation, the use of Western techniques of psychological testing is also politically-laden. According to Stead (2002, p. 87), “psychometric issues have figured prominently in debates on transformation in psychology as they were firmly embedded in western psychology and its related cultural assumptions”. The

problems with psychometric measures notwithstanding, anti-psychometric test lobbyists have yet to provide alternative methods of assessment (Stead, 2002). So while the use of questionnaires in developing country settings is admittedly problematic, there are no suitable alternatives as yet to assess relationships between variables in large samples of individuals.

Another limitation of the study is the possibility of systematic differences between those who made their way into the sample and those who did not. For example, it is possible that individuals who were unaware of the study, individuals who refused to participate, and individuals who were away at the time of questionnaire administration may have been systematically different to those who did participate. Similarly, there may also have been systematic differences between those who successfully completed the questionnaire packet ($n = 320$) and those that did not ($n = 79$). Participants who did not complete the questionnaire successfully may have had time constraints or lower levels of literacy than those who did successfully complete the questionnaire. A possible cause of the large number of poorly completed questionnaire packets is the fact that it was protracted, owing to the many variables that were measured. Questionnaire fatigue may also have prevented participants from completing the final items in the questionnaire accurately. Finally, it is possible that the results may have been confounded by social desirability bias and demand characteristics, given that the study was about the willingness of individuals to help others.

5.3 The representativeness of the sample

As this study employed a convenience sampling procedure, there is doubt as to whether the sample is representative of the population of Masiphumelele residents. To gauge the generalisability of the results of this study, I compared the demographic characteristics of the sample to the demographic make-up of Masiphumelele according to the most recent South African census data (Statistics South Africa [SSA], 2001). In some ways the sample adequately represented the population of Masiphumelele. For example, census data showed that 97.1% of the Masiphumelele residents in 2001 were Black individuals and 91.5% spoke Xhosa as a first language. In the sample, 100% were Black individuals and 98.1% spoke Xhosa as a first language. Regarding the educational level of the population according to the census data, 5.4% reported no formal education, 27.1% had attended and completed primary school, 45.1% had attended high school but did not complete matric, 18.9% had completed matric, and 0.7% had received higher education. Similar proportions were observed in the sample, as 6.3% reported no formal education, 33.1% had completed primary school, 42.2% had attended high school but did not complete matric, 16.3% had completed matric, and 0.6% had received higher education.

Nonetheless, there was divergence between the sample and the population in terms of age, gender proportions, and unemployment levels. Regarding age, census data show that 64.5% of the population were between the ages of 18 and 54 in 2001. In the sample however, a much larger proportion of individuals were from a similar age cohort (92.2% were between the ages of 16 and 49 years). The larger proportion of individuals between late teens and middle-age

suggests that the sample may not be representative of the population in terms of age. However, there is a major benefit to having over-sampled this age cohort: South Africans between the ages of 15 and 49 years are at highest risk of HIV infection (Shisana et al., 2005; UNAIDS, 2007). This cohort will therefore be most eligible to participate in an HIV vaccine trial. It might therefore be more of a strength than a weakness that the results of this study apply more acutely to individuals between late teens and middle age.

Regarding gender, half of the population (50.4%) were male according to the census data but only 10.3% were male in the sample. The under-representation of males in this study means that differences between men and women on the dependent variables could not be established.

Also, the results of this study may not be generalisable to the population of men in Masiphumelele. Even so, there are some benefits to having over-sampled women. For example, women in sub-Saharan Africa carry a disproportionately large burden of the disease (UNAIDS, 2007). Various factors, both biological and socioeconomic, have contributed to this skew. Biologically, the susceptibility of the vaginal tract makes women more likely than men to contract HIV during unprotected sexual intercourse (Wassenaar et al., 2005).

Additionally, STDs are more likely to be asymptomatic in women than in men, which increases women's risk of HIV infection (Wilkinson et al., 1999). Finally, the practice of 'dry sex', or sex where vaginal lubrication is impeded, can lead to increased tearing of the vaginal membranes resulting in an increased risk of HIV infection (Bass & Jefferys, 2001).

Socioeconomically, South Africa women experience high levels of gender inequality and intimate partner violence (Mills et al., 2006a). These factors in turn have both been shown to be important determinants of women's HIV risk after controlling for age, current relationship

status, and woman's HIV-risk behaviour (Dunkle et al., 2004). In addition to gender inequality, many women are reliant on men for economic subsistence (Basuki et al., 2002). These factors together make it very difficult for women to negotiate condom use with their partners (Fassin & Schneider, 2003). For these reasons, it is important to understand the barriers and facilitators of WTP among women more specifically if they are to benefit from the development of an HIV vaccine. The over-representation of women in this study may therefore be a positive aspect of the study rather than a limitation.

Regarding levels of unemployment, census data suggest that 58.9% of the population of Masiphumelele residents in 2001 were unemployed. In the sample however, 76.3% reported being unemployed. The difference may indicate an increase in unemployment in the period between 2001 and 2006 when the data for this study were collected. Alternatively, residents who were employed may have been under-represented. This possibility is likely as I collected data during office hours when employed individuals were at work. Considering that the poor bear the brunt of the HIV pandemic (Gilbert & Walker, 2002), it may be beneficial that the unemployed be more acutely represented in this study.

In sum then, the sample seemed to represent the population of Masiphumelele in terms of ethnicity, predominant language spoken, and educational level. However, the sample over-represented women, the unemployed, and those between late teens and middle age. Considering that Black women between the ages of 15 and 49 years who reside in urban informal settlements are at highest risk of HIV infection in South Africa, the skew in the sample may actually be beneficial rather than problematic. The results of this study are

thought to be generalisable to the most eligible Black HIV vaccine trial participants in the Western Cape of South Africa.

5.4 Factor structure of the WTPS

The factor structure of the WTPS was very difficult to interpret. The latent constructs that the factors represented were somewhat tricky to identify and name, and several factors seemed to overlap substantially. It is therefore paramount that future research be done to confirm the factor structure of the WTPS in a similar sample. Each of the factors is discussed in turn.

5.4.1 Social approval and trust

This factor was complex, as items measuring two seemingly independent dimensions of WTP loaded onto the same factor. The first dimension of the factor reflected participants' desire to receive social rewards for participating in an HIV vaccine trial, such as approval from friends and being considered a role model to others. The second dimension reflected participants' concerns over the trustworthiness of HIV vaccine researchers. Areas of concern were the extent to which vaccine researchers have trial participants' interests at heart, and being made aware of the possible shortcomings of a candidate HIV vaccine.

In the first Phase of this study, participants indicated that they would be more likely to participate if their families and community reacted positively towards their decision to participate (Swartz et al., 2006). Similarly, Jenkins et al. (2000) found that recognition from

family and friends was an important facilitator of WTP among Royal Thai army conscripted recruits. With regard to participation in clinical trials generally, the desire for approval from others has been shown to be a facilitator of enrolment. For example, Ross et al. (1999) conducted a systematic review of peer-reviewed research articles reporting barriers to participation in randomised controlled trials. They found that five peer-reviewed research papers reported that a lack of social rewards and recognition was a significant inhibitor of clinical trial enrolment.

Regarding the second dimension of this factor, participants expressed concern over the trustworthiness of HIV vaccine researchers. Areas of concern included the extent to which vaccine researchers have trial participants' interests at heart, and the degree to which researchers will communicate possible shortcomings of a candidate HIV vaccine. Mistrust of medical researchers, drug companies, and governmental organisations has been frequently reported to be an inhibitor of WTP in an HIV vaccine trial among both Whites and Blacks from developing and developed countries alike (Braunstein et al., 2008; Sengupta et al., 2000). This issue will be discussed at greater length later on in the chapter.

As mentioned previously, the factor 'Social approval and trust' seems to be factorially complex as two seemingly independent dimensions of WTP loaded together. It is conceivable that the participants in this study considered participating in an HIV vaccine trial an opportunity to show bravery by assisting potentially untrustworthy researchers. In return for their bravery, family members and members of the community may praise the individual who

in turn may be considered to be a role model to others. This hypothesis is purely speculative, however, and requires further research.

5.4.2 Stigmatisation

This factor reflected participants' concern regarding the possibility of being stigmatised and discriminated against by others as a result of participating in an HIV vaccine trial. The fear of negative social consequences as a consequence of participating in an HIV vaccine trial has been reported to be a significant inhibitor of WTP in both Western and non-Western contexts. In a study that assessed reports of trial-related discrimination among 1516 US trial participants, 57.8% reported negative reactions from friends, family and co-workers following self-disclosure of trial participation (Allen et al., 2001). The researchers reported that a common reason for the negative social reactions was concern that the candidate vaccine may have deleterious health outcomes for trial participants. Participants also reported experiencing negative social reactions due to the assumption that participants in HIV vaccine trials are infected with HIV, or are at risk of becoming infected with HIV. Additionally, participants reported experiencing stigma as a result of vaccine-induced seropositivity. Problems experienced in this regard may relate to difficulty obtaining health or life insurance, restrictions on trial participants' ability to travel abroad, being unable to donate blood, being overlooked by potential employers, and being disallowed to serve in the military (McCluskey et al., 2005).

Similar findings were reported by Sheon, Wagner, McElrath, Keefer, and Zimmerman (1998), who examined self-reported discrimination among 266 vaccine trial participants enrolled in an HIV vaccine trial in the US. Almost all of the participants (99%) reported some form of discrimination related to their participation in an HIV vaccine trial. The most common cause of negative social reactions was reported to be assumption that participants in HIV vaccine trials are infected with HIV. Some participants also reported experiencing employment problems and having applications for health and life insurance declined. While comparable results have been found in the South African context (Lesch et al., 2006; Giocos et al., 2007; Parker, 2005; Swartz et al., 2006), there is the possibility that social harms associated with participation in South African HIV vaccine trials could also manifest in domestic violence (Milford et al., 2007). As such, stigmatisation in the South African context could pose a unique problem to HIV vaccine researchers.

5.4.3 Personal costs

This factor reflected the participants' concerns over health, financial, and interpersonal costs associated with participation in an HIV vaccine trial. With regard to health costs, participants expressed concern over possible HIV vaccine physical side-effects. Fear of vaccine side effects was also found in Part I of this study, and is concern that has been frequently voiced by potential trial participants all over the world (Mills et al., 2004, 2006b). For example, a study of gay and bisexual men in the US found that 28% of the participants cited fear of physical side-effects as an inhibitor of WTP (Hays & Kegeles, 1999). Fear of possible vaccine side-effects was also reported to be an inhibitor of WTP among a large sample of IDUs and

MSM in the US (Strauss et al., 2001). A study that examined reasons for declining to enrol among persons eligible for a Phase II prophylactic HIV vaccine trial yielded similar results (Newman, Daley, Halpenny, & Loutfy, 2008). The researchers found that behind the fear of vaccine-induced seropositivity, fear of potential long-term side-effects was the most important reason for declining to participate. In another US study, researchers found that the fear of physical side-effects was a salient concern among their sample of Latinos and Blacks (Newman et al., 2006).

With regard to financial costs associated with participation in an HIV vaccine trial, participants indicated that transport costs associated with regular clinic visits would be a significant financial burden. In addition, participants were concerned about the perceived possibility that participating in an HIV vaccine trial may result in their losing their jobs. These findings have been widely reported among poor individuals in both developing and developed country contexts (Nyamathi et al., 2004; Sengupta et al., 2000; Swartz et al., 2006). As such, remuneration for transport costs has been a long-standing ethical guideline for HIV vaccine trial researchers.

Regarding interpersonal costs, participants expressed concern that their sexual relationship(s) might be strained as their sexual partner(s) might refuse to engage in sex should they participate in an HIV vaccine trial. A further concern for the participants in this study was the possibility that their sexual partner(s) may leave for fear of being at increased risk of HIV infection. The fear of possible strained sexual relationships has commonly been reported to be a robust inhibitor of WTP (Mills et al. 2004; 2006b). Celentano et al. (1995) examined WTP,

perceived benefits, and perceived barriers to enrolment in HIV vaccine trials among participants at high risk of HIV infection in northern Thailand. The researchers found that approximately 36.5% of the participants were fearful that their sexual partner(s) might refuse sexual intercourse should they participate in an HIV vaccine trial. A similar finding was reported by Sahay et al. (2005) in their study of 349 Indian respondents of lower socio-economic status at low and high risk for HIV infection. These findings are also congruent with those of Part I of this study (Swartz et al., 2006).

5.4.4 Personal gains

Personal gains reflected the participants' desire to benefit personally from participating in an HIV vaccine trial. Perceived benefits included receiving free medical care, and the attainment of information regarding the development of candidate HIV vaccines. The provision of free medical care has been widely reported to be a significant facilitator of WTP (Kerns, 1997; McGrath et al., 2001; Parker, 2005). However, cost-free treatment is a controversial ethical issue. In developing countries such as South Africa, free medical care might be a gross incentive for impoverished individuals who do not understand that treatment will be provided for trial-related ill health only (Moodley et al., 2002; Slack et al., 2000, 2005). Therefore, a central issue relating to the recruitment of HIV vaccine trial volunteers is that of informed consent. According to Lindegger and Richter (2000), it is essential that vaccine trial volunteers fully comprehend several aspects of HIV vaccine trials, including the fact that they will only receive medication for trial-related illnesses.

Participants also expressed the desire to learn more about HIV vaccines. This finding has been widely reported in previous research. In a study that examined specific features of vaccine trial designs that might encourage participation among 73 MSM in the US, participants who expressed WTP indicated that they would like to learn more about HIV vaccines (McGrath et al., 2001). The desire to become more knowledgeable of HIV vaccines has also been reported by studies of lower-socioeconomic Black South Africans (Parker, 2005; Swartz et al., 2006). From the perspective of trial participants, it is possible that they wish to be informed of the workings of a candidate HIV vaccine in order to understand the potential health risks associated with participating in an HIV vaccine trial. From the perspective of HIV vaccine researchers, such knowledge is also a requirement for informed consent (Kerns, 1997; Lindegger & Richter, 2000; Lindegger, Slack, & Vardas, 2000).

5.4.5 Personal risks

This factor reflected participants' perceived personal risks associated with participating in an HIV vaccine trial. Perceived risks included possibly contracting HIV from a candidate vaccine, and testing positive for HIV antibodies after receiving a candidate HIV vaccine. Participants were also concerned that providing intimate details of their sexual behaviour may be risky, as such information might be disclosed to others. The finding that eligible participants fear vaccine-induced HIV infection has been frequently reported by researchers in the US (Bartholow et al., 1997; Nyamathi et al., 2004), Thailand (Celentano et al., 1995), and South Africa (Parker, 2005; Swartz et al., 2006). The fear of contracting HIV from a vaccine has been reported to inhibit WTP among potential trial participants after even after they have

undergone educational workshops which deal with the issue of vaccine-induced infection (e.g.: Koblin et al., 2000). It is possible that potential participants simply do not understand the science behind how a vaccine operates, and therefore become fearful upon hearing that actual HI viruses are used in the making of an HIV vaccine (Leach & Fairhead, 2007). Alternatively, individuals might feel that there is a possibility that scientists are downright wrong, and that an HIV vaccine can in fact cause HIV infection. Researchers should aim to tests these hypotheses in future research.

The finding that eligible participants fear the possibility of testing positive for HIV antibodies has also been well documented in both developing and developed contexts (Buchbinder et al., 2004; Hays & Kegeles, 1999; Jenkins et al., 2000). As mentioned previously, testing positive for HIV antibodies after receiving a candidate vaccine is a result of the body's response to the vaccine and not to HIV (Slack et al., 2000, 2005). As such, the participants' perceived risk of vaccine-induced seropositivity and infection may be a function of low levels of knowledge of HIV vaccines. In the US, Newman et al. (2007) found that participants who reported to be fearful of vaccine-induced infection or seroconversion demonstrated poor knowledge of HIV vaccines and HIV vaccine trials. Similar results were reported by Yang et al. (2004) in a study that examined correlates of WTP in HIV/STD prevention intervention activities among 4,208 migrants in China.

The participants in this study stated that providing details of their sexual behaviour might entail a degree of risk, as intimate details may be disclosed to others. McCluskey et al. (2005) and Swartz et al. (2006) reported similar results. According to Mills et al. (2006b),

dissemination of intimate details may have deleterious effects on participants' lives, as employment opportunities, family relations, and social acceptance may be compromised. HIV vaccine researchers should therefore take great measures to protect confidentiality and develop trusting relationships with potential trial participants.

5.4.6 Convenience

This factor highlighted the participants' need for participating in an HIV trial to be convenient. Participants indicated that they would be less willing to enroll if a vaccine trial if participating will be time-consuming. Participants also reported the need for participating in an HIV vaccine trial to fit into their daily routines. These needs have been commonly reported in literature. According to Buchbinder et al. (2004), pragmatic obstacles are the most underestimated factor limiting potential participation in an HIV vaccine trial. In their study, which compared hypothetical and actual willingness to enroll in an HIV vaccine trial, 21% of the participants declined to participate based on competing time demands. Similar results were reported by Sahay et al. (2005) in their Indian sample. In addition to time constraints, conflicting familial constraints (Parker, 2005; Sahay et al., 2005) have also been reported to be significant inconveniences that may inhibit WTP. It is therefore important that HIV vaccine trials be organised in such a manner that participating be as convenient as possible for participants. Participants in Part I of this study reported that they would be less inconvenienced if vaccine trial sites were near to their homes or places of work (Swartz et al., 2006).

5.4.7 Safety

This factor reflected the participants' concerns regarding possible dangers of a candidate vaccine, and social harms that may be incurred as a result of participating in an HIV vaccine trial. With regard to vaccine dangers, participants reported that they would feel safer if researchers guaranteed the safety of the candidate vaccine. This finding was also reported by Hays and Kegeles (1999) who found that participants in their sample of MSM expressed a lower level of WTP in the absence of assured vaccine safety by researchers. Participants in this study also reported that they would feel safer if medically-trained researchers administered the candidate vaccine, and if researchers were themselves participants. It is likely that participants would regard the participation of HIV vaccine researchers as evidence for the health safety of the candidate HIV vaccine (Swartz et al., 2006). Health concerns that have been reported previously include the fear of possible short and long term vaccine side-effects, disability, or death (Celentano et al., 1995). With regard to reproductive health concerns, Rudy et al. (2005) reported that the women in their sample were fearful that receiving a candidate HIV vaccine may result in difficulties conceiving children, and that the a candidate vaccine may have negative effects on a foetus.

Regarding social harms, participants expressed concern over possible stigma and discrimination from friends, family members, and the community at large as a result of their participation. This finding was also reported by Allen et al. (2001). Lesch et al. (2006) suggest that a major source of negative social reactions stems from the perception that HIV vaccine trial participants are infected with HIV, or may at least be at high risk of HIV

infection. Additionally, many people are unaware that testing positive for HIV antibodies during an HIV vaccine trial is a result of the body's response to the candidate HIV vaccine and not necessarily to HIV (Jenkins et al., 2000; Sahay et al., 2005; Sheon et al., 1998). In contexts such as South Africa where there are high levels of gender inequality, social harms may even manifest in domestic violence (Milford et al., 2007). Possible social harms associated with participation in South African HIV vaccine trials should therefore be a key concern among vaccine researchers.

5.5 Application of the Theory of Planned Behavior

Results indicated that the theory performed sub-optimally, as little variance in WTP could be accounted for by the TPB variables. The performance of each TPB variable is discussed in turn.

5.5.1 Attitudes

The finding that attitudes towards participating in an HIV vaccine trial did not predict WTP is congruent with a study that examined the ability of the TPB to predict variance in WTP among 224 lower socioeconomic adolescents in South Africa (Giocos et al., 2007). As mentioned in Chapter 2, attitudes are thought to be influenced by behavioural beliefs regarding the behaviour. Research to date has provided empirical evidence for this assertion. For example, Armitage and Conner (1999b), who assessed the predictive validity and causal ordering of TPB constructs over a 3-month period, found that behavioural beliefs accounted

for up to 41% of the variance in attitudes. Considering that this study dealt with hypothetical WTP, it is conceivable that the participants may not yet have formulated behavioural beliefs regarding actual HIV vaccine trial participation. Furthermore, the potential lack of behavioural beliefs may be compounded by poor knowledge of HIV vaccine trials (Newman et al., 2007; Strauss et al., 2001; Yang et al., 2004).

Despite the possibility that the participants in this study may not yet have formulated behavioural beliefs regarding participating in an HIV vaccine trial, Eiser (1994) argues that behavioural beliefs change over time according to the salience of the behaviour. Therefore, as HIV vaccine trials become more salient, and knowledge regarding HIV vaccines and HIV vaccine trials improves, it is possible that beliefs concerning participating may be developed. Consequently, attitudes towards participating may in future become crystallised among eligible participants. Future researchers should therefore re-evaluate the utility of the attitudes construct once HIV vaccine trials become more salient in South Africa.

5.5.2 Subjective norms

Subjective norms was the only independent TPB variable that significantly predicted WTP. This finding was also reported by Giocos et al. (2007) in their study of WTP among South African adolescents. A number of meta-analyses that have examined the efficacy of the TPB have concluded that subjective norms may be the weakest predictor of behavioural intentions (Godin & Kok, 1996; Sheppard, Hartwick, & Warshaw, 1988; Van den Putte; 1991). Some researchers have even advocated the exclusion of subjective norms altogether (Armitage &

Conner, 2001). The finding that perceived normative pressure was not only a robust predictor of WTP, but was the only significant predictor of WTP in this study and another South African study (Giocos et al., 2007) contradicts the results of the meta-analyses. Considering that the studies that were evaluated in the meta-analyses assessed the utility of the TPB in Western samples, the divergent findings may be a function of social and economic well-being. Alternatively, the divergent findings may be accounted for by different conceptions of selves and others between the West and the non-West.

As mentioned previously, individuality is a primary objective in Western cultures where the ‘self’ is separate from the ‘other’ (Cialdini et al., 1997; Moodley, 2005). The result is decision-making that is largely independent of the beliefs, values, and desires of others. In non-Western settings like South Africa however, the definition of ‘self’ is more fluid and transcends the boundaries of the individual body. Therefore, the decision to engage in a particular behaviour is principally influenced by the beliefs and attitudes of others towards that behaviour. Future research should aim to replicate this finding so as to evidence this argument.

5.5.3 Perceived behavioural control

Results indicated that perceived behavioural control did not predict WTP. Similar results were found by Giocos et al. (2007). As no large scale HIV vaccine trials were yet underway in South Africa at the time of this study, the participants would not have had prior experience with HIV vaccine trials. Given that prior experience is an important component of perceived

behavioural control, it is conceivable that the lack of experience may have contributed to the variable's failure to predict WTP. Another important component of perceived behavioural control is an evaluation of one's capacity to engage in a behaviour based on observing the experiences of salient others (Ajzen, 1988). As this study focused on hypothetical WTP only, the participants may not have explored issues of self-efficacy and control over trial participation. In addition to a lack of prior experience and social learning, it likely that the participants may not have been knowledgeable enough regarding the requirements of HIV vaccine trials to have considered issues of control over participating (Giocos et al., 2007). When HIV vaccine trials become more salient, and eligible participants become more knowledgeable of HIV vaccines and HIV vaccine trials, perceived behavioural control may in future predict WTP.

5.6 Extension of the Theory of Planned Behavior

Results indicated that the linear combination of TPB variables (attitudes, subjective norms, and perceived behavioural control), together with the additional predictor variables significantly increased the amount of variance explained from 6.4% to 10.2%. However, the squared multiple correlation coefficient yielded a small to medium effect size. As with the first model that tested the linear combination of TPB variables exclusively, subjective norms was the only TPB variable that significantly predicted WTP. Regarding the additional predictor variables, mistrust of researchers, altruism, and perceived risk of HIV infection were significant independent predictors. Each variable is discussed in turn.

5.6.1 Mistrust of researchers

Results indicated that mistrust of researchers was a significant inhibitor of WTP in an HIV vaccine trial. This finding is congruent with those of previous studies in developed countries (Braunstein et al., 2008; Hays & Kegeles, 1999; Newman et al., 2006; Sengupta et al., 2000; Shavers et al., 2002) and in South Africa (Parker, 2005; Swartz et al., 2006). In the South African context, it is likely that high levels of mistrust of researchers may stem from memories of human rights violations during the colonial and apartheid years (Boone & Batsell, 2001; Nichter, 1995). In those periods, Blacks were exploited by white researchers as a result of their obvious vulnerability (Barsdorf & Wassenaar, 2005). It therefore follows that eligible Black HIV vaccine trial participants may be mistrustful of HIV vaccine researchers and powerful, White-controlled pharmaceutical companies (Baldwin–Ragaven et al., 1999). According to Nichter (1995), many Black Africans feel that Africa has been used as a laboratory for testing Western medicines; to the detriment of Blacks who do not benefit from the fruits of the clinical trials in which they participated.

There is also scepticism and opposition to Western medicines such as vaccines (Leach & Fairhead, 2007). According to Ross et al. (2006), many Black Africans continue to believe Western HIV ‘medicines’ are merely a hidden political conspiracy to control the birth rates of Blacks, thereby allowing Whites to regain political control. Concerns over Western medicines have not been confined to the general public. Political leaders such as South African president Thabo Mbeki and Zimbabwean president Robert Mugabe have publicly stated that AIDS is not as big a problem as the West makes it out to be, and that HIV antiretroviral drugs are a

Western initiative to undermine African autonomy, traditional values, and cultural practices (Fassin & Schneider, 2003). Research also suggests that many Blacks, from both the US and Africa, believe that an efficacious vaccine has already been developed but is being kept from them (Allen et al., 2005). To ameliorate the high levels of mistrust among Black individuals, it is imperative that researchers develop trusting relationships with eligible Black participants. A failure to do so may result in lower WTP among eligible trial participants in South Africa.

5.6.2 Knowledge of HIV vaccines and HIV vaccine trials

Previous research findings suggest that a low level of knowledge of HIV vaccines and HIV vaccine trials may be an important inhibitor of WTP (e.g.: Strauss et al., 2001; Starace et al., 2006). In contrast with these findings, this study found that knowledge was not a significant predictor of WTP. Similar results were found by Halpern et al. (2001) in their study of 610 Philadelphia residents at high risk for HIV infection. It is possible that other concerns and issues relating to HIV vaccine trial participation may have been salient for the participants in this study. For example, latent factors that emerged from the WTPS included concerns over possible negative social consequences, potential personal costs and risks, and issues of convenience. Another possible reason for the null finding may be that the distribution of knowledge scores was significantly negatively skewed. The negative skewness indicated a ceiling effect, whereby most participants scored on the upper end of the spectrum of overall knowledge scores. The grouping of scores at the positive end of the continuum suggests that variance may have been artificially constrained, limiting power to detect significant effects.

5.6.3 Altruism

Results indicated that altruism was a significant predictor of WTP in an HIV vaccine trial. This finding is congruent with previous research findings from the US (Buchbinder et al., 2004; Nyamathi et al. (2004), Thailand (Jenkins et al., 2000; MacQueen et al., 1999), Brazil (Périssé et al., 2000), India (Sahay et al., 2005) and South Africa (Parker, 2005; Swartz et al., 2006). Swartz et al. (2006) suggest that an altruistic desire to participate may be related to a high level of exposure to the deleterious effects of HIV. Considering that the prevalence of HIV is higher in South African informal settlements than anywhere else in the world (UNAIDS, 2007), exposure to HIV is potentially a useful variable to examine in future research involving South African samples. However, the question arises as to whether exposure to HIV results in a truly selfless desire to help those afflicted by the disease, or an egoistic desire to reduce aversive arousal evoked by seeing others dying from AIDS. One possible way of understanding altruism in African contexts is in terms of Ubuntu. As discussed previously, Ubuntu is an African philosophy whereby the common good of society comes before the good of any one individual (Venter, 2004). In such a case, an appeal to Ubuntu may increase the level of WTP among eligible South African participants (Moodley, 2005). This is a tentative statement however, as it goes beyond the data of this study.

5.6.4 Perceived risk of HIV infection

Participants who perceived themselves to be at high risk of HIV infection expressed a higher level of WTP in an HIV vaccine trial. This finding supports those of previous studies in both

US and South Africa. A longitudinal study by Bartholow et al. (1997) assessed changing WTP over an 18 month period among 1267 MSM in the US. A perception of being highly susceptible to HIV infection was significantly associated with WTP at each assessment over the period of the study. In another US study mentioned previously, researchers compared hypothetical and actual willingness to enrol in a prophylactic HIV vaccine trial among participants previously enrolled in an HIV vaccine preparedness study (Buchbinder et al., 2004). Participants who reported having at least five sexual partners in the previous six months expressed greater WTP in a future HIV vaccine trial. In South Africa, Smit et al. (2005) examined WTP among 198 individuals from an urban-informal community directly after their enrolment into an HIV vaccine preparedness study. Results indicated that WTP was significantly associated with self-perceived HIV risk.

According to Swartz et al. (2006), many potential trial participants consider participating in an HIV vaccine trial an opportunity to become protected from HIV infection. Participants expressed the belief that a candidate HIV vaccine will certainly demonstrate efficacy and, as such, will guard against HIV infection. Participants in this study who considered themselves to be at high risk for HIV infection may have expressed WTP for this reason. Also, participants who perceived themselves to be at high risk of HIV infection may have expressed WTP so as to protect their sexual partner(s) from HIV infection (McGrath et al., 2001). As a candidate HIV vaccine may not necessarily provide protection from HIV infection, it is important that willing participants demonstrate adequate knowledge of HIV vaccines and HIV vaccine trials before they may be enrolled.

5.7 Conclusions

Against the backdrop of the study limitations, this study yielded the first multidimensional measure of WTP in an HIV vaccine trial: the Willingness to Participate Scale (WTPS). Results suggest that the WTPS is a reliable measure of WTP among Black individuals in the Western Cape of South Africa who will be most eligible to participate in future HIV vaccine trials. The WTPS also displayed initial construct validity, as evidenced by the presence of seven latent factors that reflected inhibitors and facilitators of WTP that have been identified in the literature. This study also showed that the Theory of Planned Behavior (TPB) may not be a suitable theoretical framework for studying WTP in an HIV vaccine trial at this point in time. Finally, mistrust of researchers, altruism, and perceived risk of HIV infection were shown to be significant independent predictors of WTP among the population of interest. As these variables have also been shown to predict WTP in other contexts around the world, it seems that they may be universal predictors. While further research is required to evidence this statement, the identification of robust predictors may enable researchers to develop effective recruitment strategies that lead to sufficient numbers of trial participants, and ensure that trials are conducted in an ethical manner.

The results of this study point to several areas that require further investigation. Future research should aim to validate the factor structure of the WTPS in both this and other samples. The large amount of unexplained variance in WTP after accounting for the effect of the TPB suggests that unmeasured variables are explaining much of the residual variance. These variables need to be identified and incorporated into a suitable theoretical

underpinning. A better understanding of complex variables such as knowledge of HIV vaccines and HIV vaccine trials may be achieved by examining their relationships with WTP over time. Longitudinal studies may also allow for an assessment of causal relationships if appropriate controls are in place. Finally, researchers should examine the relationship between witnessing the deleterious effects of HIV and WTP in an HIV vaccine trial.

REFERENCE LIST

Ajzen, I. (1985). From intentions to action: A theory of planned behavior. In J. Kuhl & J. Beckman (Eds.), *Action control: From cognitions to behaviors* (pp. 11–39). New York: Springer.

Ajzen, I. (1988). *Attitudes, personality and behavior*. Chicago: Dorsey.

Ajzen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes*, 50, 179-211.

Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. New Jersey: Prentice-Hall.

Albarracín, D., Johnson, B. T., Fishbein, M., & Muellerleile, P. A. (2001). Theories of Reasoned Action and Planned Behaviour as models of condom use: A meta-analysis. *Psychological Bulletin*, 127(1), 142-161.

Allen, M. A., Israel, H., Rybczyck, K., Pugliese, M. A., Loughran, K., Wagner, L., et al. (2001). Trial-related discrimination in HIV vaccine clinical trials. *AIDS Research and Human Retroviruses*, 17(8), 667-674.

Allen, M. A., Liang, T. S., La Salvia, T., Tjugum, B., Gulakowski, R. J., & Murguia, M. (2005). Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. *Journal of Acquired Immune Deficiency Syndromes*, 40(5), 617-624.

Armitage, C. J., & Conner, M. (1999b). The theory of planned behavior: Assessment of predictive validity and perceived control. *British Journal of Social Psychology*, 38, 35-54.

Armitage, C. J., & Conner, M. (2001). Efficacy of the Theory of Planned Behavior: A meta-analytic review. *British Journal of Social Psychology*, 40(4), 471-499.

Arndt, C., & Lewis, J. D. (2000). The macro implications of the HIV/AIDS pandemic: A preliminary assessment. *South African Journal of Economics*, 68(5), 856-887.

Bachmann, M. O., & Booysen, F. L. R. (2003). Health and economic impact of HIV/AIDS on South African households: A cohort study. *BMC Public Health*, 3(14), 1-8.

Baeten, J. M., Richardson, B. A., Martin, H. L., Nyange, P. M., Lavreys, L., & Ngugi, E. N. (2000). Trends in HIV-1 incidence in a cohort of prostitutes in Kenya: Implications for HIV-1 vaccine efficacy trials. *Journal of Acquired Immune Deficiency Syndrome*, 24, 458-464.

Baldwin-Ragaven, L., de Gruchy, J., & London, L. (1999). *An ambulance of the wrong colour: Health professionals, human rights and ethics in South Africa*. Cape Town: University of Cape Town Press.

Bank, L. (2001). Living together, moving apart: Home-made agendas, identity politics and urban-rural linkages in the Eastern Cape, South Africa. *Journal of Contemporary African Studies*, 19(1), 129-147.

Baron, R. A., & Byrne, D. (2000). *Social psychology*. Boston: Allyn & Bacon.

Barsdorf, N. W., & Wassenaar, D. R. (2005). Racial differences in public perceptions of voluntariness of medical research participants. *Social Science and Medicine*, 60(5), 1087-1098.

Bartholow, B. N., MacQueen, K. M., Douglas, J. M., Buchbinder, S., McKirnan, D., & Judson, F. N. (1997). Assessment of the changing willingness to participate in Phase III HIV vaccine trials among men who have sex with men. *Journal of Acquired Immune Deficiency Syndromes*, 16(2), 108-115.

Bass, E., & Jefferys, R. (2001). Women and HIV in Kenya: An interview with Dorothy Mbori-Ngacha. *International AIDS Vaccine Initiative [IAVI] Report*, 5(8), 7-14.

Basuki, E., Wolffers, I., Deville, W., Erlaini, N., Luhpuri, D., Hargono, R., et al. (2002).

Reasons for not using condoms among female sex workers in Indonesia. *AIDS Education and Prevention*, 14(2), 102–116.

Batson, C. D. (1991). *The altruism question: Toward a social-psychological answer*.

Hillsdale: Erlbaum.

Batson, C. D. (1995). Prosocial motivation: Why do we help others? In A. Tesser (Ed.),

Advanced social psychology (pp. 333-381). New York: McGraw-Hill.

Beaton, D. E., Bombardier, C., Guillemain, F., Ferraz, M.B. (2000). Guidelines for the process

of cross-cultural adaptation of self-report measures. *Spine*, 25(24), 3186-3191.

Bless, C., Higson-Smith, C., & Kagee, A. (2006). *Fundamentals of social research methods: An African perspective* (4th ed.). Cape Town: Juta.

Boily, M. C., Masse, B. R., Desai, K., Alary, M., & Anderson, R. M. (1999). Some important

issues in the planning of Phase III HIV vaccine efficacy trials. *Vaccine*, 17, 989-1004.

Boone, C., & Batsell, J. (2001). Politics and AIDS in Africa: Research Agendas in Political

Science and International Relations. *Africa Today*, 48(2), 3-33.

Bozionelos, G., & Bennett, P. (1999). The theory of planned behaviour as predictor of exercise. *Journal of Health Psychology, 4*, 517–529.

Braunstein, J. B., Sherber, N. S., Schulman, S. P., Ding, E. L., & Powe, N. R. (2008). Race, medical researcher distrust, perceived harm and willingness to participate in cardiovascular prevention trials. *Medicine, 87*(1), 1-9.

Bryan, A., Kagee, A., & Broaddus, M. R. (2006). Condom use among South African adolescents: Developing and testing theoretical models of intentions and behaviour. *AIDS and Behavior, 10*(4), 387-397.

Bryant, F. B., & Yarnold, P. R. (1995). Principal-components analysis and exploratory and confirmatory factor analysis. In L.G. Grimm & P.R. Yarnold (Eds.). *Reading and understanding multivariate statistics*. Washington DC: American Psychological Association.

Buchbinder, S. P., Metch, B., Holte, S. E., Scheer, S., Coletti, A., & Vittinghof, E. (2004). Determinants of enrolment in a preventive HIV vaccine trial: Hypothetical versus actual willingness and barriers to participation. *Journal of Acquired Immune Deficiency Syndromes, 36*(1), 604-612.

Calnan, M. (1984). The health belief model and participation in programmes for the early detection of breast cancer: A comparative analysis. *Social Science and Medicine*, 19, 823-830.

Campbell, C. (2003). *Letting them die: How HIV/AIDS prevention programmes often fail*. Bloomington: Indiana University Press.

Celentano, D. D., Beyrer, C., Natpratan, C., Eiumtrakul, S., Sussman, L., Renzullo, P. O., et al. (1995). Willingness to participate in AIDS vaccine trials among high-risk populations in northern Thailand. *AIDS*, 9(9), 1079-1083.

Chesney, M. A., Chambers, D. B., & Kahn, J. O. (1997). Risk behaviour for HIV infection in participants in preventative HIV vaccine trials: A cautionary note. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 16, 266-271.

Cialdini, R., Brown, S., Lewis, B., Luce, C., & Neuberg, S. (1997). Reinterpretinting the empathy-altruism relationship: When one into one equals oneness. *Journal of Personality and Social Psychology*, 73, 481-494.

Clark, L. A., & Watson, D. (1995). Constructing validity: Basic issues in scale development. *Psychological Assessment*, 7, 309-319.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale: Erlbaum.

Comrey, A. L. (1988). Factor analytic methods of scale development in personality and clinical psychology. *Journal of Consulting and Clinical Psychology*, 56, 754-761.

Comrey, A. L., & Lee, H. B. (1992). *A first course in factor analysis* (2nd ed.). Hillsdale: Erlbaum.

Conner, M., Black, K., & Stratton, P. (1998). Understanding drug compliance in a psychiatric population: An application of The Theory of Planned Behavior. *Psychology, Health & Medicine*, 3(3), 337-345.

Conner, M., Graham, S., & Moore, B. (1999). Alcohol and intentions to use condoms: Applying the theory of planned behaviour. *Psychology and Health*, 14, 795– 812.

Cook, R. D., & Weisberg, S. (1982). *Residuals and influence in regression*. New York: Chapman & Hall.

DerSimonian, R., Charette, L. J., McPeek, B., & Mosteller, F. (1982). Reporting on methods in clinical trials. *New England Journal of Medicine*, 306, 1332-1337.

Des Jarlais, D. C., Marmor, M., Friedman, P., Titus, S., Aviles, E., Deren, S., et al. (2000). HIV incidence among injection drug users in New York City, 1992–1997: Evidence of a declining epidemic. *American Journal of Public Health*, 90, 352–359.

Dovidio, J. F., Allen, J., & Schroeder, D. A. (1990). The specificity of empathy-induced helping: Evidence for altruism. *Journal of Personality and Social Psychology, 59*, 249–260.

Dunkle, K. L., Jewkes, R. K., Brown, H. C., Gray, G. E., McIntryre, J. A., & Harlow, S. D. (2004). Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *Lancet, 363*, 1415-1421.

Fassin, D., & Schneider, H. (2003). The politics of AIDS in South Africa: Beyond the controversies. *British Medical Journal, 326*, 495-497.

Field, A. (2000). *Discovering statistics: Using SPSS for Windows*. London: Sage.

Field, A. (2005). *Discovering statistics: Using SPSS for Windows* (2nd ed.). London: Sage.

Fincham, D. S., Moosa, R., & Kagee, A. (2008). Dietary and fluid adherence among haemodialysis patients attending public sector hospitals in the Western Cape. *South African Journal of Clinical Nutrition, 21*(2), 7-12.

Floyd, D. L., Prentice-Dunn, S., & Rogers, R. W. (2000). A meta-analysis of research on Protection Motivation Theory. *Journal of Applied Social Psychology, 30*, 407–429.

Foxcroft, C. D. (1997). Psychological testing in South Africa: Perspectives regarding ethical and fair practices. *European Journal of Psychological Assessment, 13*, 229-235.

Francis, J. J., Eccles, M. P., Johnston, M., Walker, A., Grimshaw, J., Foy, R., et al. (2004).

Constructing questionnaires based on the Theory of Planned Behavior: A manual for health service researchers. Newcastle: University of Newcastle press.

Gagnon, M., & Godin, G. (2000). Young adults and HIV vaccine: Determinants of the intention of getting immunized. *Canadian Journal of Public Health, 91*(6), 432-434.

Gamble, V. N. (1997). Under the shadow of Tuskegee: African Americans and health care. *American Journal Public Health, 87*, 1773-1778.

Gilbert, L., & Walker, L. (2002). Treading the path of least resistance: HIV/AIDS and social inequalities: A South African case study. *Social Science & Medicine, 54*, 1093–1110.

Giocos, G., Kagee, A., & Swartz, L. (2007, August). Predicting hypothetical willingness to participate (WTP) in a future Phase III HIV vaccine trial among high risk adolescents. *AIDS and Behavior, 1090-7165*. Retrieved September 20, 2007, from
<http://www.springerlink.com/content/p620q60503w57154/>

Godin, G., & Kok, G. (1996). The theory of planned behavior: A review of its applications to health-related behaviors. *American Journal of Health Promotion, 11*, 87-98.

Golub, E. T., Purvis, L. A., Sapun, M., Safaeian, M., Beyer, C., Vlahov, D., et al. (2005).

Changes in willingness to participate in HIV vaccine trials among HIV-negative injection drug users. *AIDS and Behavior*, 9(3), 301-309.

Grinstead, O. A. (1995). Social and behavioural issues in Phase III HIV preventative vaccine trials. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*,

9, 30-35.

Hagger, M. S., Chatzisarantis, N., & Biddle, S. J. H. (2002b). The influence of autonomous

and controlling motives on physical activity intentions within the Theory of Planned Behavior. *British Journal of Health Psychology*, 7, 283–297.

Halpern, S. D., Karlawish, J. H., & Berlin, J. A. (2002). The continuing unethical conduct of

underpowered clinical trials. *The Journal of the American Medical Association*, 288(3), 358-362.

Halpern, S. D., Metzger, D. S., Berlin, J. A., & Ubel, P. A. (2001). Who will enroll?

Predicting participation in a Phase II AIDS vaccine trial. *Journal of Acquired Immune Deficiency Syndromes*, 27(3), 281-288.

Harrison, J. A., Mullen, P. D., & Green, L. W. (1992). A meta-analysis of studies of the

Health Belief Model. *Health Education Research*, 7, 107–116.

Hays, R. B., & Kegeles, S. M. (1999). Factors related to the willingness of young gay men to participate in preventive HIV vaccine trials. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 20(2), 164-171.

Hennessy, M., MacQueen, K., McKirnan, D. J., Buchbinder, S., Judson, F., Douglas, J. M., et al. (1996). A factorial survey study to assess the acceptability of HIV vaccine trial designs. *Controlled Clinical Trials*, 17, 209-220.

Herting, J. R., & Costner, H. L. (1985). Respecification in Multiple Indicator Models. In H.M. Blalock (Ed.), *Causal models in the social sciences* (2nd ed.). (pp. 321-393). New York: Aldine.

Hill, J. (1984). Human altruism and sociocultural fitness. *Journal of Social and Biological Structures*, 7, 17-35.

Hogg, M. A., & Cooper, J. (Eds.). (2003). *The Sage handbook of social psychology*. London: Sage.

Howell, D. (2008). The analysis of missing data. In W. Outhwaite & S. Turner (Eds.), *Handbook of Social Science Methodology*. London: Sage.

Janz, N. K., & Becker, M. H. (1984). The Health Belief Model: A decade later. *Health Education Quarterly*, 11(1), 1-47.

Jenkins, R. A., Chinaworapong, S., Morgan, P. A., Ruangyuttikarn, C., Sontirat, A., Chiu, J., et al. (1998). Motivation, recruitment, and screening of volunteers for a Phase I/II HIV preventative vaccine trial in Thailand. *Journal of Acquired Immune Deficiency Syndromes, 18*(2), 171-177.

Jenkins, R. A., Torugsa, K., Markowitz, L. E., Mason, C. J., Jamroentana, V., Brown, A. E., et al. (2000). Willingness to participate in HIV-1 vaccine trials among young Thai men. *Sexually Transmitted Infections, 76*, 386-392.

Kafaar, Z., Kagee, A., Lesch, A., & Swartz, L. (2007). Is participation in HIV vaccine trials a health-promoting behaviour? *AIDS Care, 19*(10), 1307-1309.

Kaiser, H. F. (1960). The application of electronic computers to factor analysis. *Educational and Psychological Measurement, 20*, 141-151.

Kaiser, H. F. (1974). An index of factorial simplicity. *Psychometrika, 39*(1), 31-36.

Kapoor, S. (2004, July). *Addressing barriers to women's enrolment in HIV vaccine trials.* Retrieved July 18, 2008, from

<http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102281221.html>

Kass, R. A., & Tinsley, H. E. A. (1979). Factor analysis. *Journal of Leisure Research, 11*, 120-138.

Kerns, T. A. (1997). *Ethical issues in HIV vaccine trials*. New York: St. Martins Press.

Klonoff, E. A., & Landrine, H. (1999). Do Blacks believe that HIV/AIDS is a government conspiracy against them? *Preventive Medicine*, 28, 451–457.

Koblin, B. A., Holte, S., Lenderking, B., & Heagerty, P. (2000). Readiness for HIV vaccine trials: Changes in willingness and knowledge among high-risk populations in the HIV network for prevention trials. *Journal of Acquired Immune Deficiency Syndromes*, 24(5), 451-457.

Krebs, D. L. (1987). Altruism and Egoism: A False Dichotomy? *Psychological Inquiry*, 2(2), 137-139.

Kulich, K. R., Madisch, A., Pacini, F., Piqué, J. M., Regula, J., Van Rensburg, C. J., et al. (2008, January). Reliability and validity of the Gastrointestinal Symptom Rating Scale (GSRS) and Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire in dyspepsia: A six-country study. *Health and Quality of Life Outcomes*. Retrieved June 6, 2008, from <http://www.hqlo.com/content/6/1/12>

Leach, M., & Fairhead, J. (2007). *Vaccine anxieties: global science, child health and society*. London: Earthscan Publications.

Lesch, A., Kafaar, Z., Kagee, A., & Swartz, L. (2006). Community members' perceptions of enablers and inhibitors to participation in HIV vaccine trials. *South African Journal of Psychology, 36*(4), 74-101.

Lindegger, G., Quayle, M., & Ndlovu, M. (2007). Local knowledge and experiences of vaccination: Implications for HIV-preventative vaccine trials in South Africa. *Health Education & Behavior, 34*(1), 108-123.

Lindegger, G., & Richter, L. M. (2000). HIV vaccine trials: Critical issues in informed consent. *South African Journal of Science, 96*, 313-317.

Lindegger, G., Slack, C., & Vardas, E. (2000). HIV vaccine trials in South Africa: Some ethical considerations. *The South African Medical Journal, 90*, 769-772.

Little, R. J. (1998). A test of missing completely at random for multivariate data with missing values. *Journal of the American Statistical Association, 83*, 1198-1202.

Loo, R. (2002). A caveat on using single-item versus multiple-item scales. *Journal of Managerial Psychology, 17*(1), 68-75.

Loue, S., Okello, D., & Kawuma, M. (1996). Research bioethics in the Ugandan context: A program summary. *Journal of Law, Medicine, & Ethics, 337*(12), 853-855.

Louw, D. J. (1998, August). Ubuntu: An African assessment of the religious other. Retrieved 18 June, 2008, from <http://www.bu.edu/wcp/Papers/Afri/AfriLouw.htm>

Lurie, M. N., Williams, B. G., Zuma, K., Mkaya-Mwamburi, D., Garnett, G. P., Sturm, A. W., et al. (2003). The impact of migration on HIV-1 transmission in South Africa: A study of migrant and nonmigrant men and their partners. *Sexually Transmitted Diseases*, 30(2), 149-156.

MacQueen, K. M., Vanichseni, S., Kitayaporn, D. S., Lin, L., Buavirat, A., Naiwatanakul, T., et al. (1999). Willingness of injection drug users to participate in an HIV vaccine efficacy trial in Bangkok, Thailand. *Journal of Acquired Immune Deficiency Syndromes*, 21(3), 243-251.

Mahoney, C., Thumbs, D., & Ford, O. (1995). Health beliefs and self-efficacy models: Their utility in explaining college student condom use. *AIDS Education and Prevention*, 7(1), 32-49.

Masiphumelele Annual Report. (2008, March). Retrieved June 20, 2008, from http://www.masip.org/MasiCorp_Background/Masiphumelele_Annual_Report_20/bdy_masiphumelele_annual_report_20.html

McCluskey, M. M., Alexander, S. B., Larkin, B. D., Murguia, M., & Wakefield, S. (2005). An HIV vaccine: As we build it, will they come? *Health Affairs*, 24(3), 643-651.

- McGrath, J. W., George, K., Svilar, G., Ihler, E., Mafigiri, D., Kabugo, M., et al. (2001). Knowledge about vaccine trials and willingness to participate in an HIV/AIDS vaccine study in the Ugandan military. *Journal of Acquired Immune Deficiency Syndromes*, 27(4), 381-388.
- McMillan, B., & Conner, M. (2003). Applying an extended version of the theory of planned behaviour to illicit drug use amongst students. *Journal of Applied Social Psychology*, 33(8), 1662-1683.
- Milford, C., Barsdorf, N., & Kafaar, Z. (2007). What should South African HIV vaccine trials do about social harms? *AIDS Care*, 19(9), 1110-1117.
- Mills, E., Cooper, C., Guyatt, G., Gilchrist, A., Rachlis, B., Sulway, C., et al. (2004). Barriers to participating in an HIV vaccine trial: A systematic review. *AIDS*, 18(17), 2235-2242.
- Mills, E., Nixon, S., Singh, S., Dolma, S., Nayyar, A., & Kapoor, S. (2006a). Enrolling women into HIV preventative vaccine trials: An ethical imperative but a logistical challenge. *PLoS Medicine*, 3(3), 0308-0311.
- Mills, E., Wilson, K., Rachlis, B., Griffith, L., Wu, P., Guyatt, G., et al. (2006b). Barriers to participation in HIV drug trials: A systematic review. *Lancet*, 6, 32-38.

Monroe, K. R. (1994). A fat lady in a corset: Altruism and social theory. *American Journal of Political Science*, 38(4), 861-893.

Moodley, K. (2005). HIV vaccine trial participation in South Africa: An ethical assessment.

In A. A. van Niekerk & L. M. Kopelman (Eds.), *Ethics and AIDS in Africa: The challenge to our thinking* (pp. 160-178). Cape Town: David Philip Publishers.

Moodley, K., Barnes, J., van Rensburg, E. J., & Myer, L. (2002). Willingness to participate in South African HIV vaccine trials: Concerns of medical professionals in the Western Cape. *South African Medical Journal*, 92(11), 904-906.

Myer, L., Morroni, C., & Susser, E. S. (2003). Commentary: The social pathology of the HIV/AIDS pandemic. *International Journal of Epidemiology*, 32(2), 189-192.

Myers, R. (1990). *Classical and modern regression with applications* (2nd ed.). Boston: Duxbury.

Nattrass, N. (2007). AIDS denialism versus science. *Skeptical Inquirer*, 31(5), 31-37.

Neuman, W. L. (2000). *Social research methods: Qualitative and quantitative approaches* (4th ed.). Boston: Allyn & Bacon.

Newman, P. A., Duan, N. D., Roberts, K. J., Seiden, D., Rudy, E. T., Swendeman, D., et al. (2006). HIV vaccine trial participation among ethnic minority communities: Barriers, motivators, and implications for recruitment. *Journal of Acquired Immune Deficiency Syndromes*, 41(2), 210-217.

Newman, P. A., Duan, N., Lee, S. J., Rudy, E., Seiden, D., Kakinami, L., et al. (2007). Willingness to participate in HIV vaccine trials: The impact of trial attributes. *Preventative Medicine*, 44, 554-557.

Newman, P. A., Daley, A., Halpenny, R., & Loutfy, M. (2008). Community heroes or “high-risk” pariahs? Reasons for declining to enroll in an HIV vaccine trial. *Vaccine*, 26(8), 1091-1097.

Nichter, M. (1995). Vaccinations in the third world: A consideration of community demand. *Social Science & Medicine*, 41(5), 617-632.

Norusis, M. (2005). *SPSS 13.0 advanced statistical procedures companion*. New Jersey: Prentice Hall.

Nunnally, J. C., & Bernstein, I. H. (1994). *Psychometric theory* (3rd ed.). New York: McGraw-Hill.

Nyamathi, A., Koniak-Griffin, D., Tallen, L., Gonzalez-Figueroa, E., Levson, L., Mosley, Y., et al. (2004). Use of community-based participatory research in preparing low income and homeless minority populations for future HIV vaccines. *Journal of Interprofessional Care*, 18(4), 369-380.

O'Connell, J. M., Hogg, R. S., Chan, K., Strathdee, S. A., McLean, N., Martindale, S. L., et al. (2002). Willingness to participate and enroll in a Phase III preventative HIV-1 vaccine trial. *Journal of Acquired Immune Deficiency Syndromes*, 31, 521-528.

Ogden, J. (2004). *Health psychology: A textbook*. Maidenhead: Open University Press.

Oldridge, N. B., & Streiner, D. L. (1990). The health belief model: predicting compliance and dropout in cardiac rehabilitation. *Medicine and Science in Sport and Exercise*, 22(5), 678-683.

Parker, F. (2005). *Willingness to participate in a future HIV vaccine trial in a high risk sample: Perceived barriers and facilitators to participation*. Unpublished master's thesis, University of Stellenbosch, Stellenbosch, South Africa.

Périssé, A. R., Schechter, M., Moreira, R.I., do Lago, R. F., Santoro-Lopes, G., & Harrison, L. H. (2000). Willingness to participate in HIV vaccine trials among men who have sex with men in Rio de Janeiro, Brazil. *Journal of Acquired Immune Deficiency Syndromes*, 25(5), 459-463.

Piot, P., Bartos, M., Ghys, P. D., Walker, N., & Schwartlander, B. (2001). The global impact of AIDS. *Nature*, 410, 968-973.

Povey, R., Conner, M., Sparks, P., James, R., & Sheperd, R. (2000). Application of the Theory of Planned Behaviour to two dietary behaviours: Roles of perceived control and self-efficacy. *British Journal of Health Psychology*, 5, 121-139.

Priddy, F. H., Cheng, A. C., Salazar, L. F., & Frew, P. M. (2006). Racial and ethnic differences in knowledge and willingness to participate in HIV vaccine trials in an urban population in the South-eastern US. *International Journal of STD & AIDS*, 17, 99-102.

Ren, X. S., Amick, B., Zhou, L., & Gandek, B. (1998). Translation and psychometric evaluation of a Chinese version of the SF-36 health survey in the United States. *Journal of Clinical Epidemiology*, 51(7), 1129-1138.

Rogers, R. W. (1975). A protection motivation theory of fear appeals and attitude change. *Journal of Consumer Psychology*, 91, 93-114.

Rogers, R. W. (1983). Cognitive and physiological process in fear appeals and attitude change: A revised theory of protection motivation. In J. Cacioppo & R. E. Petty (Eds.), *Social psychophysiology* (pp. 153-176). New York: Guilford Press.

Rogers, R. W. (1985). Attitude change and information integration in fear appeals.

Psychological Reports, 56, 183-188.

Rosenstock, I. M. (1966). Why people use health services. *The Milbank Memorial Fund Quarterly, 44*, 94-121.

Ross, M. W., Essien, E. J., & Torres, I. (2006). Conspiracy beliefs about the origin of HIV/AIDS in four racial/ethnic groups. *Journal of Acquired Immune Deficiency Syndromes, 41*(3), 342-344.

Ross, S., Grant, A., Counsell, C., Gillespie, W., Russell, I., & Prescott, R. (1999). Barriers to participation in randomised controlled trials: A systematic review. *Journal of Clinical Epidemiology, 52*(12), 1143-1156.

Rudy, E. T., Newman, P. A., Duan, N., Kelly, E. M., Roberts, J., & Seiden, D. S. (2005). HIV vaccine acceptability among women at risk: Perceived barriers and facilitators to future HIV vaccine uptake. *AIDS Education and Prevention, 17*(3), 253-267.

Sahay, S., Mehendale, S., Sane, S., Brahme, R., Brown, A., Charron, K., et al. (2005).

Correlates of HIV vaccine trial participation: An Indian perspective. *Vaccine, 23*, 1315-1358.

Seage, G. R., Holte, S. E., Metzger, D., Koblin, B.A., Gross, M., Celum, C., et al. (2001). Are US populations appropriate for trials of human immunodeficiency virus vaccine?

American Journal of Epidemiology, 153(7), 619-627.

Sengupta, S., Strauss, R. P., DeVellis, R., Quinn, S. C., DeVellis, B., & Ware, W. B. (2000).

Factors affecting African-American participation in AIDS research. *Journal of Acquired Immune Deficiency Syndromes, 24*, 275-284.

Shavers, V. L., Lynch, C. F., & Burmeister, L. F. (2002). Racial differences in factors that influence the willingness to participate in medical research studies. *Annals of Epidemiology, 12*, 248–256.

Sheeran, P., & Orbell, S. (1998). Do intentions predict condom use? Meta-analysis and examination of six moderator variables. *British Journal of Social Psychology, 37*(2), 231-250.

Sheon, A. R., Wagner, L., McElrath, M. J., Keefer, M. C., & Zimmerman, E. (1998). Preventing discrimination against volunteers in prophylactic HIV vaccine trials: Lessons from a Phase II trial. *Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology, 19*, 519–526.

Sheppard, B. H., Hartwick, J., & Warshaw, P. R. (1988). The theory of reasoned action: A meta-analysis of past research with recommendations for modifications and future research. *Journal of Consumer Research, 15*, 325-343.

Shisana, O., Rehle, T., Simbayi, L. C., Parker, W., Zuma, K., Bhana, A., et al. (2005). *South African National HIV Prevalence, HIV Incidence, Behaviour and Communication Survey*. Cape Town: HSRC press.

Sibicky, M. E., Schroeder, D. A., & Dovidio, J. F. (1995). Empathy and Helping: Considering the Consequences of Intervention. *Basic and Applied Social Psychology, 16*(4), 435-453.

Slack, C., Lindegger, G., Vardas, E., Richter, L., Strode, A., & Wassenaar, D. (2000). Ethical issues in HIV vaccine trials in South Africa. *South African Journal of Science, 96*, 291-295.

Slack, C., Stobie, M., Milford, C., Lindegger, G., Wassenaar, D., Strode, A., et al. (2005). Provision of HIV treatment in HIV preventative vaccine trials: A developing country perspective. *Social Science and Medicine, 60*, 1197-1208.

Smit, J., Middelkoop, K., Myer, L., Lindegger, G., Swartz, L., Seedat, S., et al. (2005). Sociobehavioural challenges to Phase III HIV vaccine trials in sub-Saharan Africa. *African Health Sciences, 5*(3), 198-206.

Smith, K. D., Keating, J. P., & Stotland, E. (1989). Altruism reconsidered: The effect of denying feedback on a victim's status to empathic witnesses. *Journal of Personality and Social Psychology, 57*(4), 641-650.

South African AIDS Vaccine Initiative. (2008, May). *Background and establishment of SAAVI*. Retrieved June 16, 2008, from <http://www.saavi.org.za/>

Starace, F., Wagner, T. M., Luzi, A. M., Cafaro, L., Gallo, P., & Rezza, G. (2006). Knowledge and attitudes regarding preventative HIV vaccine clinical trials in Italy: Results of a national survey. *AIDS Care, 18*(1), 66-72.

Statistics South Africa. (2001, October). *Census 2001 at a glance*. Retrieved 5 July, 2008, from <http://www.statssa.gov.za/census01/HTML/default.asp>

Stead, G. B. (2002). The transformation of psychology in a post-apartheid South Africa: An overview. *International Journal of Group Tensions, 31*(1), 79-102.

Strathdee, S. A., Hogg, R. S., Cornelisse, P. G. A., Martindale, S. A., Currie, S. L., O'Shaughnessy, M. V., et al. (2000). Factors associated with willingness to participate in HIV vaccine trials among HIV-negative injection drug users and young gay and bisexual men. *AIDS and Behavior, 4*(3), 271-278.

Strauss, A., & Corbin, J. (1998). *Basics of qualitative research: Techniques and procedures for developing grounded theory* (2nd ed.). Thousand Oaks: Sage.

Strauss, R. P., Sengupta, S., Kegeles, S., McLellan, E., Metzger, D., Eyre, S., et al. (2001).

Willingness to volunteer in future preventative HIV vaccine trials: Issues and perspectives from three U.S. communities. *Journal of Acquired Immune Deficiency Syndromes*, 26(1), 63-71.

Suligoi, B., Wagner, T. M., Ciccozzi, M., & Rezza, G. (2005). The epidemiological contribution to the preparation of field trials for HIV and STI vaccines: Objectives and methods of feasibility studies. *Vaccine*, 23, 1437-1445.

Sullivan, J. L., & Feldman, S. (1979). *Multiple indicators: An introduction*. Beverly Hills: Sage Publications.

Swanson, H. (1977). The sanitation syndrome: Bubonic plague and urban native policy in the Cape Colony: 1900-1909. *Journal of African History*, 18, 387-410.

Swartz, L., Kagee, A., Lesch, A., Kafaar, Z., Fincham, D. S., & Ntlemeza, B. (2006). *Community members' perceptions of enablers and inhibitors to participation in HIV/AIDS vaccine trials*. Stellenbosch: Sociobehavioural Group, South African AIDS Vaccine Initiative.

Tabachnick, B. G., & Fidell, L. S. (2001). *Using multivariate statistics* (4th ed.). New York: HarperCollins.

The joint United Nations program on HIV/AIDS. (2007, December). *Report on the global AIDS epidemic*. Retrieved March 18, 2008, from <http://www.avert.org/worldstats.htm>

Van den Putte, B. (1991). *20 years of the theory of reasoned action of Fishbein and Ajzen: A meta-analysis*. Unpublished manuscript.

Van de Ven, P., Kippax, S., Knox, S., Prestage, G., & Crawford, J. (1999). HIV treatments optimism and sexual behaviour among gay men in Sydney and Melbourne. *AIDS*, 13, 2289-2294.

Van de Vijver, F. J. R., & Hambleton, R. K. (1996). Translating tests: Some practical guidelines. *European Psychologist*, 1, 89-99.

Venter, E. (2004). The notion of Ubuntu and communalism in African educational discourse. *Studies in Philosophy and Education*, 23, 149-160.

Viera De Souza, C. T., Lowndes, C. M., Szwarcwald, C. L., Sutmöller, F., & Bastos, F. I. (2003). Willingness to participate in HIV vaccine trials among a sample of men who have sex with men, with and without a history of commercial sex, Rio de Janeiro, Brazil. *AIDS Care*, 15(4), 539-548.

Wassenaar, D. R., Barsdorf, N. W., & Richter, L. M. (2005). Gender and HIV vaccine trials: Ethics and social science issues. *Harvard Health Policy Review*, 6(1), 124-130.

Watson, P. W., & Myers, L. B. (2001). Which cognitive factors predict clinical glove use amongst nurses? *Psychology, Health & Medicine*, 6(4), 399-409.

Wilkinson, D., Connolly, C., & Rotchford, K. (1999). Continued explosive rise in HIV prevalence among pregnant women in rural South Africa. *AIDS*, 13(6), 740.

Yang, H., Li, X., Stanton, B., Fang, X., Lin, D., Mao, R., et al. (2004). Willingness to participate in HIV/STD prevention activities among Chinese rural-to-urban migrants. *AIDS Education and Prevention*, 16(6), 557-570.

Yin, L., Zhang, Y., Qian, H. Z., Rui, B., Zhang, L., Zhu, J., et al. (2008). Willingness of Chinese injection drug users to participate in HIV vaccine trials. *Vaccine*, 26, 762-768.

APPENDIX A

Below are some reasons people have given that would make them more or less likely to participate in a future HIV vaccine trial. In each case please indicate how much this item would affect your decision to participate. For each statement, please indicate how much it would affect your decision to participate.

The response options are as follows:

- 1** = Would make me ***very willing*** to participate in a future HIV vaccine trial
- 2** = Would make me ***somewhat willing*** to participate in a future HIV vaccine trial
- 3** = Would not affect my decision either way
- 4** = Would make me ***somewhat unwilling*** to participate in a future HIV vaccine trial
- 5** = Would make me ***very unwilling*** to participate in a future HIV vaccine trial

	1. Very willing	2. Somewhat willing	3. Would not affect my decision	4. Somewhat unwilling	5. Very unwilling
1. Knowing more about the possible benefits of an HIV vaccine would make me...					
2. Having more information about how to cope with possible side effects of an HIV vaccine would make me...					
3. Knowing that participating in an HIV vaccine trial would help stop the AIDS pandemic would make me...					
4. Receiving free medical care for trial-related illnesses would make me...					
5. The fact that participating in an HIV vaccine trial would be a new experience for me would make me...					

	1. Very willing	2. Somewhat willing	3. Would not affect my decision	4. Somewhat unwilling	5. Very unwilling
6. If I were regarded as a role model because of my participation in an HIV vaccine trial would be...					
7. Receiving money in return for enrolling in an HIV vaccine trial would make me...					
8. The possibility of falsely testing HIV positive would make me...					
9. If my friends approved of my participation in an HIV vaccine trial I would be...					
10. If I were certain that HIV vaccine researchers have my best interests at heart I would be...					
11. Knowing more about the possible shortcomings of HIV vaccines would make me...					
12. If there was a risk of being infected with HIV from the HIV vaccine being tested I would be...					
13. If participating in an HIV vaccine trial were to take up a lot of my time I would be...					
14. The possibility that I would receive injections in an HIV vaccine trial would make me...					

	1. Very willing	2. Somewhat willing	3. Would not affect my decision	4. Somewhat unwilling	5. Very unwilling
15. If my partner were to refuse to have sex with me because of my participation in an HIV vaccine trial I would be...					
16. The possibility of being discriminated against by others because of my participation in an HIV vaccine trial would make me...					
17. The possibility of experiencing mild side-effects from the HIV vaccine being tested would make me...					
18. If transportation to and from the HIV vaccine trial site is expensive I would be...					
19. HIV vaccine researchers who are clearly trustworthy would make me...					
20. If I were to lose my job as a result of participating in an HIV vaccine trial I would be...					
21. Being tested for HIV by medically trained HIV vaccine researchers would make me...					
22. The possibility that my partner might leave me because of my participation in an HIV vaccine trial would make me...					

	1. Very willing	2. Somewhat willing	3. Would not affect my decision	4. Somewhat unwilling	5. Very unwilling
23. The possibility that members of my church might react negatively to my participation in an HIV vaccine trial would make me...					
24. If other people thought I was HIV positive because of my participation in an HIV vaccine trial I would be...					
25. If my partner approved of my participation in an HIV vaccine trial I would be...					
26. Free transportation to and from the HIV vaccine trial site would make me...					
27. The possibility of becoming slightly ill from the HIV vaccine being tested would make me...					
28. If participating in an HIV vaccine trial fitted into my daily routine I would be...					
29. If HIV vaccine researchers participated in HIV vaccine trials themselves I would be...					
30. If I had a guarantee from HIV vaccine researchers that the HIV vaccine being tested is safe I would be...					

	1. Very willing	2. Somewhat willing	3. Would not affect my decision	4. Somewhat unwilling	5. Very unwilling
31. If my family reacted negatively to me because of my participation in an HIV vaccine trial I would be...					
32. Being questioned by HIV vaccine researchers about my sexual behaviour would make me...					
33. The possibility of receiving a placebo and not the HIV vaccine being tested makes me...					
34. If my community reacted negatively to me because of my participation in an HIV vaccine trial I would be...					
35. The possibility that I may not benefit personally from participating in an HIV vaccine trial would make me...					

Ngezantsi kukho izizathu ezithi zinikwe ngabantu eziNokubenza babenomdla kakhulu okanye kancinci ekuthabatheni inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo kwilixa elizayo. Kwisivakalisi ngasinye bonisa ukuba olo luvo lungasichaphazela kangakanani na isiggibo sakho sokuthabatha inxaxheba. Kwintetho nganye, nceda ubonise ukuba ingasichaphazela kangakanani na isiggibo sakho sokuthabatha inxaxheba.

Limpendulo onokukhetha kuzo zezi zilandelayo:

- 1** = Izakundenza **ndifune kakhulu** ekuthabatheni inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) kwilixa elizayo
- 2** = Izakundenza **ndifune njee** ekuthabatheni inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo kwilixa elizayo
- 3** = Ayiyi kusichaphazela isiggibo sam nangayiphi na indlela
- 4** = Izakundenza **ndingafuni njee** ukuthabatha inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo kwilixa elizayo
- 5** = Izakundenza **ndingafuni kakhulu/konke konke** ukuthabatha inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo kwilixa elizayo

	1. Ndingafuna kakhulu	2. Ndingafuna njee	3. Aiyiyikusichaphazela isiggibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/konke konke
1. Ukuba nolwazi oluninzi mayela neengeniso ezingafumaneka kugonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) lungandenzo ndi...					

	1. Ndingafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/konke konke
2. Ukuba nolwazi oluninzi mayela nendlela zokumelana neenkcahpazelo empilweni yam ezingathizenziwe lugonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) zingenza ndi...					
3. Ukwazi ukuba ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) kuzakunceda ukuphelisa ubhubhane wesifo sikaGawulayo (AIDS) kungandenza ndi...					
4. Ukufuluma unyango simahla kwisigulo eimayela nomzamo wogonyo kungenza ndi...					

	1. Ndingafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/konke konke
5. Into yokuba ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) iyinto entsha endingazange ndakhe ndayenza ingandenza ndi...					
6. Ukuba bendiza kubonwa njengomzekelo omhle ekuhlaleni ngokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) bendinga...					
7. Ukubhatalelw ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) kungandenza ndi...					

	1. Ngafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/ konke konke
8. Ukwenzeka kwento yokuba ndifunyaniswe ndinesifo sikaGawulayo ngempazamo kungenza ndi...					
9. Ukuba iitshomi zam bezingavuma ukuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) ndinga...					
10. Ukuba bendikholelw ukuba abaphandi bomzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) bendinga...					
11. Ukuba nolwazi oluninzi mayela neengxaki neempazamo zemigonyo ekhusela ukosulelw yintsholongwane kaGawulayo (HIV) ingandenzo ndi...					

	1. Ngafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/ konke konke
12. Ukuba bekukho ubungozi bokosulelwa yintsholongwane kaGawulayo (HIV) obuvela kologonyo lukhusela ukosulelwa yintsholongwne kaGawulayo luvavanywayo bindinga...					
13. Ukuba ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) bekuza kuthabatha ixesha lam elininzi bindinga...					
14. Ithuba lokuba ndisenokuncuntswa ngeenaliti kumzamo wogonyo okhusela ukosulelwa yintsholongwane kaGawulayo (HIV) lingandenzena ndi...					

	1. Ndingafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/ konke konke
15. Ukuba iTsheri yam ibingala ukulalana nam ngenxa yokuthabatha kwam inxaxheba kumzamo wogomyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) bendinga...					
16. Ithuba lokuba ndicalu- calulwe ngabanye ngenxa yokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo lingenza ndi...					
17. Ithuba lokuba ndifumane ukugulana okuncinci olwenziwa lologonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) luvavanywayo lungenza ndi...					

	1. Ngafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/ konke konke
18. Ukuba indlela yokuthuthwa ukuya nokubuya kwindawo apho wenzelwa umzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) kuxabisa kakhulu ndinga...					
19. Abaphandi bomzamo wogonyo olukhusela ukosulelw yintsholongwane kagawulayo abathembekileyo ngenene bangenza ndi...					
20. Ukuba bendinokuphelelw ngumsebenzi ngenxa yokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) bendinga...					

	1. Ngafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isiggibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/ konke konke
21. Ukuvavanyelwa intsholongwane kaGawulayo (HIV) ngabaphandi bogonyo olukhusela ukosulelw yintsholongwane kaGawulayo abaqeqliwego kwezonyango kungenza ndi...					
22. Ithuba lokuba iTsheri yam ingandishiya ngenxa yokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) lingandenzo ndi...					

	1. Ndifune kakhulu	2. Ndifune njee	3. Aiyikusichaphazela isiggibo sam	4. Ndingafuni njee	5. Ndingafuni kakhulu/konke konke
23. Ithuba lokuba abantu baseCaweni yam bangayithandi into yokuthabathabatha kwam inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) ingandenza ndi...					
24. Ukuba abanye abantu bangacinga ukuba ndinentsholongwane kaGawulayo (HIV) ngenxa yokuba ndithabatha inxaxheba kumzomo wogonyo olukhusela ukosulelwa yintsholongane kaGawulayo (HIV) ndinga...					
25. Ukuba isithandwa sam besingavuma ukuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo ndinga...					

	1. Ndifune kakhulu	2. Ndifune njee	3. Aiyikusichaphazela isiggibo sam	4. Ndingafuni njee	5. Ndingafuni kakhulu/konke konke
26. Ukufumana isithuthi simahla sokuya nokubuya kwindawo yomzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo kungandenza ndi...					
27. Ithuba lokuba ndingagula kancinci ngenxa yaloo mzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo oluvavanywayo lingandenza ndi...					
28. Ukuba ukuthabatha kwam inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) lungahambelana nezinto endizenza imihla ngemihla lingandenza ndi...					

	1. Ndifune kakhulu	2. Ndifune njee	3. Aiyikusichaphazela isiggibo sam	4. Ndingafuni njee	5. Ndingafuni kakhulu/konke konke
29. Ukuba abaphandi bogonyo olukhusela ukosulelw yintsholongwane kaGawulayo bangathabatha inxaxheba buqu kumzomo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) ndinga...					
30. Ukuba bendinokuba nesiqinisekiso esivela kubaphandi bogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) sokuba ologonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) luvavanywayo lukhuselekile...					

	1. Ndingafuna kakhulu	2. Ndingafuna njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingangafuni njee	5. Ndingangafuni kakhulu/konke konke
31. Ukuba abantu basekhaya abayithandi into yokuthabatha inxaxheba kwam kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo ndinga...					
32. Ukubuzwa ngabaphandi bogonyo olukhusela ukosulelw yintsholongwaen kaGawulayo (HIV) mayela nokuziphatha kwam kwezokulalana kungandenza ndi...					
33. Ithuba lokuba ndingafumana ugonyo olungelilo nqo (olufana nelo lenyani kodwa lube lungelilo linikelwa njee ukukholisa) endaweni yogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) oluyinyani kungandenza ndi...					

	1. Ndifune kakhulu	2. Ndifune njee	3. Aiyikusichaphazela isigqibo sam	4. Ndingafuni njee	5. Ndingafuni kakhulu/konke konke
34. Ukuba abantu basekuhlaleni banga ngayithandi into yokuthabatha kwam inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) ndinga...					
35. Ithuba lokuba kungenzeka ndingazuzi buqu ngokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) lingandenzo ndi...					

APPENDIX B

Below are some statements regarding attitudes towards participating in an HIV vaccine trial.

Please circle the number that best indicates your attitude towards HIV vaccine trials.

Participating in an HIV vaccine trial would be:

1. Harmful	1	2	3	4	5	6	7	Beneficial
2. Good	1	2	3	4	5	6	7	Bad
3. Pleasant	1	2	3	4	5	6	7	Unpleasant
4. Worthless	1	2	3	4	5	6	7	Worthwhile
5. Important	1	2	3	4	5	6	7	Unimportant
6. Admirable	1	2	3	4	5	6	7	Non Admirable
7. Necessary	1	2	3	4	5	6	7	Unnecessary
8. Beneficial	1	2	3	4	5	6	7	Non beneficial
9. Silly	1	2	3	4	5	6	7	Clever

Ngezantsi kukho iintetho ezimayela neemvakalelo/nezimvo mayelo nokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV). Nceda ubonise ngesangqa kwinani elibonisa imvakalelo/uluvo lwakho ngokupheleleyo mayela nokuthabatha inxaxheba kwimizamo yogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV)

Ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelw yintsholongwane kaGawulayo (HIV) kungaba:

1. Nobungozi	1	2	3	4	5	6	7	Kunengeniso
2. Kokulungileyo	1	2	3	4	5	6	7	Kokubi
3. Kokumnandi	1	2	3	4	5	6	7	Kokungemnandanga
4. Kokungento yanto	1	2	3	4	5	6	7	Kululutho
5. Kokubalulekileyo	1	2	3	4	5	6	7	Akululekanga
6. Kuyathandeka	1	2	3	4	5	6	7	Akuthandeki
7. Kuyimfuneko	1	2	3	4	5	6	7	Akuyomfuneko
8. Kunengeniso	1	2	3	4	5	6	7	Akunangeniso
9. Kulugezo	1	2	3	4	5	6	7	Akuyo nkapho

APPENDIX C

Below are some statements regarding participating in an HIV vaccine trial. There are no right or wrong answers. Please read each item carefully and indicate with a cross 'X' whether you strongly disagree, disagree, agree or strongly agree.

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. Most people who are important to me think that I should participate in an HIV vaccine trial.				
2. It is expected of me to participate in an HIV vaccine trial.				
3. I feel pressured by people around me to participate in an HIV vaccine trial.				
4. Most people who are important to me are willing to participate in an HIV vaccine trial.				
5. Doing what significant people in my life think I should do is important to me.				
6. Approval by others of my participation in an HIV vaccine trial is important to me.				

Ngezantsi kukho iintetho mayela nokuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV). Akukho zimpendulo zifanelekileyo nezingafanelekanga. Nceda ubonise ngo 'X' ukuba ingaba awuvumi kakhulu, awuvumi, uyavuma, okanye uyavuma kakhulu.

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
1. Uninzi lwabantu ababalulekileyo kum bacinga ukuba ndifanele ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV)				
2. Kulindelwe kuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV)				
3. Ndiziva ndinyaneliswa ngabantu abakufuphi nam ukuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo				

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
4. Uninzi lwabantu ababalulekileyo kum bathabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV).				
5. Ukwenza into abantu ababakulekileyo ebomini bam abacinga ukuba ndifanele ndiyenze kubalulekile kum				
6. Ukuvunyelwa ngabanye ukuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) kubalulekile kum.				

APPENDIX D

Below are some statements regarding your ability to participate in an HIV vaccine trial. Please read each item carefully and indicate with a cross 'X' whether you strongly disagree, disagree, agree or strongly agree

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. I am confident that I could participate in an HIV vaccine trial if I wanted to				
2. It would be very difficult for me to participate in an HIV vaccine trial				
3. The decision to participate in an HIV vaccine trial is beyond my control				
4. Whether or not I decide to participate in an HIV vaccine trial is entirely up to me				
5. I would not be able to participate in an HIV vaccine trial even if I wanted to				
6. It is up to me to decide whether or not I would participate in an HIV vaccine trial				

Ngezantsi kukho iintetho mayelana nokukwazi kwakho ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV). Nceda ufunde enye nenye intetho ngocoselelo uze ubonise ngo 'X' ukuba awuvumi kakhulu, awuvumi, uyavuma, uyavuma kakhulu.

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
1. Ndizithembile ukuba ndingathabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo xa ndifuna.				
2. Kuyakubanzima kakhulu ukuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo				
3. Isigqibo sokuba ndithabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo singaphaya kwamandla am.				

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
4. Ukuba ndigqiba ekubeni ndithabathe inxaxheba okanye ndingathabathi inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV) kuxhomekeke kum qwaba.				
5. Bendingena kukwazi ukuthabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo nokuba bendifuna.				
6. Kuxhomekeke kum ukwenza isiggibo sokuthabatha okanye ukungathabathi nxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo.				

APPENDIX E

Below are some statements regarding your feelings about researchers. Please read each item carefully and indicate with a cross 'X' whether you strongly disagree, disagree, agree or strongly agree.

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. If I were asked to participate in a research study and the study procedures were explained to me by the researcher, I would believe what he or she told me.				
2. I would not trust a researcher to tell me the truth about a study in which I was invited to participate.				
3. Researchers exploit people when they test medicines on humans.				
4. The public should be wary of researchers.				
5. I am suspicious of researchers.				
6. When a researcher gives me information I would accept it as true.				

	Strongly Disagree	Disagree	Agree	Strongly Agree
7. In research studies that test medicines on humans, the research subjects are generally treated ethically.				
8. In research studies that test medicines on humans, the subjects' rights are often violated.				
9. In research studies that test medicines on humans, the research subjects are often harmed.				

Ngezantsi kukho iintetho ezimayela nezimvo zakho mayela nabaphandi. Nceda ufunde enye nenye intetho ngocoselelo uze ubonise ngo 'X' ukuba awavumi kakhulu, awuvumi, uyavuma, uyavuma kakhulu

	Andivumi kakhulu	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
1. Ukuba bentinokucelwa ukuba ndithabathe inxaxheba kuphando/kwisisifundo, zize iinkcukacha zolo phando/zeso sifundo zicaciswe kum ngumphandi, bentinoyi kukholelwa loonto umphandi andixeletele yona.				
2. Andinakuthemba ukuba umphandi undixeleta inyaniso mayela nolo phando/sifundo endicelwe ukuba ndithabathe inxaxheba kuso.				
3. Abaphandi bayabasebenzisa babahlukumeze abantu xa bevavanya amayeza ebantwini.				
4. Abantu bafanele ukuba babalumkele abaphandi.				
5. Ndiya bakrokrela abaphandi.				
6. Xa umphandi endinika ulwazi, ndizakulamkela olo lwazi njengoluyinyaniso.				

	Andivumi kakhulu	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
7. Kuphando/kwizifundo apho amayeza avavanywa ebantwini, abathathi nxaxheba kolophando baphathwa ngokusesikweni/ngokusemtheth weni				
8. Kuphando/kwizifundo ezivavanya amayeza ebantwini, abathathi nxaxheba bayakhohlakalelwa/bayahlukuny ezwa				
9. Kuphando/kwizifundo ezivavany amayeza ebantwini, abathathi nxaxheba bayonzakaliswa.				

APPENDIX F

Below you will find statements relating to your knowledge of clinical trials, HIV vaccines and HIV vaccine trials. Please read each item carefully and indicate with a cross 'X' whether you think the statement is true or false. If you do not know whether the statement is true or false, please take your best guess.

	True	False
1. A placebo is a fake treatment that is similar to a real vaccine or drug.		
2. In a clinical trial there are usually two groups of people: one group that receives the real vaccine or drug and the other group that receives a fake vaccine or drug (placebo).		
3. It is important that the individuals placed in each group in a clinical trial are different to each other in as many ways as possible.		
4. In a clinical trial, the participants know whether they have received the real vaccine or drug or whether they have received the fake vaccine or drug (placebo).		
5. Sometimes some participants in a clinical trial may recover from an illness even though they only receive the fake vaccine or drug (placebo).		
6. When testing a new medication or vaccine it is necessary to have a group that receives only a placebo. This will help researchers to determine whether the new medication works better than the fake medication (placebo).		
7. A vaccine is given to help prevent someone from becoming infected with a disease.		
8. A vaccine is given only to children, never to adults.		
9. If a person receives a new vaccine that does not work properly, he or she may not be protected from becoming infected with the disease.		

	True	False
10. An HIV vaccine (when it becomes available) can never give you HIV or AIDS.		
11. New vaccines are tested on human beings only once they have been shown to be safe in animals.		
12. If you decide to participate in an HIV vaccine trial, you will receive information about the trial before you are included in the study.		
13. People who want to enroll in an HIV vaccine trial will be asked to sign a form saying that they agree to participate before they are included in the trial.		
14. If you receive an HIV vaccine it is possible that you may test HIV positive even though you are not really infected with HIV.		
15. If people have unsafe sex, the HIV vaccine being tested might not protect them from becoming infected with HIV.		
16. People who take part in HIV vaccine trials will receive free health care at the study clinic only for trial-related medical problems.		
17. If you enroll in an HIV vaccine trial you will receive medical and HIV tests regularly all the way through the trial.		
18. If you enroll in an HIV vaccine trial, you will not be asked questions about your health and sexual behaviour.		
19. People who take part in an HIV vaccine trial will not be allowed to stop their involvement in the trial.		
20. An HIV vaccine trial is a study in which a new HIV vaccine is tested to see if it prevents people from contracting HIV.		
21. In an HIV vaccine trial, scientists want to know whether there are fewer HIV infections in the group that receives the new HIV vaccine than in the group that receives the fake HIV vaccine (placebo).		
22. If fewer people in the group that receives the real vaccine develop HIV than those who are given the fake HIV vaccine (placebo), we may conclude that the vaccine is working effectively.		

	True	False
23. In an HIV vaccine trial, some participants have a better chance than others of being placed in the group that receives the real vaccine.		

Ngezantsi uzakufumana iintetho ezimayela nemizamo yonyango, imigonyo ekhusela ukosulelwā yintsholongwane kaGawulayo (HIV) kune nemizamo yemigonyo ekhusela ukosulelwā yintsholongwane kaGawulayo (HIV).

	Yinyaniso	Ngamampunge/bubuxoki
1. Usinga-nyango/yeza lunyango olufana nogonyo okanye isiyobisi/iyenza lenyani.		
2. Iqela elinye liye lifumane ugonyo/isiyobisi/iyenza lokwenyani lize elinye iqela lifumane usinga-gonyo/siyobisi/yeza (elifana nqwa nelenyani, libe lingelilo, linikelwa nje ukukholisa).		
3. Kubalulekile ukuba abantu ababekwe kwiqela ngalinye lomzamo wonyango bohluke omnye komnye ngeendlela ezininzi kanga ngoko.		
4. Kumzamo wonyango, abathathi nxaxheba bayayazi into yokuba bafumene ugonyo/isiyobisi/iyenza oluyinyani okanye usinga-gonyo/siyobisi/yeza (olufana nqwa nelenyani lube lungelilo, lunikelwa njee ukukholisa).		
5. Ngamanye amaxesha abanye abathathi nxaxheba bayaphila bazine bebhetele ekuguleni kwabo noxa bebenikwe usinga-gonyo/siyobisi/yeza elingelilo lenyani (elifana nqwa nelenyani libe lingelilo, linikelwa njee ukukholisa).		

	Yinyaniso	Ngamampunge/bubuxoki
6. Xa kuvalanya iyeza okanye ugonyo olutsha kuyimfuneko ukuba kubekho iqela elinikwa usingayenza/gonyo/siyobisi (olufana nqwa nelenyani lube lungelilo, linikelwa njee ukukholisa). Loo nto inceda ukuba abaphandi bakwazi ukubona ukuba ingaba elo yenza litsha lisebenza ngokugqithileyo na kuno singayenza (elifana nqwa nelenyani, libe lingelilo, linikelwa njee ukukholisa).		
7. Ugonyo lunikelwa ukuba lukhusele umntu ekosulelweni sisifo.		
8. Ugonyo lunikwa abantwana kuphela, hayi abantu abadala.		
9. Ukuba umntu unikwe ugonyo olutsha olungasebenzi kakuhle, akasayi kukhuseleka ekosulelweni sisifo.		
10. Ugonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) (xa selufumaneka, sele lukhona) alisoze likunike intsholongwane kaGawulayo (HIV) okanye uGawulayo (AIDS).		
11. Imigonyo emitsha ivavanya eluntwini emva kokuba kufunyaniswe ukuba ikhuselekile kwizilwanyana.		
12. Ukuba ugqiba kwelokuba mawuthabathe inxaxheba kumzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV), uyakufumana ulwazi mayela nomzamo lowo phambi kokuba ungeniswe kolo phando.		

	Yinyaniso	Ngamampunge/Bubuxoki
13. Abantu abafuna ukungenela umzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) bayakucelwa ukuba basayine ixwebhu elichaza ukuba bayavuma phambi kokuba bangeniswe kuloo mzamo.		
14. Xa ufumana ugonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) likhona ithuba lokuba ufunyaniswe unentsholongwane kaGawulayo noxa ungenayo konke konke.		
15. Ukuba abantu balalana ngokungakhuselelekanga (abasebenzisi isingxobo) olo gonyo lukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) luvavanywayo lusenoku ngabakhuseli ekosulelweni yintsholongwane kaGawulayo (HIV)		
16. Abantu abathabatha inxaxheba kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) bazakufumana unyango kwindlu yophando mayela nezigulo eziphathelene nemizamo kuphela.		
17. Ukuba ungenele umzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) uzakufumana uvavanyo lwezigulo kunye novavanyo lwentsholongwane kaGawulayo (HIV) rhoqo ngalo lonke ixesha lomzamo.		
18. Ukuba ungenele umzamo wogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV) awusayi kubuzwa mayela nempilo yakho kunye nokuziphatha kwakho kwezokulalana.		

	Yinyaniso	Ngamampunge/Bubuxoki
19. Abantu abathabatha inxaxheba kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV) abasayi kuvunyelwa ukuba barhoxe ekuthabatheni kwabo inxaxheba kuloo mzamo.		
20. Umzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV) lumphando/sisifundo apho ugonyo olutsha olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV) luthi luvavanywe ukuze kubonwe ukuba lunakho na ukukhusela abantu ekosulelweni yintsholongwane kaGawulayo (HIV) kusini na.		
21. Kumzamo wogonyo olukhusela ukosulelwya yintsholongwane kaGawulayo (HIV), iinzululwazi zifuna ukwazi ukuba ingaba kukho abantu abambalwa na abathe bosulelwya yintsholongwane kaGawula kutsha nje kweli qela elithe lafumana ugonyo olutsha olukhusela ukosulelwya yintsholongwane kaGawulayo xa kuqhathaniswa neli qela liye lafumana usinga-gonyo (ugonyo olufana nqwa nolululo ibe ingelulo, linikelwe ukukholisa njee).		
22. Ukuba baye babambalwa abantu abathe bosulelwya yintsholongwane kaGawulayo kweli qela lifumene ugonyo olukhusela ukosulelwya yintsholongwane kaGawulayo oluyinyani kuneqela elifumene usinga-gonyo (ugonyo olufana nqwa nolululo ibe ingelulo linikelwe ukukholisa njee), singaggiba ukuba ugonyo lusebenza ngokupheleleyo.		

	Yinyaniso	Ngamampunge/Bubuxoki
23. Kwimizamo yogonyo olukhusela ukosulelwa yintsholongwane kaGawulayo (HIV), abanye abathathi nxaxheba banethuba elingaphezulu kunabanye lokufumana ugonyo lwenyani.		

APPENDIX G

Below are some statements regarding your feelings about helping others. Please read each item carefully and indicate with a cross 'X' whether you strongly disagree, disagree, agree or strongly agree.

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. If I help others too much, they may take advantage of me.				
2. I try to help those in need.				
3. I must take care of myself before taking care of others.				
4. I would give up my own comfort to help someone else.				
5. I usually support community projects in any way I can.				
6. If I cared for others I would be wasting my time.				
7. In my own life, I have given up rewards for myself so that another person would benefit.				
8. I will lose out if I worry about other people's problems or needs.				
9. I try to use my abilities to make the world a better place.				

	Strongly Disagree	Disagree	Agree	Strongly Agree
10. I think that the most important thing in life is to look after my own interests first.				
11. My life is better when I help other people.				

Nceda ufunde enye nenyi intetho ngocoselelo uze ubonise ngo 'X' ukuba awuvumi kakhulu, awuvumi, uyavuma, uyavuma kakhulu

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
1. Ukuba ndinceda abanye kakhulu, bangandenza isisulu sabo.				
2. Ndiyazama ukubanceda abo bafuna uncedo.				
3. Ndifanele ukuba ndiqale ngokuzikhathalela phambi kokuba ndikhathalele abanye abantu				
4. Ndingancama olwam ulonwabo/ufudumalo ukwenzela ukuba ndincede omnye umntu.				
5. Exesheni elininzi ndiyancedisa kwwiiprojekhthi/imisebenzi yasekuhlaleni kangangoko ndinakho.				
6. Ukuba bendinokukhathalela abanye abantu bingingazichithela ixesha.				
7. Ebomini bam, ndiye ndancama izipho eyaye izezam ukwenzela ukuba kungenele/zifunyanwe ngomnye umntu.				

	Andivumi kakhulu/konke konke	Andivumi	Ndiyavuma	Ndiyavuma kakhulu
8. Ndizakuphulukana nezinto/namathuba ukuba ndingalibala kukuzikhathaza ngeengxaki nezidingo zabanye abantu.				
9. Ndizama ukusebenzisa izakhono zam ukwenza ilizwe ibeyindawo ebhetele				
10. Ndicinga ukuba eyona nto ibalulekileyo ebomini kukujongana nemidla/nezidingo zam kuqala.				
11. Ubomi bam bubhetele xa ndinceda abanye abantu.				

APPENDIX H

1. What is your gender?

Female	
Male	

2. Please write your age here: _____

3. What is your current marital status?

Single	
Living together	
Married	
Divorced	
Other _____	

4. What population group do you belong to?

Black	
Coloured	
Indian	
White	
Asian	
Other	

5. What is your first language?

Xhosa	
Northern Sotho	
Southern Sotho	
Zulu	
English	
Afrikaans	
Swazi	
Ndebele	
Tsonga	
Tswana	
Venda	
Other	

6. What is the highest level of education that you have completed?

No formal education	
Completed primary school	
Attended high school but did not complete matric	
Completed matric	
Attended university, college or technikon but did not graduate	
Graduated from university, college or technikon	

7. What is your current work situation?

Employed full time	
Employed part time	
Student	
Unemployed	
Retired	

8. Which of the following best describes your approximate **annual** family income from all sources, **before taxes?**

Less than R10 000	
R10 001-R40 000	
R40 001-R80 000	
R80 001-R110 000	
R110 001-R170 000	
R170 001-R240 000	
R240 001 and above	
Don't know	

1. Bong ba gago ke eng?

Mosadi	
Monna	

2. Tswee tswee, kwala dingwaga tsa gago fa: _____

3. Maemo a gago a nyalo ke afe?

Mongwe	
Re nna mmogo	
Nyetswe	
Tlhadile	
Enngwe	

4. O wela mo setlhopheng sefe sa morafe?

Montsho	
Mokhalate	
Moindia	
Mosweu	
Moasia	
Enngwe	

5. Puo ya gago ya ntlha ke efe?

Sethosa	
Sepedi	
Sesotho	
SeZulu	
Seesimane	
Seaferikanse	
Seswati	
Setebele	
SeTsonga	
Setswana	
SeVenda	
E nngwe	

6. Ke maemo a kwa godimo a thuto a o nang le ona?

Ga ke na thuto e e fomale	
Feditse thuto ya sekolo se se potlana	
Tsene sekolo se segolo mme ga ke a wetsa matiriki	
Falotse materiki	
Tsene yunibesiti, kholeje kgotsa thekenikone mme ga ke a aloga	
Alogile kwa yubesiti, kholeje kgotsa thekenikone	

7. Maemo a gago a tiro mo nakong ya jaanong ke afe?

Thapilwe nako e e tletseng	
Thapilwe nakwana	
Moithuti	
Ga ke dire	
Ke rotse tiro	

8. Ke efe ya tse di latelang e e tlhalosang sentle lotseno lwa ngwaga la `lapa la gago go tswa metsweding yotlhe, **pele go lekgetho?**

Tlase ga R10 000	
R10 001-R40 000	
R40 001-R80 000	
R80 001-R110 000	
R110 001-R170 000	
R170 001-R240 000	
R240 001 le go feta	
Ga ke itse	

APPENDIX I

STELLENBOSCH UNIVERSITY

Dylan Fincham, Researcher
Department of Psychology
Telephone Number: 083 402 2675

CONSENT FORM

Identification of factors affecting willingness to participate in an HIV vaccine trial

INVITATION TO PARTICIPATE

You are cordially invited to take part in the aforementioned research project.

AIM

The aim of this research project is to establish the factors that could affect people's willingness to participate in future HIV vaccine trials.

PROCEDURE

As a participant, you will be asked to complete a questionnaire packet that assesses attitudes towards participating in a future HIV vaccine trial, knowledge of HIV vaccines and HIV vaccine trials, mistrust of researchers, and altruism.

COSTS AND FINANCIAL RISKS

There are no financial costs directly associated with taking part in this project.

BENEFITS

There is no guarantee that you will benefit personally from the study. However, your contribution will add greatly to understanding the factors associated with willingness to participate in HIV vaccine trials.

COMPENSATION

By agreeing to take part in this research study, you will be compensated with R50 for traveling costs.

ALTERNATIVES

Participation in this research project is entirely voluntary and you may choose not to take part.

CONFIDENTIALITY

Every attempt will be made to keep all information collected in this study strictly confidential, except as may be required by court order or by law. If any publications result from this research, you will not be identified by name.

ADDITIONAL INFORMATION

Your participation in this study is completely voluntary, and you are free to decline to take part. You may stop taking part at any time. If you stop taking part in the project, you may ask that we not use the

information already given to us. You are encouraged to ask questions about the study at any time as they occur to you during the programme.

DISCLAIMER/ WITHDRAWAL

You agree that taking part in this study is completely voluntary and that you may stop at any time.

SUBJECT RIGHTS

If you have any questions regarding taking part in this research study, you may contact the researcher, Mr. Dylan Fincham, by telephoning 083 402 2675.

CONCLUSION

By signing below you are indicating that you have read and understood the consent form and that you agree to take part in this research study.

Subject's signature

Date

Witness's signature

Date

STELLENBOSCH UNIVERSITY

Dylan Fincham, Umphandi
Icandelo lePsychology
Inombolo yoqhagamshelwano: 083 402 2675

IFOMU YEMVUMELWANO

Inkqubo yokufumana iimeko ezithomalalisa umda wokuthabatha inxaxheba kuvavanyo Iweyeza elikhusela ukosulelwa yi-HIV

ISIMEMO SOKUTHABATHA INXAXHEBA

Uyacelwa ukuba uthabathe inxaxheba kolu phando lukhankanyiweyo ngentla.

INJONGO YOLU PHANDO

Injongo yolu phando kukufumanisa eyona miba ethi iphembelele okanye iphazamise umda ekuthabatheni inxaxheba kumalinge acetywayo ovavanyo Iweyeza elikhusela ukosulelwa yi-HIV.

INKQUBO-MGAQO

Njengothabatha inxaxheba, uyakucelwa ukuba ugcwalise umqulu wephepha lemibuzo ephanda ngezimvo malunga nokuthabatha inxaxheba kwixa elizayo kuvavanyo Iweyeza elikhusela ukosulelwa yi-HIV, ulwazi ngamayeza athintela i-HIV, novavanyo Iweyeza elikhusela ukosulelwa yi-HIV, ukungathembi abaphandi, nokunikezela ngolwazi ngokukhulilekileyo.

INTLAWULO NONGCIPHEKO NGEZEMALI

Akusayikubakho zintlawulo eziqondene nokuthabatha inxaxheba kolu phando.

INZUZO

Akukho siqinisekiso sokokuba kungakho inzuko eqondene nolu phando. Kodwa ke, igalelo lakho liyakongeza kakhulu kulwazi ngeemeko ezinxulumene nomdla wokuthabatha inxaxheba kuvavanyo Iweyeza elikhusela ukosulelwa yi-HIV.

IMBUYEKEZO

Ngokuvuma ukuthabatha inxaxheba kolu phando, uyakubuyekezwa ngesipho se-R50 eyakujongana nokukhwela into yokuhamba.

OKUNYE OKUNOKWENZEKA

Ukuthabatha inxaxheba kolu phando kuse kuzinikezeleni kwakho ngokupheleleyo kwaye ungakhetha ukungathabathi nxaxheba.

IMFIHLELO

Ziyakwenziwa zonke iinzame zokuba ulwazi oluqokelelweyo kolu phando luhlale luyimfihlelo, ngaphandle kwaxa lunokufunwa ngokomyalelo wenkundla okanye ngokwasemthethweni. Xa kungakho papasho olwenziwayo kolu phando, igama lakho alisayi kukhankanya.

ULWAZI OLONGEZELELWEYO

Ukuthabatha inxaxheba kolu phando lolokuzinikela ngokupheleleyo, kwaye ukhululekile ukwala ukuthabatha inxaxheba. Unganqumama nangaliphina ilixa. Ukuba uyarhoxa ekuthabatheni inxaxheba kolu phando, unakho ukucela ukuba ulwazi onikezele ngalo lungasetyenziswa. Uyakhuthazwa ukuba ubuze imibuzo phando nangaliphina ilixa ngendlela evela ngayo kuwe ngexesha lenkqubo.

UKUYEKA

Uyavuma ukuba ukuthabatha inxaxheba kolu phando lolokuzinikela ngokupheleleyo kwaye ungayeka nangaliphina ilixa.

AMALUNGELO ABATHABATHI-NXAXHEBA

Ukuba unemibuzo malunga nokuthabatha inxaxheba kolu phando, ungaqhagamshelana nomphandi, u-Mr. Dylan Fincham, kule nombolo 083 402 2675.

ISIPHELO

Ngoku sayina ngaphantsi uqondisa ukuba uyifundile wayiqonda ifomu yemvumelwano kwaye uyavuma ukuthabatha inxaxheba kulo phando.

Igama lomthathi nxaxheba

Umhla

Igama lengqina

Umhla