Getting started

Sample protocol for an integrated bio-behavioral survey (IBBS) for men who have sex with men (MSM) using time location sampling (TLS)

UCSF

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Sample protocol for an IBBS of MSM using TLS

This chapter is a sample protocol for an IBBS using TLS. Versions of this example have been approved by several country and university ethical committees as well as the Centers for Disease Control and Prevention (CDC). In this example, FSW are the key population. However, this protocol can be adapted to many populations that meet the underlying assumptions of RDS (see below).

We have provided a comprehensive sample protocol, but check with the ethical committees you will work with before submitting your protocol. Even though we have used this protocol several times, each review is different. Make sure to allow time in your planning process for addressing a round (or two) of questions and revisions.

This chapter will cover the following sections

- Title of the project
- Investigators and institutional affiliations
- Location and funding source
- Abstract
- Background and justification
- Survey objectives
- Survey methods
- Formative assessment
- Population size estimation methods
- TLS survey procedures and logistics
- Data management and analysis
- Ethical considerations
- Projected timeline
- Dissemination of findings
- References
- Appendices including consent forms, sample TLS enumeration forms, data and specimen flow chart, employee confidentiality agreement, incident form, model venue and VDT sampling frames, and model sampling event calendar

Instructions

These materials provide an example to guide you in creating a protocol for your study. You can download an editable version of this protocol here. Begin by reading through the entire protocol and marking sections that you can use or adapt and sections that you need to create.

- Tips and resources for writing sections of the protocol are included as footnotes
- Instructions to you are in brackets and italicized, e.g. [INSERT name here]
- In this sample protocol, we have used the following terms to represent key population, location and language. These terms should be changed to reflect your own context.
  - Men who have sex with men
  - MSM
  - Francisco (we used this as a generic country name)
  - Mission, Castro (we used these as generic city names)
  - Language X
- Once you have finished a draft of your protocol, make sure that you have edited sections from this example to reflect your study. You can use the *Find* function in Word to help you with this task.
  1. Open the Word document and place your cursor at the beginning of the text
  2. Click on the *Edit* menu, and select *Find*
  3. In the *Find what* field enter “Francisco” (or other terms mentioned above)
  4. Click on *Find Next* to locate every instance of the word “Francisco”

The rest of this Toolkit provides sample questionnaires for FSW, MSM and PWID, operations manuals and other resources for implementing an IBBS.

GSI provides technical assistance (TA) in implementing IBBS. Please visit our website and contact us for trainings and TA.

Contents

Men's Health Monitoring Survey: Protocol for an integrated biological behavioral survey using time-location sampling among men who have sex with men

1. Title of the project

Men's Health Monitoring Survey: Protocol for an integrated biological survey with population size estimation using time location sampling among men who have sex with men in Francisco

Operating title: Men's Health Monitoring Survey

Clarification of titles: The full protocol title reflects the

- Key population (men who have sex with men - MSM)
- Primary measures of HIV and other markers of infectious diseases with related risk behaviors
- Population size estimation objective
- Sampling design (time location sampling - TLS)

The term "integrated biological behavioral survey" (IBBS) refers to an overarching approach to tracking HIV prevalence and related factors among key populations at higher risk for HIV infection.

2. Investigators and institutional affiliations

The University of California, San Francisco has an implementing role in this project, and will provide training, technical assistance, survey monitoring, and data analysis. In-country partners will be engaged in the survey and direct its conduct. The current survey will be implemented by employees and agents of Francisco-based institutions.[1]

The University of California San Francisco

UCSF principal investigator:

Name, Title; Address; Telephone; IBBS specialist responsible for oversight of technical assistance on the survey design, implementation, statistical analysis, and training and capacity building.

Ministry of Health (MoH)

The MoH will ensure adherence to ethical principles in Francisco and national public health priorities. The MoH will contribute to the development of the survey protocol and data collection instruments and will also support field implementation activities including data collection procedures and data analysis. The MoH will also assist in dissemination of findings and ensure centralized testing of survey specimens.

Co-investigators identified by the MoH will serve as technical experts on the Francisco HIV epidemic and local adaptations of the survey methodology. The MoH will have final decision on interpretations of findings in the Country context. Laboratory testing for surveillance purposes will be done by MoH laboratories.

MoH principal investigator:

Name, Title; Address; Telephone; responsible for overseeing all aspects of survey planning and implementation including the development of the survey protocol, procedures, centralized testing, results, and distribution of publications.

Local institution/NGO

_____ will be the logistical and administrative arm for the implementation of the behavioral surveillance among MSM. They will be responsible for hiring and supervising survey staff and interviewers. _____ will also provide support in the training of the interview teams, training of health providers, establishment of linkages and flows between IBBS teams and health services, and will also collaborate with recruitment of participants and identification of venues.

Local institution co-investigator:

Name, Title; Address; Telephone; provide input on the protocol and all research instruments, and coordinate national and regional organizations.

Other collaborating institutions: A technical working group/stakeholders group exists to provide guidance about working with the key populations and to assist with linkages to health care and social services. The group is comprised of representatives from _____.

3. Location and funding source

Location: Mission, Francisco for project headquarters, see Section 7.1 for proposed survey sites.

Funding: [*INSERT funding source*]

1 *Describe roles of the institutions involved. Then, list all investigators and their particular role under each institution.*

4. Abstract

This protocol describes survey activities among men who have sex with men in one location in Francisco to measure HIV prevalence, related risk behaviors, and access to prevention and care services. The overall approach is based on standardized methods for IBBS used around the world with adaptations for the Francisco context. A formative assessment phase and multiple methods to estimate the size of the MSM population of Mission, Francisco are included within the survey protocol. Given that MSM are hard to reach, time location sampling (TLS) is proposed to enroll participants, since MSM are accessible at certain venues (e.g. depending on the country context and MSM specific venues in Francisco*)*. TLS is a sampling method that seeks to approximate probability sampling by mapping the universe of venues where the key population can be found, randomly selecting the day, time, and location for recruitment and systematically selecting participants from the venue. MSM age 18 and over who reside, work or socialize in Mission, Francisco will be eligible for this confidential survey. In accordance with Francisco ethical standards, informed consent will be required. Stringent safeguards will be implemented to restrict access to all survey forms and documentation. Further, for the protection of participants, staff will not ask for identification for those agreeing to be part of the survey.

Proposed procedures include

- Administration of a risk behavior questionnaire
- Rapid HIV testing with individual diagnosis and disclosure counseling
- Specimen collection and dried blood spot (DBS) preparation
- ELISA testing for HIV at [*Francisco National Laboratory*]
- External quality assessment testing for HIV

The risk behavior questionnaire will be required for participation in the survey. Participants may consent to or decline all other parts of the survey (e.g. rapid HIV testing, sample collection for surveillance testing). Persons testing positive on rapid HIV tests will be referred to collaborating clinics for care and support services. A sample size of 400 MSM in the survey site is based on providing 80% power to detect a significant ($p<0.05$) 15% absolute change in self reported condom use between the proposed survey and future rounds of IBBS among MSM using a chi-square test and assuming a design effect of 2.0. Findings of the survey will be disseminated to stakeholders to advocate for needed services for MSM, develop appropriate prevention and care interventions, guide future research, and assess the impact of the response to the HIV epidemic over time.

5. Background and justification

Men who have sex with men (MSM) in sub-Saharan Africa are at high risk for acquiring and transmitting HIV.[1, 2] A recent meta-analysis found African MSM are nearly four times more likely to be HIV infected than the general population.[3] Published studies of MSM from Botswana, Malawi, Namibia, Senegal, South Africa, and Uganda have noted high rates of unprotected anal intercourse (UAI) between men.[4-8] In addition, the Senegal survey[5] and VCT[9] and vaccine preparedness[10] data from Kenya report HIV prevalence figures for MSM much higher than their corresponding national prevalence estimates. In South Africa, HIV prevalence among Black, peri-urban township MSM was estimated at 13%, and 34% among the sub-set of gay-identified men.[11] Many MSM are using condoms and water-based lubrication inconsistently; few MSM are aware of their HIV status; and among those who are HIV-positive, few are accessing available treatment.[7] Across much of Sub-Saharan Africa, homosexuality is criminalized to varying degrees, so MSM remain a particularly disadvantaged and marginalized population. Prevailing social attitudes that stigmatize same-sex sexuality further complicate MSM's access to educational and employment opportunities, and the accumulated effects of homonegative experiences contribute to MSM risk behavior.[12]

HIV surveillance in Francisco has typically focused on the general population; with HIV prevalence estimates calculated using data from antenatal clinics (ANC) and periodic probability-based surveys of the general population. These data provide useful information regarding HIV prevalence in Francisco by region, gender, age, and other socioeconomic and behavioral factors.

The most recent national prevalence data suggest that Francisco has a stabilizing epidemic with an overall prevalence of 8% among adults 15-49 years and persistent regional variation with higher prevalence in the central and eastern regions and lower prevalence in the west. Francisco has wide variation in HIV prevalence, with women accounting for more cases than men, rising prevalence in urban areas, and certain high risk populations experiencing higher prevalence rates than the general adult population. Francisco also has diverse potential drivers of the epidemic, including multiple and concomitant partnerships, population mobility, serodiscordancy in partnerships, and low condom use with some partners.[2] While results from surveys of the general population provide valuable information about the HIV prevalence rates in the general population, less is known about the risk of HIV infection among key populations at higher risk for HIV infection, including men who have sex with men (MSM). Less information is therefore available to gauge the specific prevention, care and treatment needs of this population.

Data on HIV infection among key populations at higher risk for HIV infection are limited, although the existence of vulnerable groups and high risk behaviors in Francisco has been documented. Men who have sex with men (MSM) are a vulnerable population that has been recognized by Francisco as an at-risk group in the National HIV/AIDS Strategic Plan. As a hard-to-reach population with limited access to health and legal services, MSM are especially vulnerable to the transmission of HIV and other STIs. While seldom prosecuted in Francisco, there are laws criminalizing homosexuality, and social stigma against MSM is high. In addition to inconsistent use of condoms and water-based lubricants, few MSM are aware of their status, and access to treatment among those who know they are HIV-positive remains low. In addition, many MSM report multiple sexual partners within the past year, though not necessarily concurrent partnerships.

Without knowing how many men have sex with men in Francisco it is hard to evaluate the impact of MSM on national HIV prevalence or the necessary scope of programs designed to meet the needs of MSM. Some non governmental organizations currently have programs that work with MSM in the city selected for surveillance. No national systematic population size estimates have been conducted of MSM in Francisco. MSM are thought to be especially visible within specific urban centers, geographical regions, and specific neighborhoods within Mission.[3]

To effectively design HIV/AIDS policies and interventions for MSM in Francisco, reliable prevalence estimates of HIV and other STIs and related behavioral, social, and environmental risk factors are needed. Further, to appropriately allocate resources, estimates of the number of MSM in Francisco are needed. This protocol proposes to conduct a cross-sectional survey among MSM in one location in Francisco using TLS. We envision that future serial cross-sectional surveys of the same design will be a part of the national behavioral surveillance system that tracks changes in the HIV epidemic among key populations at higher risk for HIV infection and the national response to the epidemic. Data from the formative assessment, the IBBS survey, and the size estimation efforts will enrich our understanding of MSM and their health needs in the Francisco context.

6. Survey objectives

This study is proposed to develop a better understanding of the prevention, care and treatment needs of the MSM population and to develop programs targeted toward MSM in Mission, Francisco. These activities include

- Formative assessment
- Size estimation
- IBBS

Formative assessment activities are intended to inform the methodological and logistical requirements for successful implementation of IBBS activities.

The purpose of the IBBS is to gather in-depth data that can be used to better understand characteristics and behaviors of MSM. The IBBS will provide important information on prevalence of HIV and risk behaviors in this population that will ultimately be used to develop appropriate

2 *Remember to insert citations.*

3 *Include pertinent information and citations from published literature, official reports.*

prevention interventions. Specific objectives include

- Estimate the prevalence of HIV and associated risk behaviors among MSM in Mission, Francisco
- Estimate the population size and distribution of MSM in Mission, Francisco
- Identify and assess determinants of access and utilization of health and social welfare programs among MSM in Mission, Francisco
- Enhance the national capacity to conduct IBBS for key populations in Francisco as a key component of a strengthened second generation national HIV surveillance system

Estimation of MSM population size will provide program staff and policy makers more information on the scope of the HIV epidemic, which will assist them in planning appropriate interventions and allocation sufficient resources. Multiple size estimation methods will be implemented to triangulate results, as recommended by UNAIDS guidelines on size estimation of most-at-risk-populations. Census and enumeration will be conducted with formative mapping and observation, while the multiplier method will be used in conjunction with the IBBS.

7. Survey methods

7.1 Survey location

The MSM IBBS will take place in Mission, Francisco. Mission was chosen a key location through formative assessment. During formative assessment, various key informants made reference to Mission being a key site for conducting the IBBS. Mission has a sizeable gay community, with numerous potential venues for TLS, including bars, taverns, restaurants, public parks where MSM are known to meet and socialize. The precise recruitment venue day time periods in Mission will be determined prior to IBBS implementation based on information from field work preparation activities.

7.2 Overall survey design: TLS with formative assessment

Worldwide, MSM comprise a highly stigmatized population making them hard to reach through conventional population-based survey methods. In response, specialized surveillance methods have been developed that attempt to approximate probability-based sampling through mapping venues of MSM concentrations (e.g., time location sampling - TLS) or through MSM peer referral (e.g., RDS). A stakeholder meeting was held in Mission to discuss the options for conducting IBBS among MSM in Francisco. The meeting included representatives from _____. Participants to this meeting agreed on the need to conduct an IBBS among MSM in Mission, using TLS, preceded by a formative assessment phase in this location

TLS is a probability-based method for enrolling members of a key population at times and places where they congregate. TLS is a procedure in which venues (e.g. bars, parks, taverns, nightclubs, restaurants, streets, gyms) and their associated attendance periods are the primary sampling units. First, formative assessment creates a comprehensive map or universe of venues where the key population can be found and the days of the week and the hours of the day when they can be found in number. This universe or map is used to develop a sampling frame. Second, venues are randomly selected from the sampling frame of the universe of potential venues. Third, a specified day and time period associated with the venue is then randomly selected. Fourth, selected venues are visited during the specified period, and those attending the venue are consecutively or systematically recruited. Conceptually, each member of the key population has a nonzero probability of being selected. Counts of attendance at the venues are used to calculate sampling fractions for weights to produce population-adjusted estimates for key measures and standard errors are adjusted for clustering at venues.[4]

Prior to the launching of the TLS survey, fieldwork preparation for TLS will be conducted at the locations where the IBBS will be conducted. Participants may consent to or decline each part of the study. Persons testing HIV-positive on rapid

4 *Please refer to Resources and references in the Toolbox for key time location sampling methodological references*

testing will be referred to collaborating clinics for care and support services.

7.3 Survey methods

During the planned formative assessment activities, in-depth interviews and focus groups will address specific logistical issues such as feasibility of recruitment through TLS, type of compensation for participating in the survey, and choice of educational materials. All key informants and focus group participants will be asked for verbal informed consent prior to a discussion or interview (*Appendices A and B*).

The following describe TLS methods that will be utilized. Type I and II enumeration as described below will have been conducted during formative assessment activities, this is an iterative process and we will conduct these enumerations again immediately prior to IBBS survey implementation to validate and update formative assessment data, specifically the sampling frame of VDTs.

The mapping portion of the formative assessment will serve to identify all potential venues and times where MSM may be recruited. Venues will be categorized into street locations, dance clubs, bars, taverns, pickup points, commercial establishments, businesses, social organizations, health clubs, and other public places (e.g., parks, beaches). Staff will visit these potential venues during potential times to validate information from formative assessment, carry out standardized counts of patrons who appear to fit the eligibility criteria (enumeration), conduct brief interviews with venue owners and/or key informants on site, and obtain approval of venue owners or managers to conduct recruitment inside or outside these venues during the implementation phase. Once the initial list of venues and associated day-time periods are identified using the formative assessment venue enumeration form (Appendix C) and reviewed by key stakeholders, a sampling frame will be constructed from the set of venues expected to yield at least seven eligible MSM during an average 4-hour sampling event. The minimum of 7 MSM is selected for cost and logistical reasons. A unique five-digit ID code will be assigned to each venue. The first two digits will identify the venue category and the last three digits will identify the specific venue. Only venue owners who agree to let the research team conduct recruitment inside or outside the venues will be included in the sampling frame.

For venues exclusively attended by MSM, enumeration (type I, Appendix D) will be conducted by one or two staff members who will count individuals attending venues during 30 to 60 minute periods. Counts produced in a 30-minute period will be multiplied by eight while counts produced in a 60-minute period will be multiplied by four to estimate the number of participants that might attend a four-hour sampling event at a specific venue. Duplicate visits by the same participant will not be counted.

For venues attended by a mix of people, enumeration (type II, *Appendix E*) will be conducted by two staff members. One will count individuals consecutively and one will systematically approach and briefly interview MSM on their eligibility to participate in the survey. Counts produced in a 30-minute period will be multiplied by eight while counts produced in a 60-minute period will be multiplied by four to estimate the number of participants attending a venue during a specific venue-date-time event. Duplicate visits by the same participant will not be counted.

The field coordinator will notify the venue owner and manager that the team will conduct the survey one or two weeks prior to recruitment and as soon as the team reaches the venue on the specific day and time. The coordinator will also be responsible in completing the recruitment event checklist (*Appendix F*), the data corrections log (*Appendix G*), the enumeration type I, type II, and type III Forms (*Appendices D, E, H*), sample of universe venues form (*Appendix I*), and the recruitment monitoring form (*Appendix J*) to ensure the appropriate information is collected prior, during and after the recruitment event.

Findings from the formative assessment will be used to inform the best location to interview participants. Typically, TLS interviews are conducted in a mobile van or on the street. Regardless of the interview location, it will be selected to ensure the anonymity and confidentiality of the participant.

Prior to the launching of the full TLS survey, formative assessment will be conducted in Mission, Francisco.

7.4 TLS

Assuming that results from the formative assessment indicate that the appropriateness of TLS as the sampling method for MSM in Mission in Francisco, a sample can be obtained by TLS in Mission where MSM congregate and could be easily intercepted.

TLS combines the methods of targeted sampling and cluster sampling to produce a probability sample where clusters (called venue-day time periods VDTs in TLS) are defined by location (e.g., venues where MSM congregate) and time (e.g., early morning or late afternoon). Enumeration will be conducted during the sampling events to provide counts that can construct survey weights for adjusting data to a regional sample.

7.4.1 TLS fieldwork preparation

Before implementing TLS, the sampling frame of clusters (VDTs) must be created. Fieldwork preparation work will be conducted to gauge volume flow of participants at specific venues using input from key informants, observation, and enumeration. The fieldwork preparation will confirm the physical locations within each site where MSM can be systematically intercepted, interviewed, and tested. These will be selected venues where MSM congregate and socialize (e.g. restaurants, bars, nightclubs, taverns, parks, streets, hotels, gyms, etc.).[5] At each venue, the research team will determine the MSM volume/flows and will estimate the number of MSM at each venue and the hours spend at the venue.

More specifically the fieldwork preparation builds on the formative assessment and will encompass the following

- Conduct key information interviews with at least six MSM
- Identify the flow of MSM within specific venues (the flow is the number of MSM passing a reference point per unit of time, and is measured in MSM per hour. This will be done by counting the number day (one hour counts) during early morning, mid-morning, early afternoon, late afternoon, and evening for each day of the week.
- Enumerate the volume of MSM attending each specific venue
  - Manual counts will be taken during one or two day/time periods
  - Manual counts will be recorded onto tally sheets. The data will be recorded with a tick mark on a pre-prepared field form.
- Confirm the physical locations where MSM can be intercepted, interviewed, and provided referrals (e.g. clusters where MSM congregate and socialize)
- Identify further logistical considerations for implementing the IBBS
- Finalize list of services for referrals
- Field test the survey questionnaire
- Pilot test the complete standard operating procedures
- Begin to distribute unique object for size estimation

7.4.2 TLS plan

The sampling plan is developed from information gathered in the fieldwork preparation. The sampling frame is a list of VDTs expected to yield at least eight eligible participants during the sampling event. The sampling frame will reflect the variety of volume/flow of MSM during different time periods and locations venues where MSM congregate and socialize.

The sampling plan will have three stages. Stages 1 and 2 will be conducted sequentially and not simultaneously.

Stage 1 – For each month, 19 to 21 VDTs will be randomly selected (without replacement) from the sampling frame to achieve a sample size of 500 in five months. If there are more sampling events planned than venues available all the venues will be used and additional random selection of venues (without replacement) will be performed until the number of planned events is reached. Random alternates will be selected when the first random selected event is canceled for external reasons.

Stage 2 – For each venue, one of the four-hour periods associated with that venue will be randomly selected. The venues with the least number of four-hour periods will be selected first and scheduled on a monthly calendar. This process will continue until all venues selected in stage 1 are

5 *Insert specific VDTs likely to be sample venues for MSM in Francisco*

scheduled for the upcoming month. If scheduling conflicts occur as the calendar becomes filled, then the remaining four-hour periods of that venue will be randomly selected until a sampling event is scheduled at that venue. If a sampling event is canceled, it will be rescheduled or replaced with a venue not originally selected for that month. Venues that close, or sampling events that consistently produce fewer than seven eligible participants, will be deleted from the sampling frame. As any new venues are discovered, these are added to the sampling frame for subsequent months.

Stage 3 – For each sampling event, the enumerator will count the number of eligible participants in a defined area (e.g., entering the venue, entering a zone near the venue, or crossing a line in the area) in a 4-hour period and interviewers will approach enumerated people consecutively and conduct eligibility interviews. If eligible, enumerated people will be recruited and the field coordinator/enumerator will record the information using the TLS enumeration type III form (*Appendix H*). Consecutive recruitment will continue until all available interviewers are conducting interviews. Once an interviewer becomes available, recruitment will resume. Reasons for intercept and enrollment refusal will also be collected. For venues with low attendance, the enumerator can approach enumerated people and conduct eligibility interviews if all interviewers are occupied. If eligible, up to two enumerated people will be given a same-day appointment or be told when the next interview will be available. The enumerator will complete the enumeration type III form for each venue visited.

A sampling frame (*Appendix K*) will be updated each month and a sampling calendar (*Appendix L*) will be developed each month during survey implementation. The selected venues and VDTs are scheduled on a calendar as primary sampling events. Although venues and VDTs will be randomly selected, the actual sampling days available are purposefully chosen to accommodate administrative and staff needs. For example, staff may need a day to catch up on paperwork, debrief, and provide additional training.

Each VDT sampled is expected to yield between 8-15 MSM. The number enrolled and the number enumerated will be used as survey weights to adjust estimates. The VDT will also serve as the primary sampling unit to adjust for clustering.

7.4.3 TLS implementation

In accordance with expected attendance at venues, teams of two to five staff members conduct the sampling events. During sampling events, all seemingly eligible people, who enter into a defined space or cross a certain line, are consecutively approached, and asked to complete a brief eligibility interview. Recruiters will be trained to approach possible participants by identifying themselves, their organization, their purpose, and to confidentially and discreetly conduct the brief eligibility interviews. Clearly identifiable project clothing such as t-shirts, identification badges, or a clipboard will be used to help assure clients of the legitimacy of the IBBS. All eligible people will be asked to participate in the IBBS.

Each venue will have pre-defined private and discrete locations for interviewing. Individuals who agree to participate in the IBBS are accompanied to these locations. These locations will be easily accessible from the recruitment area, quiet, private, and spacious enough so that biological specimens and completed questionnaires can be kept out of the sight of participants and staff members who are not cleared for access. At these locations participants will be asked for verbal informed consent for conducting the survey interview, having a blood sample prepared for HIV-related testing, and having a rapid HIV test performed on site. Characteristics of certain sampling venues may require temporary utilization of tents and/or project vehicles to set up outside of the locations and/or rooms next to the locations will be rented out. Focus groups and pre-implementation activities will determine the best option for each location.

7.4.4 TLS participant eligibility criteria

Eligibility for the MSM IBBS includes the following reported criteria

- Biologically male
- Age ≥ 18 years
- Able to speak one of the study languages (see section 7.6)

- Had anal and/or oral sex with a biological male in the past six months with ability to answer screening questions to verify knowledge of MSM sexual behavior
- Approached by study staff in designated venue/time
- Capable and willing to provide informed consent to participate

Exclusion criteria

- Previous participation in the survey
- Inability to provide informed consent (including persons incapable of providing consent do to the influence of alcohol or drugs)

Nationality and citizenship will not be inclusion or exclusion criteria under the rationale that foreigners living in Francisco may form part of the MSM population in the survey areas.

7.5 Language

It is anticipated that the majority of people living in the urban and peri-urban areas comprising the potential survey regions will speak Language X. All interviewers will be fluent in Language X for administration of consent and the questionnaire, which will be forward and back translated from English to Language X by a certified translator. During the formative assessment phase of this survey, we will determine if it is necessary to translate survey materials into languages other than Language X (i.e., local languages spoken in the survey area). If it is found that a sizeable proportion of the potential survey population is not conversant in Language X and speaks another local language, we will consider translation of all survey materials into the appropriate language. The appropriate ethical review boards will be informed of any changes prior to recruitment of subjects, and will be provided with copies of translated survey materials.

7.6 Sample size and power estimates

The sample size estimate is based on the surveillance purpose of tracking important changes in the epidemic over time; that is from earlier estimates of HIV prevalence (i.e., between rounds of IBBS). In the proposed study, each site will constitute a separate survey with the sample size needed to track changes at each location. The needed sample size is 400 MSM participants per city in Francisco, which is calculated as the ability to estimate the difference between the null hypothesis for the prevalence of HIV, versus an alternative hypothesis, with a given precision. The estimation is based on the following formula and assumptions:

Where:

$$N = Deff \left[\frac{Z_{\alpha}\sqrt{Pn\,(1-Pn)} + Z_{\beta}\sqrt{Pa\,(1-Pa)}}{Pn-Pa} \right]^2$$

Deff = design effect of 2.0. A low to moderate design effect is projected for TLS surveys based on clustering characteristics among persons recruited at specific venues. A design effect of 2.0 is therefore reasonable for this study, and produces a feasible sample size to recruit in multiple locations in Mission, Francisco.

P_n = the null hypothesis for the proportion of the key variable or behavior. For the purposes of estimation, we will use HIV prevalence of ___% for MSM, which was the HIV prevalence found most recently among MSM in Francisco.

P_a = the alternative hypothesis for the proportion of the key variable or behavior. For the purposes of estimation, we will use a difference of 10% in HIV prevalence, or an HIV prevalence of (X + 10)% in HIV prevalence for MSM.

N = desired sample size

Z_{α} = Standard normal deviate at the significance level ($\alpha = 0.05$, two-sided)

Z_{β} = Power of 80%

For this study, we use a 95% significance level and corresponding two-sized z-score, and 80% power and corresponding two-sided z-score.

The above parameters allow for the detection of a 10% difference in HIV prevalence from the produce needed sample sizes of ___ MSM participants. To allow for missing data (particularly because previous experience indicates that many

participants will refuse to participate in the HIV testing), the sample size goal will be ___.

In order to establish the sample size, the prevention indicator of condom use at last sex was used. Condom use at last sex was 70% in a clinic geared for MSM friendly services in Mission, Francisco. The sample size was calculated in R 2.11.1 (R Development Core Team, 2010) using the bsamsize function from the Hmisc library (Harrell, 2009). The estimation is based on the method of Fleiss, Tytun, and Ury (without the continuity correction) to estimate the sample size to achieve a given power of a two-sided test for the difference in two proportions (Fleiss et al, 1980).

Two hundred fifty six (256) MSM in Mission is required to provide 80% power to detect a significant ($p<0.05$) 15% change in condom use between the proposed survey and future rounds of IBBS with MSM using a chi-square test and assuming a design effect of 2.0. We then rounded up 400 to account for the possibility of larger design effects on some variables [e.g., design effects ranged from 1.2 to 4.6 in recent TLS surveys of men who have sex with men in Soweto (Lane et al. 2009, Kajubi et al. 2008)] and to improve overall precision.

In addition, to ensure we meet our primary objective of estimating a prevalence of HIV with an acceptable confidence interval, the sample size was calculated for the confidence interval for a single proportion. Using the R function "n.for.survey" from the library "epicalc", it was determined that a sample size of 377 is sufficiently large to ensure a confidence interval of +/- 0.07 around an assumed prevalence estimate of 50% with a design effect of 2.0 in a population size of 5,000 MSM (Chongsuvivatwong, 2007).[6]

8. Formative assessment

8.1 Formative assessment phase

The formative phase will allow us to better understand MSM networks, practices, and healthcare and other service availability and service seeking behavior. The formative assessment will have two areas of focus

- Identify the operational and logistical needs of conducting TLS in Mission
- Conduct a rapid physical and ethnographic mapping of MSM venues and sub-populations

The objectives of the formative assessment are to

- Describe the context[7] in which HIV risk behaviors take place for MSM
- Describe the factors that contribute to the ways in which MSM use HIV/STI and health services
- Estimate the size of the MSM population in each location
- Identify the operational and logistical needs of conducting IBBS for MSM, including
  - Language of survey administration
  - Locations and times for TLS universe of venue-time periods
  - Feasibility and acceptability of computer assisted personal interviewing [CAPI]
  - Acceptability of using biometric software for participant registration and identification
  - Appropriate type and value of reimbursements for survey participation
  - Providers/clinics interested in being trained to provide appropriate services
  - Other potential barriers and facilitators to a TLS survey
  - Areas of the survey instrument requiring fine-tuning or revisions
  - Extent of social networks across urban and surrounding areas

The second focus will comprise a mapping of the physical locations and types of venues where MSM congregate. The purpose of the mapping is to

- Provide information on where programs may reach MSM
- Make final determination of whether sufficient MSM exist in the area to feasibly meet the full TLS survey sample size

6 *R Code: n.for.survey (p= 0.25, delta = 0.06, popsize = 40000, deff = 2, alpha = 0.05)*

7 *Context refers to the environment in and circumstances under which sexual activity and related HIV risk behaviors occur.*

8.2 Formative assessment methods

The formative assessment phase of the Francisco IBBS-MSM will be conducted using qualitative ethnographic methods, which elicit detailed descriptions of the context and meaning of risk behaviors from the experience and perspective of members of the key population.

For this study, the formative assessment of the Francisco IBBS-MSM will be through rapid assessment using qualitative methods and tools common to ethnographic studies and will include:

- Key informant interviews (KII)
- Focus groups (FG)
- Community mapping
- Walks through/verification of venues by observation

All KII and FG will be facilitated by two members of the research staff (one primary interviewer and one note-taker). Participants will be recruited purposively through our survey partners providing services to MSM in each community or through observation in venues where no services are available. Participants will be asked to sign a consent form (*Appendices A, B*). Participants will be provided a copy of the consent form to take with them, if they so choose. For the protection of participants, staff will not ask for identification for those agreeing to be part of the KIIs or FGs. All KII and FG will be conducted in private settings and last no more than 90 minutes.

Research staff will be trained in mapping, observation and interviewing. Teams will be composed of university-trained field team lead researchers, and field team members, who will be recruited from the local community and employed for the duration of the formative assessment. Teams will participate in a one to two-week training to develop skills in interviewing and focus group facilitation, street safety, confidentiality, and dealing with ethical issues. To increase the capacity of organizations to conduct rapid assessments, additional staff may be invited to participate in the one or two-week training.

Sample size in qualitative research is not set a priori, but based on when data saturation is reached - the point at which further analysis of the data does not yield any new information or does not add anything new to the theory being derived from the data. It is estimated that a minimum of ten KIIs and at least three FGs (with six to ten participants in each group) in Mission will be adequate to reach data saturation (i.e. redundancy).

To protect the anonymity of participants, KII and FG will not be video-taped. With the consent of participants, KIIs/FGs will be audio-taped to capture the discussion and for transcription purposes. However, prior to recording, participants will be instructed not to use their name, the name of other participants, or people that could suffer negative consequences if they are identified (e.g. they should not use the names of friends; however, they could use an alias).

During the sessions, the research staff will generate notes as the discussion unfolds to help formulate follow-up questions and probes. Notes will be taken with no identifying information. At the end of each session, responses will be analyzed. Formative staff will write up their impressions about the session, its main themes and the comments and reactions of participants.

Key informants and focus group participants will not receive incentives. However, light snacks and non-alcoholic refreshments will be provided.[8] Key informants and focus group participants who travel to a KII/FG site will also receive a one-time reimbursement valued at $2-$4 USD in cash for transportation costs.

8.2.1 Key informant interviews

Key informants serve as cultural experts, offering insight into the context of HIV risk behavior among MSM locally, as well as the types of locations where MSM congregate and can be recruited. Although good key informants may not know everything there is to know about MSM who are at risk for HIV infection, they should be able to contribute to the understanding of how best to approach potential participants and identify problems that Francisco IBBS-MSM staff may encounter in the field. A diverse group of key informants should be interviewed to accurately reflect the characteristics of the MSM locally (Schensul et al. 1999).

8 *This is up to the policies of the country for conducting surveys*

Key informants will include individuals important to and well informed about the MSM community in the proposed sites. Examples of key informants include: MSM community leaders (current and former MSM), persons doing outreach work among MSM, researchers familiar with local MSM, healthcare and other service providers.9

After a brief introduction of the survey, the interviewer will obtain informed consent from the key informant participant. Trained staff will conduct all interviews using an interview guide. Interviews with key informants will be semi-structured and open-ended, allowing for detailed and in-depth discussions of issues. The interview guide will aim to elicit information on healthcare and other service provision to MSM in Francisco and potential referral for HIV care and treatment. Information collected through key informant interviews will be exploratory in nature (e.g., health concerns of MSM and the demographic characteristics of local MSM) and focused on particular topics (e.g., healthcare services sought by MSM, barriers to healthcare provision, social assistance provided to MSM, the identification of local HIV prevention programs for MSM, and the possibility of conducting testing and treatment of other STI or blood borne disease).

8.2.2 Focus groups

Focus groups are semi-structured interviews conducted with several individuals at a time, under the direction of a moderator (Kreuger and Casey 2000). This interview format can provide quick information about general topics of interest (e.g., risk behaviors among local MSM, social networks among MSM, means of recruiting MSM to participate in the survey, acceptability of proposed technology to be used in the research, and the identification of MSM community stakeholders and local leaders) or specific information on issues about which little is known (e.g., where local MSM look for sexual partners and/or drugs and how the MSM survey should be marketed locally). Information collected through these focus groups may be used to validate findings from other formative assessment activities. Focus groups can be used to explore issues that were raised by key informants or were observed by staff in the field.

Participants in focus groups will be recruited at Mission. Participants will be recruited for focus groups using purposeful sampling techniques, which is the intentional recruitment of participants who are best suited to provide a full description of the phenomenon being investigated. The composition of each focus group will be relatively homogenous in terms of relevant socio-demographic characteristics in order to encourage individuals to freely share their ideas and perceptions. Focus group participants will include MSM and stakeholders; however, the groups will not be mixed.

After a brief introduction of the survey, the moderator will obtain informed consent from each participant, separately. The objectives of the session will be outlined with the aid of the interview guide and the session will proceed. FG will be conducted by two trained assistants (a primary interviewer and a note taker) with the aid of interview guides that will be used to elicit individual responses within the context of a group. The interview guide will aim to elicit discussion on issues related to MSM behavior, socio-demographic characteristics of MSM, acceptability of proposed survey procedures and sampling method, healthcare and other services seeking and availability and the feasibility of the survey in Mission, Francisco.[10]

8.2.3 Community mapping and observation

Ethnographic mapping involves the use of simple graphics or maps to convey information about the environment of a survey site (Schensul et al., 1999) to help investigators understand the social organization of behaviors under survey in the targeted area (Bluthenthal & Waters, 1995). In the context of the formative assessment for IBBS, survey staff will conduct ethnographic mapping and observation to document the environment, such as hotspots[11], high risk venues, services, and potential locations for recruiting participants for focus groups, in-depth key informant interviews and TLS. Mapping and observations will also be

9 *Please see KII and FGF instruments in this Toolboxfor the KII instrument*

10 *Please see KII and FGF instruments in this Toolbox for the FG instrument*

11 *Hotspots are defined as locations where activities or behaviors take place that are associated with the potential for increased risk of HIV transmission, including substance abuse, high risk sexual encounters, and sex for money exchanges.*

used as the foundation for the size estimation exercise. Observation will be used to describe activities or behaviors in terms of person, time, and place, and to identify patterns of activities that will be relevant for interventions. During observation the field team members will document the characteristics of the location, people, and interactions among people.

The purpose of mapping is to

- Provide information on where programs may reach the key population
- Assist the study team in developing a sampling frame of venues to recruit participants from
- Make a final determination of whether sufficient numbers of MSM exist in the area to feasibly meet the sample size

This study will draw on existing data and local expert knowledge of the area to document through observation and mapping the following

- Areas and neighborhoods where MSM meet and interact with each other including bars, public parks, taverns, nightclubs, restaurants, bookstores, streets, gyms, and entertainment venues
- Location and types of HIV/STI and health services offered both used and not used by MSM
- The main zones of activity of community-based organizations focusing on MSM or who may be able to reach out to MSM
- Locations of potential barriers to the implementation of interventions; for example, the location of police stations, times and days that are not convenient to MSM, etc.

Data collectors will map and observe the above at different times during the day to identify different activities that may take place at different times of the day. Observation and mapping will be conducted periodically throughout the data collection process. No personal names will be included and the names of streets/venues may be changed to protect the key population.

During mapping and observation, census and enumeration size estimation activities will be conducted.

8.2.4 Walk through and venue verification

The principal tools used in this stage of the research are collating the areas mentioned in KIIs and FGs followed by direct observation and verification of social settings through systematic walk through on foot or by car.

Walk throughs consist of conducting systematic street-level observations of the people, homes, businesses, venues, and traffic in these sections on a street-by-street basis. Field notes are produced for each section. Based on KII and FG participant suggestions, walk throughs may be conducted during daylight hours on weekdays (Bluthenthal & Waters, 1995) as well as during night-time hours in order to identify the broadest number and type of sub-populations and risk-group profiles as possible. For examples of ethnographic maps, see Schensul et al. (1999) and Singer et al. (2000).

8.3 Triangulation

We will use other information to help confirm the conclusions from the FG and KII and to increase understanding of the MSM survey population.

Information may include

- Written documents (e.g., policy documents; meeting minutes; organization charts; reports; procedural manuals; and official material such as websites, brochures, press releases, advertising, web pages, and annual reports)
- CBO, NGO and other related events, conference and meeting materials
- Sites/locations where MSM activities are conducted, and the local environment in which they operate such as open and closed spaces (i.e. parks and buildings), safety, accessibility, crowded or quiet

8.4 Transcription and translation

Interviews will be conducted in Language X. Transcription of qualitative data will be carried out as soon as possible by the analysis team. Transcribers should be fluent in all local languages used in the formative assessment phase. Should translation of all qualitative data into one principal language be required, audio recordings will be prepared using a direct meaning-based translation into that principal language or directly if the interviews are conducted in that principal

language. Interview guides will be piloted and modified as necessary.

8.5 Formative assessment analysis plan

Although this is not a formal qualitative assessment, data analysis will be guided by grounded theory methodology. This is a form of qualitative data analysis that uses a constant comparative method to generate theories of human behavior.

Grounded theory works as follows: (a) transcripts of interviews or detailed notes are produced, (b) data is coded and potential analytic categories or themes are identified, (c) data under the same categories or themes are put together and compared, (d) categories that are alike are associated, (e) relations among categories are used to interpret the data or generate hypothesis, explanations about human action/behavior and about the data obtained, but checking the explanatory model with cases that can refute it, and (f) present the results using examples from the data, as stored in interview transcripts or field notes (see Bernard, 2006: 492).

Specifically for this survey, all audiotapes will be summarized immediately after each individual interview and focus group session, and will be later transcribed and translated into English. Field notes from walk throughs and venue verification (systematic observation) will be typed. The information generated from this formative phase will be stored in a common word processing format in order to facilitate analysis. Data will be coded using the main themes in the interview guide as the analytical categories. Other categories that might emerge from the data will also be included in the analysis. Finally themes uniting the categories will be identified.

Data will be organized and analyzed with the aid of qualitative research software such as Nvivo or Atlas.ti. Both software assists in coding chunks of word data and grouping them into discrete units of texts and provides descriptive statistics of the categories and codes. This formative assessment data will aid in identifying the operational and logistical needs of conducting TLS in each location (e.g. identification of potential survey sites, determination of appropriate incentive). See Section 8.1 for the full list of operational and logistical issues to be determined based on information from the formative assessment.

The formative assessment will precede launching of the TLS but continue to update information as the survey progresses (e.g. revision of size estimates, updating of MSM venue lists and maps, and improvements to field logistics). If the sample size is not deemed likely to be met or where appropriate referral services are not available, a different survey methodology may be considered, or only the formative assessment phase will be conducted.

8.6 Formative assessment quality control/assurance

All staff involved with handling and analyzing the data will be trained to adhere to all data collection, management, and analysis procedures. Transcripts will be checked against their recordings by study staff fluent in all the interview languages to ensure accuracy. Socio-demographic data will double-entered and monitored by study staff to reduce errors.

The field team managers and coordinators will meet with data collectors (field team members) daily to monitor progress and ensure quality. Field managers and members from the analysis team will meet regularly to discuss study goals, progress, modifications, recruitment, data analysis, confidentiality and other issues or concerns. Any instances of protocol deviations or other problems identified during the meetings will be addressed by the investigators. In addition, in all stages of the formative assessment, a supervisory group comprised of key stakeholders will conduct field visits for quality assurance checks of all procedures.

9. TLS survey procedures and logistics

9.1 Survey sites

Discreet spaces will be used to administer interviews and counseling in private, collect specimens, and provide service referrals. The location will be quiet and secure. Only IBBS staff, investigators, and recruits will be granted access

to these spaces during the times surveys are being conducted. To avoid stigma by the public, signs will not reveal the actual purpose of the space.

9.2 Survey participation

Individuals will be approached and asked to give their age and confirm they are MSM using the eligibility screening form (*Appendix M*). Team members will explain survey procedures and ask participants to provide verbal consent (*A*ppendix N) before administering a 30-45 minute standardized questionnaire. Depending on the venue, interviews will take place in quiet areas within the venue, in a nearby location, or in a mobile van. After participating in the survey, each participant will receive educational materials and the incentive. This process will be repeated until the quota of participants is reached at each venue. We will also collect the number of persons passing through the venue intercept area during the sampling event and limited demographic data on men who refuse to participate in the survey.

Participation in the study will last no more than 90 minutes. We project approximately 10 minutes for initial screening and consent, 45 minutes for the behavioral survey, 10 minutes for pre-test counseling, 10 minutes for specimen collection, and 15 minutes for results disclosure counseling. The additional procedures for the population size estimation make little or no time demands: service multipliers use counts from existing data, the unique object method entails handing out objects, and the unique event method entails independently attending the event for other reasons.

9.3 Incentives

Based on other projects of similar scope with this population in Francisco, the amount of the incentive for the survey will be ___. We will confirm the local appropriateness of these incentives during formative assessment activities. In addition, participants will receive an HIV prevention packet consisting of condoms and water-based lubricant and safe sex informational pamphlets, specific to MSM population.

9.4 Survey ID codes

The proposed IBBS survey will be confidential. Non-identifying survey ID codes will be used for all data components pertaining to the IBBS survey, including the actual questionnaire. The use of survey codes will prevent linking consent forms with actual surveys and recruitment history. Multiple codes are associated with each individual and used for different purposes:

9.4.1 Unique testing code (UTC)

The UTC used in this IBBS will be a code composed of non-identifying information. The information will be alphanumeric: using measurements that do not change over time (e.g. wrist circumference, feet size, distance from the wrist to the elbow) or using letters of information known to the individual (e.g. first letter of city born in, last letter of first name, etc). The UTC does not go physically on the questionnaire (or electronic database) or on the lab specimen. The UTC will be temporarily linked to the participant's survey code. The UTC is used both for registration and survey identification purposes, and is a method to avoid duplicate participation.

The specific elements of the UTC for the proposed survey will be reviewed for acceptability and modified accordingly during the formative assessment, but may include the following elements

- The first 2 letters of the participant's mothers name
- The participant's shoe size
- The participants age in years at time of initial interview
- The first two letters of the Province of residence.

9.4.2 Survey code

The survey code will be serially assigned. The survey code becomes associated with the questionnaire when the participant is enrolled; it is also recorded on the laboratory samples and tests. The survey code will be delinked from the UTC before samples are tested at the national laboratory.

9.4.3 Biometric technology

Biometric technology is being increasingly used in a variety of settings worldwide (e.g., welfare benefits, fitness club membership, school meal programs). Electronic biometric data can be used to detect duplicate recruits at first visits and to confirm or recreate the recruit's ID at the time of the follow-up visit. The biometric software translates a part of the body, such as a fingerprint, into a code containing numbers and letters; no image of the fingerprint will be stored. The same finger will yield the same code at subsequent occasions in >99.9% of cases. The code is not a personal identifier as it cannot be used to recreate a fingerprint. These codes will be stored separately from interview and laboratory data.

Participants will be asked to provide to provide a biometric identification at the time of initial registration through the use of a commercially available digital reader. Each participant's biometric identification code will be linked to his survey code. The biometric identification code will be used both for registration and identification purposes. Following biometric registration, participants will be asked to provide biometric identification at each follow-up survey visit. In the event that the participant opts not to provide their biometric identification, the UTC will be used to link to the participant's survey code.

After all data collection for the survey and prior to beginning and testing of specimens at the national lab, the database containing the link between UTC and the survey code will be destroyed.

9.5 Eligibility screening

The UTC will confirm that the potential participant had not been enrolled previously. The potential participant's eligibility will be assessed through a short personal interview to screen for eligibility (*Appendix M*) covering the eligibility criteria listed above. When doubts about eligibility remain, staff or MSM volunteers may pose additional (non-standardized) questions to confirm true eligibility.

9.6 Informed consent

Eligible potential participants will be able to read and have read to them an information sheet for informed consent, herein referred to as information sheet, according to their preference with the opportunity to have any questions answered by the interviewer. The information sheet will cover all procedures, potential risks, benefits, and who to contact in Francisco to report complaints or concerns. The document allows for separate consent or declining of components of the survey including

- Completion of the questionnaire
- DBS preparation for HIV surveillance testing
- Rapid HIV testing and results return

Participants will also be informed that if they provide consent for surveillance testing and blood storage, they will not be able to have their stored specimen removed and destroyed after the blood has been sent to the central laboratory.

After the contents of the information sheet are clearly understood by participants, they will be asked for verbal consent. Whenever possible, we recommend verbal informed consent as the best means to preserve anonymity and security. Nonetheless, we recognize that some countries and circumstances require written informed consent. In this example, we assume verbal consent is being obtained. We further recommend consulting and conforming to local requirements with respect to verbal or written consent and the formats and contents required. Staff will not ask for identification (such as government issued ID) from any participant.

A copy of the information sheet will be provided to participants.

9.7 Survey data collection

Standardized data collection instruments adapted for MSM in Francisco will be used for quantitative data collection. Data items will include indicators needed to track the HIV epidemic and the national response for MSM, conforming to international standards (e.g., UNGASS indicators, local Key Performance Indicators), national program needs, and comparability with similar surveys in the region. These instruments collect data on demographics, behaviors potentially correlated with HIV, symptoms of STI among MSM, as well as on HIV-related knowledge, attitude, practices, stigma, discrimination, and risk perceptions.[12]

12 *Please see IBBS behavioral questionnaires in this Toolbox for the data collection instruments*

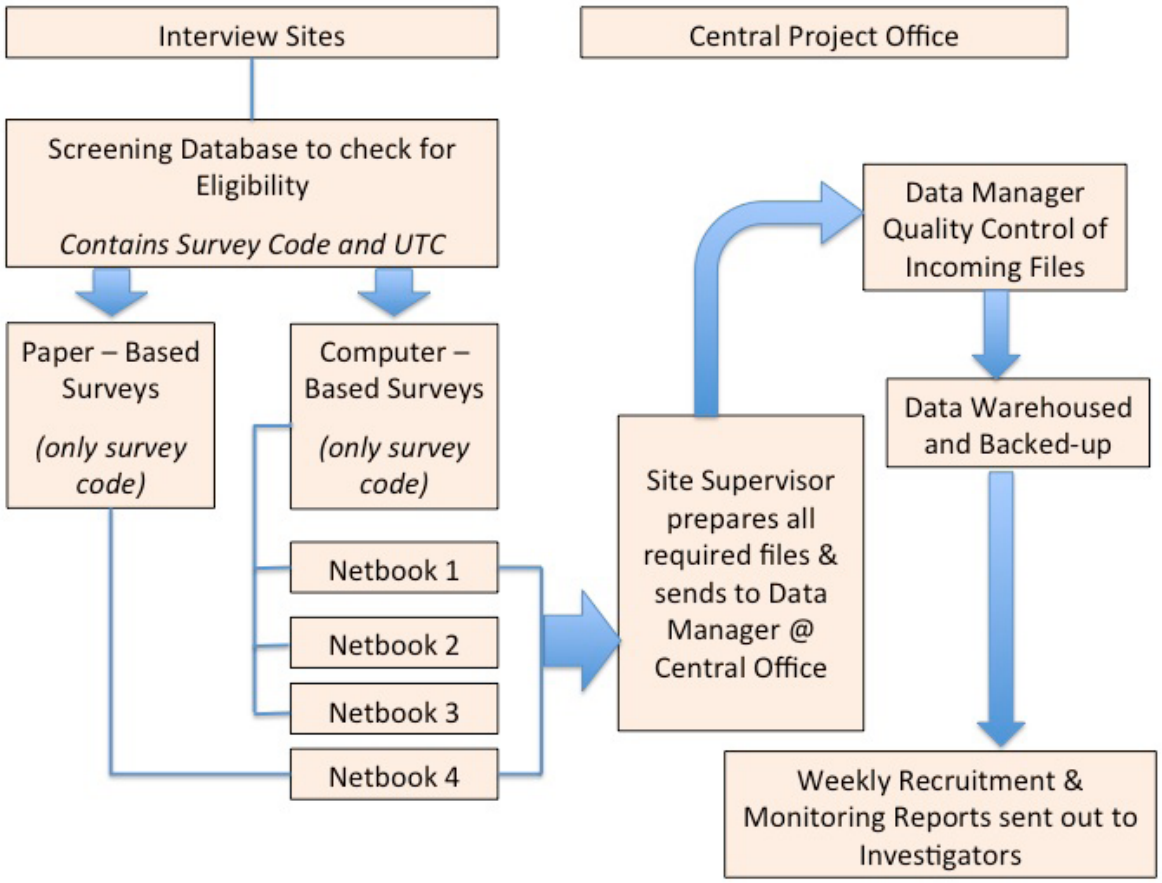
Sample TLS protocol

The questionnaire will undergo development and review in several stages. First, the instrument will be reviewed by the stakeholders during protocol development. A second phase of development will occur through piloting the questionnaire with interactive feedback by key informants during the formative assessment. During the third and final phase, investigators and interview staff will finalize the questionnaire using findings from the formative assessment.

The most appropriate method of administering the questionnaire will be explored during the formative assessment. If feasible and acceptable, the questionnaire will be completed using Computer-Assisted Personal Interview (CAPI), meaning the interview will take place in person with the interviewer posing questions to the participant and noting the participant's answers on a computer. Trained interviewers familiar with the instrument will introduce CAPI to participants, and answer any questions they have about the process. The training of interviewers will also entail a question by question discussion and consensus building process on how to ask each question based on intent and current terms in common usage.

In cases where the participant is not comfortable with the CAPI method of data collection or when there is a failure with the device, a paper-based questionnaire will be used instead. In this situation, the responses will be later entered into the computer application and verified by a second enterer using built-in verification checks in the software. Skip patterns will be programmed in with the questionnaire to ensure appropriate questions are asked of the participants during the interview. The CAPI program will prevent the interviewer from entering any illogical data values. Throughout each interview, verification of completeness and internal consistency will be performed. Additionally, in order to ensure quality of the interviews, interviewers will successfully

Francisco TLS study data flow



complete a minimum of three practice interviews prior to the start of data collection. Once data collection begins, interviewers must be evaluated at least once during the first week by the field coordinator. The field coordinator will also oversee one out of every ten of the interviews conducted by each interviewer. A checklist based on the checklist for medical monitoring project (MMP) structured interviews (*Appendix O*) will be developed for the field coordinator to fill during these interviews. Following each evaluation, the evaluator and interviewer should meet to review the completed checklist and discuss areas where the interviewer could improve. The survey instrument will be in Language X.

9.8 Laboratory testing

Serological testing for HIV will follow national serology laboratory SOPs used for surveillance surveys in Francisco. Participants will consent separately for preparation of a DBS, on site HIV testing, and for HIV surveillance testing at the national laboratory. HIV rapid/point-of-care tests will be conducted on site using capillary blood from a finger prick. Please see *Appendix P* for a data and specimen flow chart.

9.8.1 HIV rapid testing

HIV rapid testing will be conducted at the survey site after completion of pre-test counseling by certified personnel. Rapid testing will be conducted using a serial testing scheme based on the Francisco national algorithm and approved commercial test kits. All participants who consent will be tested using Alere Determine™HIV-1/2 rapid test kits. Non-reactive results will be considered negative, and reactive results will be confirmed with Uni-Gold™ HIV rapid test.[13] If Uni-Gold results are nonreactive, results will be recorded as indeterminate. All participants will receive post test counseling, with specific messages tailored to their test result. Persons with any reactive result, or indeterminate result, will be given referral to HIV care services and further counseling and testing

9.8.2 Dried blood spots creation

Creation of dried blood spots (DBS) specimens on Whatman filter paper for HIV surveillance testing in the National Laboratory will be done with the explicit consent of the participant only, using a dried blood spot card prepared at the same time as the rapid tests. DBS specimens will be labeled with cryogenic bar-coded labels containing the participant's laboratory code. If participants give consent to have a DBS card made, they will be informed that they may not request that the DBS be destroyed once it has been sent to the national laboratory. Specimens will be stored in waterproof boxes on site and sent on a weekly basis to the National Laboratory.

9.8.3 Centralized HIV testing

A serial testing algorithm will be used for HIV surveillance testing of DBS samples. Screening will be done with Vironostika HIV Uniform II plus O (bioMérieux, France). Positive samples will be confirmed with Murex HIV 1-2-O. (Abbot/Murex, Germany). Discordant samples will be tested with Genscreen HIV ½ Version 2 (Bio-Rad, França). Internal quality assurance procedures and external quality assessment procedures will be carried out to guarantee the quality of laboratory testing. Test results will be entered into a CSPro data entry program.

9.8.4 Testing quality assurance

The national laboratory will receive and process a proficiency panel of DBS filter papers before initiating HIV testing for the round. Proficiency testing on a monthly basis will continue until testing for the round concludes. Negative and positive DBS controls are included in each ELISA batch test run. These serve as an internal control measure in addition to those that are included and used in the commercial test kits. In addition a random selection of 10% of samples negative with the screening ELISA will be tested for confirmation of the negative result for internal quality assurance.

External quality assessment for HIV will be done on a simple random sample of 2% of negative specimens and 5% of positive specimens tested each month. DBS spots are separated for these samples and shipped to an external lab. A CSPro data entry program will be used to randomly select the specimens. The samples will be sent without

13 *This is an example of an HIV testing algorithm. Adapt all testing algorithms in this protocol to your own country.*

test results in order to blind them to the external lab. After the samples are tested results will be returned to the central lab in order to calculate the discrepancy rate (number of specimens with different test results over total number of specimens tested). Discordance above 10% will trigger an investigation as to the cause of the discrepancy. Re-testing of some or all samples at an external laboratory may be required. In addition training will be provided to the national laboratory to prevent future testing errors.

9.9 Pre-test risk reduction counseling

Upon completion of the survey and prior to collection of specimens for laboratory testing, participants will receive pre-test risk reduction counseling for HIV and other STIs. Francisco national HIV guidelines for HIV counseling, testing, and referral services will be followed using nationally certified counselors, with adaptations made specifically for the MSM population. Specific training on MSM counseling issues will be conducted to better equip counselors to serve the needs of the population. Pre-test risk reduction counseling will include an explanation of HIV infection and transmission, the meaning of test results, risks associated with sexual behaviors, as well as means to prevent and treat HIV and sexually transmitted infections. Following the pre-test risk reduction counseling, participants who consent will be tested for HIV.

9.10 Post-test counseling and linkage to services

Receiving test results from rapid tests conducted on-site will be strongly encouraged, but will not be mandatory for survey participation.

Results disclosure, post-test counseling, and referral to care and treatment will be provided by the interviewer/counselor immediately following the rapid tests to those participants who opt to receive their results. Post-test counseling messages will be tailored to participants' test results and risk profiles. Post-test counseling will include goals, means, and strategies for behavioral risk reduction, maintenance of risk reduction, and explanation of risk reduction methods (e.g., condom use). Counseling of HIV-infected participants will include an assessment of psychosocial needs, a discussion of living with HIV-infection, treatment and care, and issues related to discrimination. HIV transmission to partners will also be discussed and strategies for behavioral change will be addressed.

For all participants, condoms and lubricants will be provided free of charge. At all locations conducting HIV testing for this survey, collaborations will be developed between the survey team and local clinics that can provide appropriate HIV and other STI treatment services and linkage to care. In addition to linkage to treatment following rapid HIV testing, participants reporting symptoms of STIs (e.g., urethral discharge, genital ulcer) will be referred to the collaborating clinics where they are able to receive STI services. A peer educator will provide direct assistance to persons who need it in order to access referrals. Participants will be referred to healthcare facilities where healthcare personnel will have been sensitized about MSM and the importance of providing friendly and non-discriminatory services to this population. Referral will be done using a referral guide and a card. The referral guide is a form in use in Francisco national health system, it will be previously stamped by the referral healthcare facility, and will contain the participant survey ID, the name of the survey, the name of the counselor, the name of the healthcare facility to which referral is being made and the reasons for reference (for example, HIV positive or STI). Collaborating clinics will be asked to keep numerical counts (no patient identifying information) of referrals from this survey. Survey investigators will follow-up with the collaborating providers at regular intervals to determine whether participants are accessing care and treatment.

9.11 Staff training

Field staff includes a project coordinator, field supervisor, outreach workers, and interviewer/counselors.[14]

The survey staff including (but not limited to) interviewer/counselors, outreach workers, field supervisor, and project coordinator, will participate in a formalized two-week mandatory training on the protocol implementation using a standard operating procedures (SOP) manual. This SOP

14 *You may want to insert a field staff reporting/communication scheme here*

manual will cover training on the protocol, data management, ethics, safety, human subjects, and confidentiality. Interviewer/counselors will also be required to participate in a training on the national guidelines for HIV counseling, testing, and referral services.

Rapid testing and counseling will be conducted by interviewer/counselors. Behavioral questionnaires will be administered to participants by interviewer/counselors using netbooks. Interviewer/counselors will key in responses during the course of the interviews. Electronic data will be sent to the data manager by the field supervisor. The data manager will be responsible for data cleaning and management. Centralized laboratory-based testing and data entry of lab results will be conducted by national laboratorians (results not returned to participants).

Interviewer/counselors will receive training on the administration of the questionnaire, question by question. Skip patterns will be programmed in the questionnaire to ensure appropriate questions are asked of the participants during the interview. The QDS™ program, or interviewers in the case of paper-based interviews, will inform the participant of any illogical data values. Additionally, throughout each interview, verification of completeness and internal consistency will be performed.[15]

10. MSM population size estimation methods

The second survey objective is to estimate the size of the MSM population in Francisco. In the absence of a gold standard, such estimates are imprecise and prone to potential biases. The use of multiple methods strengthens confidence in estimates, provides upper and lower plausibility bounds, and reduces the likelihood that biases of any single method will substantially alter results. The present survey proposes a combination of approaches to produce multiple estimates of the key population sizes embedded within the proposed survey. The following size estimation methods may be used in the IBBS to estimate the size of the key population in the city where the survey is conducted:

literature review, unique object multiplier, unique event multiplier, service multiplier, the wisdom of crowds, and census and enumeration. Many of the size estimation have been used elsewhere and are available in published literature.[16][17]

[*For further guidance on population size estimation methods please consider the following references*]

Estimating the Size of Populations Most at Risk to HIV Infection. UNAIDS, UCSF. Accessed from globalhealthsciences.ucsf.edu/prevention-public-health-group/training-resources/hivaids-epidemiologic-surveillance-trainings

Guidelines on Estimating the Size of Populations Most at Risk to HIV. UNAIDS, WHO. Accessed from www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2011/2011_estimating_populations_en.pdf

Method 1: Literature review. A literature review leverages existing data to calculate key population size estimates. Demographic data is obtained which provides the total number of adult males and adult females (16 and up) then using literature based prevalence of MSM or FSW the size estimate is calculated. For example: in Francisco there are 31,000 adult males. Literature suggests that the prevalence of MSM in a similar country and culture is 1.2% of adult males: 31,000 * 0.012 = an estimate of 372 MSM. No new data is collected for this size estimation method. No human subjects are involved in this size estimation method. The estimates obtained from the literature will be referenced. [*Below are examples of some references for population size estimates*]

Aceijas C, Friedman SR, Cooper HLF, et al. Estimates of injecting drug users at the national and local level in developing and transitional countries, and gender and age distribution. Sex Transm Infect. 2006; 82 Suppl 3:iii10-17.

Cáceres C, Konda K, Pecheny M, et al. Estimating the number of men who have sex with men in low and middle income countries. Sex Transm Infect. 2006; 82 Suppl 3:iii3-9.

15 *Depending on the sponsor, staff may be required to have certification in human subjects research training, such as Collaborative Institutional Training Initiative (CITI) or Good Clinical Practice (GCP)*

16 *Okal J, Geibel S, Muraguri N, et al. Estimates of the size of key populations at risk for HIV infection: men who have sex with men, female sex workers and injecting drug users in Nairobi, Kenya. Sex Transm Infect. 2013;89: 366-371.*

17 *Raymond HF, Bereknyei S, Berglas N, et al. Estimating population size, HIV prevalence and HIV incidence among men who have sex with men: a case example of synthesizing multiple empirical data sources and methods in San Francisco. Sex Transm Infect. 2013;89(5):383-7.*

Carael M, Slaymaker E, Lyerla R, et al. Clients of sex workers in different regions of the world: hard to count. Sex Transm Infect. 2006; 82 Suppl 3:iii26-33.

Marcus U, Schmidt A, Kollan C, et al. The denominator problem: Estimating MSM-specific incidence of sexually transmitted infections and prevalence of HIV using population sizes of MSM derived from internet surveys. BMC Public Health. 2009, 9: 181.

Mathers B, Degenhardt L, Phillips B, et al. Global Epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. Lancet 2008; 372: 1733-45.

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Method 2: Unique object multiplier.

Procedures for unique object multipliers entail two basic steps

1. Distribution of a fixed number of memorable, unique objects (e.g., a bracelet) to members of the survey population in the geographic areas of the survey shortly prior to the survey launch

2. Adding questions to the survey instrument asking about whether survey participants received the unique object. These questions are as follows

- Over the past six months, did you receive an object similar to this I'm showing you?
- Can you show me?
- Can you tell me how you received this object?
- Can you tell me the place and city where you received it?

Using these two data sources, the multiplier method provides a population size estimate with the formula:

$N = n / p$

Where N is the estimated key population size, n is the total number of unique objects distributed in the survey location, and p is the proportion of the key population reporting in the survey questionnaire that they received the unique object.

To strengthen accuracy and recall, the distribution will be done shortly before the launch of the survey and about 500 objects per survey location will be distributed by outreach workers who know how to find the key population. Outreach workers will wear distinctive clothing (e.g., red hat). Outreach workers will instruct the key population not to give the object to anyone else and they will keep a tally of how many objects they distributed each day.[18]

Method 3: Unique event multiplier.

Procedures for a unique event entail hosting a memorable event (e.g., a mobilization fair or a launching party for the IBBS) that records the number of unique key population individuals in attendance. Then, during the survey, all respondents are asked whether they attended the event. The number of the key population counted attending the event and the proportion reporting to have attended the event in the survey questionnaire provide the parameters for the same formula as the unique object multiplier above.

To strengthen accuracy and recall, the unique event will be conducted shortly before the launch of IBBS.[19]

Method 4: Service multiplier. Procedures for a service multiplier entail obtaining program data from a clinic or other program servicing the key population on the total number of key population members who accessed that service during a specific period (e.g. number of FSW accessing a specific clinic). This information will be

18 *Please see Unique object and unique event operations manual in this Toolbox for unique object standard operating procedures*

19 *Please see Unique object and unique event operations manual in this Toolbox for unique event standard operating procedures*

gathered during the formative assessment phase in order to be able to tailor the survey questionnaire accordingly. During administration of the survey questionnaire, all respondents are asked whether they accessed this service during the specified time period. The number of key population members from the service data count and the proportion reporting having accessed this service in the survey questionnaire provide the parameters for the same formula as the unique object multiplier above.

To strengthen accuracy, every effort will be made to ensure that service data counts include all the key population members accessing the service, are unduplicated (no one counted twice), and that service data are for the appropriate period.

Method 5: Wisdom of crowds and modified Delphi. The proposed survey also will produce an estimate of the number of the key population in the survey location through the synthesis of survey participant opinion, also called the wisdom of crowds method (Surowiecki 2004) or modified Delphi.

Participants of the IBBS will be asked their best estimate of the number of key population members like them in their location. Such an approach produces a measure of the perception of community members of the population size of the key population. The wisdom of crowds method theorizes that members of the population have specialized information on the population and that personal opinion formulated in private will not be influenced by others' responses. The estimate will be examined as the median, mode, and mean responses and compared to the other size estimation methods. The wisdom of crowds method has been used in IBBS surveys in Ghana, Kenya, Mozambique, and South Africa, producing estimates close to other methods.

Method 6: Census and enumeration. In both census and enumeration, venues where the key population congregate and meet sex/drug partners are identified by individuals familiar with the local key population context. Censuses are efforts to count all members of the key population at all hotspots (i.e. venues). This method assumes that key populations can be reached at identified venues and then counted, yet members of the key population can be hidden. Thus, visualized numbers may serve as the lowest number in the estimate range. Enumeration is similar to census, but instead of counting every individual at every site, a sample of sites are chosen from a sample frame or list of venues, and only the individuals within those chosen venues are counted. The number counted is then scaled up according to the size and structure of the sample frame.

Drawing on the mapping and observations carried out during the formative phase, a comprehensive list of venues/hotspots where the key population congregates will be compiled. Further mapping may be needed to identify all the hotspots in the survey city and document the days and times the key population frequents each venue/hotspot. From this information staff will prepare a final list of hotspots with the address, time and day the key population frequent the venue/hotspot. Each venue/hotspot on this list will be assigned a unique identification code. The original list with the names of the hotspots/venues and associated code will be kept in a secure cabinet with the site supervisor and destroyed after data analysis. The unique identification code for each venue will be used in data collection forms, analysis and reporting.

Once the list of venues for the survey city is validated and assigned a unique identification code the staff will decide to implement either a census or enumeration method. If the number of venues per key population is less than 30 each, hotspot/venue will be included and a direct count of each key population member will be taken. If more than 30 venues are identified, a random sample of venues will be selected and the key population members in these venues will be counted. Teams will be trained on conducting and documenting counts. Two field team members will visit each venue or a sample of venues and either directly count the number of key population members present using a clicker counter or ask key informants knowledgeable about the site how many members of the key population are at the site, which will be reviewed by the field team manager daily. To account for the possibility of duplicate counting of individuals who frequent multiple hotspots, direct counts will be conducted within a short time frame to minimize mobility between venues.

For both census and enumeration, field team members will spend one to two hours in a hotspot/venue and directly count the number of key population members or ask key informants about the count of key population members. The

field team members will visit the venue/hotspot at peak hours. Peak hours are days and times in the week where key population members frequent the location. Field team members will visit venues/hotspots only once and document the number of key population members they directly see and can identify as the key population or the lower and upper estimates of number of key population members reported by key informants. Field team members will include community guides and stakeholders to assist with identifying members of the key population.

Synthesizing results. Multiple population size estimation methods will produce various size estimates for the key population size in the city where the survey is conducted. These data will be compiled using tables and graphs, then presented at a national stakeholders meeting and discussed. To add to the discussion, other information about population size including published literature estimates will be discussed and confirmed. This discussion will include relative strengths and limitations of each size estimation method, establishment of upper and lower plausibility bounds based on shared local and international data as well as expert opinion. Plausibility bounds, sometimes called credible intervals, are not the same as statistical confidence intervals, but rather they are bounds established that make plausible sense in the local context.[20]

Data entry and analysis. Census and enumeration data were included in the formative data management and storage procedures; these data are currently being entered and analyzed. For the census or enumeration, field team members or other trained data entry staff will double-enter direct counts of the key population for each venue into an excel spreadsheet. The data analysis team will aggregate the reported results to obtain the total number of the key population documented in each city.[21]

Data from the wisdom of the crowds and Delphi method will be extrapolated to other areas of Francisco based on similarities of characteristics (e.g., adult male population size, level of urbanization, presence of key population services and organizations, websites). However, please note estimates are weaker the further data is extrapolated. The modified Delphi method will be concluded with a reconvening of stakeholders to synthesize the new information gathered during the proposed study to revise estimates and apportion the population to different regions of Francisco. All assumptions and formulae will be documented in the final report.

For the multiplier methods, two types of data will be collected. The unique object distribution logs will be double-entered into an electronic database. The data analysis team will aggregate the reported results to obtain the total number of objects distributed to the key population documented in each city. The IBBS data will be entered as described above. Using these two data sources, the multiplier methods provide population size estimates by the formula:

$N = n/p$

Where N is the population size, given by n as the number of the key population using a particular service in a specified time period and p as the proportion of the key population reporting using the particular service in the time period collected in the questionnaire. For example, if an outreach program reached 500 MSM in Mission in 2009 and 10% of survey respondents reported meeting one of the program's outreach worker in 2009, then there are an estimated 5,000 (= 500 / 0.10) MSM in Mission. A variance for this estimate, and hence confidence interval for a population size estimate can be given by:

$$V(S) \approx n_1^2 * (1-m/n_2) / \{ n_2 * (m/n_2)^3 \} + n_1(1/r)^2$$

Size estimation quality control/ assurance. For size estimation methods, staff involved with handling and analyzing the data will be trained to adhere to data collection, management, and analysis procedures. No personal identifiers will be collected. Electronic data will be stored in password-protected databases on portable computers and the original data will be kept in locked file cabinets until they are destroyed. Entry of direct counts from census and enumeration will also be monitored by field team managers and the site coordinator. The field team managers and coordinators will meet with data collectors (field team members) daily to monitor progress and ensure quality of census/enumeration and multiplier data collection activities. Field managers and members from the

20 Please see Population estimate worksheets in this Toolbox for a population size estimate summary spreadsheet.

21 Please see Population estimate worksheets in this Toolbox for a census and enumeration spreadsheet.

analysis team will meet or call CDC staff regularly to discuss study goals, progress, modifications, recruitment, data analysis, confidentiality and other issues or concerns. Any instances of protocol deviations or other problems identified during the meetings will be addressed by the investigators.

Size estimation study limitations. Census and enumeration methods are considered more conservative due to the direct counts of the key population sizes visible at venues. The resulting population size estimates from this method will account for members of the population at the identified venues; more hidden subgroups or populations may not be counted. For instance, FSW who are contacted by clients via cell phone most likely will not be counted. Identification of the key population will depend on field team member knowledge of the community therefore only those key populations recognizable to the field team member will be counted while others may be omitted from the estimation.

The multiplier methods are subject to a number of assumptions that may be difficult to meet and may bias resulting estimate of population size. The members of the population must have a chance of being included in both sources of data. Program and survey data will be evaluated for any potential barriers to inclusion of members of the population. Where this assumption is violated, this will be clearly documented and reported, and other sources of data will be considered.

In addition, the multiplier methods require clear and consistent population definitions, time reference periods, and catchment areas between the different data sources. During preparation for implementation of multiplier activities and collection of programmatic, unique object, and survey data, these issues will be carefully considered, and investigators will ensure that definitions across data sources will be coordinated.

11. Data management and analysis

11.1 Data management

Electronic data from the formative assessment will be stored on a password-protected computer and sent from the site supervisor to the data manager after the completion of each KII or FG. Original paper-based forms from the formative phase and size estimation will be kept in a secure locked cabinet in a locked office at the survey site and brought to the central survey office at the end of the formative phase. Access to data will be limited to research assistants, data analysts, and investigators.

Survey data will be entered in electronic format (CAPI) directly by the interviewer during the interview process using QDS™. To ensure quality of data, built in checks will be programmed into the QDS™ control file and verification of completeness and internal consistency will be performed automatically. Additionally, the site supervisor will oversee one out of every ten of the interviews conducted by each interviewer.

At the end of each day, the site supervisor will upload all interview files from the laptops to a QDS™ data warehouse located on a password-protected computer at the site, and encrypt and email files (de-identified) to the data manager. The site supervisor will also store a back-up copy of the files on a flash drive that will be kept in a locked cabinet at the surveillance office. The interview files will then be deleted from the computers. The data manager will upload all files to a central data warehouse located on a password-protected computer.

Any paper-based questionnaires will be entered daily at the survey site by the interviewer and the site supervisor, using the QDS™ Data Entry module which supports double entry (also called key verification or double keying) for increased quality assurance. The corresponding file will be uploaded to the local data warehouse and emailed to the data manager. Original paper-based forms will be kept in a secure locked cabinet at the survey site, and brought to the central survey at the end of the survey. Questionnaires will not contain identifiable information, only an unidentifiable unique sequential coupon code, and a unique sequential survey code. Access to data will be limited to the data manager, site supervisor, data analysts, and investigators.

Management of codes from both survey results and HIV test results will be performed by the site supervisor on a daily basis. UTC will be used to identify duplicate recruits at that location. The database will be encrypted and emailed to the

data manager on a weekly basis for uploading to the central data warehouse.

Continuous quality checks will be performed to ensure that code numbers are recorded properly for each participant. Merging of data sources (i.e., the laboratory and survey responses) will be conducted under the supervision of the investigators and data manager. All databases will be password protected and data will be encrypted before transmission over public networks.

Once recruitment ends, the UTC will be destroyed. At this time, the specimens will be considered unlinked anonymous tests (UAT). Specimen testing for HIV using ELISA will commence. HIV test results will be extracted from the CSPro data entry program and merged with the QDS warehouse.

11.2 Analysis overview

Standard statistical software packages R, Stata or SAS will be used for the analysis, with commands for complex survey data that incorporate sampling weights and adjustments to standard errors for clustering on day-time sampling events. As a basic surveillance activity, the primary analyses will be the adjusted population point estimates of prevalence of HIV infection, of use of health care services, and of key risk behaviors (e.g., multiple/concurrent partners, drug/alcohol use), prevalence of condom use and access to health care and prevention programs. Potential future waves of the survey will track changes and trends in prevalence over time. Stratified analyses will also be done to present key outcomes by priority sub-populations (e.g., by age, region of origin, etc.).

Multivariate analyses (e.g., regression and logistic regression) will be performed to identify correlates of HIV infection and use of prevention and health care services also using sampling weights and adjustment for clustering. Some possible explanatory variables that can be entered into these models include age; education; province of residency; sexual identity (gay/bisexual/MSM); sexual behaviors (insertive, receptive, or both); marital status; knowledge of HIV; number of sexual partners; alcohol consumption; STI symptoms; and exposure to an HIV/AIDS explicit message. Variables in each model with a p value of 0.05 or less will be included in the model.

Based on similar studies and due to the fact that there will be a large number of small day-time sampling events, we project high heterogeneity within vs. across sampling units, and therefore small adjustments to standard errors. Survey weights will be constructed from the sample fractions for the randomly selected day time sampling units and clustering will be adjusted using standard statistical software package programs for survey-weighted data (e.g. SURVEYFREQ, SURVEYMEANS, SURVEYLOGISTIC, in SAS and the Survey package in R)

Finally, we are aware that there are many approaches to the adjustment of TLS data and the appropriate analysis of TLS data is an area of current research. We will therefore keep abreast of new recommendations and incorporate them into our analysis.

11.3 Long-term data storage

The clean file of de-identified survey data will be the property of the MoH in Francisco. All data (including any paper-based data) will be kept in electronic format on password protected computers. Archival copies of the de-identified survey database will be maintained by the MoH for at least ten years after publication of the final report. Only investigators of the survey will have access to this data. Any person having a copy of the database will have to sign a data use agreement (*Appendix Q*).

A committee composed by the MoH, and _____ has been formed to govern issues related to data use including access and destruction of data. Only MoH, and _____ investigators have access to the final cleaned data and each person with the dataset must sign a data use agreement. All paper-based data will be scanned and then shredded.

In the interest of promoting maximum use of the survey results, the technical working group (TWG) will develop procedures to make the survey database available to interested research individuals from national or international organizations (investigators) once the final report is released. The procedures will include a request application process and a request approval process. The procedures will establish a time limit for fulfilling requests and a responsible party for ensuring that requests are reviewed and fulfilled

within the specified time limit. Prior to publication of the final report, the TWG will approve the use of the de-identified survey data.

12. Ethical considerations

12.1 Potential harm and measures to mitigate harm

A primary ethical concern of this survey includes that participation in the survey may reveal that respondents are engaging in illegal and stigmatized behaviors, including same sex sexual activity, illegal drug use, and commercial sex work. Inadvertent disclosure of information collected from survey procedures may subject persons to discrimination and potential harm. HIV serostatus may also subject participants to stigma and discrimination if inadvertently revealed to persons outside the survey. Although participants will be asked to sign a consent form to be part of the survey, several procedures will be taken to minimize the risk of these disclosures

- Names or other identifying information will not be written on the survey, survey forms, or on any lab specimens
- All paper-based survey materials will be stored in locked file cabinets, in locked offices and access will be limited in the same manner as for electronic data
- Staff will not ask for identification (such as government issued ID) from any participant
- All staff working with participants will be required to sign an employee confidentiality agreement (*Appendix R)*.

During the formative phase, investigators will take all necessary precautions to protect the MSM community, key informants, and focus group participants and not put them in danger of harassment or arrest. They will ensure that mapping exercises will not expose venues where MSM congregate. Each focus group will be composed of persons with similar characteristics to help preserve the privacy of FG participants. Furthermore, FG participants will be reminded that topics discussed in the group should not be shared with other individuals.

Same sex sexual behavior, individual illegal drug use, commercial sex and HIV test results will not be reported to authorities. Prior to initiating the survey a community sensitization event will be held in which key members of the community, including law enforcement, are informed of the survey. Permission for conducting the survey will be obtained by each city government. All survey staff will receive ethical training and will sign confidentiality agreements. Any staff breaching the agreement will be immediately terminated. Site supervisors will immediately report any breach of confidentiality to the project coordinator who will report to all principal investigators.

Diagnosis of HIV infection may also subject participants to psychological and emotional stress. To minimize these harms, we will use trained counselors. Participants will also be referred to HIV care and support services that are identified by survey staff to be appropriate for MSM seeking services. Reports of rape and other violence will be handled in consultation with local human rights organizations which provide such services for other populations. Any participant reporting rape or violence will be provided information on his rights and provided information on further resources available to them. Survey team member will not contact law enforcement agencies.[22]

12.2 Age of respondents

This activity will recruit only persons age 18 or older; no minors will be included.

12.3 Approvals and consultations

This project proposal will be submitted for human subjects review and approval at the Internal Review Board within the MoH in Francisco and _____. Survey personnel will be trained in ethics and good clinical practice.

12.4 Reporting adverse incidents

Adverse incidents will be reported to _____. Potential incidents may include protocol violations, security incidents harming participants or staff, breach of confidentiality,

22 *In some places it is mandated by law to connect a participant to authorities if a participant reports child abuse or domestic violence. Please check the local laws.*

or adverse physical or mental reactions to HIV counseling and/or testing.

In case of any adverse event, each site supervisor will report the incident in writing (via email) to the project coordinator within 24 hours of discovering the adverse event (see *Appendix S* for incident reporting form). Site supervisors will have daily team meetings where, among other issues, he/she will attempt to discover whether any adverse events took place. Any adverse events or protocol violations will be reported to the principal investigators within 24 Hours and to IRBs within 5 to 10 days (depending on severity and needed information collection) with follow-up reporting of any pending information, action, or follow-up.

12.5 Data security, privacy and protocol adherence

It will be the responsibility of the MoH principal investigator to ensure protocol adherence. A data manager will be tasked with receiving all data and communicating with the site supervisor on a daily basis.

We will monitor data and safety during the implementation of the survey through regular communication with the site supervisor, and weekly meetings and conference calls with survey partners. These calls will review recruitment accrual, HIV test results, data quality, and follow-through for referrals.

Regular supervision visits from teams of survey partners to field sites will be conducted in order to evaluate protocol fidelity, regulatory compliance, organization of survey files, etc.

Although consent is required for participation in the survey, names or other identifying information will not be written on the survey, survey forms or on any lab specimens. Access to participant data will be limited to the data manager, site supervisor, data analysts, and investigators. Data files will be password protected. Any hard copy participant data will be stored in locked file cabinets, in locked offices and access will be limited in the same manner as for electronic data.

Phone numbers will never be attached to survey ID numbers in any way. Phone numbers will be erased from the survey phone on a daily basis. Phones are also password protected.

12.6 Potential benefits

The primary benefit of the proposed survey is to produce reliable data on the health and social welfare needs of MSM communities in Francisco. MSM population size estimates will also help advocate for the appropriate levels of funding and types of interventions for MSM. While HIV counseling and testing is available to all persons free of charge in Francisco, survey participants have individual benefits that include the provision of the following free of charge at the survey site

- Counseling for HIV and other STIs
- Testing for HIV
- Condoms and lubricants, health information, and referral services
- Referrals for care and treatment for HIV-infected participants

The proposed project site is located in an area that is in the process of training select providers who will be able to deliver appropriate services for MSM. Investigators will ensure that suitable services will be available at referral clinics by the time of survey initiation.

12.7 Participant compensation/ incentives

Formative assessment participants: Key informants and focus group participants will not receive incentives, however snacks and refreshments will be provided. Key informants and focus group participants who travel to a KII/FG site will also receive a one-time reimbursement valued at $2-$4 USD in cash for transportation costs.

Participant reimbursements should be enough to motivate participants to participate (i.e. should cover their time), but should not be too high that it would motivate non-eligible people to participate. The proposed reimbursement structure for this surveillance is outlined below.

Past IBBS studies suggest that reimbursements should be offered to compensate participants for the substantial commitment of time and effort required to complete the survey and biological testing. Participants will be given a reimbursement for completing the surveillance activities. The amount of the incentive will be determined through formative assessment. In addition,

participants will be provided with a variety of prevention materials (i.e. condoms, lube).

Based on these considerations and past experience with projects of similar scope in Francisco, we have determined _____ to be appropriate reimbursement amount.[23] We will confirm the appropriateness of this amount through our formative assessment activities.

13. Projected time line

This surveillance project will start in YYYY with the expectation of all phases being complete within 14 months. The following outlines the projected work plan/timeline for the IBBS, beginning with receipt of all ethical approvals.

Upon completion of primary data analysis and prior to finalizing a IBBS-MSM report, findings will be shared with small community forum in the survey city in Francisco to confirm and contextualize results. Upon completion of this local forum a writing workshop will be held to draft the IBBS-MSM Francisco report to ensure the involvement of key stakeholders in the report writing process.

The results of the final report, as well as the final report itself, will be disseminated at a national IBBS-MSM dissemination event. Other meansof dissemination will include presentations at international meetings and workshops, and submission of scientific manuscripts to peer reviewed journals. Data will also be used to inform

Proposed Activity	Month													
	YYYY				YYYY									
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
Formative training	X													
Formative implementation		X	X											
Formative assessment analysis			X	X										
TLS implementation training						X								
TLS implementation						X	X	X	X	X	X			
Data cleaning/lab QA/data merging											X	X		
Data analysis and writing training												X	X	
Final report														X
National dissemination workshop														X

14. Dissemination of findings

A TWG composed of representatives from relevant government agencies, non-governmental agencies, and private institutions, was formed. The main role of the TWG is to guarantee effective communication between the multiple players involved in the implementation of IBBS. Key stakeholders will be given monthly updates regarding the survey progress.

and engage the government, the private sector, and MSM organizations in taking ownership and responsibility regarding the prevention of HIV/AIDS.

A scientific manuscript advisory panel (SMAP) was created and its mission is to promote the dissemination of findings from this IBBS survey through presentations, posters, and scientific

manuscripts to be presented through national and international conferences and peer-reviewed journals, and other fora and publications. Upon release of the final report, the SMAP will convene to discuss potential presentations and scientific manuscripts of interest.

For publications developed by members of the partner institutions, the most appropriate first

23 *We recommend making the incentive amount a range, as during the course of the survey you may find that you need to decrease or increase your incentive depending on under- or over-estimating the incentives during the formative assessment. In addition, many countires do not allow cash payments. Be familiar with local guidelines.*

and senior (last) author will be jointly decided by members of the SMAP. The designated first author should take the lead on writing and production of the paper or abstract. First authors should propose potential journals, to which the manuscript may be submitted, and gather the editorial and formatting requirements for that journal. Any individual appearing as an author on any publication must have assisted in writing the publication or provided a written contribution. The SMAP may make additional recommendations regarding potential journals and provide edits to the manuscript.

Any research individual from national institutions, as well as international organizations that publish any articles and/or books based on data from the Francisco MSM survey will be obliged to cite the source of the data and send copies of the article, report, and/or book to the MoH in Francisco. These data are not to be used for personal gain or profit by any individual or group of individual investigators or partner institutions.[24]

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Background

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24 *Any publications or presentations produced should adhere to those guidelines established by the funding agency.*

Formative assessment and mapping

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Appendix A: Consent form for key informant interview

Men's Health Monitoring Survey

Key informant participant information sheet for informed consent

Principal investigators: [*LIST here*]

The name of this survey is the Men's Health Monitoring Survey. This paper tells you about the survey. An interviewer will also talk about the survey with you today. We want you to ask **ANY** question about **ANY** part of the survey that you do not understand. After you understand the survey, we will ask you to decide if you want to be in any part of it, or not. We will give you this paper to take home with you.

You can choose if you want to be in the survey or not. If you say yes, you can also later choose to say no at any time you want to. You do not have to do all the survey.

A. Purpose

Many adults have HIV and other diseases from sex. This survey is to find out what adults do that make them get HIV and other diseases from sex. In this survey, we will learn about types of sex partners' men who have sex with men have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many men who have sex with men (MSM) have HIV. This survey will help the ministry of health and its partners know more about HIV. Then they can make programs that can help prevent HIV. These programs teach people to use condoms all the time. They give counseling and testing for HIV. They help people with HIV live a healthy life.

You are asked if you want to be in this interview because you may know someone who is at risk of HIV from sex. Only the interviewer who asks you the questions will know the answers you give. Your name or any other information that can make someone know that you gave the answers will not be taken. Nobody else will know that it was you that gave the answers.

B. Procedures

1. If you agree to be in this survey as a key Informant you will meet with a trained Interviewer. You will have an informal discussion for 1 – 1-1/2 hours.
2. During the discussion, we will ask you for your opinion about:
   - Ways that we can encourage MSM to take the survey
   - Reasons MSM might not want to take an HIV test, and ways to encourage them to do so
   - Appropriate incentives for doing the survey
   - Locations where MSM can be interviewed
   - Appropriate language for the interview, etc.
3. You do not need to answer all the questions in the interview if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question. You can also stop the Interview at any time without any penalty.
4. The interview is confidential. We will not record your name or anything else about you that could identify you. No one except the survey staff will ever see or know the information you give us.
5. We will take notes on paper and also tape-record the Interview so we can listen to it later. At the end of the survey, the notes and tape recording from the Interview will be destroyed.
6. We will provide you with refreshments during the Interview.

C. Discomforts and risks

Because the Interview is about people who are at risk of HIV because of behavior that is sensitive, some of the questions might make you feel uncomfortable. If other people in your community find out that you are in this interview, you could suffer from a loss of privacy or discrimination in your community. To protect you from this, your name will not be asked for or written down at any point during the interview. No one on the staff will tell anyone else that you were in the interview. The place where the interview takes place will be private and unmarked. There will not be a written list of people who were interviewed at any time. In addition, no one will ask about your own behaviors, and you should not share this information during your interview.

D. Benefits

The information you give us may help us to plan a better survey for men who have sex with men who might be at high risk of HIV and STI. This could benefit society through improved health and social programs.

E. Persons to contact

You can ask the survey staff any questions that you have at any time. You may also contact the people in charge of this survey.

[*ADD contact here: name, phone, email*]

If you have any questions about your rights as a survey participant, about ethical matters, or wish to complain you can call [*ADD bioethics committee contact information here*], who reviewed and approved this survey.

G. Confidentiality statement

What you tell us is confidential. No one except the survey staff will have access to the interview notes or audio recordings.

H. Right to refuse or withdraw

Being in this Interview is voluntary. You have the right to refuse to discuss any questions. You can leave the interview at any time.

I. Agreement

Do you have any questions?

Interviewer: Answer the participant's questions about the interview before proceeding to the next question.

You have read and/or had read to you the explanation of this survey, you have been given a copy of this form, a chance to ask questions, and you know that you can refuse to participate. I am going to ask for your consent to do this interview. By saying yes, you agree to do the interview. By saying no, you decline to do the interview. Do you agree to take part in the interview?

☐ This person agrees to take part in the interview.

☐ This person does not agree to take part in the interview.

I have explained to the participant the survey purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability that the participant had.

Signature of interviewer _____ Date ___/___/___

Copy to: ☐ Participant ☐ Investigator's file

Appendix B: Consent form for focus group

Men's Health Monitoring Survey

Focus group information sheet for informed consent
(Flesch-Kincaid grade level: 6.3)

Title of survey: Men's Health Monitoring Survey

Principal investigators: [*LIST here*]

The purpose of this discussion is to plan for a survey that will occur in the next couple months called the Men's Health Monitoring Survey. This paper tells you about the survey. An interviewer will also talk about the survey with you today. We want you to ask **ANY** question about **ANY** part of the survey that you do not understand. After you understand the survey, we will ask you to decide if you would want to be in any part of it, or not. We will give you this paper to take home with you.

You can choose to participate in this discussion or not. If you say yes, you can also later choose to say no at any time you want to. You do not have to take part in the entire discussion.

Why do we do this survey?

Many adults have HIV and other diseases from sex. This survey is to find out what adults do that can make them get HIV and other diseases from sex. In this survey, we will learn about types of sex partners men who have sex with men (MSM) have, the way people act toward people that have HIV, and the use of alcohol and drugs. We will also know how many men who have sex with men have HIV. This survey will help the Ministry of Health and its partners to know more about HIV. Then they can make programs that can help prevent HIV. These programs teach people to use condoms all the time. They give counseling and testing for HIV. They help people with HIV live a healthy life.

You are being asked to be part of this discussion today because you have ideas and opinions that can help us to plan the survey.

What will happen if I choose to participate in the discussion?

- If you agree to be in this discussion you will be with approximately 6 men who have sex with men. The discussion will take about 90 minutes and will be led by a trained facilitator. In the discussion everyone will be asked to talk about the following issues:
  - Ways that we can encourage MSM to take the survey
  - Reasons MSM might not want to take an HIV test, and ways to encourage them to do so
  - Appropriate incentives for doing the survey
  - Locations where MSM can be interviewed
  - Appropriate language for the interview, etc.
- You do not need to talk about anything that is asked or discussed if you do not want to. If a question makes you feel uncomfortable or you do not want to say anything in the group, you can remain silent. You can also leave the discussion at any time without any penalty to you.
- The discussion is confidential. We will not record your name or any other characteristics that might identify you at any time during the discussion. The Facilitator will tell all of the participants not to use their name or anyone else's name during the discussion. No one except the survey staff will have access to the information you provide to us.
- During the discussion, we will take notes on paper and also tape-record the Interview so we can listen to it later. At the end of the survey, the notes and tape recording from the Interview will be destroyed.

- We will provide you with refreshments during the discussion.

What risks may I have from being in the discussion?

There may be some risks or discomforts from being in this discussion.

The most important risk is that someone you know can see you coming to the discussion and treat you badly because they do not understand what this discussion is for. If other people in your community find out that you are in this discussion, you could suffer from a loss of privacy or from discrimination in your community. To protect you from this, your name will not be asked for or written down at any point during the discussion. No one on the staff will tell anyone else that you were part of the discussion. The discussion location will be private and unmarked, and there will not be a written list of people who attended. The Facilitator will tell all of the participants not to use their name or anyone else's name during the discussion. In addition, no one will ask about your own behaviors, and you do not need to share this information.

Are there any benefits from taking part in this discussion?

Yes, because the information you give us may help us to plan a better survey for men who have sex with men. This could benefit society through improved health and social programs

Will I be compensated for taking part in the discussion?

You will be given refreshments as a token of thanks for your participation in the discussion.

What if I want to stop being in the discussion?

Being in this discussion is voluntary. You have the right to refuse to discuss any questions. You can leave the discussion at any time.

Will my information be kept a secret from others?

What you tell us is confidential. No one except the survey staff will have access to the interview notes or audio recordings.

Who can answer my questions about the discussion?

You can ask the survey staff any questions that you have at any time. You may also contact the people in charge of this survey.

[*ADD contact here: name, phone, email*]

If you have any questions about your rights as a survey participant, about ethical matters, or wish to complain you can call [*ADD bioethics committee contact information here*], who reviewed and approved this survey.

Interviewer: Answer the participant's questions about the interview before proceeding to the informed consent authorization.

INFORMED CONSENT AUTHORIZATION

You have read and/or had read to you the explanation of this discussion, you have been given a copy of this form, a chance to ask questions, and you know that you can refuse to participate. I am going to ask for your consent to do this interview. By saying yes, you agree to do the discussion. By saying no, you decline to do the discussion. Do you agree to take part in the discussion?

☐ This person agrees to take part in the interview.

☐ This person does not agree to take part in the interview.

Sample TLS protocol

I have explained to the participant the survey purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability that the participant had.

Signature of interviewer _____ Date ___/___/___

Copy to: ☐ Participant ☐ Investigator's file

Appendix C: TLS formative assessment venue enumeration form

Men's Health Monitoring Survey

Date: ____/____/_____ Start Time: ____:____ am pm

End Time: ____:____ am pm

Informant ID: _____

In which locations do MSM that you are in contact with meet? In what other places can we find more MSM?

Code	Location name	Address	Venue type	No. of persons who meet/work at this place		Day of the week	Hour
				Min	Max		
1							
2							
3							
4							
5							

Appendix D: TLS enumeration type I form

Men's Health Monitoring Survey

Page _____ of _____

Staff ID # _____ Date: _____

Event ID#: _____ Venue type* _____ # Clicked: _____

Venue ID #: _____

Venue Name:_____

Begin time: ____:____ a.m. p.m. End time: ____:____ a.m. p.m.

Day of the week: Sun M T W Th F Sat

*Venue type codes:
1=Street location
2=Dance club
3=Bar/tavern
4=Pick up points
5=Commercial establishment/business
6=Social organization
7=Health club
8=Public place
9=Other: _____

Comments: (weather, safety, etc.)

Draw area of intercept line/area below:

Appendix E: TLS enumeration type II form

Men's Health Monitoring Survey

Page _____ of _____

Staff ID#: ___ | ___ | ___ Event #: ___ | ___ | ___ Venue ID #: ___ | ___ | ___ | ___ Venue name: _____

Date: ___| ___| ___S-Time: ___: ___a.m. p.m. E-Time: ___: ___a.m. p.m. Day of week: Sun M T W Th F Sat # Clicked: _____

# Counted	Refused intercept	Age	Resident of [study site]	Previous encounter	Ever had sex	Sexual behavior	Study eligible
1	Y N		Y N U	Y N U	Y N	M W B N	Y N
2	Y N		Y N U	Y N U	Y N	M W B N	Y N
3	Y N		Y N U	Y N U	Y N	M W B N	Y N
4	Y N		Y N U	Y N U	Y N	M W B N	Y N
5	Y N		Y N U	Y N U	Y N	M W B N	Y N
6	Y N		Y N U	Y N U	Y N	M W B N	Y N
7	Y N		Y N U	Y N U	Y N	M W B N	Y N
8	Y N		Y N U	Y N U	Y N	M W B N	Y N
9	Y N		Y N U	Y N U	Y N	M W B N	Y N
10	Y N		Y N U	Y N U	Y N	M W B N	Y N
11	Y N		Y N U	Y N U	Y N	M W B N	Y N
12	Y N		Y N U	Y N U	Y N	M W B N	Y N
13	Y N		Y N U	Y N U	Y N	M W B N	Y N
14	Y N		Y N U	Y N U	Y N	M W B N	Y N
15	Y N		Y N U	Y N U	Y N	M W B N	Y N
16	Y N		Y N U	Y N U	Y N	M W B N	Y N
17	Y N		Y N U	Y N U	Y N	M W B N	Y N
18	Y N		Y N U	Y N U	Y N	M W B N	Y N
19	Y N		Y N U	Y N U	Y N	M W B N	Y N
20	Y N		Y N U	Y N U	Y N	M W B N	Y N
Subtotal							

Contact Person (Name, title, phone #)

Reviewed by: _____

_____ Interviewer ID#: ____ ____ ____ Date: ____/____/____

Clicker #: ____ ____ ____ Date: ____/____/____

_____

Supervisor #: ____ ____ ____ Date: ____/____/____

Appendix F: TLS recruitment event checklist

Men's Health Monitoring Survey

Recruitment event and calendar information

Day/time period: ___ : ___ AM PM to ___ : ___ AM PM
Random or non-random recruitment event? R N
Scheduled date/time: ___ / ___ / _____
Venue name: **Venue ID:** **Venue owner/contact:** **Event number:**
Alternate 1: **Venue ID:** **Venue owner/contact:** **Event number:**
Alternate 2: **Venue ID:** **Venue owner/contact:** **Event number:**

Tasks to complete 1-2 weeks prior to recruitment event

Contact the venue manager or their designated contact person by phone to notify them that the team will be in or near the venue conducting an event on the specific day and time.
If van is used, obtain permit to block off parking space near the venue from the appropriate local office. (if necessary)

Staff

	Evaluation scheduled?	**Handheld #**
Field supervisor:		
Recruiter(s):		

Sample TLS protocol

Interviewers:	
	__ __
	__ __
	__ __
	__ __
	__ __
	__ __
	__ __
	__ __

Recruitment event information to gather right before recruitment event

First survey ID:
Event number:

Tasks to complete right before recruitment event

Batteries for the handheld computers are fully charged
Data from the previous recruitment event are downloaded from the handheld computer to the main database(s)

Equipment, supplies and other materials checklist

Equipment
- Handheld computers (1 for each interviewer and a backup)
- Tally counter (i.e., clickers)
- Communication equipment (e.g., 2-way radios or cell phones)

Blank forms/logs
- Intercept Forms
- Consent forms for each interviewer and participant
- Blank data corrections log
- Paper copies of the questionnaire (for emergency use only)
- Incentive tracking

Reference material
- Protocol
- Operations manual
- Interviewer guide

Other materials
- Enough incentives to cover the expected number of participants
- The current month's recruitment calendar
- Educational materials
- Other item: _____
- Other item: _____

Event notes:

Actual recruitment start/end time:
Describe recruitment type and the area within the venue where the recruitment took place:
Describe any barriers to project activity at the venue:
Was there any significant change in the population at the venue? If yes, explain:
What new VDTs were suggested by venue attendees?
Should the venue be removed from the frame? If yes, explain:
If the event was moved to an alternate, explain why:

Post-event checklist

Check with interviewers and update the data corrections log if necessary Unusual events (participant ended survey early) Problems with handheld computers Check with recruiters Collect intercept forms Review forms for accuracy Calculate and review recruitment stats Calculate intercept statistics for event and update the recruitment monitoring form Upload data from handheld computers

Appendix G: TLS data corrections log

Men's Health Monitoring Survey

Interview date	Event #	Venue ID	Interviewer ID	Survey ID	Problem	Correction	Initials

Appendix H: TLS enumeration type III form

Men's Health Monitoring Survey

Page _____ of _____

Staff ID#: ___ | ___ | ___ Event #: ___ | ___ | ___ Venue ID #: ___ | ___ | ___ | ___ Venue type: P A B Venue name: _____

Date: ___ | ___ | ___ S-Time: ___: ___ a.m. p.m. E-Time: __ : __ a.m. p.m. Day of week: Sun M T W Th F Sat # Count: _____

#	Refused intercept	Age	Resident of [study site]	Previous respondent (TLS enrolled)	Previous non-respondent (eligible but refused)	Sexual behavior	Study eligible	Enrolled	Reason for intercept or enrollment refusal
1	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
2	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
3	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
4	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
5	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
6	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
7	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
8	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
9	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
10	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
11	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
12	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
13	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
14	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
15	Y N		Y N	Y N U	Y N U	M W B N	Y N	Y N	
Sub-Total									

Contact Person (Name, title, phone #)

Reviewed by: _____

_____ Interviewer ID#: ____ ____ ____ Date: ____/____/____

Clicker #: ____ ____ ____ Date: ____/____/____

_____

Supervisor #: ____ ____ ____ Date: ____/____/____

Comments: (weather, safety, etc.)

Draw area of intercept line/area below:

Appendix I: Sample universe of venues form

Men's Health Monitoring Survey

Page _____ of _____

Venue info				VDT info						
Venue ID	Name	Address	Phone	M	T	W	R	F	Sa	Su

Appendix J: TLS recruitment monitoring form

Men's Health Monitoring Survey

Page _____ of _____

Event #	Date	Conducted VDT: Venue code	Conducted VDT: Start time	Conducted VDT: Random (Y/N)	Counted No.	Approached No.	Previously participated No.	Previously asked No.	Accepted intercept No.	Accepted intercept %	Eligible No.	Eligible %	Consented to interview No.	Consented to interview %	Comments

Appendix K: Model venue and VDT sampling frames

Men's Health Monitoring Survey

Venue sampling frame	VDT sampling frame						
Venue ID*	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
4480F001	6p – 10p		6p – 10p				
4480X002			8p – 12a	8p – 12a	8p – 12a	8p – 12a	
4480C019 4480C019		6p – 10p	6p – 10p	6p – 10p	6p – 10p 10p – 12a	6p – 10p 10p – 12a	4p – 8p
4480P007						2p – 6p	4p – 6p
4480D101					11:30p – 3:30a		
4480R045	6p – 10p	6p – 10p	6p – 10p	6p – 10p	6p – 10p	6p – 10p	
4480S033 4480S033 4480S033	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a	4p – 8 p 8p – 12a 12a – 2a
4480D052			8p – 12a	8p – 12a	8p – 12a	8p – 12a	
4480O004			8p – 9p				
4480O008		1st and 3rd 7p –10p					
4480Z001	8p – 12a						
4480X021 4480X021 4480X021	6p – 10p 10p – 2a	6p – 10p 10p – 2a	6p – 10p 10p – 2a	6p – 10p 10p – 2a	6p – 10p 10p – 2a	2p – 6p 6p – 10p 10p – 2a	2p – 6p 6p – 10p 10p – 2a
4480S001 4480S001	6p – 10p	6p – 10p	6p – 10p	6p – 10p	6p – 10p 10p – 12a	6p – 10p 10p – 12a	4p – 8p 6p – 10p
4480C001	6p – 10p	6p – 10p	6p – 10p	6p – 10p	8p – 12a	8p – 12a	

Appendix L: Model sampling event calendar

Men's Health Monitoring Survey

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1 PR: O008 7p-10p A1: S033 A2: X021	**2** PR: 0004 8p-9p A1: D052 A2: X002	**3**	**4** PR: D101 11:30-3:30a A1: S033	**5**
6	**7** PR: Z001 8p-12a A1: S033 A2: X021	**8**	**9** PR: F001 6p-10p A1: C019 A2: C001	**10**	**11** PR: X002 8p-12a A1: D052 A2: C001	**12**
13	**14** PR: R045 6p-10p A1: F001 A2: Z001	**15**	**16**	**17** PR: D052 8p-12a A1: X021 A2: S033	**18** PR: C019 10p-12a A1: D101 A2: S033	**19** PR: C001 8p-12a A1: X021 A2: X002
20	**21**	**22** PR: S033 12a-2a	**23**	**24** PR: S001 6p-10p A1: R045 A2: X002	**25**	**26**
27 PR: P007 4p-6p A1: X021 A2: C019	**28**	**29**	**30** PR: X021 6p-10p A1: O004 A2: F001			

Appendix M: TLS MSM eligibility screening form

Men's Health Monitoring Survey

No.	Questions	Coding of answers
FOR PARTICIPANT: Please answer the following questions.		
1	How old are you? (If participant responds <18 years, inform them that they are ineligible)	_____ years
2	Have you participated in this study before?	❑ 1. Yes → **Ineligible** ❑ 2. No
3	Were you born biologically male?	❑ 1. Female → **Ineligible** ❑ 2. Male
4	Do you currently live in Mission?	Zone ____
5	Have you had oral or anal sex with a man in the last **6 months**? [If necessary, probe with additional questions to verify knowledge of MSM behavior, see additional screening questions below	❑ 1. Yes ❑ 2. No → **Ineligible**
6	Do you agree to participate in a face-to-face structured survey?	❑ 1. Yes ❑ 2. No
7	What are the reasons for **NOT** agreeing to participate in a face-to-face structured survey?	❑ 1. Too busy ❑ 2. Fear of being stigmatized for participation ❑ 3. Not interested ❑ 4. Incentive is not worth the time ❑ 5. Already answered survey ❑ 6. Other: _____ ___
FOR INTERVIEWER: Please answer "Yes" or "No" to the following statements.		
8	Participant is under the influence of alcohol, drugs, or other substance.	❑ 1. Yes ❑ 2. **No**
9	Participant has provided verbal informed consent.	❑ 1. **Yes** ❑ 2. No
10	Participant was recruited from a selected site.	❑ 1. **Yes** ❑ 2. No
11	Eligible to participate in the survey.*	❑ 1. Yes ❑ 2. No

* **Eligible** = answers to questions 8-11 must match answers in bold.

12. Additional screening questions

[Check with supervisor which questions to use today]

Was it oral sex? What are some of the words you use to describe oral sex with a man?

Was it anal sex? What are some of the words you use to describe anal sex with a man?

Can you tell me, when someone is on top in oral sex, what is he doing?

Can you tell me, when someone is on bottom in oral sex, what is he doing?

Can you tell me, when someone is on top in anal sex, what is he doing?

Can you tell me, when someone is on bottom in anal sex, what is he doing?

What do you call it when a man performs both active and passive roles during sex with a man?

Which role do you prefer in sex with another man?

13. Confidence in MSM status

How confident are you that the participant is truly a member of the key population? [Please circle your response]

Highly confident

Somewhat confident [state reason why]: _____

Not confident [**please see supervisor for further instructions**]

Appendix N: Consent form for IBBS-MSM TLS survey

Men's Health Monitoring Survey

Survey information sheet for verbal informed consent
(Flesch-Kincaid grade level: 6.5)

Title of survey: Men's Health Monitoring Survey

Principal investigators: [*LIST here*]

The name of this survey is the Men's Health Monitoring Survey. This paper tells you about the survey. A counselor will also talk about the survey with you today. We want you to ask **ANY** question about **ANY** part of the survey that you do not understand. After you understand the survey, we will ask you to decide if you want to be in any part of it, or not. We will give you this paper to take home with you.

You can choose if you want to be in the survey or not. If you say yes, you can also later choose to say no at any time you want to. You do not have to do all the survey.

Why do we do this survey?

Many adults have HIV and other diseases from sex. This survey is to find out what adults do that can make them get HIV and other diseases from sex. In this survey, we will learn about types of sex men who have sex with men have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many men who have sex with men (MSM) have HIV. This survey will help the ministry of health and its partners know more about HIV. Then they can make programs that can help prevent HIV. These programs teach people to use condoms all the time. They give counseling and testing for HIV. They help people with HIV live a healthy life.

You were invited to do the survey because you may be at risk for HIV. Only the interviewer who asks you the questions will know the answer you give. Your name or identity will not be asked at any time.

What will happen if I choose to do this survey?

This survey will take less than 90 minutes of your time. In this time you will

- Get a survey code so nobody can know who you are. The code is made of a mixture of letters and numbers known only to you.
- Take a survey with a trained interviewer. The interviewer will ask some info like your age and habits. The interviewer will ask about alcohol and drugs, sex and sex partners, HIV and diseases from sex, and health care.
- Get information about HIV prevention, HIV testing, and HIV treatment
- Have a fingerprick to do an HIV test and to put some drops of blood on a card that will be sent to the national lab for HIV tests. You can be in the survey and not do the HIV test or the card with the blood spots.
- Receive the test results with a trained counselor who will help you make a plan that is best for you, and talk about treatment options and medical referrals if needed
- Get a gift worth approximately [*INSERT incentive amount here*] for being in the survey today. You will get this gift even if you do not do all parts of the survey.

What risks may I have from being in the survey?

There may be some risks or discomforts from being in this survey.

- The most important risk is that someone you know can see you coming to the survey and treat you badly because they do not understand what this survey is for. Although the information from this

survey is not shared with anyone, this could still occur. If you know the interviewer, you may ask for another interviewer so that you can feel comfortable that the information you tell is won't be known to anybody you know.

- There is a small chance that someone outside of the survey staff could find out about your HIV test results and you experience bad treatment. But we have taken many steps to make sure that this does not ever happen.
- The survey includes personal questions about sex and other private things that may make you feel uncomfortable or embarrassed. If any question makes you feel uncomfortable or embarrassed, you can refuse to answer it, and you can terminate the interview at any time. Doing this will not have bad consequences for you, and you will not be asked to leave the survey because of this request.
- A fingerprick may hurt and will make you bleed. You may feel faint but this is very rare. To make it not hurt so much the nurses have been trained especially to do this.
- If you test positive for HIV you may feel anxious or depressed. The counselors working for this survey can help you with these feelings. You may also be referred to local counselors or support groups to help you with these feelings.

Are there any benefits from taking part in this survey?

Yes. If you choose to be in this survey, you can receive

- Free counseling and testing for HIV and learn your test results
- Referral to clinics that can provide you with medical care and/or treatment as needed
- Free condoms, lubricant, and educational information on HIV and STIs

There is also a benefit to health professionals and others in your community who will learn more about who is most at risk for HIV and STIs to help plan better education, prevention, and medical programs

Does it cost me for me to be in the survey?

It does not cost anything to be in this survey.

Will I be compensated for taking part in the survey?

You will be offered a snack, and a hygiene and prevention kit worth approximately [*INSERT incentive amount here*] for your time and effort today.

What if I want to stop being in the survey?

You can stop being in the survey at any time. You can choose to be in all parts of the survey, or only some of them. We will give you a chance to do this at the end of this form. Also, you may be asked to leave the survey if we feel it is best for you or you are not able to do the survey.

Will my information be kept a secret from others?

Being in a survey may involve you telling someone things about you that are private. But, this is a survey that other people cannot know that it is you that shared this information. To make sure that nobody knows it was you that gave the information

- We never ask for your name or write it on any survey documents, lab tests, or specimens
- Only a survey number will be placed on your survey, survey records, and laboratory specimens
- All the written information you give us will be kept in a file cabinet that is locked at all times
- Nothing about your health status or your test results will be told to anyone except the researchers in this survey
- We do the survey in a space that nobody can see or hear you except the person doing the survey

Who can answer my questions about the survey?

You can ask the survey staff any questions that you have at any time. You may also contact the people in charge of this survey.

[*ADD contact here: name, phone, email*]

If you have any questions about your rights as a survey participant, about ethical matters, or wish to complain you can call [*ADD bioethics committee contact information here*], who reviewed and approved this survey.

Interviewer: Answer the participant's questions about the survey before proceeding to the informed consent authorization.

INFORMED CONSENT AUTHORIZATION

Interviewer: Ask participant to document response to each question by checking the appropriate box.

Participants may consent or decline each part of the survey.

Do you agree to participate in part or all of the survey or do you decline participation?

❑ 1. YES, agree to participate in part or all of the survey.

❑ 2. NO, decline to participate. [if NO participant not eligible to participate].

If declined:

We're interested in knowing why people do not want to do this survey. Would you mind telling me which of the following best describes the reason you do not want to do this survey?

I don't have time	q 1
I don't want to talk about these topics	q 2
Some other reason; Specify_____	q 3
I would rather not say why	q 9

Do you agree or decline to complete the **survey questionnaire**?

❑ 1. YES, agree.

❑ 2. NO, decline. [if NO participant not eligible to participate].

Do you agree to a fingerprick to prepare a blood sample that will be sent to the national laboratory for additional HIV-related testing?

❑ 1. YES, agree.

❑ 2. NO, decline.

Do you agree to rapid HIV testing to receive your results today?

❑ 1. YES, agree.

❑ 2. NO, decline.

I have explained to the participant the survey purpose and procedures and we have discussed all the risks involved. The participant has read this document or had the document read to them.

- I have informed the participant about the nature, conduct, benefits and risks of this survey
- I have informed the participant that the results of the survey including personal details regarding sex, age, HIV status will be anonymously processed into a survey report

Sample TLS protocol

- I have informed the participant that they may, at any stage during the interview, without prejudice, withdraw consent and participation in the survey
- The participant has been given the chance to ask any questions and I have answered to the best of my ability

Name of person obtaining consent_____

Signature of person obtaining consent _____

Date ___/___/___ Time ___/___

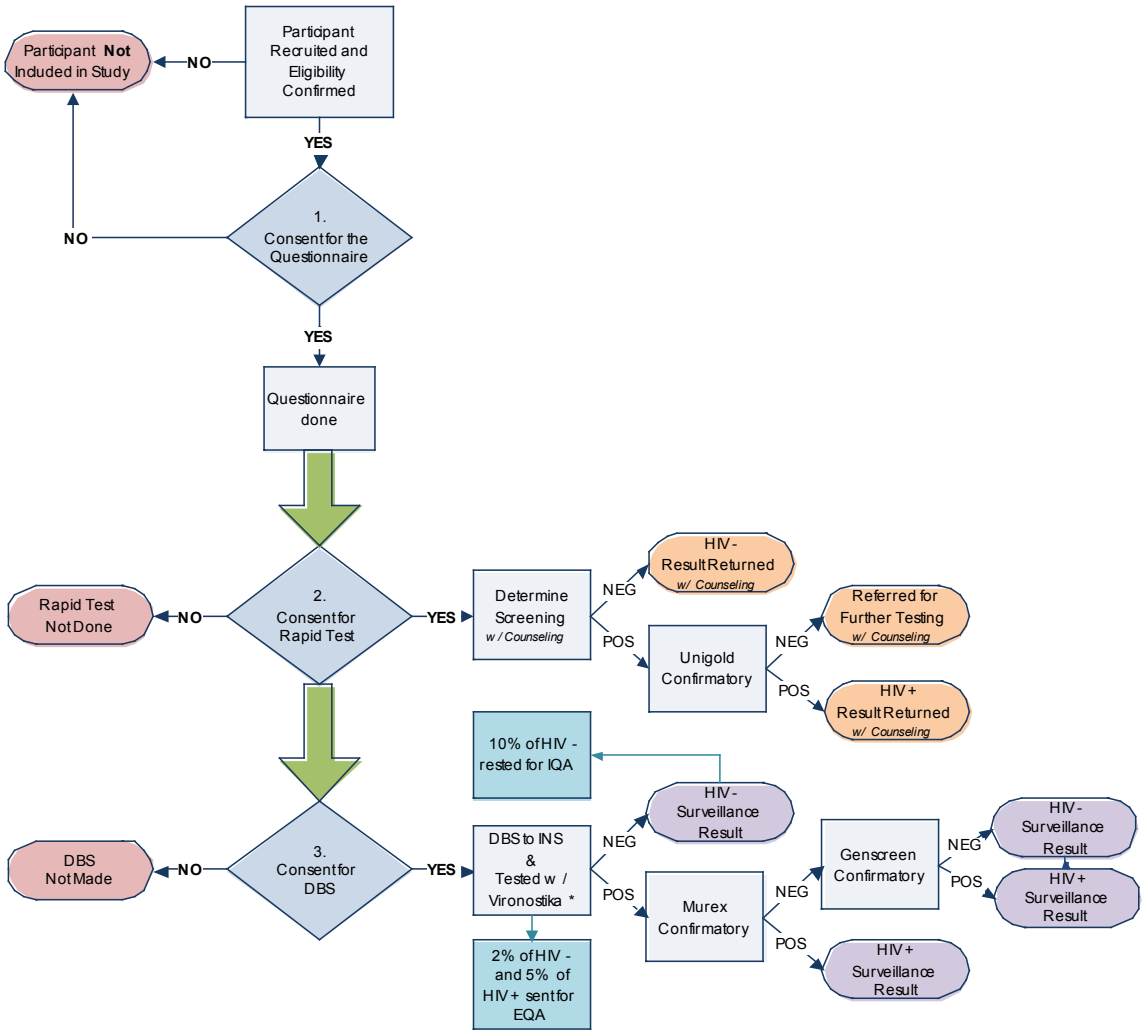
Copy to: ☐ Participant ☐ Investigator's file

Appendix O: Checklist for monitoring structured interviews

Men's Health Monitoring Survey

Criteria		Mark box: Y=Yes I=Needs improvement N=Not done	Comments
Preparation			
1.	Interviewer had all necessary materials including: consent forms, handheld or laptop device, labels, blood collection and DBS preparation kits, HIV testing kits, educational materials and referrals.		
2.	Confidential materials were stored in a locked container before and after the interview.		
3.	Interviewer greeted participant in a friendly manner.		
Consent process			
4.	Interviewer followed all aspects of informed consent according to local protocol.		
5.	Interviewer gave the participant a personal copy of the consent form.		
6.	Interviewer inquired about and if applicable addressed any questions or concerns about the consent form.		
Questionnaire administration			
7.	Interviewer read questions exactly as written.		
8.	Interviewer read questions at an appropriate pace.		
9.	Interviewer avoided leading the participant to a particular response.		
10.	Interviewer demonstrated a neutral attitude.		
11.	Interviewer followed instructions: "READ CHOICES" and "DO NOT READ CHOICES".		
12.	Interviewer read Say boxes verbatim.		
13.	Interviewer used all response cards when indicated.		
	Rapport		
14.	Interviewer established a good rapport with the participant at beginning of interview and maintained it throughout interview.		
	Closing		
15.	Interviewer provided educational materials and referrals when appropriate.		
16.	(If applicable) Interviewer clarified any factual errors expressed by the participant during the interview.		
Additional comments:			

Appendix P: Data and specimen flow chart



*Testing will begin only after all samples have been collected and any links destroyed

Appendix Q: Data use agreement form

Men's Health Monitoring Survey

Request of IBBS Data

The purpose of this form is to make a request for data from the integrated behavioral surveillance surveys (IBBS) and supporting documentation. The use of this data is regulated by memorandum of understandings and research protocols between [LIST all institutions involved]. Existence of this document indicates that the Institutional Review Boards granting approval for the survey have also approved of third party use of the data under conditions governing respectful, responsible, and ethical research. This form is to be filled out by any investigator or researcher requesting to use the data. All requests for access to the data and supporting documents will be reviewed by the IBBS scientific manuscript advisory panel made up of representatives from the organizations listed above.

The requirements set forth in this document cover the person requesting the data, herein referred to as the "requestor," and any other people making up his/her research team.

Given the issues ethical, responsible, and respectful use of data, the requestor agrees to

- **Limit presentation of quantitative results to aggregate statistics**
- **Use TLS specific data analysis methods when appropriate**
- **Use these data only for analysis purposes and not take actions to identify individuals or institutions**
- **Present all data and results in such a way as to prevent deductive disclosure of individuals**
- **Not share data with others or used beyond the purpose(s) outlined above without requesting and receiving approval from the IBBS scientific manuscript advisory panel**
- **Ensure data security including storing survey datasets on password-protected computers and not giving access to data sets and data print outs to people outside the research team**
- **Alert the IBBS scientific manuscript advisory panel of any mistakes made in imputed identification of persons**
- **Communicate any publicly available publications or reports resulting from the analysis to the IBBS scientific manuscript advisory panel (please see the contact below)**
- **Acknowledge the implementing organizations, in any publications, presentations or reports, out of respect for their intellectual contributions**
- **Include the standard funding acknowledgment statement**
- **Understand that the data are being released 'as is' and only limited documentation exists**

Failure to comply with these terms and conditions will result in future exclusion from access to other data resources available from the IBBS scientific manuscript advisory panel and may result in further disciplinary action.

Should you have questions regarding this agreement please contact the IBBS scientific manuscript advisory panel: [*INSERT contact information here*]

Sample TLS protocol

Please provide the following information

Contact information. The following contact information of the requestor of this project is required.

Name:
Organization:
Address:
Telephone:
E-mail:
Request date:

Statement of purpose. Please describe the proposed use of the data including the primary research question/hypotheses/aim and the description of analytic methods. If there is an existing proposal or study protocol, please submit it with this form and only provide a brief summary below (if more room is needed, please attach additional pages).

Statement of familiarity with TLS data analysis methods. Please provide any information about the requestor's familiarity with TLS data analysis and any technical assistance that the requestor would need to have in order to conduct his/her analysis of the IBBS data correctly using TLS methods.

Certification by requestor. By submitting this application, I (the requestor) certify that the information provided above is true and I agree to the data use requirements listed above.

Signature of requestor Date

Appendix R: Employee confidentiality agreement

Men's Health Monitoring Survey

Employee confidentiality agreement

- I recognize that in carrying out my assigned duties as a staff member on the *Men's Health Monitoring Survey* I may obtain access to private information about persons in this survey that was provided under an assurance of confidentiality.
- I understand that I am prohibited from disclosing or otherwise releasing any personally identifying information, either directly or indirectly, about any individual in the survey. Should I be responsible for any breach of confidentiality, I understand that civil and/or criminal penalties may be brought against me.
- I acknowledge that my responsibility to ensure the privacy of protected health information contained in any electronic records, paper documents, or verbal communications to which I may gain access shall not expire, even after my employment or affiliation with this survey has terminated.
- By my signature, I acknowledge that I have read, understand, and agree to comply with the terms and conditions of this confidentiality agreement.

Employee name (printed) _____

Employee signature _____

Date _____

Supervisor name (printed) _____

Supervisor signature _____

Date _____

Appendix S: Incident form

Men's Health Monitoring Survey

Adverse/unusual event report form

Name of person writing report:	
Date of writing report:	
Date of incident:	
Staff involved:	
Location:	

Adverse/unusual event category (Check all that apply to incident)	
CLIENT HARMED OR THREATENED	**VENIPUNCTURE/FINGERPRICK INCIDENT**
Staff harmed or threatened	Venipuncture/fingerprick difficulty
Stipend issue	Specimen transport or storage issue
Theft or loss of equipment	Confidentiality issue
Other safety issue	Other

Narrative description of incident

Recommendations

Resolution