HPTN 075
Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men in Sub-Saharan Africa

A Study of the HIV Prevention Trials Network

Sponsored by:

Division of AIDS, US National Institute of Allergy and Infectious Diseases
US National Institutes of Health

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LIST OF ABBREVIATIONS AND ACRONYMS

AE	Adverse Event
ALT	Alanine Transaminase
ART	Antiretroviral Therapy
AST	Aspartate Transaminase
CAB	Community Advisory Board
CASI	Computer-assisted Self-Interviewing
CAPI	Computer-assisted Personal Interviewing
CBC	Complete Blood Count
CD4	Surface glycoprotein that denoting helper T cells
CI	Confidence Interval
CRM	Clinical Research Manager
CRS	Clinical Research Site
CT	Chlamydia
CTU	Clinical Trials Unit
DAIDS	Division of AIDS
EC	Ethics Committee
EQA	External Quality Assurance
GC	Gonorrhea
GCP	Good Clinical Practices
GEE	Generalized Estimating Equation
HBcAb	Hepatitis B Virus Core Antibody
HBV	Hepatitis B Virus
HBsAb	Hepatitis B Virus Surface Antibody
HBsAg	Hepatitis B Virus Surface Antigen
HIV	Human Immunodeficiency Virus
HPTN	HIV Prevention Trials Network
IOR	Investigator of Record
IQA	Internal Quality Assurance
IRB	Institutional Review Board
LC	Laboratory Center
LDMS	Laboratory Data Management System
LL	Local Laboratory
LOC	Leadership and Operations Center
MOH	Ministry of Health
MSM	Men who have Sex with Men
NAAT	Nucleic Acid Amplification Test
NIAID	(United States) National Institute of Allergy and Infectious Diseases
NIH	(United States) National Institutes of Health
QA	Quality Assurance
QC	Quality Control
PAC	Protocol Advisory Committee

PEPFAR	President's Emergency Plan for AIDS Relief
PrEP	Pre-Exposure Prophylaxis
PRO	Protocol Registration Office
PSRC	Prevention Science Review Committee
RE	Regulatory Entity
RNA	Ribo-Nucleic Acid
RSC	Regulatory Services Center
SDMC	(HPTN) Statistical and Data Management Center
SMS	Short Message System
SOC	Standard-of-Care
SOP	Standard Operating Procedures
SRC	(HPTN) Scientific Review Committee
SSA	Sub-Saharan Africa
SSP	Study Specific Procedures
STI	Sexually Transmitted Infection
UK NEQAS	United Kingdom National External Quality Assessment Service
VBS	Venue-Based Sampling
VQA	Virology Quality Assurance Program
WHO	World Health Organization

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I, the Investigator of Record, agree to conduct this study in full accordance with the provisions of this protocol. I agree to maintain all study documentation for a minimum of three years after submission of the site's final Financial Status Report to the Division of AIDS (DAIDS), unless otherwise specified by DAIDS or the HIV Prevention Trials Network (HPTN) Coordinating and Operations Center. Publication of the results of this study will be governed by HPTN policies. Any presentation, abstract, or manuscript will be made available by the investigators to the HPTN Manuscript Review Committee and DAIDS for review prior to submission.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

_____
Name of Site Investigator of Record

_____
Signature of Site Investigator of Record Date

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SCHEMA

Purpose: This study aims to determine the feasibility of recruiting and retaining men who have sex with men (MSM) in a multi-country prospective cohort study in preparation for human immunodeficiency virus (HIV) prevention studies in sub-Saharan Africa (SSA).

Design: HPTN 075 is an observational cohort study. Participants will be accrued over six months at four sites in SSA using convenience sampling strategies, with no replacement for participants lost to follow-up. Each participant will be followed for 12 months, during which five study visits involving structured HIV behavioral assessments, medical examinations, and collection of biological samples will be conducted (including enrollment and quarterly follow-up visits). Participants who do not complete 12 months of follow-up will be contacted to explore reasons for no longer participating.

Study Population: Men, regardless of HIV infection status, aged 18-44 years living in SSA who report anal sex with a man in the past 3 months.

Study Size: A total of approximately 400 men, about 100 per site, will be enrolled. Enrollment of HIV-infected men will be capped at 20 men per site.

Study Duration: Total study duration in the field is 21 months: 3 months of implementation preparation, 6 months of accrual, and 12 months of follow-up.

Primary Objective: To assess study recruitment and retention of a prospective cohort of approximately 400 MSM in SSA to inform feasibility, power calculations and sample size calculations for future HIV prevention studies.

Secondary Objectives:

- To identify factors related to study participation and retention among MSM in SSA, including potential barriers for study participation.
- To assess the experience of MSM in SSA of participating in a cohort study that includes biomedical and behavioral assessments.
- To evaluate the social impact of participating in a biomedical and behavioral cohort study on participants.
- To assess prevalence and incidence of HIV and sexually transmitted infections (STIs), and the prevalence of hepatitis B virus (HBV) infection in the study cohort.

- To obtain baseline laboratory data (chemistry and hematology) to evaluate the cohort's suitability for possible future pre-exposure prophylaxis (PrEP) intervention studies.
- To identify demographic, behavioral, and socioeconomic factors related to prevalence of HIV infection, newly diagnosed HIV infection, HBV infection, and STIs.
- To identify demographic, behavioral, and socioeconomic factors related to uptake of standard HIV prevention interventions; accessing HIV- and non-HIV-related care and treatment; as well as interest in potential HIV prevention strategies and participation in future HIV intervention trials.
- To explore the possibility of including female sex partners of MSM participants in future HIV intervention trials.
- To compare substance use data obtained by self-report to data obtained by retrospective testing for substances of abuse in stored urine samples. Note that this objective will only apply to sites that have IRB approval for urine storage for substance use testing.

Exploratory
Objective:

- To perform secondary laboratory assessments that may include evaluation of factors related to HIV infection, hepatitis infection, or STIs; ARV drug use; characterization of HIV in infected participants, including phylogenetic analysis; evaluation of the host response to infection; and evaluation of laboratory assays and methods related to the study objectives.
- To explore participant attitudes towards and experiences with PrEP by conducting in-depth interviews (IDIs) and focus group discussions (FGDs).

Study Sites:

- KEMRI/CDC, Kisumu, Kenya
- Blantyre CRS, Blantyre, Malawi
- Soweto HPTN CRS, Soweto, SA
- Groote Schuur HIV CRS (Desmond Tutu HIV), Cape Town SA

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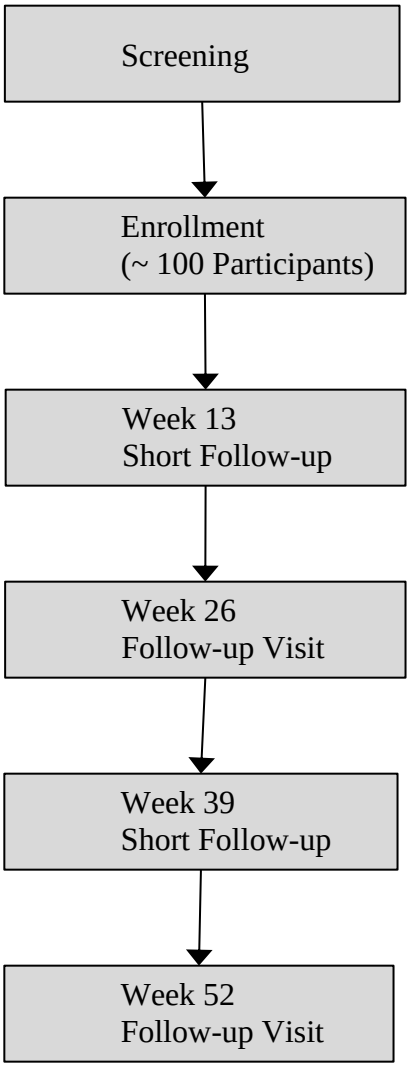
OVERVIEW OF STUDY DESIGN



1.0 INTRODUCTION

1.1 Background and Prior Research

MSM as a priority for HIV prevention: In all countries where MSM-specific epidemics have been studied, MSM have been identified as a key population in HIV epidemics (1-3). Even in African countries with generalized epidemics and high HIV prevalence overall, the HIV prevalence among MSM is 3-4 times higher than in the general population (4). Because of the high levels of bisexual sexual activity and bisexual concurrency in this population it has been argued that efforts to address generalized HIV epidemics will be unsuccessful unless they also address nested, concentrated HIV epidemics among MSM (5).

MSM in SSA are at alarmingly high risk of HIV acquisition and transmission (6-18), and face two distinct structural disadvantages to accessing prevention and treatment. First, the major HIV prevention programs in SSA target heterosexual persons and pregnant women, and thus do not meet the specific prevention needs of MSM. Second, in many parts of SSA, MSM cannot safely seek HIV prevention or treatment services because of the social, cultural, and legal aspects of stigma, discrimination, and criminalization (19-21).

Relevant previous studies: To date, the vast majority of studies of MSM in SSA have been cross-sectional, integrated bio-behavioral surveillance surveys with convenience or respondent-driven sampling. These studies have been largely aimed at describing HIV risk behaviors and determining HIV prevalence in these populations (2). Based on existing studies, prevalence of HIV in MSM in SSA is estimated to be 17.9%, compared to 5.0% among all adults in the same countries (1). To date, HIV incidence data for MSM in SSA are lacking with the exception of findings from studies in Nairobi and Kilifi, Kenya, where an incidence of 9% per 100 person-years was documented for the period of 2005-2011 (12, 15). The scarcity of HIV incidence data in MSM in SSA indicates that more work is needed to understand these epidemics (1). The high HIV prevalence and incidence among MSM in SSA indicate an urgent need to identify strategies to prevent HIV transmission in this population.

A small, but emerging, body of literature suggests the urgent need to increase access to and use of HIV testing (6, 22-24); to increase condom use for anal sex, especially with main or regular partners (25, 26); to address and treat STIs (27); and to address structural barriers which, if unaddressed, will make it challenging to bring HIV prevention for MSM to scale (25, 28-30).

There are also many important but unstudied areas that set the context for feasibility studies related to HIV prevention in MSM in SSA. These include possible social consequences of participating in such studies; local/regional heterogeneity of substance use patterns and their relationship to risk behaviors; the sexual networks of behaviorally bisexual MSM; and the epidemiology of STIs as they relate to HIV acquisition risk.

These issues are all poorly understood and are central to the ability to mount larger scale HIV prevention studies with MSM in SSA. It is promising that communities of providers, MSM, and prevention researchers have engaged in preliminary dialogues about providing comprehensive prevention services to MSM in SSA, and that there is substantial consensus among stakeholders about the type of services that will be required to have substantial impact on HIV prevention (31).

1.2 Rationale

HPTN 075 is a multi-site, prospective study that will evaluate the feasibility of enrolling and retaining MSM in HIV prevention studies. Eligible men will be enrolled and followed for one year, with regular HIV and STI testing and behavioral assessments. Retention at 12 months will be the primary study objective.

There is little information regarding the feasibility, acceptability, or efficacy of HIV interventions addressing the HIV prevention needs of MSM in SSA (2). A recent comprehensive literature review indicated that nearly all high-quality efficacy data for HIV prevention interventions for MSM have emerged from trials in the global North, especially the United States (28).

To date, HIV prevention trials in SSA have enrolled individuals primarily at risk of heterosexual transmission; i.e., they have not specifically targeted MSM. Two important exceptions are the Global iPrEX trial, which enrolled a relatively small number of MSM in South Africa (N=88 with over 80% non-White participants, (32)) and a Phase I PrEP trial, which enrolled 67 MSM in Kenya in 2010 (33). There are only a few ongoing intervention studies among MSM in SSA. These include: 1) an NIAID-funded Health Empowerment study in Mpumalanga Province, South Africa (R01-AI089292), 2) a pilot combination prevention study for MSM in Cape Town and Port Elizabeth, South Africa, funded through a Methods for Prevention Packages Program (MP3) grant (R01-AI094575), 3) an operations research prospective cohort study of 1200 MSM, aged 15 and older, that evaluates the linkage of clients to combination prevention and comprehensive HIV and medical services in Nigeria, funded through the President's Emergency Plan for AIDS Relief (PEPFAR), 4) a pilot intervention research project to improve ART adherence among Kenyan MSM through provider and peer support (R34-MH099946), and 5) feasibility studies in Malawi and Senegal, funded by USAID. There is one well-established cohort of MSM in Africa in Kilifi, Kenya with follow-up since 2005 (14, 15); behavioral and clinical data have been reported on a clinic-based sample in Abuja, Nigeria (27). Other studies seek to evaluate factors, experiences, and co-morbidity concerns related to HIV risk behaviors in MSM in Tanzania (R21 -MH090908) and South Africa (F31-MH088943 and R01-MH083557).

Relevance to long-term global goals of HPTN: HPTN 075 is particularly relevant to the network's goal of conducting prevention research in populations and geographical regions that bear a disproportionate burden of HIV infection. MSM in SSA clearly meet this criterion. Further, this study will help the HPTN understand the requirements for future, larger-scale research studies of HIV prevention interventions in MSM in SSA.

Estimates of retention and HIV incidence (although limited by the small size of this study) will inform the design and power calculations for future trials with HIV incidence endpoints.

This study will also help the HPTN understand the challenges and opportunities of future, multi-site trials of HIV prevention among MSM in SSA. Because MSM typically face unique barriers to participation in HIV prevention studies, it is critical to demonstrate the feasibility of enrolling and retaining them. It is also important to understand the biases that impact enrollment of MSM in a research study. Are there some populations of MSM who preferentially present for enrollment or avoid presenting for enrollment? Do some MSM present in-authentically, because of desire for study incentives or services? What preparatory steps are key to preparing study sites and communities to engage in research with MSM? Further, understanding more about the relationship of sexual risks with male and female partners and the epidemiology of STIs will help evaluate the priority of considering these elements in future studies.

Study retention is not only a critical issue for HIV-uninfected MSM, but also for HIV-infected MSM. Inclusion of HIV-infected MSM in HPTN 075 help identify factors that may impact their linkage and retention in care. This information would be helpful for design of potential future studies of treatment as prevention in MSM cohorts. Stored samples from men who are HIV infected at enrollment could also be tested to obtain information about HIV drug resistance and super-infection in this population, and to provide a cross-sectional estimate HIV incidence at enrollment. However, these analyses may be limited by the small number of HIV-infected men enrolled (up to 20/site, maximum of 80).

In the initial consultative phases of developing HPTN 075, stakeholders and concept committee members raised issues of social harms and safety. Evaluating potential social harms associated with cohort participation is also critical to the design of future studies that are safe for participants, acceptable to communities, and supportable by institutional review boards (IRBs)/ethics committees (ECs); especially because future studies are likely to include some sites less accustomed to working with MSM. This pilot study will provide insights into the challenges that sites and communities in SSA may need to be aware of as they prepare for future, larger studies. In addition to social harms, knowing what potential benefits are of participating in a cohort study will contribute to successful implementation of future studies.

Critical pathway to efficacy evaluation: Other ongoing efforts, including an MP3 study, are examining the components and composition of a comprehensive HIV prevention package for MSM in South Africa. It is expected that HPTN 075, conducted at four sites, will provide information on feasibility of recruiting MSM in several additional settings in SSA. The HPTN 075 study team has connections with the current MP3 project, which will provide information on prevention package components and delivery. In addition, as socio-behavioral studies are completed and written up, this additional information will inform safe and effective ways to engage MSM in Africa and meaningfully include this vulnerable population in prevention research. It is likely that HPTN 075 and the current MP3 study will provide complementary data needed to design and implement a feasible and acceptable prevention package for MSM in SSA.

A number of African National HIV/AIDS programs (34) are giving attention to specific components of a prevention package for a key populations such as MSM. It is thought that this may include biomedical interventions such as PrEP. Research that demonstrates feasibility and effectiveness will be critical in enabling policy decisions on HIV Prevention in MSM to be made.

1.3 Background and Rationale for Qualitative Component

Injectable pre-exposure prophylaxis (PrEP) is a critical addition to the strategies to further reduce transmission of human immunodeficiency virus (HIV), particularly among populations that engage in high risk sexual practices. Before injectable PrEP can be implemented on a large scale, studies are needed to show that it is efficacious and safe, as well as what adoption in the real world would look like. It is also important to understand this for the benefit of future studies of these agents in the same populations. For such studies to be successful, it is critical to understand how PrEP in general, and injectable PrEP in particular, are perceived by populations at increased risk, including men who engage in sex with men (MSM) in sub-Saharan Africa (SSA).

The main aim of the qualitative component is to assess and understand the knowledge and willingness to use PrEP in general, the future acceptability of injectable PrEP, as well as the willingness to participate in injectable PrEP trials and demonstration projects. Interest in PrEP will be explored in relation to currently available HIV preventive strategies.

Study findings will identify issues that need to be addressed before new studies can be implemented. There currently is some understanding of the way MSM, predominantly in high income countries, perceive PrEP in general. Knowledge regarding injectable PrEP and participation in efficacy trials and demonstration projects is practically nil, although lessons from vaccine preparedness studies are informative.

It is likely that what is known about PrEP and MSM in high income countries cannot automatically be applied to MSM in SSA. There are several reasons why this is the case. In general, the social situation in which sub-Saharan African MSM live differs substantially from that of MSM in high income countries, due to the criminalization of homosexuality, as well as the strong societal rejection. This has consequences for the men's lifestyle, their sexual as well as preventative practices, their thinking about health and health care. In addition, acceptability of PrEP in these men is likely to be affected by traditional medicine in SSA countries, which interferes with trust in Western medicine.

To address the research questions, we will conduct two focus group discussions (FGDs) and twenty in-depth interviews (IDIs) at each of the four sites involved in HPTN 075. Both strategies will deliver complementary information—the FGDs generating an assessment of the social climate and the IDIs an understanding from a more personal perspective—as well as an opportunity for triangulation. Furthermore, information garnered through in-depth interviews could be linked to a host of behavioral and

psychosocial data collected in the cohort study (in case men are selected for these interviews among the HIV-negative cohort participants). The number of focus groups and interviews is based on the expectation that they will allow for saturation. The reason for involving all four sites is that the acceptability of injectable PrEP will vary across sites; involving the four sites will allow exploration of this variety.

2.0 STUDY OBJECTIVES AND DESIGN

2.1 Primary Objectives

The primary objective of this study is to assess the feasibility of study recruitment and retention of a prospective cohort of approximately 400 MSM in SSA to inform feasibility, power calculations, and sample size calculations for future HIV prevention studies.

2.2 Secondary Objectives

The secondary objectives of this study are as follows:

- To identify factors related to study participation and retention among MSM in SSA, including potential barriers for study participation;
- To assess the experience of MSM in SSA of participating in a cohort study that includes biomedical and behavioral assessments;
- To evaluate the social impact of participating in a biomedical and behavioral cohort study on participants;
- To assess prevalence and incidence of HIV and sexually transmitted infections (STIs), and the prevalence of hepatitis B virus (HBV) infection in the study cohort;
- To obtain baseline laboratory data (chemistry and hematology) to evaluate the cohort's suitability for possible future pre-exposure prophylaxis (PrEP) intervention studies;
- To identify demographic, behavioral, and socioeconomic factors related to prevalence of HIV infection, newly diagnosed HIV infection, HBV infection, and STIs;
- To identify demographic, behavioral, and socioeconomic factors related to uptake of standard HIV prevention interventions; accessing HIV- and non-HIV-related care and treatment; as well as interest in potential HIV prevention strategies and participation in future HIV intervention trials;
    - To explore the possibility of including female sex partners of MSM participants in future studies;
    - To compare substance use data obtained by self-report to data obtained by retrospective testing for substances of abuse in stored urine samples. Note that this objective will only apply to sites that have IRB approval for urine storage for substance use testing.

2.3 Exploratory Objective:

- To perform secondary laboratory assessments that may include evaluation of factors related to HIV infection, hepatitis infection, or STIs; ARV drug use; characterization of HIV in infected participants, including phylogenetic analysis; evaluation of the host response to infection; and evaluation of laboratory assays and methods related to the study objectives.
- To explore participant attitudes towards and experiences with PrEP by conducting in-depth interviews (IDIs) and focus group discussions (FGDs).

2.4 Study Design

This is an observational cohort study of approximately 400 MSM - about 100 men at up to four clinical research sites (CRSs) in up to four countries in SSA. The four selected sites are: KEMRI/CDC, Kisumu, Kenya, Blantyre CRS, Blantyre, Malawi, Soweto HPTN CRS, Soweto, SA, Groote Schuur HIV CRS (Desmond Tutu HIV), Cape Town SA. The cohort will be accrued over a 6-month period, with no replacement for participants lost during the 52 weeks (12 months) of follow-up. After Screening, there will be five study visits (including enrollment and quarterly follow-up visits). Each visit will include physical examinations, collection of biological samples, HIV testing, HIV risk reduction counseling, behavioral assessments, and assessment of the social impact related to the study participation (see Schedule of Study Visits and Procedures, Appendices I-III). A subset of visits will include STI testing. The study will be implemented according to international guidelines for HIV prevention trials (35, 36) and for conducting research with MSM in rights-constrained environments (37).

To obtain a diverse sample of high-risk MSM in high-incidence environments, we will design recruitment strategies in collaboration with local MSM communities, making use of peer outreach, participant-referral, indirect recruitment (outreach via venues and social media), and referral through key figures.

HIV testing will take place at the Screening and~~,~~ Enrollment visits and, for those who are HIV-uninfected at Enrollment, at each of four quarterly visits. In all cases, acquisition of HIV infection after Screening will be based on HIV test results obtained on specimens collected on two different dates. For participants who are HIV-uninfected at Screening, but have a reactive or positive HIV test result at Enrollment or a follow-up visit, the second specimen should be collected ideally 2-3 weeks after an initial positive HIV test result. If HIV infection is confirmed at the HIV confirmation visit, participants will be referred for culturally-competent HIV treatment and care as per national guidelines (either on site [external to the study] or elsewhere).

Enrollment of HIV-infected MSM will be capped at 20 per site. These men will be maintained in the cohort to assess study retention and to evaluate their engagement in HIV care. Participant accrual will be monitored to ensure that no more than 20 HIV-infected participants are enrolled at each study site. Any additional individuals who have one or more reactive/positive HIV test at the Screening visit will be referred for

culturally-competent HIV treatment and care as per national guidelines. All enrolled men who are HIV-infected at Screening or acquire HIV infection after the screening visit will have CD4 cell count and HIV viral load testing. Uptake of care by HIV-infected men will be assessed. HIV-infected men who are already on ART or in care are not eligible for enrollment; baseline data on these men will be collected at Screening, even though they will not be enrolled.

At Enrollment, all men will have a medical history assessment and complete physical examination. In addition to HIV testing, laboratory testing will include hematology and chemistry testing, HBV testing, and STI testing. STI testing will include testing urine as well as rectal and pharyngeal swabs. Referral for appropriate care and treatment will be provided as needed. Also, plasma will be stored for quality assurance (QA) testing and other assessments. Urine will be stored for substance use testing (if permitted by local IRBs).

At Screening, Enrollment and subsequent study visits, data will be collected to 1) identify barriers and facilitators to study participation, factors that promote study retention, and potential social harms and benefits from study participation; 2) evaluate participants' experience of participating in a cohort study and involvement in biomedical and behavioral assessments; 3) identify demographic, behavioral, and socioeconomic factors related to: prevalence of HIV infection, newly diagnosed HIV infection, HBV infection, and STIs; uptake of standard HIV prevention interventions; accessing HIV- and non-HIV-related care and treatment; and interest in potential HIV prevention strategies and participation in future research; and 4) assess explore feasibility of including female sex partners in future studies. The behavioral assessment at Screening, Week 13 and 39 Visits, will be abbreviated and only include a selection of the concepts listed above.

At each visit, all men will be offered a package of clinical and standard-of-care (SOC) services as part of their involvement in the study. This will include HIV risk-reduction counseling, and provision of condoms and water-based lubrication (both approved according to guidelines from the World Health Organization (WHO)). In addition to the clinic visits, there will be monthly off-site peer-education visits for willing study participants to promote retention and elicit timely feedback regarding study implementation.

Men who indicate that they wish to withdraw from the study will be asked to complete a short assessment survey to assess their reasons for no longer participating in the study. Men who do not return for follow-up visits will be contacted to remind them of missed visits.

Implementation of the study will be preceded by site preparation and community consultation using a standardized framework (37) to ensure readiness for the culturally-appropriate conduct of the study and availability of culturally-competent care for men who are identified as HIV-infected at enrollment or during the study. Study staff will document and evaluate implementation of activities to prepare study sites to optimally engage MSM will be documented and evaluated. Ongoing community engagement, which is of critical importance for research with this population in SSA settings, will be arranged through a Community Advisory Board (CAB) and a Protocol Advisory

Committee (PAC) at each site. The PAC will consist of members most familiar with MSM issues and other members of the MSM community and assist researchers in protocol-specific matters such as education and communication materials, appropriate study materials, and may provide feedback on proposed study procedures. The CAB will advise on general matters.

2.5 Study Design for Qualitative component

One time semi-structured in-depth interviews (IDIs) and focus group discussions (FGDs) will be conducted with participants at all four HPTN 075 sites. The IDIs are designed to gather detailed information on participant experiences with and perceptions of PrEP, whereas the FGDs will be used to better understand the context and social climate around PrEP in each location.

The qualitative component will assess:

- Knowledge of PrEP and perceptions of the benefits and concerns about the use of PrEP;
- Product characteristics (e.g., perceived efficacy, attitudes towards injections);
- Social risks (e.g., receiving HIV medication in a context of high HIV prevalence, being misperceived as being HIV positive);
- Trust in the health care system (in general or specifically in relation to being MSM, whether or not related to actual experiences, preference for traditional instead of Western medicine);
- Pragmatic obstacles (e.g., transportation, costs, personal inconvenience);
- Study design concerns or misunderstandings (e.g. use of placebo control, double-blinding, possibility of not getting the real treatment).

2.5.1 In-Depth Interviews

IDIs will generate an understanding of PrEP and PrEP use from a more personal perspective. Twenty IDIs will be conducted with HPTN 075 participants. Demographic information will be collected from participants (e.g., race, age, income, sex, education).

2.5.2 Focus Group Discussions

Participants from each site will be invited to participate in two FGDs (per site) to explore perceptions and experiences around the use of PrEP. Each FGD will be comprised of 5 participants, one group with men between 18 and 25 years old and one group with men older than 25 years. Efforts will be made to include FGD participants representative of the diverse range of sites participating in the parent study.

3.0 STUDY POPULATION

The study population will consist of approximately 400 MSM between the ages of 18-44 years old who report having had anal sex with a man at least once in the past 3 months, who are living in SSA, and who are eligible based on the inclusion and exclusion criteria listed below. The upper age limit has been chosen to ensure an inclusive assessment of SSA MSM.

Site recruitment efforts will ensure that the sample will predominantly be black/African. Both HIV-infected and HIV-uninfected men will be enrolled; however, there will be a cap on the number of HIV-infected men. At each site, no more than 20 of the participants will be HIV-infected at Enrollment.

3.1 Inclusion Criteria

- Men must meet all of the following criteria to be eligible for inclusion in this study:
- Biologically male at birth, according to self-report;
- 18-44 years old (inclusive);
- Willing and able to provide informed consent;
- Willing to undergo HIV testing throughout the study and to receive those test results;
- Reporting at least one act of anal intercourse in the previous 3 months (12 weeks) with a person reported by the participant to be biologically male;
- Able to provide complete locator identification for themselves and at least two other personal contacts;
- Willing to participate in all scheduled study assessments, including specimen collection, laboratory assessments, and sample storage;
- Committing to not participate in any HIV intervention or vaccine study while participating in HPTN 075;
- Planning to remain in the study area for at least one year;
- For HIV-uninfected men: All HIV test results at the Screening visit must be non-reactive/negative;
- For HIV-infected men: All HIV test results at the Screening visit must be reactive/positive.

Men who are already on PrEP will not be excluded. Additionally, self- or other-identified transgender women and male sex workers will not be excluded. There will, however, be no specific effort to recruit these groups.

3.2 Exclusion Criteria

Men who meet any of the following criteria will be excluded from this study:

- Unwilling to adhere to study procedures;
- Past or current participation in a biomedical and/or behavioral HIV/STI intervention or cohort study, including HIV vaccine studies; however, participation in local/area PrEP demonstration projects does not preclude participation in HPTN 075;
- HIV-infected men who report that they are already on ART or in HIV care;
- Any other reason or condition that in the opinion of the Investigator of Record (IOR) would interfere with participation, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.
- Men who have discordant HIV test results at Screening (i.e., at least one reactive or positive result and at least one non-reactive or negative result). These men will receive HIV counseling and will be referred for further diagnostic tests and care.

3.3 Recruitment Process

Each study site will be responsible for enrolling approximately 100 MSM. Recruitment procedures will be site-specific because 1) it allows for the development of strategies in consultation with community; 2) it allows for customization to local circumstances; and 3) it makes it easier to adjust strategies if recruitment outcomes lag at specific sites. It is our aim to recruit diverse samples that do not necessarily have to be representative for the MSM population. The primary aim is to recruit a cohort of high-risk black/African MSM who would be likely to participate in future intervention studies. That participants are high-risk is safeguarded by the selection criteria and screening process. We expect most recruitment efforts to take place in urban contexts; developing strategies in consultation with local communities will allow adaptation of strategies to rural circumstances if needed.

Sites will develop, in consultation with the community and after collaboratively mapping of the variety of MSM expressions in the community, site-specific strategies for the promotion of study awareness and acceptability in the community, and for recruitment, making use of the following strategies:
1) Peer outreach: MSM hired and trained as peer outreach workers to approach MSM based on their personal connections to and knowledge of the MSM population;
2) Participant referral: eligible participants will be asked to refer their friends to participate in the study;
3) Indirect recruitment: distribution of announcements via actual and virtual “gay” venues and events;
4) Key figures referral: trusted persons with access to MSM networks who can distribute study information and encourage MSM to participate.

The details of site-specific strategies for the promotion of study awareness and acceptability in the community, and for recruitment are included in the SSP Manual.

There is little information available to inform an expected screening to enrollment ratio. Data from the Cape Town site of the Global iPrEx study showed that a large number of men were initially engaged, followed by a pre-screening protocol that screened out HIV-infected individuals. Of the initial 629 MSM engaged at community level, 20% were finally screened, with a screening to enrollment ratio of 1.4:1. Experiences from protocol team members in Africa suggest that about 50% of the people who are eligible as MSM do not enroll in cohorts.

In relation to the primary objective of this study, we will explore whether the MSM that are recruited for this study represent the MSM present in the various communities, or whether the cohort of recruited men is biased/selective. This will be assessed through ongoing interactions with local communities. As part of the development of the recruitment strategies, community representatives will be asked to identify the various MSM groups present in the community. Their projections will be used to collaboratively review recruitment outcomes.

3.4 Co-Enrollment Guidelines

Men participating in other biomedical and/or behavioral HIV/STI intervention or cohort studies will not be eligible for enrollment in HPTN 075; this includes both past and current participation in an HIV vaccine study. In addition, co-enrollment in one or more vaccine or device study during the HPTN 075 study will not be permitted and men must agree not to enroll in these types of studies while they are participating in HPTN 075. However, men may enroll and participate in local PrEP demonstration projects, as it would be unethical for HPTN 075 to disallow men from obtaining PrEP in this way.

3.5 Compensation

Participants will receive compensation for their time and transportation costs. The exact amount might vary per study site and will be determined in consultation with local IRBs to ensure that they encourage participation without being coercive.

3.6 Participant Retention

Once a participant enrolls in HPTN 075, study staff will make every effort to retain him for 52 weeks of follow-up to minimize possible bias associated with loss-to-follow-up. Study staff are responsible for developing and implementing local standard operating procedures to achieve this goal.

Retention will be promoted by building trust in the study through the involvement of the study community at large before the implementation of the study (38-41) (see also

Section 9). This communication with the community will be ongoing during the study to explain the purpose of HIV prevention research and the importance of completing research study visits, and to increase awareness about HIV/AIDS more generally.

On the level of the participant, standard procedures will include:

- Thorough explanation of the study visit schedule and procedural requirements during the informed consent process and re-emphasis at each study visit;
- Thorough explanation of the importance of individual participation to the overall success of the study;
- Collection of detailed locator information at the study Screening Visit, and active review and updating of this information at each subsequent visit;
- Use of appropriate and timely visit-reminder mechanisms, making use of all available contact mechanisms and channels, such as cell phones and short message system (SMS) technology;
- Immediate and multifaceted follow-up on missed visits;

Additionally, retention will be promoted by measures that have proven to be successful in other studies and include: emphasizing benefits of participation (e.g., education about HIV prevention, provision of condoms and lubrication, treatment of STI if needed), providing incentives (and timely payment thereof) and instrumental support, and giving control to participants about how and when they are contacted for study participation. Structural measures that will promote retention include: maintaining between-assessment contacts through monthly off-site peer-education visits for willing study participants, fostering supportive staff attitudes (e.g., being respectful, patient yet persistent, flexible) resulting in rewarding relationships, establishing a project identity to be developed in collaboration with CAB and PAC, maintaining clinical staff and preventing turnover, and having a toll-free phone number to participants to increase accessibility to the project.

3.7 Participant Withdrawal

Regardless of the participant retention methods described above, participants may voluntarily withdraw from the study for any reason at any time. Should a participant indicate that he would like to withdraw, study staff will ask him if he will agree to complete a short assessment survey characterizing reasons for withdrawal.

The IOR also may withdraw participants from the study in order to protect their safety and/or if they are unwilling or unable to comply with required study procedures after consultation with the Protocol Chair, DAIDS Medical Officer, Statistical and Data Management Center (SDMC) Protocol Statistician, and Leadership and Operations Center (LOC) Clinical Research Manager (CRM).

Participants also may be withdrawn if the study sponsor, government or regulatory authorities, or site IRBs/ECs terminate the study prior to its planned end date.

Participants who decide to withdraw from the study prior to the Week 52 Visit will be asked if they will complete a final evaluation performing the procedures that would have been completed at Week 52, but will not be required to do so. Additionally, study staff will record the reason(s) for all withdrawals from the study in participants' study records (regardless of whether participants fill out the short questionnaire) to further understand reasons for withdrawal.

4.0 STUDY POPULATION AND SAMPLING FOR QUALITATIVE COMPONENT

A heterogeneous sample will be used to collect information that is representative of the range of experiences, perspectives, and behaviors exhibited throughout the course of the study at the various sites involved.

4.1 Study Population for IDIs

At all four sites, IDIs will be conducted with twenty participants per site.

4.1.1 Inclusion Criteria for IDIs

- Study participants for the qualitative component will be:
    - Participants who have completed the Week 26 assessment of the parent HPTN 075 study,
    - MSM from the community
- Having an HIV-negative serostatus.
- Able and willing to provide informed consent.
- Able and willing to participate in an hour-long interview.
- Willing to allow the in-depth interview to be recorded.

4.1.2 Exclusion Criteria for IDIs

- Any condition that, in the opinion of the study staff, would make participation in the study harmful to the participant, complicate interpretation of study data, or otherwise interfere with achieving study objectives, including evidence of altered mentality, inebriation, or substance abuse.

4.2 Study Population for FGDs

Each site will conduct two FGDs with five participants per FGD, one group with men between 18 and 25 years old and one group with men older than 25 years.

4.2.1 Inclusion Criteria for FGD

- Study participants for the qualitative component will be:
    - Participants who have completed the Week 26 assessment of the parent HPTN 075 study,

- MSM from the community
- Having an HIV-negative serostatus.
- Able and willing to provide informed consent.
- Able and willing to participate in a focus group discussion approximately two hours long.
- Willing to allow the focus group discussion to be recorded.

4.2.2 Exclusion Criteria for FGD

- Any condition that, in the opinion of the study staff, would make participation in the study harmful to the participant, complicate interpretation of study data, or otherwise interfere with achieving study objectives, including evidence of altered mentality, inebriation, or substance abuse.

5.0 STUDY PROCEDURES

An overview of the study visit and procedures schedule is included in Appendices I-III. Presented below is additional information for visit-specific study procedures. Detailed instructions to guide and standardize all study procedures across sites will be provided in the SSP Manual.
Visits will take place at Screening, Enrollment, and at Weeks 13, 26, 39 and 52. Screening will include administrative procedures, collection of biological samples, and HIV testing. A subset of visits will include STI testing. Enrollment and the Week 13, 26, 39 and 52 Visits will include structured behavioral assessments, HIV risk reduction counseling, assessment of social impact, collection of biological samples, HIV testing, and medical examinations. ART adherence assessment and counseling will be provided as appropriate. Visit duration is approximately two hours for Enrollment, Week 26 and Week 52 Visits. The Week 13 and Week 39 Visits involve an abbreviated behavioral assessment and are expected to last approximately 90 minutes.

5.1 Screening Visit

All participants must provide written informed consent for screening before completing any other procedures. Men who are eligible but who do not consent to screening will be asked about their reasoning to understand motivations; these reasons will be documented without linking it to any personal information.

The following activities will occur during the Screening Visit:

Administrative and Counseling Procedures
- Obtain informed consent
- Collect locator information
- Provide HIV risk reduction counseling
- Provide condoms and lubricant

- Brief behavioral assessment, including eligibility criteria and risk factors for social impact

Clinical Procedures

- Blood collection
- HIV rapid testing

Laboratory Procedures

- Analyses to be performed on blood sample
  - HIV testing (see SSP Manual)
- Plasma storage (for those who opt in).

Screening will be completed for all participants to be able to assess eligibility. HIV counseling and testing will be offered to everyone who consents to screening. Sites will follow the HIV testing algorithm included in the SSP Manual.

HIV-infected: Up to a total of 20 men enrolled at any one site may be HIV-infected. Once that cap is reached, men who have reactive HIV rapid tests during Screening will be provided HIV counseling and referred for culturally appropriate HIV care.

If screening indicates that an individual is eligible for the study and is interested in enrolling in the study, the individual will be asked to return for an Enrollment visit. Those who are not eligible will be informed that they do not meet the requirements of the study and, if necessary, will be referred for appropriate medical care. The Screening and Enrollment visits must be on different days. All HIV test results from the Screening visit must be available at the time of the Enrollment visit. There will be no more than 30 calendar days between Screening and Enrollment.

Men who have discordant HIV test results at Screening (at least one reactive or positive result and at least one non-reactive or negative result) will not be eligible for Enrollment. These men will receive HIV counseling and will be referred for further diagnostic tests and care.

5.2 Enrollment Visit

Individuals who satisfy all Inclusion and Exclusion Criteria may enroll. Participants must be present at the study site for enrollment. If more than 30 calendar days have passed between Screening and Enrollment, men must be re-screened. Participants are allowed to rescreen once only. Enrollment into the study will start with consenting participants into the cohort. Men who are eligible but who do not consent to participate will be asked about their reasoning to understand motivations not to participate; these reasons will be documented and combined with information

provided by the participant during Screening. Participants are considered to be enrolled in the study after they have consented.

The following activities will occur during the Enrollment Visit:

Administrative and Counseling Procedures

- Review locator information
- Collect demographic information
- Full behavioral assessment
- Social impact assessment
- Provide HIV risk reduction counseling
- Provide condoms and lubricant

Clinical Procedures

- Complete medical history, including medications taken in the preceding 3 months
- Full physical exam
- Blood collection
- Urine collection
- HIV rapid testing
- Collection of swabs for STI testing (rectal and pharyngeal)
- Collection of rectal swabs for storage

Laboratory Procedures (Local Laboratory (LL))

- Analyses to be performed on blood sample
  - HIV testing (see SSP Manual)
  - CD4 cell count (if classified as HIV infected at Screening)
  - HIV viral load (if classified as HIV infected at Screening)
  - Hematology (CBC with platelets and differential)*
  - Chemistry (creatinine, phosphate, ALT/AST, bilirubin)*
  - Hepatitis B testing (HBsAg, HBsAb, HBcAb)*
  - Syphilis testing
- Analyses to performed on urine sample
  - Dipstick for protein and glucose*
  - Gonorrhea/Chlamydia (GC/CT) testing
- Analyses to be performed on swabs
  - GC/CT testing**
- Plasma storage
- Urine storage
- Rectal swab storage

* These assessments will be performed to evaluate whether men in the cohort would meet criteria for participation in a future PrEP study.

** In some cases, GC/CT testing using swabs will be performed at the HPTN Laboratory Center (LC) (e.g., if sites do not have the capacity for this testing or do not have validated assays for one or more of the specimen types).

5.3 Follow-up Visits (Weeks 13 and 39)

The following procedures will occur during follow-up visits at Weeks 13 and 39:

Administrative and Counseling Procedures

- Review locator information
- Abbreviated behavioral assessment
- Social impact assessment
- ART adherence assessment and counseling, as appropriate
- HIV risk reduction counseling
- Condoms and lubricant provision

Clinical Procedures

- Interim medical history, including medications
- Symptom-directed physical exam
- Blood collection
- HIV rapid testing (not required if HIV-infection was confirmed at a previous visit, see SSP Manual)

Laboratory Procedures (LL)

- Analyses to be performed on blood sample
  - HIV testing (not required if HIV-infection was confirmed at a previous visit, see SSP Manual)
- Plasma storage

* In week 13, a participant who tested hepatitis B negative at Enrollment and would like to be vaccinated will be referred to an appropriate clinic.

5.4 Follow-up Visits (Weeks 26 and 52/Exit)

The following procedures will occur during follow-up visits at Weeks 26 and 52/Exit:

Administrative and Counseling Procedures

- Review locator information
- Full behavioral assessment
- Social impact assessment
- ART adherence assessment and counseling, as appropriate
- HIV risk reduction counseling
- Condoms and lubricant provision

Clinical Procedures

- Interim medical history, including medications
- Symptom-directed physical exam
- Blood collection
- Urine collection
- HIV rapid testing (not required if HIV infection confirmed at a previous visit, see SSP Manual)
- Collection of swabs for STI testing (rectal and pharyngeal) – Week 52 Visit only

Laboratory Procedures (LL)

- Analyses to be performed on blood sample
  - HIV testing (not required if HIV-infection was confirmed at a previous visit, see SSP Manual)
  - CD4 cell count (if any HIV test is reactive/positive)
  - Syphilis testing
- Analyses to performed on urine sample
  - GC/CT testing
- Analyses to performed on swabs – Week 52 Visit only
  - GC/CT testing*
- Plasma storage
- Urine storage

* In some cases, GC/CT testing using swabs will be performed at the HPTN Laboratory Center (LC) (e.g., if sites do not have the capacity for this testing or do not have validated assays for one or more of the specimen types).

5.5 HIV Confirmation Visit

Additional procedures are required for men who were HIV-uninfected at Screening and have a reactive or positive HIV test at Enrollment or at a follow-up visit. These procedures must be performed on a separate date (see Appendix II).

Clinical Procedures

- Blood collection

Laboratory Procedures (LL)

- Analyses to be performed on blood sample
  - HIV testing (see SSP Manual)
  - CD4 cell count
  - HIV viral load
- Plasma storage

All participants with confirmed HIV infection will be referred for culturally-competent HIV treatment and care as per national guidelines. The continuum of care (including linkage/uptake, retention, and adherence) by HIV-infected men will be assessed.

Note: If a participant has signs or symptoms consistent with acute HIV infection, testing will be performed using an HIV RNA test (see Appendix III). Regardless of whether HIV RNA testing is used for diagnostic testing, HIV infection must be confirmed in all cases using two independent samples collected on different days.

5.6 Behavioral Assessment

Behavioral assessments will be conducted at Screening, Enrollment, Week 13, Week 26, Week 39, and Week 52. The length of the assessment as well as the specific content varies with the assessment moment (e.g., sexual history will only be assessed at Enrollment). The assessment at Screening will focus on basic behavioral characteristics and eligibility criteria. Assessment at Week 13 and Week 39 will be abbreviated and focus on sexual risk practices.

The behavioral assessment instruments will assess: 1) barriers and facilitators to study participation; 2) factors that promote study retention; 3) social harms and benefits from study participation; 4) evaluation of cohort participation experience (including involvement in biomedical and behavioral assessments); 5) uptake of standard HIV prevention interventions; 6) accessing HIV- and non-HIV-related care and treatment; 7) interest in potential HIV prevention strategies and participation in future research; and 8) demographic, behavioral, and socioeconomic characteristics. The last group of concepts includes:

- Demographics (e.g., age, education, employment status, income);
- Psychosexual characteristics (e.g. sexual and gender identification, preference for specific roles in sex, internalized homophobia; sexual practices (e.g., sexual partners, number of acts of receptive and insertive anal intercourse, status of partners, use of condoms and lubrication, sex under the influence);
- Sexual history (e.g., Sexual abuse, forced sex, transactional sex/sex work;
- HIV/STI related factors (e.g., perceived HIV risk, testing history, knowledge of STI

symptoms);

- Substance use (e.g., frequency and kind of use, alcohol- or drug use related problems);
- Experienced stigma and discrimination (homophobia and HIV/AIDS stigma); social and sexual networks characteristics;
- Gay community cohesion and general social capital;
- Access to health care and health seeking practices;
- Mental health;
- Social desirability.

In addition, men who report current female sexual partners will be asked about the possibility of including female sex partners in future studies.

Information will be collected from study participants using a combination of computer-assisted personal interviewing (CAPI) and computer-assisted self-interviewing (CASI). The latter will be offered to participants for the assessment sensitive behaviors, known to be underreported in personal interviews. With illiterate persons and persons who do not prefer to use CASI, CAPI will be used for the assessment of sensitive behaviors. Sites will document whether CASI or CAPI was used.

5.7 Site Recruitment and Retention Monitoring and Reports

Recruitment strategies and outcomes will be monitored allowing the protocol team, 1) to see on a regular basis recruitment progress at the sites; 2) to timely identify recruitment problems; and 3) to explore these problems and develop solutions and additional recruitment strategies.

Because recruitment strategies are site-specific, each site will document recruitment plans and activities, as well as how they evolve during study implementation. Additionally, because of the need to understand recruitment outcomes, sites will document recruitment outcomes per specific implemented strategy throughout the study period. Sites will also document planned and implemented retention procedures.

6.0 STUDY PROCEDURES FOR THE QUALITATIVE COMPONENT

6.1 Study Procedures for IDIs

6.1.1 Recruitment for IDIs

Recruitment of IDIs for this study will be done by site staff in advance of the interviews. During the Week 26 follow-up questionnaire, HPTN 075 participants indicate knowledge and interest in PrEP as an HIV prevention intervention. At SCHARP, the HPTN Statistical and Data Management Center (SDMC), participant identification numbers (PTIDs) will be identified by positive/negative responses to certain questions during the Week 26 interview. In terms of interest in PrEP, participants will be selected who have no or a limited interest in PrEP, as well as men who have a strong interest in PrEP. Those

PTIDs will be sent to designated staff at the respective site, who will recruit potential participants by PTID via the contact information they have provided.

6.1.2 Enrollment for IDIs

The participant will be consented before the interview takes place or any data are collected.

During the interview, participants will receive or undergo the following:

- Informed Consent
- Confirmation of their parent study participant ID number (PTID)
- Interview lasting approximately 60 minutes

6.1.3 Data Collection for IDIs

IDIs will be conducted over approximately four to six weeks. All IDIs will be conducted in a private room at the participant's research site. Interviews will be semi-structured and will last approximately 60 minutes. Interviewers will be trained data collectors. Interviews will be conducted in the local language, digitally recorded, then transcribed and subsequently translated into English.

All participants will receive a monetary incentive for their time and travel, which will vary by site.

6.2 Study Procedures for FGDs

6.2.1 Recruitment for FGDs

Recruitment of FGDs for this study will be done by site staff. During the Week 26 follow-up questionnaire, HPTN 075 participants indicate knowledge and interest in PrEP as an HIV prevention intervention. At SCHARP, the HPTN Statistical and Data Management Center (SDMC), participant identification numbers (PTIDs) will be identified by positive/negative responses to certain questions during the Week 26 interview. In terms of interest in PrEP, participants will be selected who have no or a limited interest in PrEP, as well as men who have a strong interest in PrEP. Those PTIDs will be sent to designated staff at the respective site, who will recruit potential participants by PTID via the contact information they have provided.

6.2.2 Enrollment for FGDs

FGD participants will be consented prior to the start of the focus group. FGDs will last approximately two hours. All FGD participants will receive a monetary incentive for their time and travel, which will vary by site.

6.2.3 Data Collection for FGDs

FGDs will be conducted within a month after training. All FGDs will be conducted at participants' local research site. One facilitator will lead each FGD; facilitators will be trained data collectors. All FGDs will be digitally recorded and transcribed. FGDs will be conducted in the local language.

7.0 SAFETY MONITORING AND ADVERSE EVENT REPORTING

The study team will not collect or report Adverse Events (AEs) because there is no biomedical intervention. However, the team will collect and report all social harms that are reported to study staff members, using a study-specific incident report form. This form will query common and MSM-specific social harms such as altered personal relationships, forced change in housing, and physical violence. The form will also include space for a written narrative to document additional details of any social harm experienced. All research staff will be trained to properly complete the form. As a part of study training, research staff will also be trained on the provision of referrals to counseling and social service support. Reports of social harms will be reviewed by the Protocol Chair, DAIDS Medical Officer, Protocol Biostatistician, SDMC Project Manager, and LOC CRM quarterly or more often, if indicated, and reported to the medical officer together with any actions that are taken. Social harms will be summarized and reported to appropriate IRB(s) following IRB guidelines.

8.0 STATISTICAL CONSIDERATIONS

8.1 Review of Study Design

This is an observational, prospective cohort study, following approximately 400 MSM in SSA. The primary objective of this study is to assess study retention to inform feasibility and power and sample size calculations for future combination HIV prevention studies.

8.2 Endpoints

8.2.1 Primary Endpoints

Primary endpoints are:

1) Recruitment rate within a 6-month period, overall and by site.

2) Cumulative retention rate, measured by the percent of participants who remain in the study at the end of the one-year (Week 52 Visit) follow-up period, overall and by site.

We expect a recruitment rate of 90% of each site's recruitment target within a 6-month period and a cumulative retention rate of 95%, which is measured by the percent of participants who complete the Week 52 Visit (calculated from the moment of informed consent at study enrollment).

We considered a longer follow-up period than one year, more closely reflecting a full scale trial and providing more reliable HIV incidence estimates. However, the primary endpoint can be achieved with a shorter follow-up; HIV incidence is a secondary

outcome and increase in reliability of incidence estimates through extension would be marginal.

8.2.2 Secondary Endpoints

The endpoints associated with relevant secondary objectives are as follows:

- Completed study visits over the full course of the study;
- Self-reported potential barriers to study participation, including internalized homophobia, experienced homophobia, limited social capital, alcohol and drug use problems, mental distress;
- Self-reported experience of study participation, including experienced intrusiveness of biomedical procedures, participation burden, and satisfaction with study participation;
- Self-reported number and types of positive and negative social impact as experienced by participants;
- Prevalence of HIV infection and STIs at baseline;
- Incidence of HIV infection and STIs during follow-up;
- Prevalence of HBV infection at baseline;
- Frequency of abnormal chemistry or hematology results that might exclude participation in a future PrEP study;
- Self-reported uptake of standard of HIV prevention interventions and self-reported access to HIV- and non-HIV-related care and treatment;
- Self-reported interest in future HIV prevention strategies and participation in future HIV intervention trials.

8.2.3 Accrual, Follow-up, and Sample Size

A total of approximately 400 men who report anal sex with a man in the past 3 months (12 weeks), ages 18-44 years, and living in SSA, irrespective of HIV status, will be followed (approximately 100 per site); enrollment of participants who are HIV-infected at Screening will be capped at a maximum of 20 men per study site. The total study duration in the field is 21 months. There will be 3 months of implementation preparation, 6 months of accrual (3 maximum additional months will be allowed for sites who are lagging in enrollment), and 12 months of follow-up.

The primary endpoint is the retention rate (95%) at the end of the one-year (52 week) follow-up. Table A shows two-sided 95% confidence intervals (CI) for the true retention rate based on various possible observed rates, given the sample size of approximately 100 men at an individual site and the sample size of approximately 400 MSM at all sites combined, respectively. For example, if the retention rate is observed as moderate as 75% at a particular site, then the 95% CI for the true retention rate for that site is 67%-83%.

Table A.95% CIs for the True Retention Rate Given Possibly Observed Retention Rates

N	Observed retention rate	95% CI for true retention rate

100 of individual site	50%	40%, 60%
	75%	67%, 83%
	85%	78%, 91%
	95%	91%, 99%
400 of all sites combined	50%	45%, 55%
	75%	71%, 79%
	85%	81%, 88%
	95%	93%, 97%

The leading secondary endpoint is the incident HIV infection rate per 100 person-years. Table B shows two-sided CI for the true HIV infection rate based on various observed number of events and retention rate, assuming that the loss to follow-up occurs uniformly during the one-year of follow-up. For example, if a total number 12 incident HIV infections are observed among four sites with a retention rate of 75%, then the 95% CI for the true HIV infection rate is 2.2%-7.5%.

Table B. 95% CIs for the True HIV-infection Rate Given Possibly Observed HIV Infection Rates*

Observed retention rate (person-years expected)	Observed number of events (infection rate)	95% CI for true incidence rate
50% (60)	1 (1.7%)	0.0%, 9.3%
75% (70)	3 (4.3%)	0.8%, 12.5%
85% (74)	5 (6.8%)	2.2%, 15.8%
95% (78)	7 (8.9%)	3.6%, 18.5%
50% (240)	4 (1.7%)	0.4%, 4.2%
75% (280)	12 (4.3%)	2.2%, 7.5%
85% (296)	20 (6.8%)	4.2%, 10.4%
95% (312)	28 (8.9%)	6.0%, 13.0%

*Assumes that 20% of participants are HIV-infected at Enrollment.

8.3 Data Analysis

8.3.1 Primary Analyses

Primary data analysis will be performed on all enrolled participants. Ideally, each enrolled participant shall be followed-up for one full year (Week 52 Visit). Only those who are retained at the end of the year will be considered to have reached the endpoint. Primary data analysis will tabulate the number of primary endpoints observed during the study, and calculate its percentage of the total enrolled participants. Variance will be calculated under binomial distributions.

Primary data analysis also will calculate the Kaplan-Meier estimates of the primary endpoint taking into account potential loss-to-follow-up during the study. Their variances will be calculated by Greenwood's formula.

8.3.2 Secondary Analyses

Secondary data analyses will be performed to characterize the distribution of secondary endpoints and their potentially associated predictors. Exploratory analyses will first be performed on both secondary endpoints and their potential associated risk factors. Time-to-event secondary endpoints will be analyzed by the Kaplan-Meier estimates, log-rank tests and the Cox proportional hazards model. Binary secondary endpoints will be analyzed by chi-square tests and the logistic regression model. Repeated measurements will be analyzed by Generalized Estimating Equation (GEE) methods.

8.4 Qualitative Data Analysis

Data collected during IDIs and FGDs will be analyzed using qualitative content analysis methods, and qualitative data analysis software that can support team-based analyses. Analysis will proceed through steps of reading, coding, data display, and data reduction.

8.4.1 Reading

Data analysis will begin as soon as possible after the IDIs or FGDs are conducted and transcribed, then translated interviews are sent from the sites to the data analysis team at Columbia University. Transcript text will be read by members of the study team in order to (1) become familiar with the content of the IDIs and FGDs; (2) identify text that may be unclear; (3) point out areas in which interviewing and transcription techniques could be improved; and (4) identify recurrent themes.

8.4.2 Coding

Using a standardized iterative process, a codebook will be developed for retrieving text for key concepts related to the overall objectives, and applied to the data. A software program will be used to organize all qualitative data and prepare it for analysis. Initially, double coding will be completed, in order to uncover any discrepancies. Coding discrepancies will be discussed by the analysis team, the codebook revised accordingly, and recoding performed when necessary to ensure consistent application of codes.

8.4.3 Data Display and Reduction

Once all the transcripts have been coded, textual coding reports will be produced. Data display matrices and memos will be developed to examine each code in detail for subthemes and patterns across interviews, followed by data reduction tables in order to summarize primary themes and subthemes. References to verbatim text will support interpretation of thematic relationships and provide additional explanation to patterns observed.

8.4.4 Analysis of Additional Participant Data

Comparison groups will be defined by demographic profiles and site location, based on the additional participant data collected. Once themes have been synthesized, thematic content will then be compared across these groups to assess similarities and differences in responses, and explore trends in perceptions and motivators across different sites. Participants' qualitative responses will be captured and categorized in Dedoose. Coding memos will then be used to incorporate contextual descriptions and explanations.

9.0 ETHICAL CONSIDERATIONS

Because participants engage in sexual practices that are in varying degrees socially unacceptable and possibly legally prohibited, they are vulnerable to discrimination as part of or as a consequence of study participation. Staff at the various sites may have judgmental attitudes towards study participants and potentially object to study aims and engagement of MSM, for example for religious reasons. Identification of men participating in the study as "gay" or "MSM" could result in social sanctions including targeted violence (e.g., "gay bashing") or arrest; a mob attack on a research clinic (Kilifi, Kenya) has been documented. Beyond standard procedures to protect study participants and staff, and to secure data safety, the following measures will be taken.

- Study sites will be assessed in terms of readiness of conducting the study and treating participants in a culturally competent way; all study staff will receive training to interact with study participants in a non-judgmental, MSM-affirming way before the start of the study.
- There will be an ongoing, dynamic engagement with the MSM community and the broader general community, starting before study implementation.
- The community will be involved in the study through 1) a CAB, consisting of community representatives, including government administrators (e.g., area chief, and police officer), religious leaders, health care workers, opinion leaders, representation of MSM organizations if possible, and, if available, a human rights lawyer; and 2) a PAC consisting of members most familiar with MSM issues and members of the MSM community. The CAB will likely advise on general matters, and the PAC will likely assist researchers in protocol-specific matters such as education and communication materials, appropriate study materials, and may provide feedback on proposed study procedures.
- Research staff, CAB, and PAC will collectively identify and share with the study team concerns and priorities of the communities hosting the research, explore the study's social impact, and may develop responses for addressing any issues. To facilitate a direct response to study participant- and staff-related emergencies, we will install at each site an emergency committee of three persons, consisting of study staff, community representation and an on-call security firm.
- Each study site will develop and implement in collaboration with the protocol team a site-specific risk mitigation plan.

Some men may be diagnosed with HIV at Screening, at Enrollment or during the course of the study. All HIV-positive participants will receive standard, comprehensive counseling and be referred for culturally competent HIV care and treatment.

It is possible that some HPTN 075 participants may also want to join a PrEP demonstration project, as these have been rolled out at most of the sites. It would be unethical to restrict enrollment to just HPTN 075, in this case. Individual use of PrEP will be documented throughout the study.

The sustainability of the services offered to study participants is limited to the study duration. It is expected that an increase in cultural competence in servicing MSM is an added, sustainable outcome of this study. We will work with the host-country Ministry of Health (MOH) and PEPFAR-supported programs, as appropriate, to increase the likelihood of continuity of MSM-affirming services in the study communities.

10.0 HUMAN SUBJECTS CONSIDERATIONS

10.1 Ethical Review

This protocol and the template informed consent forms contained in Appendix IV and V — and any subsequent modifications — have been reviewed and approved by the HPTN Scientific Review Committee (SRC) and DAIDS Prevention Science Review Committee (PSRC) with respect to scientific content and compliance with applicable research and human subjects regulations.

The protocol, site-specific informed consent form, participant education and recruitment materials, and other requested documents — and any subsequent modifications — also will be reviewed and approved by the ethical review bodies responsible for oversight of research conducted at the study site.

Subsequent to initial review and approval, the responsible IRBs/Ethics Committee (ECs) will review the protocol at least annually. The Investigator will make safety and progress reports to the IRBs/ECs at least annually, and within three months of study termination or completion. These reports will include the total number of participants enrolled in the study, the number of participants who completed the study, all changes in the research activity, and all unanticipated problems involving risks to human subjects or others. Study sites will submit documentation of continuing review to the DAIDS Protocol Registration Office (PRO), in accordance with the current DAIDS Protocol Registration Policy and Procedure Manual.

10.2 Informed Consent

Written informed consent will be obtained from each study participant. Each study site is responsible for developing a study informed consent form for local use, based on the template in Appendix IV and V, which describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations. The study site also is responsible for translating the template form

into local languages, and verifying the accuracy of the translation by performing an independent back-translation.

Literate participants will document their provision of informed consent by signing their informed consent forms. Non-literate participants will be asked to document their informed consent by marking their informed consent forms (e.g., with an X, thumbprint, or other mark) in the presence of a literate third party witness. (Further details regarding DAIDS requirements for documenting the informed consent process with both literate and non-literate participants are provided in the DAIDS Standard Operating Procedure for Source Documentation.) Any other local IRB/EC requirements for obtaining informed consent from non-literate persons also will be followed.

Participants will be provided with a copy of their informed consent forms if they are willing to receive them.

10.3 Risks

Sensitive questions
The questions we will ask participants about their sexual behavior or drug use may make them feel uncomfortable.

Phlebotomy
Phlebotomy may lead to discomfort, feelings of dizziness or faintness, and/or bruising, swelling and/or infection.

HIV Testing Stress
Participants may become embarrassed, worried, or anxious when completing their HIV risk assessment and/or receiving HIV counseling. They also may become worried or anxious while waiting for their HIV test results. Trained counselors will be available to help participants deal with these feelings.

Confidentiality and Discrimination
Although study sites make every effort to protect participant privacy and confidentiality, it is possible that participants' involvement in the study could become known to others, and that social harms may result. For example, participants could be treated unfairly or discriminated against, encounter violence, or could have problems being accepted by their families and/or communities. Outsiders might think that men are infected with HIV or are at high risk for infection with HIV, which could result in having trouble finding or keeping a job.

10.4 Benefits

There may be no direct benefits to participants in this study, however, participants and others may benefit in the future from information learned from this study. Specifically,

information learned in this study may lead to the development of a safe and effective intervention that prevents HIV infection.

In addition, men will receive HIV counseling and testing as part of the study screening process, condoms and lubricant (both approved according to WHO guidelines), as well as physical exams. Men enrolled into the study will also be screened for a number of STIs and hepatitis B virus infection and referred for care and treatment, as appropriate. Participant who are hepatitis B negative and would like to be vaccinated will be referred to an appropriate clinic. HIV-infected participants will receive ART adherence counseling.

10.5 Incentives

Pending IRB/EC approval, participants will be compensated for their time and effort in this study, and/or be reimbursed for travel to study visits and time away from work. Site-specific reimbursement amounts will be specified in the study informed consent forms.

10.6 Confidentiality

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with access limited to study staff. All laboratory specimens, reports, study data collection, process, and administrative forms will be identified by a coded number only to maintain participant confidentiality. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access.

Participant's study information will not be released without the written permission of the participant, except as necessary for monitoring by the NIAID and/or its contractors; representatives of the HPTN LOC, SDMC, and/or LC; other government and regulatory authorities, and/or site IRBs/ECs.

10.7 Communicable Disease Reporting Requirements

Study staff will comply with all applicable local requirements to report communicable diseases identified among study participants to local health authorities. Participants will be made aware of all reporting requirements during the study informed consent process.

10.8 Study Discontinuation

The study may be discontinued at any time by NIAID, the HPTN, other government or regulatory authorities, and/or site IRBs/ECs.

11.0 LABORATORY SPECIMENS AND BIOHAZARD CONTAINMENT

11.1 Local Laboratory Specimens

As described in Section 5, specimens will be collected for the following tests at the LL:

- HIV testing (see SSP Manual)
- CD4 cell count testing
- HIV viral load
- Hematology testing (CBC with platelets and differential)
- Chemistry testing (creatinine, phosphate, ALT/AST, bilirubin)
- Urine dipstick for protein and glucose
- HBV serology (HBsAb, HBsAg, HBcAb)
- Syphilis testing
- GC/CT testing (urine, rectal swabs, and pharyngeal swabs)*
- Plasma storage
- Urine storage for substance use testing
- Rectal swab storage

* In some cases, GC/CT testing using swabs will be performed at the HPTN LC (e.g., if sites do not have the capacity for this testing or do not have validated assays for one or more of the specimen types).

Each study site will adhere to standards of good clinical laboratory practice, and local Standard Operating Procedures (SOPs) for specimen management, including proper collection, processing, labeling, transport, and storage of specimens to the LL. Specimen collection, testing, and storage at the LL will be documented using the Laboratory Data Management System (LDMS) as described in the SSP Manual.

11.2 Laboratory Center Specimens

As described in Section 5, specimens will be collected for the following testing at the HPTN LC:

- Pharyngeal and rectal swab testing for GC/CT.

Retrospective testing:

- QA for HIV diagnostic testing, including confirmation of HIV seroconversion;
- Other assessments, which may include: HIV incidence testing, HIV resistance testing, HIV subtyping, phylogenetic analysis, assessment of HIV super-infection, characterization of the virus and/or the host response to infection. Stored plasma may be tested for the presence of antiretroviral drugs and other substances. Stored plasma may also be used for HSV-2 testing;
- Urine testing for substance use (if permitted);
- Rectal swab testing for research related to STIs (retrospective, research testing).

NOTE: Results of QA and other retrospective testing will not be returned to study sites or study participants (with the possible exception of HIV testing, if results differ from results obtained at study sites). At the discretion of the LC, some testing may be performed at another institution or at a commercial laboratory, designated by the HPTN LC.

11.3 Quality Control and Quality Assurance Procedures

The study sites will participate in External Quality Assurance (EQA) programs that are approved by the HPTN LC. LC staff will conduct periodic visits to each site to assess the implementation of on-site Quality Control (QC) procedures, including proper maintenance of laboratory testing equipment and use of appropriate reagents.

The LC will inform site staff of the samples selected for QA testing, and site staff will ship the selected specimens to the LC. LC staff will follow-up directly with site staff to resolve any problems identified through this process.

11.3.1 QC for HIV Diagnostic Testing

Before performing HIV diagnostic testing, all sites must validate their testing algorithm, and the validation study must be approved by the HPTN LC. Local laboratories (or clinics) will perform testing for HIV diagnosis at Screening, Enrollment, and other scheduled visits. Algorithms for HIV diagnostic testing are provided in the SSP Manual.

Laboratories must participate in an EQA program for HIV testing that is approved by the HPTN LC. In addition, the HPTN LC will perform QA for HIV testing.

In addition, if a participant has signs or symptoms consistent with acute HIV infection, testing will be performed using an HIV RNA test. Regardless of whether HIV RNA testing is used for diagnostic testing, HIV infection must be confirmed in all cases using two independent samples collected on different days.

11.3.2 QC for CD4 Cell Count Determination

LLs must be enrolled in the United Kingdom National External Quality Assessment Service (UK NEQAS) program through the DAIDS IQA program, with EQA results that are deemed satisfactory by the HPTN LC.

11.3.3 QC for HIV Viral Load Determination

LLs must be enrolled in the Virology Quality Assurance (VQA) program through the DAIDS, with EQA results that are deemed satisfactory by the HPTN LC.

11.4 Specimen Storage and Possible Future Research Testing

Study sites will store all plasma, urine and swab specimens from all enrolled participants at least through the end of the study and until all protocol-specified assessments have been completed (see Section 11.2 and Appendices I-III). In addition, study participants will be asked to provide written informed consent for their specimens to be stored after the end of the study for possible future testing; swabs that are sent to the HPTN LC for GC/CT testing may also be stored for future testing. The specimens of participants who do not consent to long-term storage and additional testing will be destroyed after all QA and protocol-related testing has been performed. As noted in Section 11.2, results from some HPTN LC testing/assessments will not be returned to study sites or study participants. Sites will also store plasma from the subset of men who are screened but not enrolled who opt in for sample storage.

11.5 Biohazard Containment

As the transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions will be employed by all personnel in the drawing of blood and shipping and handling of all specimens for this study, as currently recommended by the United States Centers for Disease Control and Prevention. All infectious specimens will be transported in accordance with United States regulations (42 CFR 72).

12.0 ADMINISTRATIVE PROCEDURES

12.1 Protocol Registration

Prior to implementation of this protocol, and any subsequent full version amendments, each site must have the protocol and the protocol consent form(s) approved, as appropriate, by their local IRB/ethics committee (EC) and any other applicable regulatory entity (RE). Upon receiving final approval, sites will submit all required protocol registration documents to the DAIDS Protocol Registration Office (DAIDS PRO) at the

Regulatory Support Center (RSC). The DAIDS PRO will review the submitted protocol registration packet to ensure that all of the required documents have been received.

Site-specific informed consent forms (ICFs) will not be reviewed and approved by the DAIDS PRO. Sites will receive an Initial Registration Notification from the DAIDS PRO that indicates successful completion of the protocol registration process. A copy of the Initial Registration Notification should be retained in the site's regulatory files.

12.2 Protocol Amendments

Upon receiving final IRB/EC and any other applicable RE approval(s) for an amendment, sites should implement the amendment immediately. Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. The DAIDS PRO will review the submitted protocol registration packet to ensure that all the required documents have been received. Site-specific ICF(s) will not be reviewed and approved by the DAIDS PRO, and sites will receive an Amendment Registration Notification when the DAIDS PRO receives a complete registration packet. A copy of the final amendment Registration Notification issued by the DAIDS PRO should be retained in the site's regulatory files.

For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual.

12.3 Study Activation

Pending successful protocol registration and submission of all required documents, LOC staff will "activate" the site to begin study operations. Study implementation may not be initiated until a study activation notice is provided to the site.

12.4 Study Coordination

Study implementation will be directed by this protocol as well as the SSP Manual. The SSP Manual will contain reference copies of the *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* and will outline procedures for conducting study visits; data and forms processing; and other study operations.

Study case report forms and other study instruments will be developed by the protocol team and HPTN SDMC. Data will be transferred to the HPTN SDMC for data entry, cleaning, reporting and analysis. Quality control reports and queries will be generated and distributed to the study sites on a routine schedule for verification and resolution.

Close coordination between protocol team members will be necessary to track study progress, respond to queries about proper study implementation, and address other issues in a timely manner. Rates of accrual and retention will be monitored closely by the team as well as the HPTN Study Monitoring Committee. The Protocol Chair, DAIDS Medical Officer, Protocol Biostatistician, SDMC Project Manager, and LOC CRM will address issues related to study eligibility, documentation, and information-sharing across sites.

12.5 Study Monitoring

On-site study monitoring will be performed in accordance with DAIDS policies. Study monitors will visit the site to:

- verify compliance with human subjects and other research regulations and guidelines;
- assess adherence to the study protocol, SSP Manual, and local counseling practices; and
- confirm the quality and accuracy of information collected at the study site and entered into the study database.

Site investigators will allow study monitors to inspect study facilities and documentation (e.g., informed consent forms, clinic and laboratory records, other source documents, case report forms), as well as observe the performance of study procedures. Investigators also will allow inspection of all study-related documentation by authorized representatives of the HPTN LOC, SDMC, LC, NIAID, and US and in-country government and regulatory authorities. A site visit log will be maintained at the study site to document all visits.

12.6 Protocol Compliance

The study will be conducted in full compliance with the protocol. The protocol will not be amended without prior written approval by the Protocol Chair and NIAID Medical Officer. All protocol amendments must be submitted to and approved by the relevant IRB(s)/EC(s) and the DAIDS RSC prior to implementation.

12.7 Investigator's Records

The study site IOR will maintain, and store in a secure manner, complete, accurate and current study records throughout the study. The investigator will retain all study records for at least three years after submission of the Clinical Trials Unit's (CTU's) final Financial Status Report to DAIDS, which is due within 90 days after the end of the CTU's cooperative agreement with DAIDS, unless otherwise specified by DAIDS or the HPTN LOC.

Study records include administrative documentation — including protocol registration documents and all reports and correspondence relating to the study — as well as documentation related to each participant screened for and/or enrolled in the study — including informed consent forms, locator forms, case report forms, notations of all contacts with the participant, and all other source documents.

12.8 Use of Information and Publications

Publication of the results of this study will be governed by the HPTN Manual of Operations and Policies. Any presentation, abstract, or manuscript will be submitted by the Investigator to the HPTN Manuscript Review Committee and DAIDS for review prior to submission.

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14.0 SCHEDULE OF STUDY VISITS AND PROCEDURES

14.1.1 Appendix I: Schedule of Evaluations and Procedures

	Screening	Enrollment	Week 13	Week 26	Week 39	Week 52/Exit
Administrative and counseling procedures						
Informed consent	X	X				
Locator information	X					
Review locator information		X	X	X	X	X
Demographic information		X				
Social impact assessment		X	X	X	X	X
Abbreviated behavioral assessment	X		X		X	
Full behavioral assessment		X		X		X
ART adherence assessment & counseling (if applicable)		X	X	X	X	X
HIV risk reduction counseling	X	X	X	X	X	X
Condom and lubricant supply	X	X	X	X	X	X
Clinical procedures						
Complete medical history including medications		X				
Interim medical history including concomitant meds			X	X	X	X
Full physical exam		X				
Symptom-directed physical exam			X	X	X	X
Blood collection	X	X	X	X	X	X
Urine collection		X		X		X
HIV rapid testing (1)	X	X	X	X	X	X
Pharyngeal and rectal swab collection for STI testing (2)		X				X
Rectal swab collection for storage		X				
Laboratory procedures						
HIV testing (1)	X	X	X	X	X	X
CD4 cell count (3)		X		X		X
HIV viral load (4)		X				
Hematology (CBC with platelets and differential)		X				
Chemistry (creatinine, phosphate, ALT/AST, bilirubin)		X				
Urine dipstick for protein and glucose		X				
Hepatitis B virus serology (5)		X				
Syphilis testing (6)		X		X		X
Urine testing for GC/CT (2)		X		X		X
Pharyngeal and rectal swab testing for GC/CT (2)		X				X
Plasma storage (7)	X	X	X	X	X	X
Urine storage (8)		X		X		X
Rectal swab storage (9)		X				

(1)The HIV testing algorithm is provided in the Study Specific Procedure (SSP) Manual. Confirmation of HIV acquisition at/after Enrollment requires HIV testing at two different study visits (different days). Additional laboratory procedures are required for men who acquire HIV infection during the study (see Appendix II). HIV testing is not required after HIV infection is confirmed.
(2)GC/CT testing will be performed using Nucleic Acid Amplification Tests (NAAT). In some cases, swab testing for GC/CT will be performed at the HPTN LC.
(3)At Enrollment, CD4 cell count testing will only be performed for participants who were classified as HIV-infected at Screening. At subsequent visits, CD4 cell count testing will be performed only for men with confirmed HIV infection

(this includes men who were HIV-infected at Enrollment and men who acquire HIV during the study). CD4 cell counts will be obtained at multiple visits to provide data related to cross-sectional HIV incidence estimation.
(4)At Enrollment, HIV viral load testing will only be performed for participants who were classified as HIV-infected at the Screening visit.
(5)HBV testing will include hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (HBcAb) tests. This testing will be performed using blood specimens.
(6)Syphilis testing will be performed using blood specimens according to local standards.
(7)Stored plasma will be used for Quality Assurance testing and other assessments at the HPTN LC that may include: HIV incidence testing, HIV resistance testing, HIV subtyping, phylogenetic analysis, assessment of HIV super-infection, characterization of the virus and/or the host response to infection. Stored plasma may also be tested for the presence of antiretroviral drugs and other substances. Stored plasma may also be tested for HSV-2. These assessments will be performed retrospectively; results will not be returned to study sites or participants (with the possible exception of HIV diagnostic testing, if results obtained at the HPTN LC differ from site results). Individuals may opt out of sample storage at the Screening visit.

(8)Stored urine will be tested for substance abuse (if permitted by local IRBs). These assessments will be performed retrospectively; results will not be returned to study sites or participants.

(9)Rectal swabs will be stored for possible future testing at the HPTN LC; this may include testing for pathogens such as HSV1/2 and HPV. These assessments will be performed retrospectively; results will not be returned to study sites or participants.

14.1.2 Appendix II: Additional Laboratory Procedures for Men Who Acquire HIV Infection During the Study (HIV Confirmation Visit)

	Confirmation of HIV infection
Clinical procedures	
Blood collection	X
Laboratory procedures	
HIV testing (1)	X
CD4 cell count	X
HIV viral load	X
Additional plasma storage (2)	X

(1)The HIV testing algorithm is provided in the SSP Manual.
(2)Stored plasma will be used for Quality Assurance testing and other assessments that may include: incidence testing, HIV resistance testing, HIV subtyping, phylogenetic analysis, assessment of HIV super-infection, characterization of the virus and/or the host response to infection. Stored plasma may also be tested for the presence of antiretroviral drugs and other substances. Stored plasma may also be tested for HSV-2. These assessments will be performed retrospectively; results will not be returned to study sites or participants (with the possible exception of HIV diagnostic testing, if results obtained at the HPTN LC differ from site results).

14.1.3 Appendix III: Additional Laboratory Procedures for Men Who Have Symptoms of Acute HIV Infection During the Study

	HIV Testing
Clinical procedures	
Blood collection	X
Laboratory procedures	
HIV RNA testing	X
Additional plasma storage (1)	X

(1)Stored plasma will be used for Quality Assurance testing and other assessments that may include: HIV incidence testing, HIV resistance testing, HIV subtyping, phylogenetic analysis, assessment of HIV super-infection, characterization of the virus and/or the host response to infection. Stored plasma may also be tested for the presence of antiretroviral drugs and other substances. Stored plasma may also be tested for HSV-2. These assessments will be performed retrospectively; results will not be returned to study sites or participants (with the possible exception of HIV diagnostic testing, if results obtained at the HPTN LC differ from site results).

15.0 SAMPLE INFORMED CONSENT FORM

15.1.1 Appendix IV: Sample Screening Consent Form

HPTN 075: Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men in Sub-Saharan Africa

Protocol Version 3.0
15 November 2016
DAIDS Document ID: 11943

Study Implementers: TBD

Study Sponsors: National Institutes of Health (NIH), US National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS)

PRINCIPAL INVESTIGATOR: [Insert Name]
PHONE: [Insert Number]

INTRODUCTION
You are being asked to take part in a screening process to find out if you are eligible to take part in the research study named above. The goal of the study is to find out if African men who have sex with men are willing to participate in a 1 year-long research study.

Before you decide if you want to be a part of this screening, we want you to know about the study. This consent form will give you information about the screening process. The study staff will discuss the screening with you, and you are free to ask any questions. After the screening has been fully explained to you, you can decide whether or not you want to participate. This process is called informed consent. If you decide to participate in the screening, you will be asked to sign this consent form or make your mark in front of someone. You will be offered a copy to keep.

What will happen during the Screening visit?
Screening visit: The first study visit (today) is called the Screening visit. The Screening visit will take about 60-90 minutes and will help us to know if you are eligible to join the study. During this visit, you will be asked questions about your health, sexual practices, and personal life to see if you are eligible to participate. Study staff will ask your name and contact information so that we can keep in touch with you during the study.

At this visit, we will draw ~XX mL of blood (about X tablespoons) and your blood will be tested for HIV infection. If tests show that you have HIV infection, you may still be able to participate and will be referred for counseling. We are inviting HIV positive men and HIV negative men to participate in this study, but we are enrolling fewer HIV positive men. We will also counsel you about HIV infection and risks you may be taking. You will be given condoms and lubrication.

The data collected at the Screening visit will be analyzed to learn more about the HIV epidemic among men who have sex with men in Africa.

Leftover samples
Some blood samples will be leftover after the testing for this visit has been completed. We will ask you if we may store these samples. If you agree to store your samples but change your mind later, you can contact study staff. We will then destroy your samples. Stored samples may be sent to laboratories in the United States for testing. Stored samples will not be sold or used for commercial reasons. The samples may be tested for drugs used to treat HIV infection or other substances. If you are HIV-infected, the samples may also be used to study the HIV virus or your body's response to HIV infection. Some of this work may involve studying how HIV spreads within the community. Results from testing stored blood samples will not be returned to the study site or you**.** If you agree to have your samples stored, we will ask you to initial the end of this form.

What are your rights as a research participant?
- Your participation in the screening is entirely voluntary.
- You may decide not to take part in the screening tests or to leave at any time without losing the benefits of your standard medical care or other services. You will be treated the same no matter what you decide.
- If you decide not to participate in the screening, you cannot participate in this research study.
- Even if you agree to participate in the screening, it does not mean you have agreed to participate in the research study.
- We will tell you about new information from this or other studies that may affect your health, welfare or willingness to stay in this study.

What are the risks/discomforts of this screening?
Taking blood may cause pain and bruising at the place where the blood is taken. Sometimes, drawing blood causes people to feel lightheaded or even faint. The questions about your sexual activity might make you uncomfortable or embarrassed. Getting an HIV test may cause you anxiety.

We will make every effort to protect your privacy and confidentiality while you are in this screening. However, it is possible that you could have problems if people learn that you are here for this screening. People may think that you are infected with HIV or at risk of HIV because of sexual behavior. If you are infected with HIV, you may have problems finding or keeping a job. Others may treat you unfairly, including your family and community.

Are there potential benefits to screening?
These screening tests may or may not be of direct benefit to you. If you take part in this screening, you will learn information about HIV and your HIV status.

What about confidentiality?
All efforts will be made to keep your personal information confidential to the extent permitted by law, but we cannot promise complete confidentiality. On your screening records, a code will be used

instead of your name. Only the study staff will know this code. The study staff will not give out any information that identifies you without your written consent. However, the clinic's Ethics Committee or Institutional Review Board, NIAID and or its contractors, representatives of the HPTN LOC, SDMC, and/or LC, and other government and regulatory authorities may review your screening records for study purposes.
(Insert local requirements for reporting of communicable diseases)

A description of this study will be available on www.ClinicalTrials.gov. This web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.

What are the costs or payments to you?
There will be no cost to you for these visits, examinations, laboratory tests or other procedures.

What should you do if you have problems or questions about the screening?
For questions about this screening or a research-related injury, contact:

- [Name, physical address, phone number of the investigator or other study staff]

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

- [Name, title, and contact information of person on the Institutional Review Board (IRB) or other organization appropriate for the site]

STATEMENT OF CONSENT

I have read (or someone has read and explained to me) this consent form. I understand the purpose of the screening, the procedures to be followed, and the risks and benefits as described in this consent form. I voluntarily agree to be screened for my potential participation in this research study.

_____

Participant's Name (print) Participant's Signature or Thumbprint and Date

For staff: I have explained the purpose of the screening to the volunteer and have answered all of his/her questions. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this study screening.

_____

Study Staff ConductingStudy Staff Signature and Date
Consent Discussion (print)

For witnesses for illiterate volunteers: I attest that the information contained in this written consent form has been read and explained to the participant. He/she appears to understand the purpose, procedures, risks and benefits of the study screening and has voluntarily accepted to participate in this screening.

For those placing thumbprint only: I attest that the participant who states that his/her name is _____ has placed his/her thumbprint on this consent form of his/her own free will on this day _____.

_____

Witness' Name (print) Witness' Signature and Date

Please initial below to indicate whether you agree to have your leftover samples from this visit stored.

____ My initials indicate that my leftover samples from this visit may be stored for study-related testing.

____ I do not agree to allow leftover samples from this visit to be stored for study-related testing.

15.1.2 Appendix V: Sample Enrollment Consent Form

HPTN 075: Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men in Sub-Saharan Africa

Protocol
Version 3.0
15 November 2016
DAIDS Document ID: 11943

Study Implementers: TBD

Study Sponsors: National Institute of Health (NIH), US National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS)

PRINCIPAL INVESTIGATOR: [Insert Name]
PHONE: [Insert Number]

INTRODUCTION
You are being asked to take part in a research study. About 400 men in southern Africa will participate in this study. The goal of the study is to find out if African men who have sex with men are willing to participate in a 1 year-long research study. Whether you join the study or not is up to you. If you choose to join the study, you may stop taking part at any time.

There may be no direct benefits for you if you participate in this study. There may be some risks with taking part in the study. Before you can make an informed decision about whether to take part in this study, you should understand the possible risks and potential benefits of being in this study. This document, an informed consent form, will describe what will take place during the study. This consent form might contain some words that are not familiar to you. Please ask us to explain anything that you do not understand before you sign this form. If you tell us that you understand the study and have decided that you want to participate, you will be asked to read, sign, and date this form. You will also be offered a copy of this form to keep.

What happens if you do not want to join the study?
Before you learn more about the study it is important that you know the following:

- You do not have to be in this study if you do not want to and you can stop taking part in the study at any time without affecting the services you get at [insert clinic].
- If you decide to stop taking part in the study, you may still join another study if one is available and you qualify.
- During the study, you may be told of important new information about the study that may affect your original decision to join. It will be up to you to decide if you want to continue in the study. If you decide to stay in the study, we may ask you to sign an updated informed consent form.
- If you or your doctor decides that you should withdraw from the study we may ask you to come in for a final visit.

What will happen if I want to join this study?
You are reading this form because you are eligible to participate in the study. If you decide to join the study, you will need to agree to:

- come to 5 study visits at this clinic over the course of 1 year (12 months);
- get tested for HIV infection, hepatitis B infection, and other sexually transmitted infections by us, and receive the test results;
- answer some personal questions related to ways that HIV is spread;
- not participate in other HIV research studies, other than local PrEP demonstration projects, while you are in this study.

What will happen during the study visits?

Enrollment visit: The Enrollment visit will take about 2 hours. During the Enrollment visit, study staff will confirm your name and update your contact information. We will ask you about anything that has happened as a result of your study participation thus far.

We will draw ~XX mL of blood (about X tablespoons). Your blood will be tested for HIV, to see if you have a new HIV infection (if your tests were negative at the Screening visit) or to confirm that you are infected (if your HIV tests were positive at the Screening visit). Your blood will also be tested for hepatitis B virus and syphilis, and to learn more about your general health. We will also collect a urine sample (up to XX mL). We will test the urine for sexually transmitted infections and for tests of kidney function. We will also collect swabs (of your throat and rectum) during the visit to test for sexually transmitted infections. Some of the blood, urine and swab samples collected at this visit will be stored for other testing which is described below. At this visit, you will be asked about your sexual practices and other things that might impact the spread of HIV. We will counsel you about HIV infection, risks you may be taking, and how to avoid getting or giving others HIV. If you are taking HIV medication (ART) we will talk to you about taking your medicine.- You will be asked questions about any changes in your health and medications and we will give you a full physical exam.

Study staff will inform you of the results of the tests performed at this visit. You will be given condoms and lubrication.

Follow-up Visits: Each follow-up visit (4 visits at week 13, 26, 39, 52) will take about 1.5 to 2 hours. Study staff will confirm your name and update your contact information. We will ask you about anything that has happened as a result of your study participation. You will be asked about your sexual practices and other things that might impact the spread of HIV.

We will draw blood ~XX mL of blood (about X tablespoons). If you have not been confirmed to have HIV infection, your blood will be tested to see if you have HIV infection. Your blood will also be tested for syphilis at some of the follow-up visits. We will also collect a urine sample at some follow-up visits (up to XX mL). We will test the urine for sexually transmitted infections. We will also collect swabs (of your throat and rectum) at the last study visit to test for sexually transmitted infections. Some of the

blood, urine and swab samples collected at follow-up visits will be stored for other testing which is described below.

We will counsel you about HIV infection, risks you may be taking, and how to avoid getting or giving others HIV. If you have started taking HIV medication (ART) we will talk to you about taking your medicine. You will be asked questions about any changes in your health and medications and we will give you a physical exam if you report symptoms. If the tests indicate that you may be infected with HIV, you may be asked to come back to the clinic again for additional testing to confirm the results.

You will be given condoms and lubrication.

What will happen if you have a positive test result during the study?

What if your blood shows that you may have HIV?

If you do not have HIV infection at Screening, and tests from this visit or a later visit indicate that you may have been infected with HIV, we will need to do additional HIV testing and you will need to return to the clinic for this testing. If the additional tests show that you have HIV infection, we will do lab tests to see how well your body can fight off infections, and we will measure the amount of HIV virus in your blood. This will help us to learn more about HIV infection and the HIV epidemic in African men who have sex with men. We will also need to do additional HIV testing if you tested HIV positive at the screening visit, but the HIV test from Enrollment visit is negative; if this happens, additional testing will be performed to determine if you are or are not infected. If testing shows that you are HIV infected, we will also refer you for HIV treatment and care.

What if a test result shows that you have hepatitis B or a sexually transmitted infection?
If a test results shows that you have hepatitis B or a sexually transmitted infection, you may still participate in the study. We will refer you for appropriate medical care and treatment.

Stored Samples
Some of the blood, urine and swab samples collected at the enrollment and follow-up visits will be used for other testing as part of this study. Samples may be tested for drugs used to treat HIV infection or other substances. If you have HIV infection, the stored blood may also be used to study the HIV virus or your body's response to HIV infection. Some of this work may involve studying how HIV spreads within the community. Stored rectal swab samples may be tested to learn more about sexually transmitted infections in your community. Stored urine samples may be tested for substances you may be using. Results from testing stored blood, urine and swab samples will not be returned to the study site or you.

Storage of Samples
There may be some blood, urine or swab samples left over after all of the study testing has been completed. We would like to use these samples for future research studies to

develop new HIV tests, HIV vaccines and treatments or to learn more about HIV infection. If you agree for us to use the samples, you will be asked to sign this form.

If you do not agree to have your samples stored, you can still be in this study. If you agree to store your samples but change your mind later, you can contact study staff. We will then destroy your samples.

If you agree to this use of your samples, we will ask you to initial the end of this form. Your blood, urine or swab samples will be sent to designated laboratories in the United States for further testing. Your samples may be stored indefinitely [insert local guidelines]. Any future use or the ability to store your samples longer needs to be reviewed and approved by the NIH and local authorities. If these studies involve other laboratories, we will need approval from your local authorities to store or transfer them elsewhere. Your left over samples will not be sold or used for commercial reasons.

What are the possible risks or discomforts?

Sensitive questions

The questions we will ask you about your sexual behavior or drug use may make you feel uneasy. However, you do not have to answer any question that you do not want to and you can stop answering the questions at any time. You might also feel some discomfort such as gagging as a result of the throat swab and embarrassment during the genital exams.

Blood samples

Taking blood samples may cause some pain, bruise your arm, or make you feel lightheaded. In rare cases, you may faint. There is also a slight chance of infection when blood is drawn.

HIV Testing Stress

You may be nervous while you are waiting for your HIV test result. If the tests show that you have HIV, you may worry about your health and future. You will receive counseling before and after the test to help address your concerns.

Confidentiality

We will make every effort to protect your confidentiality during the study. The study staff will not give out any information that identifies you without your written consent. However, the clinic's Ethics Committee or Institutional Review Board, NIAID and or its contractors, representatives of the HPTN LOC, SDMC, and/or LC, and other government and regulatory authorities may review your screening records for study purposes.

(Insert local requirements for reporting of communicable diseases)

It is possible that others may think that you are "gay" or that you like to have sex with men. They may also learn that you are part of this study and they may think that you are infected with HIV or are at high risk for infection with HIV. Because of this you could have trouble finding or keeping a job. You could also have problems with your family, friends and community.

A description of this study will be available on www.ClinicalTrials.gov. This web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.

What are the potential benefits?
At study visits we will check to see if you have HIV infection, hepatitis B infection, or other sexually transmitted infections. If you do not have a hepatitis B infection and would like to be vaccinated against hepatitis B, we will refer you for that. The counseling you get during this study may help you to avoid HIV, hepatitis B, and other sexually-transmitted infections. If tests show that you have HIV, hepatitis B virus, or another sexually transmitted infection, counseling we provide may help you to learn how to better care for yourself and avoid passing an infection to your sexual partners. We will refer you for care and/or treatment of an infection.

During the study you will have tests to check on the health of your blood, liver, and kidneys. If any health problems are found, you will be referred for care.

At every visit you will be offered condoms and lubricant free of charge.

What are some reasons you may be withdrawn from the study without your consent?
You may be withdrawn from the study without your consent for the following reasons:

- The research study is stopped or canceled, for instance by local authorities, such as the ethical review committee, or by other agencies, such as the study sponsor or other oversight agencies.
- The study staff feels that staying in the study would be harmful to you.
- The study investigators identify other reasons that they believe would prevent you from continuing in the study.

What are the alternatives to participating in this study?
You do not have to join this study.

[Sites to amend as applicable] There may be other studies going on at this study clinic or in the community for which you may be eligible. If you wish, we will tell you about other studies that we know about. There may also be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish.

How will your privacy be protected?
All the information you give us as part of this study will be kept confidential. All your laboratory test results will also be kept confidential. You will get a unique study identification number that will be used instead of your name on your documents. However, at every study visit we will ask you to identify yourself. This is to make sure that it is you who provides samples and information to us. Also we want to make sure that no other person than you can get your confidential laboratory test results. Only the study staff will be able to see records that identify you by name. This information will not be shared with others. All records will be stored in locked file cabinets at the study clinic. Results of your laboratory tests will be made available only to you when you visit

the clinic. Your name will never be used in any publication or presentation about the study.

Your records may be reviewed by the sponsor of the study, the US National Institutes of Health (NIH), and their representatives, ***[insert name of site]*** IRB/EC, study staff, study monitors and [insert applicable local regulatory authorities].

What happens if you are injured by this research?
Taking part in this study may put you at risk for personal injury.

It is unlikely that you will be physically injured by any study activities that are conducted at the clinic. If you are injured, the [*institution*] will give you the treatment needed for your injuries. You [*will/will not*] have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries. You do not give up any legal rights by signing this consent form.

Who can you contact if you have any questions?
We are happy to answer any questions that you may have. It may be that you have questions about your rights as a study participant or that you think you have been injured because you were in this study. In this case you can contact [insert name of the investigator or other study staff] at [[insert telephone number and physical address].

If you have any questions or concerns about whether you should join this study, or your rights as a research participant, you should contact [insert name ore title of person on the IRB/EC or other organization appropriate for the site] at [insert physical address and telephone number].

What is the cost of study participation?
There is no cost to you for being in this study. You will receive [insert local amount] for your time, effort, and travel to and from the clinic for each study visit. You will be given condoms and lubricants, free of charge at each visit.

What should you do if you have problems or questions about the study?
For questions about this study or a research-related injury, contact:

- [Name, physical address, and phone number of the investigator or other study staff]

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

- [Name, title, and contact information of person on the Institutional Review Board (IRB) or other organization appropriate for the site]

HPTN 075: Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men in Sub-Saharan Africa

Protocol Version 3.0
15 November 2016
DAIDS Document ID: 11943

US National Institute of Allergy and Infectious Diseases (NIAID)
US National Institutes of Health (NIH)
Sponsor: NIH, NIAID, DAIDS

ENROLLMENT INFORMED CONSENT FORM

INVESTIGATOR OF RECORD:[*insert name*]
PHONE:[insert number]

SIGNATURE PAGE
Study Participation
If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below.

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

For witnesses for illiterate volunteers: I attest that the information contained in this written consent form has been read and explained to the participant. He/she appears to understand the purpose, procedures, risks and benefits of the study screening and has voluntarily accepted to participate in this screening.

For those placing thumbprint only: I attest that the participant who states that his/her name is _____ has placed his/her thumbprint on this consent form of his/her own free will on this day _____.

_____

Witness' Name (print) Witness' Signature and Date

Samples Stored for Future Testing

Blood:
____ My initials indicate that my blood samples may be stored for future testing after study-related testing has been completed.

____ I do not agree to allow my blood samples to be saved for long-term storage and future testing after study-related testing has been completed.

Urine
____ My initials indicate that my urine samples may be stored for future testing after study-related testing has been completed.
____ I do not agree to allow my urine samples to be saved for long term storage and future testing after study-related testing has been completed.

Swabs:
____ My initials indicate that my swabs may be stored for future testing after study-related testing has been completed.
____ I do not agree to allow my swabs to be saved for long term storage and future testing after study-related testing has been completed.

15.1.3 Appendix VI: Sample In-Depth Interview Consent Form

Interests in PrEP and PrEP-related Studies—In-depth Interviews

Purpose and Overview

You are being asked to take part in an extra portion of HPTN 075. The goal of this part is to find out how MSM feel about PrEP (pre-exposure prophylaxis). PrEP is a new way to stop the spread of the human immunodeficiency virus, or HIV. The main purpose of this part is to understand what some men in the HPTN 075 study think about PrEP and about studies that look at whether various forms of PrEP work. For this part, we will be conducting interviews and group discussions. You have been invited to participate in an interview. About 20 men who have sex with men (MSM) at [insert clinic] will participate in this part of the study.

Voluntary
Whether you join the study or not is up to you. If you choose to join this study, you may stop taking part at any time. If you decide not to participate or to withdraw from the study, it has no consequences for the services you receive here.

Procedures
Your participation will consist of a one-on-one interview with an interviewer in a private room about your thoughts about and experiences with PrEP. This is called an in-depth interview. The interview will last approximately 1 hour. The interview will be recorded. If you do not want the interview to be recorded, you cannot participate in this part of the study.

Risks and Inconveniences
Some questions we will ask you may make you feel uncomfortable and some of the information we would like you to share with us is of a sensitive nature. You may decline to answer any question. You may also stop the interview at any time.

Benefits
There may be no direct benefits for you if you participate in this study. You might find it interesting to share your thoughts and experiences with an interviewer. What you and other men tell us will help us improve HIV prevention for men who have sex with men and design better studies.

Confidentiality
An exact record of what you say during the interview will be recorded. Your name will not be on the recording. The interview will be transcribed [and then translated into English]. All information that might identify you or anybody else will be deleted from the transcription. The recording of your interview will be destroyed once the interview is transcribed and checked, no later than six months after the interview took place. The transcripts will be sent to the Principal Investigator of this study in New York for analysis.

All the information you give us as part of this study will be kept confidential. Your unique study identification number from HPTN 075 will be used instead of your name on your documents for this study. Only study staff here at [fill in] will be able to see records that identify you by name. This information will not be shared with others. All records will be stored in locked file cabinets at the study clinic. In New York, the translated transcript of your interview will be stored on pass-word protected computers. Your name will never be used in any publication or presentation about the study.

Your records may be reviewed by the sponsor of the study, the US National Institutes of Health (NIH), and their representatives, [insert name of site] IRB/EC, study staff, study monitors and [insert applicable local regulatory authorities].

A description of this study will be available on www.ClinicalTrials.gov. This web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.

Study Compensation
You will receive XXXX in cash to compensate you for your participation in the study and XXXX to cover transportation expenses.

Questions
I am happy to answer any questions about the study before we start the interview. If questions come up after the study, you can contact [insert name of the investigator or other study staff] at [insert telephone number and physical address].

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call [insert name ore title of person on the IRB/EC or other organization appropriate for the site] at [insert physical address and telephone number]. (An IRB is a committee that protects the rights of participants in research studies).

Interests in PrEP and PrEP-related Studies

Protocol Version 3.0
15 November 2016

Sponsor: US National Institutes of Health (NIH), US National Institute of Mental Health (NIMH)

IN-DEPTH INTERVIEW INFORMED CONSENT FORM

INVESTIGATOR OF RECORD:[*insert name*]
PHONE:[insert number]

SIGNATURE PAGE
Study Participation
If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below.

_____	_____	_____
Participant Name (print)	Participant Signature	Date

_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

For witnesses for illiterate volunteers: I attest that the information contained in this written consent form has been read and explained to the participant. He/she appears to understand the purpose, procedures, risks and benefits of the study screening and has voluntarily accepted to participate in this screening.

For those placing thumbprint only: I attest that the participant who states that his/her name is _____ has placed his/her thumbprint on this consent form of his/her own free will on this day _____.

_____	_____	_____
Witness' Name (print)	Witness' Signature	Date

15.1.4 Appendix VII: Sample Focus Group Discussion Consent Form

Interests in PrEP and PrEP-related Studies—Group Discussions

Purpose and Overview

You are being asked to take part in an extra portion of HPTN 075. The goal of this part is to find out how MSM feel about PrEP (pre-exposure prophylaxis). PrEP is a new way to stop the spread of the human immunodeficiency virus, or HIV. The main purpose of this research study is to understand what some men in the HPTN 075 study think about PrEP and about studies that look at whether various forms of PrEP work. For this part of the study we will be conducting interviews and group discussions. You have been invited to participate in a group discussion. About 10 men who have sex with men (MSM) at [insert clinic] will participate in this part of the study.

Voluntary
Whether you join the study or not is up to you. If you choose to join this study, you may stop taking part at any time. If you decide not to participate or to withdraw from the study, it has no consequences for the services you receive here.

Procedures
You will have a discussion with a group of other men who participate in HPTN 075. This is called a focus group. The discussion will focus on sexual risk and HIV prevention, and PrEP in particular. PrEP is a way of reducing the risk of HIV transmission by using specific drugs. The discussion will last approximately 2 hours. The discussion will be recorded so we have an exact record of what everyone says, as there is too much information to write down during the discussion. If you do not want the interview to be recorded, you cannot participate in this part of the study.

Risks and Inconveniences
Some questions we will ask you may make you feel uncomfortable and some of the information we would like you to share with us is of a sensitive nature. You may decline to answer any question. You may also stop participating in the group discussion at any time.

Benefits
There may be no direct benefits for you if you participate in this study. You might find it interesting to share your thoughts and experiences with other participants. What you and other men tell us will help us improve HIV prevention for men who have sex with men and design better studies.

Confidentiality
Because you will take part in a group discussion, the other people in the group will also hear your responses. We ask that everyone respect the confidentiality of the other participants. If you decide to participate, please do not discuss what is shared in this group with anyone outside of the group.

An exact record of what is said in the group discussion will be recorded. Your name will not be on the recording. The discussion will be transcribed [and then translated into English]. All information that might identify you or anybody else will be deleted from the transcription. The recording of the discussion will be destroyed once the discussion is transcribed and checked, no later than six months after the discussion took place. The transcript of the discussion will be sent to the Principal Investigator of this study in New York for analysis.

All the information you give us as part of this portion of the study will be kept confidential. Your unique study identification number from HPTN 075 will be used instead of your name on your documents for this part. Only study staff here at [fill in] will be able to see records that identify you by name. This information will not be shared with others. All records will be stored in locked file cabinets at the study clinic. In New York, the translated transcript of your interview will be stored on pass-word protected computers. Your name will never be used in any publication or presentation about the study.

Your records may be reviewed by the sponsor of the study, the US National Institutes of Health (NIH), and their representatives, [insert name of site] IRB/EC, study staff, study monitors and [insert applicable local regulatory authorities].

A description of this study will be available on www.ClinicalTrials.gov. This web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.

Study Compensation
You will receive XXXX in cash to compensate you for your participation in the study and XXXX to cover transportation expenses.

Questions
I am happy to answer any questions about the study before we start the group discussion. If questions come up after this portion of the study, you can contact [insert name of the investigator or other study staff] at [insert telephone number and physical address].

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call [insert name ore title of person on the IRB/EC or other organization appropriate for the site] at [insert physical address and telephone number]. (An IRB is a committee that protects the rights of participants in research studies).

Interests in PrEP and PrEP-related Studies

Protocol Version 3.0
15 November 2016

Sponsor: US National Institutes of Health (NIH), US National Institute of Mental Health (NIMH)

GROUP DISCUSSION INFORMED CONSENT FORM

INVESTIGATOR OF RECORD:[*insert name*]
PHONE:[insert number]

SIGNATURE PAGE
Study Participation
If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below.

_____	_____	_____
Participant Name (print)	Participant Signature	Date

_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

For witnesses for illiterate volunteers: I attest that the information contained in this written consent form has been read and explained to the participant. He/she appears to understand the purpose, procedures, risks and benefits of the study screening and has voluntarily accepted to participate in this screening.

For those placing thumbprint only: I attest that the participant who states that his/her name is _____ has placed his/her thumbprint on this consent form of his/her own free will on this day _____.

_____
Witness' Name (print)Witness' Signature Date