Getting started

Sample protocol for an integrated bio-behavioral survey (IBBS) for female sex workers (FSW) using respondent driven sampling (RDS)

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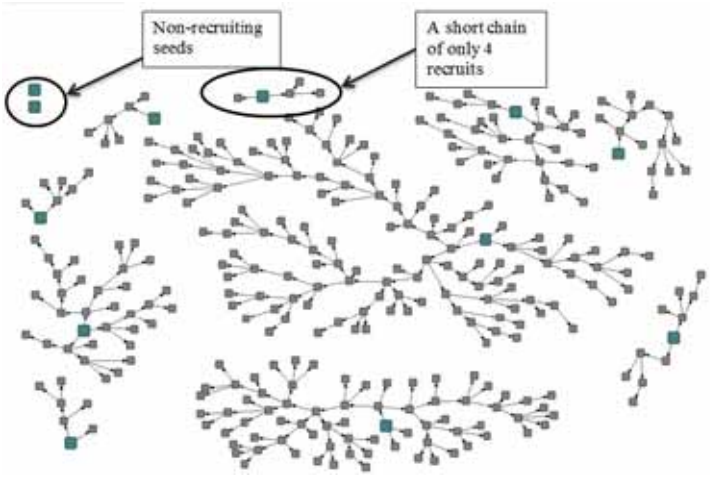
Sample protocol for an IBBS of FSW using RDS

This chapter is a sample protocol for an IBBS using RDS. 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
- RDS survey procedures and logistics
- Data management and analysis
- Ethical considerations
- Projected timeline
- Dissemination of findings
- References
- Appendices including consent forms, sample RDS peer recruitment coupon, data and specimen flow chart, employee confidentiality agreement, incident form



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

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Sample RDS protocol

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.
  - Female sex worker
  - FSW
  - 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.

Women's Health Monitoring Survey: Protocol for an integrated biological behavioral survey (IBBS) with population size estimation using respondent driven sampling (RDS) among female sex workers

Sample RDS protocol

1. Title of the project

Women's Health Monitoring Survey: Protocol for an Integrated Biological Survey with Population Size Estimation using Respondent Driven Sampling among Female Sex Workers in Francisco

Operating title: Women's Health Monitoring Survey

Clarification of title: The full protocol title reflects the

- Key population (female sex workers [FSW])
- Primary measures of HIV and other markers of infectious diseases with related risk behaviors
- Population size estimation objective
- Sampling design (respondent-driven sampling - RDS).

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 FSWs. They will be responsible for hiring and supervising survey staff and interviewers. _____ will also provide support in the training of the interview teams, establishment of linkages and flows between survey sites/teams and health services, and in recruitment of seeds.

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 7.2 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 FSW 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 integrated biological and behavioral surveys (IBBS) used around the world with adaptations for the Francisco context. A formative assessment phase and multiple methods to estimate the size of the FSW population of Mission, Francisco are included within the survey protocol. The survey will use respondent-driven sampling (RDS) for recruitment of FSW through peer-referrals using non-identifying codes to link enrolled participants to those whom they refer to the survey and collecting social network size data for statistical adjustments. FSW 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 results 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 four hundred (400) FSW 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 FSW 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 FSW, 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

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.[2] 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 (Heckathorn, 2002). 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 FSW. 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.

2 *Remember to include citations in this section. Include pertinent information and citations from published literature, official reports. We have inserted (Heckathorn, 2002) as an example.*

FSW 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, FSW are especially vulnerable to the transmission of HIV and other STIs. There is no law protecting or prohibiting sex work in Francisco, although social stigma against FSW is high. In addition to multiple partners, including both clients and non-clients, low condom use poses a risk for infection. Access to prevention and care may also be low among FSW in Francisco. In a study conducted in a small sample of sex workers in Francisco, few sex workers had ever previously had an HIV test, yet 50% of sex workers tested positive in the survey itself.

Without knowing how many women sell sex in Francisco it is hard to evaluate the impact of sex work on national HIV prevalence or the necessary scope of programs designed to meet the needs of sex workers. Some non governmental organizations currently have programs for female sex workers in the city selected for surveillance. No national systematic population size estimates have been conducted of female sex workers in Francisco. Sex work is thought to be especially common along the main transport corridors, where truck drivers, another at risk population, are common clients (Heckathorn, 2002).

To effectively design HIV/AIDS policies and interventions for FSW 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 FSW in Francisco are needed. This protocol proposes to conduct a cross-sectional survey among FSW in one location in Francisco using RDS. 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 FSW and their health needs in the Francisco context.

6. Survey objectives

- To estimate the prevalence of HIV and associated risk behaviors among FSW in Mission, Francisco.
- To estimate the population size of FSW in Mission, Francisco.
- To assess the use of and access to health and social welfare programs among FSW in Mission, Francisco.

7. Survey methods

7.1 Overall survey design: Respondent-driven sampling with formative assessment

Worldwide, FSW 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 FSW concentrations (e.g., time-location sampling - TLS) or through FSW peer referral (e.g., RDS). A stakeholder meeting was held in Mission to discuss the options for conducting IBBS among FSW in Francisco. The meeting included representatives from _____. Participants to this meeting agreed on the need to conduct an IBBS among FSW in Mission, using respondent driven sampling (RDS), preceded by a formative assessment phase in this location. RDS was chosen as FSW are a hard to reach and hidden, and there is a precedent of program interventions reaching FSW through peer education/outreach in the country. Further statistical arguments for sampling hard to reach populations using RDS are presented below.

The theoretical underpinnings of RDS have been well established in published literature (Heckathorn, 2002). In brief, RDS begins with the selection of seeds who are known members of the FSW population. The seeds are instructed to refer a limited number of other FSW from their social circle, who in turn are enrolled (if eligible) and instructed to refer other FSW and so on. The number of referrals per person is usually restricted to three in order to ensure that recruitment

chains progress through diverse social networks. Coded coupons are used to link who refers whom. A primary incentive is given for completion of the survey and secondary incentives are given for each successfully referred peer. RDS reduces the biases inherent in referral methods through statistical adjustments that attempt to account for social network size and similarity among persons within social networks. Although sampling begins with a purposely chosen set of initial subjects, the composition of the final sample approaches independence from the starting point. Recruitment progresses until both the sample size is met and equilibrium (i.e., stability with respect to the composition of the sample) is achieved.

Specialized analysis (i.e., using RDSAT software) is used to produce population prevalence estimates and confidence intervals of variables adjusting for unequal probabilities of inclusion due to varying social network sizes and the similarities in characteristics of persons within their social networks. To conduct analysis, the survey must link enrolled participants to the friends whom they refer and ask the number of persons in the participant's social network who would be eligible for recruitment into the survey. Advanced aspects of the analysis of RDS data, such as adjusted multivariate analysis, are currently under research and we will keep abreast of the most up to date accepted standards during the analysis phase.

Prior to the launching of the full RDS survey, formative assessment will be conducted in the city included in the IBBS-FSW.

7.2 Selection of survey location

Survey activities will be conducted in Mission and surrounding geographic areas. This location was identified because stakeholders believe that this area account for the large majority of FSW in Francisco, there is geographic and cultural diversity, they have an adult population size large enough to be likely to have sufficient numbers of FSW to meet the needed sample size, and there are FSW-friendly HIV services for referrals. Contiguous areas that share social networks are included. The precise geographic boundaries for survey areas will be determined prior to survey implementation based on information (e.g. estimates of FSW population size and geographic extent of social networks) from the formative assessment.

The formative assessment phase will be conducted in the proposed survey location. Mission will be assessed for the potential number of FSW through key informants from organizations providing services to FSW. These data will assist with extrapolation of FSW population size estimates (see section 7.6). An estimate of the percent of the population who are FSW is unknown in Francisco; however, world estimates suggest it may be on the order of 1% to 1.5% (Heckathorn, 2002). The experience of RDS surveys conducted by the investigators in Uganda, South Africa, and San Francisco (Kajubi, 2006; Lane, 2009) is that the peer recruitment coupon rate of return is approximately 30% to 40%. Therefore, a projected minimum number of eligible FSW present in a location would need to be approximately 1,333 (400 / 0.30) in order to complete a sample size of 400. If formative assessment suggests that this minimum FSW population size is likely to exist in a proposed survey location, plans for implementation of IBBS will proceed. However, if during formative assessment it is determined that the minimum population size does not exist in the proposed survey location, the geographic boundaries may be expanded, a different survey methodology may be considered for that location, or the location may be excluded from the IBBS.

Formative assessment will also determine the extent of social networks across urban and surrounding areas, and along corridors of transportation to indicate the geographical bounds of the RDS survey and potential for coupon distribution.

7.3 Fieldwork preparation

The fieldwork preparation will allow us to further identify the operational and logistical needs of conducting RDS in each location, including

- Selecting starting seeds
- Finalizing list of services for referrals
- Identifying project sites to conduct survey operations
- Identifying potential social network connections and bottlenecks
- Field testing the survey questionnaire

- Pilot testing the complete standard operating procedures
- Beginning to distribute unique object for size estimation (see size estimation methods below)

7.4 RDS participant eligibility criteria

Eligibility for the FSW IBBS includes the following reported criteria

- Biologically female
- Age ≥ 18 years
- Received money for sex in the last six months, from someone other than main partner
- In possession of a valid peer recruitment coupon
- Resided, worked or socialized in the survey area for at least the last six months
- Capable and willing to provide [*written/verbal*][3] 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 FSW 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 (i.e., between rounds of IBBS). The needed sample size is 400 FSW participants for Mission.[4]

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 FSW 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) women 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 FSW 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 RDS 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 sample size and power estimation, the sample size for RDS needs to reach equilibrium on key variables such as age, education, nationality, type of sex worker,

3 *Please refer to IBBS Toolkit informed consent section to decide on appropriate consent, written or verbal.*

4 *A design effect of 2 has been commonly used for IBBS worldwide. However, this may be a minimum. A review of data from RDS surveys found actual design effects of 3 - 4 for many key variables. Johnston LG, Chen YH, Silva-Santisteban A, et al. An empirical examination of respondent driven sampling design effects among HIV risk groups from studies conducted around the world. AIDS Behav. 2013;17(6):2202-10.*

and had a previous HIV test. We will track these variables during recruitment to ensure equilibrium is achieved; we will therefore plan to enroll FSW until we have achieved at least 400 completed interviews and equilibrium on the above listed variables.

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 female sex workers (Chongsuvivatwong, 2007).[5]

8. Formative assessment

8.1 Formative assessment phase

The formative phase will allow us to better understand FSW networks, practices, and healthcare and other service availability and service seeking behavior. The formative assessment will have two areas of focus: 1) identifying the operational and logistical needs of conducting RDS in Mission, and 2) conducting a rapid physical and ethnographic mapping of FSW venues and sub-populations. The first focus will identify

- Starting seeds
- Project site to conduct survey operations
- Operational definitions for the proposed survey location
- Appropriate method and language(s) for RDS survey administration
- Acceptability of Computer Assisted Personal Interview [CAPI] survey administration, conducted by interviewers
- Appropriate type and value of incentives for survey participation
- Providers/clinics interested in being trained to provide appropriate services
- Other potential barriers and facilitators of the full RDS survey
- Potential social network connections and bottlenecks
- Areas of the survey instrument requiring fine-tuning or revisions

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

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

8.2 Formative assessment methods

The formative assessment phase of the Francisco IBBS-FSW 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 2 members of the research staff (1 primary interviewer and 1 note-taker). Participants will be recruited purposively through our survey partners providing services to FSW in each community or through observation in venues where no services are available. Participants will be asked to sign a consent form (see *Appendices A and B*). Participants will be provided a copy of the consent form to take with them. 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.

The issue of 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 (10) KIIs and at least three FGs

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

(with 6-10 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 videotaped. With the consent of participants, KIIs/FGs will be audio-taped to capture the discussion and for transcription. 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 memos 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. 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.[6]

8.2.1 Key informant interviews

Key informants serve as cultural experts, offering insight into the context of HIV risk behavior among FSW locally, as well as the types of locations where FSW congregate and can be recruited. Although good key informants may not know everything there is to know about FSW 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-FSW staff may encounter in the field. A diverse group of key informants should be interviewed to accurately reflect the characteristics of the FSW locally (Schensul et al. 1999).

Key informants will include individuals important to and well informed about the FSW community in the proposed sites. Examples of key informants include: FSW community leaders (current and former FSW), persons doing outreach work among FSW, researchers familiar with local FSW, healthcare and other service providers.[7]

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 FSW 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 FSW, the demographic characteristics of local FSW and characteristics of social networks) and focused on particular topics (e.g., healthcare services sought by FSW, barriers to healthcare provision, social assistance provided to FSW, the identification of local HIV prevention programs for FSW, 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 FSW, social networks among FSW, means of recruiting FSW to participate in the survey, acceptability of proposed technology to be used in the research, and the identification of FSW community stakeholders and local leaders) or specific information on issues about which little is known (e.g., where local FSW look for drugs and how the FSW 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 also 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

6 *It is up to the policies of the country for conducting surveys to decide what incentives will be provided*

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

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 FSW and peer educators; 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 FSW behavior, socio-demographic characteristics of FSWs, acceptability of proposed survey procedures and sampling method, healthcare and other services seeking and availability and the feasibility of the survey in Mission, Francisco.[8]

8.2.3 Community mapping

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 to identify the locations of physical structures, geographic areas, or social behaviors relevant to the survey of HIV risk behaviors among FSW. Mapping will help identify locations or venues where FSW are likely to congregate and where they can be approached for initial seed recruitment. This process is helpful in providing a rapid way for the team to become familiar with the key places, people and behaviors relevant to the survey. The objectives of mapping are to

- Gain insider understanding of the social and geographic boundaries of FSW communities
- Refine site area boundaries according to social and sexual networks and geography
- Identify and cultivate a geographically diverse group of FSW social networks and contacts who can inform RDS seed selection
- Verify that FSW population and social networks in the area are sufficient to achieve the target sample size

To gain insider knowledge about the social and spatial organization of FSW communities, we will utilize at least one FG in Mission to engage FG participants in a participatory mapping exercise. The primary concern is not cartographic accuracy. Rather, it is to gather useful information that sheds light on operational issues related to a successful RDS recruitment strategy. This will be triangulated with data from the other FGs. During mapping, participants will be asked to assist in sketching on paper a rough physical map of their community, naming the important venues, meeting places, service providers, etc. that define their community. As described below, survey staff and community volunteers will verify these features during walks through prior to initiation of RDS activities.

8.2.4 Walk through and venue verification

The principal tools used in this stage of the research are to collate the areas mentioned in key informant interviews and focus groups 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 KI and FG participant suggestions, a walk through 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 *Please see KII and FGF instruments in this Toolbox for the FG instrument*

8.3 Triangulation

We will use other information to help confirm the conclusions from the FG and KII and to increase understanding of the FSW 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)
- Community based organization (CBO), NGO and other related events, conference and meeting materials
- Sites/locations where FSW 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 Formative assessment analysis plan

Although this is not a formal qualitative research study, 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 Dedoose.com. This 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 RDS 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 recruitment chains but continue to update information as the survey progresses (e.g., the need for new seeds, revision of size estimates, updating of FSW 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.

9. RDS survey procedures and logistics

9.1 Identification of seeds

The formative phase will identify the initial seeds among the KII and FG participants directly or indirectly through their referrals. Seeds are the initial FSW who start the chains of recruitment among their social networks. Seeds are purposely selected to reflect the diversity of social networks in the location in order to logistically enable the survey to reach equilibrium in a feasible time period. In theory, the characteristics of the starting seeds are irrelevant if chains progress long enough. However, in practice time constraints dictate that seeds should be selected from each

of the major sub-populations identified in the formative assessment (i.e., to avoid bottlenecks between distinct groups or areas). Seeds must meet the survey eligibility criteria and will be given coupons and instructions in peer referral. Seeds will be oriented and motivated at the survey start to promote a feeling of survey ownership and enthusiasm about the project.

Formative assessment will identify approximately 6-8 seeds for Mission. More seeds may be added during the course of data collection if recruitment speed is slower than anticipated or too many chains die out. To ensure rapid recruitment, ideal seeds should be well connected within their networks (among their peers), well regarded by their peers, and sympathetic to the survey's goals. We will make an attempt to select seeds that are diverse with regard to the following

- Age
- Education
- Socioeconomic status
- Area of residence
- Nationality
- Language spoken
- Type of sex worker (e.g., street based, venue based, etc.)

During implementation of RDS, we will also track crude sample stability on these characteristics.

9.2 Survey office

One to two discreet office spaces in Mission will be used to administer interviews and HIV counseling in private, collect specimens, and provide service referrals. The location will have central access and be quiet and secure. Only survey staff, investigators, and potential participants with valid peer recruitment coupons will be granted access beyond the reception area. The office will have enough rooms to serve several participants concurrently and avoid overcrowding. To avoid stigma by the public, signs will not reveal the actual purpose of the office. The survey office will remain open up to 4 weeks after the last enrollment to ensure all participants can receive results, referrals, and secondary incentives.

9.3 Interview scheduling

Potential participants will receive a peer recruitment coupon from an enrolled participant that provides the survey site location, a phone number to call or beep (i.e., calling a single ring without connecting to signal the receiver to call back), and hours of operation for drop in. Upon returning the call, the most convenient available interview slot will be offered to the potential participant. If a participant is more comfortable being interviewed in another location, preparation will be made to satisfy that need. The survey team will attempt to accommodate drop-ins at the survey office. However, if there are too many drop-ins, potential participants will be offered to schedule an appointment for a later time and date, and will be given an appointment voucher.

If a person were to appear at the survey site without a valid peer recruitment coupon, staff would inform them that it is the office of a 'health survey' and escort them out of the survey site, so that confidentiality is preserved.

9.4 Eligibility screening

The coupon manager will examine the coupon presented by the potential participant for dates and originality. The unique testing code (UTC), (*see description below)*, 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 (see *Appendix C*) covering the eligibility criteria listed above. When doubts about eligibility remain, staff or FSW volunteers may pose additional (non-standardized) questions to confirm true eligibility.

9.5 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 participants clearly understand the contents of the consent form, 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. *Appendix D* provides two versions of the consent form, one verbal and one written. For the remaining parts of this Toolbox, 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 I.D.) from any participant. A copy of the information sheet will be provided to participants (see *Appendix D*).

9.6 Survey data collection

Standardized data collection instruments adapted for FSW 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 FSW, 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 FSW, as well as on HIV-related knowledge, attitude, practices, stigma, discrimination, and risk perceptions.[9]

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.

The questionnaire will be interviewer administered using a netbook with Questionnaire Design Studio (QDS™). In cases where the participant is not comfortable with the method of data collection, a paper-based questionnaire will be used instead.

9.7 Survey ID codes

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

Peer recruitment coupon code. The peer recruitment coupon code will be serially assigned. The coupon code becomes associated with the questionnaire when the coupon bearer is enrolled. Coupon codes will be pre-printed. In addition to their own coupon ID number, each participant is given three uniquely numbered coupons to refer others to the survey. The linkage between enrolled participants and those whom she refers to the survey is preserved for statistical analysis.

Laboratory code. A separate laboratory code will be used to identify participant results from rapid tests and to label all specimens for laboratory testing. Each participant will be assigned a laboratory code that will be linked to their coupon code in order to link behavioral and biological data. Laboratory codes will be pre-printed.

Unique testing code (UTC). The UTC is an alphanumeric code created by elements of information known to the participant. A UTC will be created for every participant and will be linked to her coupon code. The UTC is used both for registration and identification purposes, and is one method to avoid duplicate participation. Participants will be asked to give their UTC for identification at each follow-up contact or survey visit.

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

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

- 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

Biometric Identification. 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 her coupon code. The biometric identification code will be used both for registration and identification purposes for secondary visits. In the event that the participant opts not to provide their biometric identification, the UTC will be used to link to the participant's coupon code.

9.8 Coupon management

The peer recruitment coupon (herein referred to as coupon) is essential to link enrolled participants to those whom they refer to the survey and is necessary for the analysis of RDS data to adjust for network size and homogeneity within social circles. Being in possession of a valid coupon is an eligibility criterion. Issuance and receipt of coupons will be monitored electronically using RDS Coupon Manager software. Initially, participants will be given three coupons each. Once the sample size approaches the target and equilibrium has been achieved on the key variables (see Section 9.1), coupon dispersal to remaining participants may be reduced and then slowly phased out. Conversely, if referral is slow, the number of coupons issued can be increased.

The coupon will be designed in consultation with FSW community representatives to appeal to the population; will include images recognized by FSW; and have a consistent survey logo. No information that would directly divulge the FSW focus of the survey will appear on the coupons. Coupons will have the following elements: coupon number (which becomes the participant's survey ID code), coupon number of the referring participant, the name of the survey, telephone number to call or beep, days and hours of operation for drop-in, activation date (date before which the coupon may not be used for enrollment), expiration date (date after which coupon should not be used-though this does not need to be enforced), and date of collection (returned and retained by coupon manager, left blank until collected). In practice, the activation and expiration dates are flexible. A coupon may be invalid if expired, tampered with, unreadable, or already used. Invalid coupons will be retained and stamped "VOID". Valid coupons of potential participants undergoing screening for eligibility will be retained and stamped "USED". Participants who are re-scheduled for a future visit have their coupons returned to them. Re-scheduled visit dates may be past the coupon expiration date without rendering the coupon invalid. (See *Appendix E* for sample RDS peer recruitment coupon).

9.9 Referral of peers

Following completion of the above procedures, the coupon manager will explain the handling of the peer recruitment coupons and the referral process to participants. Three coupons will be given to the participant (fewer to slow and end recruitment and up to five to be considered when recruitment is slow). The participant will be asked to identify three peers and tell them about the survey. Participants who do not consent to provide a blood sample for laboratory based surveillance testing will not receive coupons for referral.

Interested peers who receive a peer recruitment coupon can call for an appointment or present themselves at the survey office. Survey participants who indicate they are not interested in referring their friends will still be encouraged

to take the peer recruitment coupons in case they change their mind. As the survey approaches the needed sample size and crude sample stability, the number of peer recruitment coupons will be reduced to two, then one, then zero.

9.10 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 refer to *Appendix F* for a data and specimen flow chart.

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. 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

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.

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.

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 approved by _____. A CSPro data entry program will be used to randomly select the specimens. The samples will be sent without 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.[10]

9.11 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

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

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 FSW population. Specific training on FSW 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.

9.12 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 FSW 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.

9.13 Staff training

Field staff includes a project coordinator, field supervisor, receptionist, coupon manager, outreach workers, and interviewer/counselors.[11]

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

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

national lab technicians (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.

10. FSW population size estimation methods

The second survey objective is to estimate the size of the FSW 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.[12]

[*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. 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. 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 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.

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.

Paz-Bailey G, Jacobson JO, Guardado ME, et al. How many men who have sex with men and female sex workers live in El Salvador? Using respondent-driven sampling and capture-recapture to estimate population sizes. BMJ. 2011;87(4):279-82.

12 *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.*

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.

Vandepitte J, Lyerla R, Dallabetta G, et al. Estimates of the number of female sex workers in different regions of the world. Sex Transm Infect. 2006; 82 Suppl 3:iii18-25.

Zhang D, Lv F, Wang L, et al. Estimating the population of female sex workers in two Chinese cities on the basis of the HIV/AIDS behavioral surveillance approach combined with a multiplier method. Sex Trans Infect. 2007; 83:228-231.

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. [13]

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.[14]

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

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 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

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

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

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 (i.e. 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.[15]

Data entry and analysis. Census and enumeration data were included in the formative data management and storage procedures. 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.[16]

Data from the wisdom of the crowds and Delphi method will be extrapolated to other areas in 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 IBBSS 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 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.

15 Please see opulation estimate worksheets in this Toolbox for a population size estimate summary spreadsheet.

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

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.

10.1 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 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. 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/coupon 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 and coupon manager on a daily basis. At present, we will use RDS Coupon Manager for data management. RDS Coupon Manager is used to track referral processing and coupons; UTC will be used 1) to identify duplicate participants, 2) to confirm correct ownership of a peer recruitment coupon), and 3) to re-establish the peer recruitment coupon of participants who present themselves for follow-up without a coupon. The coupon manager will enter coupon data into the RDS Coupon Manager software on a daily basis, and the Coupon Manager 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 removed from the Coupon Manager system. 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.

10.2 Analysis overview

The analysis of RDS data requires adjustment for social network size and homophily within networks. Specialized analyses will be conducted to produce population prevalence estimates and confidence intervals of variables adjusting for unequal probabilities of inclusion due to varying social network sizes and the similarities in characteristics of persons within their social networks. Advanced aspects of the analysis of RDS data, such as adjusted multivariate analysis, are currently under research and we will keep abreast of the most up to date accepted standards during the analysis phase.

At present, we will use RDS Analysis Tool (RDSAT) (Versions 7.1, www.respondentdrivensampling.org), SAS (Version 9.2, Cary, NC), Stata, (Version 10, College Station, TX) and R for analyses. RDSAT is software developed for analysis of RDS data which produces population point prevalences and 95% confidence intervals for key indicator variables. RDSAT also produces survey weights. The data (along with the individual survey weights) can then be exported into standard statistical packages (e.g., SAS, Stata, or R) for more complex analysis.

As a basic surveillance activity, the primary analyses will be the adjusted population estimates of disease prevalence (HIV), key risk behaviors (e.g., unprotected sex), and access to and use of HIV prevention programs and services. Stratified analyses will also be done to identify sub-populations at higher risk. Using the RDSAT exported weights, conventional analyses will be done to identify significant associations between HIV and risk behaviors.

10.3 Long-term data storage

The clean file of de-identified survey data will be the property of the Ministry of Health 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 Ministry of Health for at least 10 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 (see *Appendix G)*.

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 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 approved requests. Prior to the publication of the final report, the TWG will approve the use of the de-identified survey data.

11. Ethical considerations

11.1 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 commercial sex work and illegal drug use. 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 I.D.) from any participant.

- All staff working with participants will be required to sign an employee confidentiality agreement (see *Appendix H)*.

During the formative phase, investigators will take all necessary precautions to protect the FSW 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 FSW 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.

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 FSW seeking services. Reports of rape and other violence will be handled in consultation with local human rights organizations that provide such services for other populations. Any participant reporting rape or violence will be provided information on his/her rights and provided information on further resources available to them. Survey team member will not contact law enforcement agencies.[17]

11.2 Approvals and consultations

This project proposal will be submitted for human subjects review and approval at the International Review Board within the MoH in Francisco. Survey personnel will be trained in ethics and good clinical practice.[18]

11.3 Reporting adverse incidents

Adverse incidents will be reported to _____. Potential incidents may include protocol violations, security incidents harming participants or staff, breach of confidentiality, 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 I*). 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, of follow-up.

11.4 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 survey partners to the field site 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 questionnaire, survey forms, or on any lab specimens. Access to participant data will be limited to the data/coupon manager, site supervisor, data analysts,

17 *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.*

18 *List all ethical committees in addition to MoH*

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.

11.5 Potential benefits

The primary benefit of the proposed survey is to produce reliable data on the health and social welfare needs of FSW communities in Francisco. FSW population size estimates will also help advocate for the appropriate levels of funding and types of interventions for FSW. 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 areas that are in the process of training select providers who will be able to deliver appropriate services for FSW. Investigators will ensure that suitable services will be available at referral clinics by the time of survey initiation.

11.6 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 receive a one-time reimbursement valued at $2-$4 USD in cash for transportation costs.[19]

19 *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.*

Compensation for participation is common in IBBS surveys conducted by RDS. Past RDS studies suggest that incentives should be offered to compensate participants for the substantial commitment of time and effort required to complete the survey questionnaire and biological testing, as well as the referral of additional participants. RDS relies on survey participants to identify, approach, and inform future participants. To facilitate recruitment chains, primary incentives are offered for completing the survey and secondary incentives for each referral. Further, participants are typically compensated for their travel expenses as they need to travel to the survey office for the interview and return for one or more visits to collect secondary incentives.

For RDS participants, the following compensation/ incentives scheme is proposed:

RDS survey participation: RDS survey participants will receive a primary incentive for participation in the survey, in addition to HIV counseling, testing, and referral. The primary incentive will include a prevention and hygiene kit (i.e., condoms, lubricants and health information) and a mobile phone credit voucher (valued between approximately $6-$10 USD). We anticipate that mobile phone credit vouchers will be an effective and appropriate referral incentive because they are valued by participants and they enable them to communicate efficiently with members of their social networks in order to propagate the recruitment chains required to achieve sample size. Survey participants will also receive the equivalent of $2-$4 USD in cash for transportation costs.

RDS peer referral: Survey participants who refer their friends will receive another smaller secondary incentive for each successful peer referral. The secondary incentive will be an additional mobile phone credit voucher (valued between $2-$4 USD) for each referred peer who completes a survey. Each participant may refer three (3) peers and can receive a maximum of $6-$12 USD worth of mobile phone credit in secondary incentives. Participants will also receive the equivalent of $2-$4 USD in cash for transportation costs to return to the survey office for their secondary incentives.

Secondary incentives are provided to participants who refer eligible participants to the survey. Participants can stop by or call survey office to

determine whether any of their referrals have come in and whether they have secondary incentives to collect. Disbursement of secondary incentives will be tracked using coupon manager software and backup forms.

The combined maximum value of primary and secondary incentives including transportation is USD $16-$30 per RDS participant, over the entire period of data collection (approximately five months).

Precise values of incentives and transportation reimbursements will be determined based on information collected in the formative assessment, and by the exchange rate at the time of the survey.

12. Projected time line

This surveillance project will start in 2012 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.

13. Dissemination of findings

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

Upon completion of primary data analysis and prior to finalizing an IBBS-FSW report, findings will be shared with a small community forum in the survey city to confirm and contextualize results. Upon completion of this local forum a writing workshop will be held to draft the IBBS-FSW 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-FSW dissemination event. Other means of 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 and engage the government, the private sector, and FSW organizations in taking ownership and

Proposed activity	Month													
	2012				2013									
	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										
RDS implementation training						X								
RDS implementation						X	X	X	X	X	X			
Data cleaning/lab QA/data merging											X	X		
RDS analysis and writing training												X	X	
Final report														X
National dissemination workshop														X

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 forums and publications.[20] 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 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 IBBS-FSW will be obliged to cite the source of the data and send copies of the article, report, and/or book to the MoH. These data are not to be used for personal gain or profit by any individual or group of individual investigators or partner institutions.

Any publications or presentations produced should follow the funding source clearance guidelines.

20 *Creating a SMAP has been helpful to track data use for abstracts, avoid duplication of ideas, and make sure authors follow through with their concepts in a timely fashion.*

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Appendix A: Consent form for key informant interview

Women's Health Monitoring Survey

Key informant participant information sheet for informed consent

Principal Investigators: [*LIST here]*

The name of this survey is the Woman'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' women have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many female sex workers (FSW) 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 to encourage FSW to take a survey
   - Reasons FSW might not want to take a test for HIV
   - Ways to encourage FSW to take the test and the best incentive for doing the survey
   - Locations where FSW live and go out
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 and $3 to reimburse you for your transportation.

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 FSW 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 an information sheet, 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

Women's Health Monitoring Survey

Focus group information sheet for informed consent

Principal Investigators: [*LIST here*]

The name of this survey is the Woman'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' women have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many female sex workers (FSW) 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 being asked to be in the survey today because you have ideas and opinions that can help us to plan the bigger survey. In the survey today, we are asking people to be in a special discussion group called a focus group (FG). This will help us to learn about the best way to plan our future survey.

B. Procedures

1. If you agree to be in this survey you will come to a FG with 5-11 people from your community. 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 to encourage FSW to take a survey;
   - Reasons FSW might not want to take a test for HIV
   - Ways to encourage FSW to take the test
   - The best incentive for doing the survey
   - Locations FSW live and go out
2. You do not need to talk about anything that is asked or discussed during the FG 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 FG at any time without any penalty to you.
3. The FG is confidential. We will not record your name or any other information that might identify you. The group leader 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.
4. During the discussion, we will take notes on paper and the Leader will tape-record, so that our team can listen to it later. We will not ask for your name or any other information that might identify you or connect you to what you said during the FG. You should not talk about who said what in the group to anyone else outside the survey group.

5. At the end of the discussion, the notes and tape recordings from the FG will be destroyed.
6. We will provide you with refreshments during the FG and $3 to reimburse you for your transportation.

C. Discomforts and risks

The discussion in the group will be about people who are at risk or HIV because of certain behaviors. These behaviors may not be acceptable to all persons in a community. Some of the questions may make you feel uncomfortable. If other people in your community find out that you are in this survey, they might treat you badly. To protect you from this, your name will not be asked for or written down at any point. No one on the staff will tell anyone that you were in the survey. The location will be private and unmarked. There will not be a list of people who attended. The leader will tell all of the participants not to use their name or anyone other persons name at any time. Also no one will ask about your own behaviors. You do not need to share this information. But there is a risk that people who participate in the survey could talk about what was said in the survey to people outside of the group.

D. Benefits

The information you give us may help us to plan a better survey for FSW and 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 an information sheet, 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.

Sample RDS 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: Eligibility screening questionnaire

Women's Health Monitoring Survey

Instructions: Complete the entire screening questionnaire for every candidate that comes to the survey site for the 1st visit. Only questions that are not in brackets should be made to a participant. If the person is eligible to enter the call number on the netbook and refer the participant to an interviewer.

"Hello. My name is ____. I would like to first thank you for taking the time to participate in the survey. The person who asked you to participate in the survey may have told you that this survey is about beliefs and perceptions around HIV and behaviors of female sex workers. But before we start the survey, I need to first find out if you are eligible to participate. If you are eligible to participate, then I will introduce you to one of our interviewers who will do a survey with you. Let me also tell you that everything you tell us will be completely confidential. We will not take your name and no one will be able to link your responses to you personally. Do you mind if I start?"

[Date]	[___|___]-[___|___]-[___|___|___|___] (dd) (mm) (yyyy)
[Does the candidate have a valid coupon?]	Yes No → Ineligible
[Coupon # person came in with]	(alpha) (# # # #) [Write 'Z 9999' if recruit comes in with NO coupon. [If seed, write 'Seed prefix' and '0000']
[Is this person a seed?]	Yes ____ (Enter Seed Prefix) No
[Is the candidate a female?]	1 Female 2 Male → Ineligible
Have you participated in this survey before?	1 Yes → Ineligible 2 No
How old are you now?	Age in completed years: _____ [Under 18 years → Ineligible]

Sample RDS protocol

Have you had sex in the last 6 months?	1 Yes 2 No → Ineligible
Did you receive money for sex in the last 6 months? [If necessary, probe with additional questions to verify FSW sexual behavior]	1 Yes 2 No → Ineligible
Interviewer: [Is participant able to provide verbal informed consent?] (i.e.: not under the influence of alcohol/drugs; able to communicate in mutually understood language).	1 Yes 2 No → Ineligible
[Do you have confidence that this person is FSW?]	1 Confident 2 A little confident 3 Not confident

SCREENER: Is the candidate eligible? [Circle] YES NO

Not eligible because candidate [Circle ALL that apply, then END]

- Did not have a valid coupon
- Is under the age of 18
- Participated in the survey before
- Is not a female
- Did not have sex in the last 6 months
- Did not receive money for sex in the last 6 months
- Is too drunk/high to do questionnaire
- Is unable to communicate in understood language
- Other: _____

Appendix D: Written and verbal consent forms for IBBS-FSW RDS survey implementation

Women's Health Monitoring Survey

Survey information sheet for written informed consent
(Flesch-Kincaid Grade Level: 6.3)

Title of survey: Women's Health Monitoring Survey

Principal investigators: [*LIST here*]

The name of this research survey is the Women'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. 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 partners' women have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many female sex workers (FSW) 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?

If you do this survey, you will be asked to come to **2** visits with us. The **1st visit** is a long visit. It will take about 90 minutes. At this visit, you will

- Get a survey code. This way nobody can know who you are. We have this code because we do not want to know your name or any information that can make someone find out that it was you who did this study.
- Take a survey with a trained interviewer. The interviewer will ask questions 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 trained counselor take blood from a fingerprick. The blood will be used to do a rapid HIV test and to put some drops of blood on a card that will be sent to the national lab for HIV testing. 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 for being in the survey today. You will get this gift even if you do not do all parts of the survey.
- Get some coupons to invite some friends to be in the survey

When you come back for the **2nd visit.** You will only stay a few minutes. You will get a small gift for each friend you gave a coupon to that was in the survey.

What risks can I expect from being in the survey?

There may be some risk or discomfort from doing this survey.

- The most important is that someone might find out you took the survey. If this happens, someone in your community might treat you badly. But the study is secret and we do all we can to keep it private. If you know the interviewer, you may ask for another one so that your privacy is protected.
- Somebody outside of the study staff could find out about your HIV results. If this happens, someone in your community might treat you badly. But we do not use your name or any information that can make anybody know that a test result is yours.
- The survey includes personal questions about sexual activity and other private things. This can make you feel embarrassed. If any question makes you feel uncomfortable, you can refuse to answer it. You can terminate the interview at any time. If you do this, you will not be asked to leave the study. You can still get your gift for your time spent.
- The fingerprick may hurt. The spot my bleed, bruise or get infected. You may feel faint, but this is very rare. Only trained counselors will do the fingerprick, so that these things might not happen.
- If you test positive for HIV you may feel anxious or depressed. The counselor working with you can help you with these feelings. You may also be referred to local counselors or support groups to help 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 on-site testing for HIV and the opportunity to learn your test results
- Referral to clinics that can give you medical care and treatment as needed
- Free condoms, lubricant, and educational information on HIV and STIs
- There is also a benefit to your community because we will know more about those at risk for HIV. This can help plan better education, prevention, and medical programs.

What are the alternatives for being in the survey?

You can choose not to participate in the survey. This will not impact your access to services. The survey staff can give you a list of health and social services and refer you to testing locations.

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

It does not cost anything to be in this survey.

Will I get anything for taking part in the survey?

You will be offered a snack and a prevention kit worth [*INSERT incentive amount here*] for your time and effort today. You will also be given phone credit worth up to [*INSERT incentive amount here*] for each person you peer educate and help to enroll in the survey, which you will receive when you return on your second visit. You will also receive $3 to reimburse you for your transport here today.

Will my medical and other information be kept confidential?

Being in a survey can reduce privacy. This is a secret survey. We take many steps to keep your information top secret. To protect your identity

- We do not ask for your name. We do not write it on any survey documents or lab sample.
- Only your survey ID number will be on your survey, survey records, and lab sample

- All the information you give will be kept in a cabinet. It will be locked at all times.
- Your test result will not be known to anyone except you and the counselor
- Only survey staff and participants can be in the survey area. The office has private rooms. No signs will show the purpose of the site.

What if I want to stop being in the survey?

Your participation is entirely voluntary. 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. Your access to health services will not be impacted if you stop or are asked to stop being in the study. Once your blood sample is sent to the national laboratory you can not change your mind about it being used for testing because we cannot know which sample is yours.

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.

1. 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

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

   ☐ 1. YES, agree.

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

3. Do you agree to a fingerprick to prepare a blood sample that will be sent to the national laboratory for additional HIV testing?
   - ☐ 1. YES, agree.
   - ☐ 2. NO, decline.
4. Do you agree to rapid HIV testing to receive your results today?
   - ☐ 1. YES, agree.
   - ☐ 2. NO, decline.

If you have read this document or had the document read to you, have been given the chance to ask any questions, and agree to participate in the above procedures (as marked), please sign below.

- I have been informed by the interviewer about the nature, conduct, benefits and risks of this survey
- I have also received, read and understood the above written information regarding the survey
- I am aware that the results of the survey including personal details regarding sex, age, HIV status will be anonymously processed into a survey report
- I may, at any stage during the interview, without prejudice, withdraw my consent and participation in the survey
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the survey

Signature or mark of participant _____

Date ___/___/___ Time ___/___

I have explained to the participant the study 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.

Name of person obtaining consent_____

Signature of person obtaining consent _____

Date ___/___/___ Time ___/___

Copy to: ☐ Participant

☐ Investigator's file

Information sheet for verbal informed consent

Women's Health Monitoring Survey
(Flesch-Kincaid Grade Level: 6.3)

Title of survey: Women's Health Monitoring Survey

Principal investigators: [*LIST here*]

The name of this research survey is the Women'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. 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 partners' women have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many female sex workers (FSW) 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?

If you do this survey, you will be asked to come to **2** visits with us. The **1st visit** is a long visit. It will take about 90 minutes. At this visit, you will

- Get a survey code. This way nobody can know who you are. We have this code because we do not want to know your name or any information that can make someone find out that it was you who did this study.
- Take a survey with a trained interviewer. The interviewer will ask questions 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 trained counselor take blood from a fingerprick. The blood will be used to do a rapid HIV test and to put some drops of blood on a card that will be sent to the national lab for HIV testing. 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 for being in the survey today. You will get this gift even if you do not do all parts of the survey.
- Get some coupons to invite some friends to be in the survey

When you come back for the **2nd visit.** You will only stay a few minutes. You will get a small gift for each friend you gave a coupon to that was in the survey.

Sample RDS protocol

What risks can I expect from being in the survey?

There may be some risk or discomfort from doing this survey.

- The most important is that someone might find out you took the survey. If this happens, someone in your community might treat you badly. But the study is secret and we do all we can to keep it private. If you know the interviewer, you may ask for another one so that your privacy is protected.
- Somebody outside of the study staff could find out about your HIV results. If this happens, someone in your community might treat you badly. But we do not use your name or any information that can make anybody know that a test result is yours.
- The survey includes personal questions about sexual activity and other private things. This can make you feel embarrassed. If any question makes you feel uncomfortable, you can refuse to answer it. You can terminate the interview at any time. If you do this, you will not be asked to leave the study. You can still get your gift for your time spent.
- The fingerprick may hurt. The spot my bleed, bruise or get infected. You may feel faint, but this is very rare. Only trained counselors will do the fingerprick, so that these things might not happen.
- If you test positive for HIV you may feel anxious or depressed. The counselor working with you can help you with these feelings. You may also be referred to local counselors or support groups to help 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 on-site testing for HIV and the opportunity to learn your test results
- Referral to clinics that can give you medical care and treatment as needed
- Free condoms, lubricant, and educational information on HIV and STIs
- There is also a benefit to your community because we will know more about those at risk for HIV. This can help plan better education, prevention, and medical programs.

What are the alternatives for being in the survey?

You can choose not to participate in the survey. This will not impact your access to services. The survey staff can give you a list of health and social services and refer you to testing locations.

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

It does not cost anything to be in this survey.

Will I get anything for taking part in the survey?

You will be offered a snack and a prevention kit worth [*INSERT incentive amount here*] for your time and effort today. You will also be given phone credit worth up to [*INSERT incentive amount here*] for each person you peer educate and help to enroll in the survey, which you will receive when you return on your second visit. You will also receive $3 to reimburse you for your transport here today.

Will my medical and other information be kept confidential?

Being in a survey can reduce privacy. This is a secret survey. We take many steps to keep your information top secret. To protect your identity

- We do not ask for your name. We do not write it on any survey documents or lab sample.
- Only your survey ID number will be on your survey, survey records, and lab sample
- All the information you give will be kept in a cabinet. It will be locked at all times.
- Your test result will not be known to anyone except you and the counselor

- Only survey staff and participants can be in the survey area. The office has private rooms. No signs will show the purpose of the site.

What if I want to stop being in the survey?

Your participation is entirely voluntary. 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. Your access to health services will not be impacted if you stop or are asked to stop being in the study. Once your blood sample is sent to the national laboratory you can not change your mind about it being used for testing because we cannot know which sample is yours.

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.

1. 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

2. Do you agree or decline to complete the **survey questionnaire**?
   - ☐ 1. YES, agree.
   - ☐ 2. NO, decline. [if NO participant not eligible to participate].
3. Do you agree to a fingerprick to prepare a blood sample that will be sent to the national laboratory for additional HIV testing?
   - ☐ 1. YES, agree.
   - ☐ 2. NO, decline.

4. 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.

The participant has agreed to participate in the above procedures (as marked).

- 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
- 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 _____

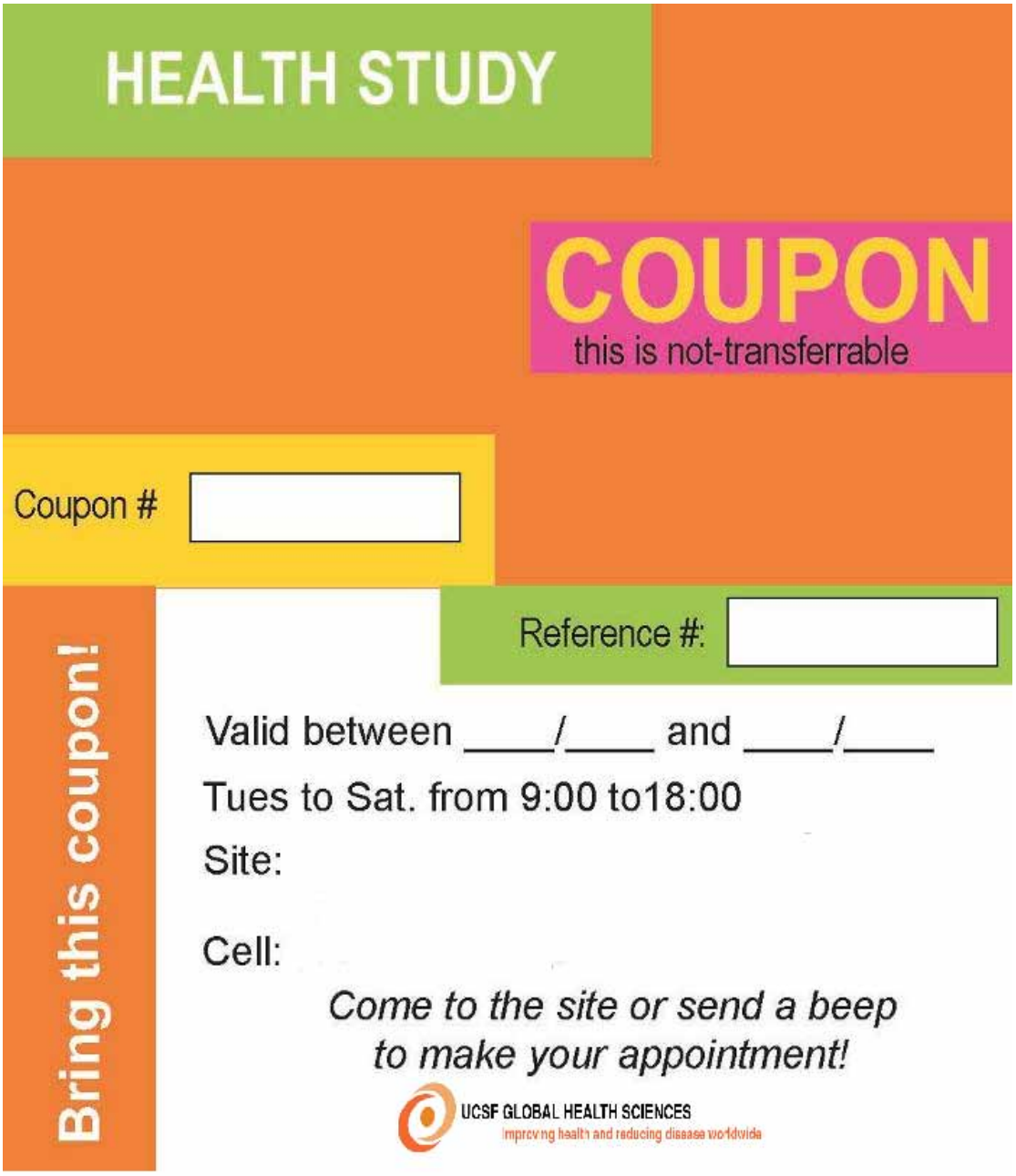
Date ___/___/___ Time ___/___

Copy to: ☐ Participant

☐ Investigator's file

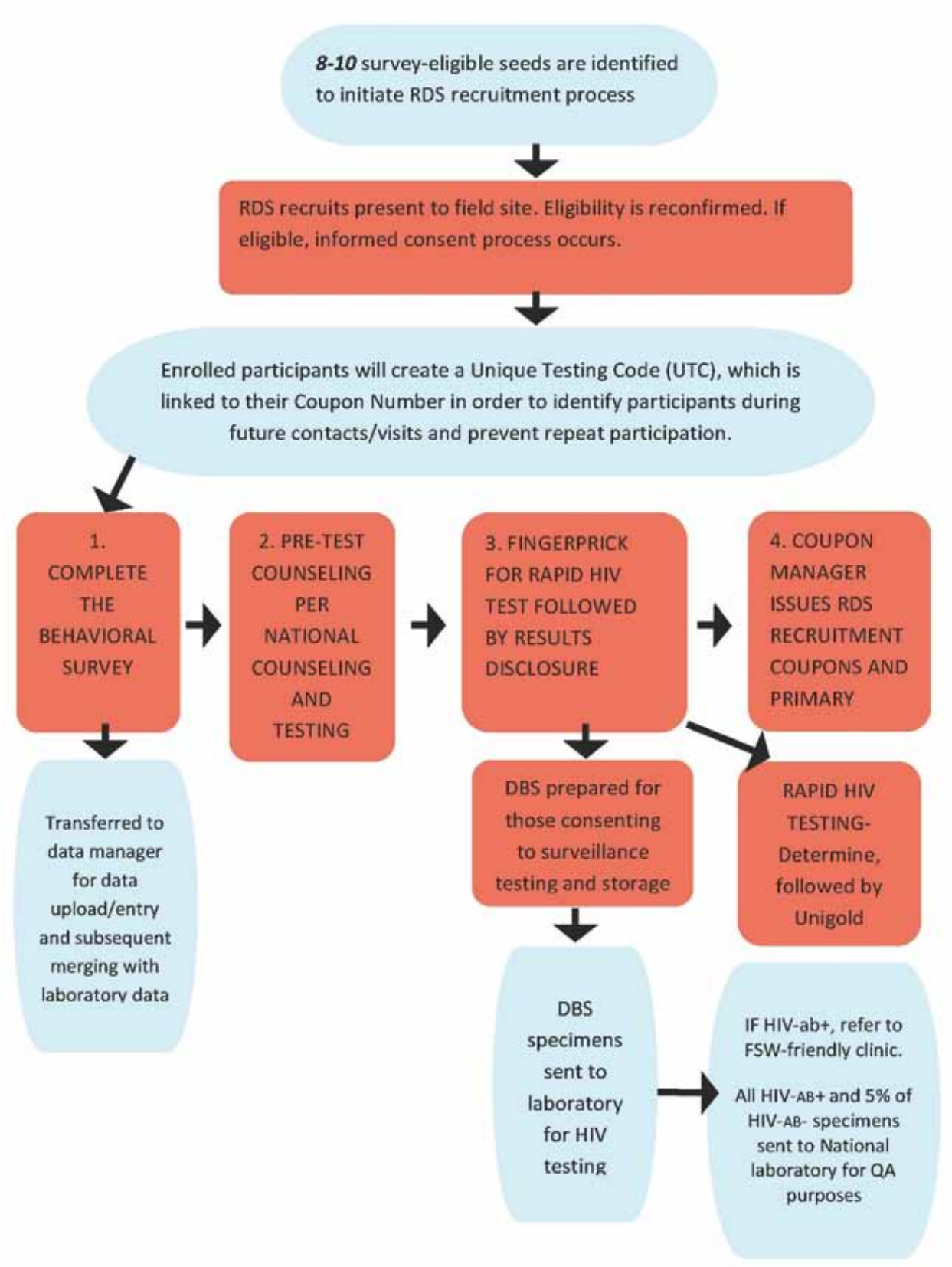
Appendix E: Sample RDS peer recruitment coupon

Women's Health Monitoring Survey



Appendix F: Data and specimen flow chart

Women's Health Monitoring Survey



Appendix G: Data use agreement form

Women'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 RDS 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 RDS 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 RDS data analysis methods: Please provide any information about the requestor's familiarity with RDS 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 RDS 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 H: Employee confidentiality agreement

Women's Health Monitoring Survey

Employee confidentiality agreement

- I recognize that in carrying out my assigned duties as a staff member on *the Woman'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 I: Incident form

Women'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	**FINGER PRICK INCIDENT**
Staff harmed or threatened	Finger prick 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