UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

Instructions for completing the Research Plan are available on the HRPP website.
The headings on this set of instructions correspond to the headings of the Research Plan.
General Instructions: Enter a response for all topic headings.
Enter "Not Applicable" rather than leaving an item blank if the item does not apply to this project.

January 31, 2017

1. PROJECT TITLE

***ESTIMA*: Economic and Social Empowerment To Increase upwards Mobility Among women**

2. PRINCIPAL INVESTIGATOR

Elizabeth Reed, ScD, MPH

3. FACILITIES

San Diego State University is the lead institution on this project and where the PI is located. Although no direct contact with participants will occur at this institution, SDSU will be responsible for all regulatory matters. This includes coordination of all IRB approvals, quality assurance, data safety and monitoring and protocol development. Some data analyses of de-identified data shared through secure servers will be conducted by collaborators to the study at the UCSD School of Medicine, Division of Global Public Health.

The field operations for the study will be carried out in Tijuana, Mexico, which borders the U.S. Our offices are located near the Zona Roja where human subject research will be performed. This office space is complete with 1 waiting room, 1 small meeting room, and storage space.

4. ESTIMATED DURATION OF THE STUDY

The study will be conducted over a 4 year period of time.

Overall Project Timeline

Year 1 2014-2015				Year 2 2015-2016				Year 3 2016-2017				Year 4 2017-2018			
Quarter				Quarter				Quarter				Quarter			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Preparatory activities, regulatory approvals, qualitative interview instrument refinement and interview facilitation, curriculum and program development and refinement, survey interview development and refinement															
		Peer educator training													
		Recruitment & enrollment, random assignment, baseline survey and specimen collection													
		ESTIMA Project Implementation													
			Process evaluation and 6, and 12 month follow up including survey/specimen data collection												
									Data entry, analyze data, refine intervention and study instruments						
										Develop reports for community stakeholders, publications, and presentations for dissemination of findings						
										Prepare, submit, revise, and resubmit R01 NIH grant						

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

Given the increasing recognition of the contribution of structural-level factors (e.g. gendered economic and social power imbalances) on both HIV and gender-based violence (GBV) among women, and thereby, the need for interventions that aim to alter such structures within communities, we have developed the proposed research to address the *intersection of GBV and HIV.* The proposed research aims to pilot a multi-strategy structural intervention combining community mobilization to promote gender equity alongside an economic intervention (microfinance and business training) in order to reduce gender-based violence and HIV risk among female sex workers (FSW) in Tijuana, Mexico. The program will be called ESTIMA: "Economic and Social empowerment To Increase upwards Mobility Among women". The evaluation will employ a randomized controlled design, recruiting FSW (n=120, 60 in each arm) who will be randomized to: 1) ESTIMA (gender equity/community mobilization program and economic intervention) or 2) a wait-list control group. Women will be part of groups of approximately 6-10 women each, and each group will be randomized to intervention or control conditions. For this preliminary work, at 12 months follow-up, we hypothesize that compared to control participants, intervention participants will have: 1) significantly greater economic security (e.g. decreased debt, increased income, decreased number of sex trades) and 2) significantly greater perceived collective power (i.e. collective efficacy) to address gendered power imbalances within social structures and the community. The long-term goal of this program, upon future refinement and large scale implementation, is to reduce HIV risk behaviors, STI/HIV, GBV, and ultimately, alleviate a multitude of health burdens among women. Furthermore, we expect that such work will highlight the need for HIV prevention initiatives in Mexico, and elsewhere, to more broadly consider women's 'life contexts' – addressing economic and social burdens in women's lives, to reduce the burden of poverty, gender, and HIV, as well as the intersection of these among women.

6. SPECIFIC AIMS

We aim to develop, implement, and evaluate a program called *ESTIMA* (Economic and Social empowerment To Increase upwards Mobility Among women), which translates to "valuing myself" in Spanish. ESTIMA is a program that will incorporate gender equity content into an existing microfinance program, Our microfinance partner, *Via International* (*Via*), which has provided microloans in Tijuana since 1999, provides over $200,000 in microloans yearly. *Women's Empowerment International* (WEI), which has sponsored over 9300 microloans to women in Mexico, will provide the capital for *Via* to expand their microfinance program for the proposed ESTIMA program, and has a long history in sponsoring business training and microfinance programs in Latin America and elsewhere. Economic vulnerability is a critical factor in heightening risk for HIV among FSW and this combined program addresses such vulnerability while also supporting women via community mobilization to address both economic and social burdens.

The specific aims include:

Phase I

1. To identify key priorities and strategies for a program focused on promoting gender equity to be incorporated within the *Via* microfinance program in Tijuana, Mexico. We will conduct 30 qualitative interviews among FSW residing in Tijuana. Data will be used to assess: 1) how to best engage and maintain participants in the intervention, as well as to ensure participant confidentiality, 2) how to best address the intersection of gender inequities, GBV, poverty, and women's risk for HIV (including whether to limit the initial pilot of the program to women with no or low drug use), and 3) how the intervention can enhance women's economic mobility and independence. Findings will be used to refine ESTIMA program strategies.

Phase II

2. To assess preliminary outcomes of the ESTIMA HIV Prevention Program Using a two-armed randomized controlled design, we will recruit FSW (n=120, 60 in each arm) who will be randomized to: 1) the ESTIMA intervention (gender equity program and *Via* microfinance program) or 2) a wait-list control group. Women will be part of groups of approximately 10 women each, and each group will be randomized to intervention or control conditions. At 12 months follow-up, we hypothesize that compared to control participants, intervention participants will have: ***a)*** Significantly greater economic security (e.g. decreased debt, increased income, decreased number of sex trades) and ***b)*** Significantly greater perceived collective power (i.e. collective efficacy) to address gendered power imbalances within social structures and the community.

3. To assess feasibility regarding all aspects of implementation, receptivity by participants and staff, and capacity to be maintained by *Via* microfinance efforts Qualitative focus groups (n=2 or less per intervention group, 10 women per session), individual interviews (approximately 5 per intervention group), and quantitative assessments will be conducted with intervention participants, along with staff feedback via post-training evaluation forms, to inquire about satisfaction with and appropriateness of the program, as well as aspects pertinent to the ethical conduct of the intervention. We will also monitor recruitment, random assignment, adherence to intervention design, retention of participants, contamination across arms, and the incidence of adverse events.

7. BACKGROUND AND SIGNIFICANCE

High rates of sex trade and drug use, as well as the intersection of these, exacerbate the spread of HIV in Tijuana, the largest Mexican city bordering the US.[9] Female sex workers (FSW) are among the groups most affected by HIV in this region. Among FSW, HIV prevalence is 5-8% and as high as 14% among FSW who inject drugs[10-12]Sexual risk behaviors (unprotected sex with clients and male partners) increases HIV risk among FSW.[10,13,14,46,47] Widespread drug use is also a primary factor in contributing to high rates of HIV in this context (e.g. via sharing of injection equipment), and overlaps with the sex trade industry (drug use is common among both FSW and clients) to further increase prevalence of HIV more broadly. Drug use (e.g. cocaine, heroin, methamphetamine), common among FSW in Tijuana (14-22% report injecting drugs and 50% or more report using non-injection drugs), is also a primary HIV risk factor among FSW via sharing of injection equipment, as well as reducing condom negotiating ability when used in the context of sex trade.[10-15] Tijuana has red light districts supported by sex tourism from the United States and Mexico.[10] Recent work estimates approximately 9,000 FSW in Tijuana.[48,49] Notably, Tijuana's drug populations report high levels of a) migration from other parts of Mexico, b) current mobility, and c) experiences of deportation from the US.[50] Thus, sex and drug-related HIV risk behaviors in Tijuana are critical to HIV prevention, have implications for increasing HIV prevalence in other parts of Mexico, and are also of immense significance to HIV prevalence within the U.S., given high cross-border mobility and sex tourism.

In Tijuana and across Mexico, poor economic conditions contribute to women's involvement in sex trade,[13-15;16-19] **and also heighten sexual and drug related HIV risks among FSW**.[17-20] Among FSW, economic urgency (e.g. debt, inability to provide for the needs of children or other family) has been identified as a primary factor for HIV risk, and linked to (1) increased unprotected sex (e.g. agreeing to unprotected sex trades in exchange for more money) and (2) increased experiences of gender-based violence (GBV).[18,20] Forms of GBV experienced by FSW include physical and sexual violence from managers, clients and police, as well as from male partners. All of these forms of GBV reduce women's negotiating power to avoid dangerous clients/situations and unprotected sex.[20-30] Economic urgency also increases women's drug-related HIV risks (e.g. reducing negotiating power when buying drugs and resulting in being "second on the needle;"[31-34] sex trade for drugs which also reduces condom negotiating power).[35-39]

Across the global south, only one tested intervention (***Intervention with Microfinance for AIDS and Gender Equity, IMAGE***), which included incorporating gender equity mobilization (community mobilization to alleviate gender inequity) into an existing microfinance program, has documented improvements in both GBV and reduced HIV risk behaviors among women;[40-42] The IMAGE program in South Africa demonstrated significant improvements in economic indicators, reduction in reports of GBV by more than half, and a reduction in HIV risk behavior as well (e.g. decreased unprotected sex with non-spousal partners).[43-45]

The proposed work will provide preliminary findings on the utility of combining both economic intervention and community mobilization strategies to reduce HIV risk among FSW in Mexico. While community mobilization and microenterprise approaches used separately have had some success on reducing HIV risk among FSW**,** evidence suggests that a combined approach may be most effective. Community mobilization strategies have documented some success in improving social conditions and reducing HIV risk among FSW in India, as well as other vulnerable populations of women elsewhere (e.g. South Africa, Uganda), including substance using populations;[7,66-73] but may be limited in terms of addressing economic deprivation (e.g. housing and economic stability, debt).[1,53] Preliminary work as also shown microfinance to alleviate HIV risk among FSW as well.[74-75] However, economic interventions, when implemented alone, may not fully consider the social challenges women face that may impede their effectiveness in carrying out a business activity (e.g. low social mobility, male figure required to rent space or open a bank account).[2,66] Findings from the IMAGE program suggest that a combined approach is effective in reducing HIV and GBV among women.[43-45] Thus, the proposed work aims to pilot test these two strategies together, and will be critical to inform future efforts to address the burden of poverty, GBV, and HIV risk among FSW in Tijuana, as well as have implications for replication elsewhere. Notably, a combined approach has been identified in recent meta-analytic investigations as most promising to decrease GBV and HIV risk among women[1,53,76-80]

8. PROGRESS REPORT

Sample size needs for this study were initially expected to be satisfied by recruiting from participants of the parent study (MAPA de Salud, PI: Dr. Brouwer, protocol #100148).

9. RESEARCH DESIGN AND METHODS

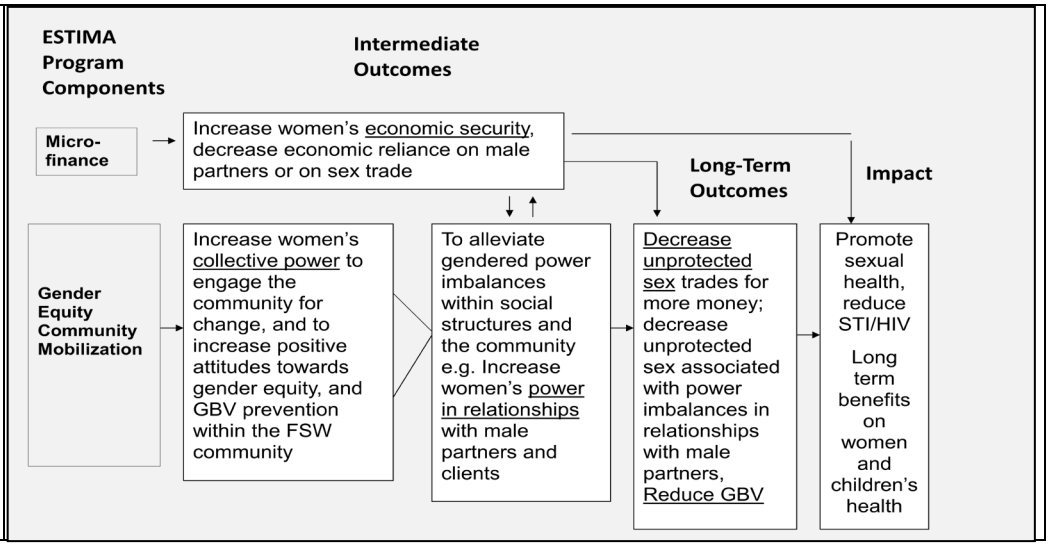
The ESTIMA program will consist of the 1) *Via* microfinance program, which includes providing women with monetary loans (loan money funded by Women's Empowerment International) as a group and training them to initiate a business or other investment endeavor, and 2) gender equity community mobilization, which involves initiating groups of women (i.e.

collectives) and engaging in social action within the community, with a focus on addressing issues relevant to gender inequities and women's economic mobility and power (such as client or police violence/harassment). Like the IMAGE program in South Africa, community mobilization will be incorporated into the *Via* microfinance trainings.

Via International, which will implement the microfinance program along with the community mobilization, has provided microfinance loans in Tijuana since 1999, providing over $200,000 in microloans yearly. Women's Empowerment International, which will be providing the capital for the loans, has sponsored over 9300 microloans to women in Mexico, and has a long history in sponsoring business training and microfinance programs in Latin America and elsewhere. Facilitation will be by the *Via* training team, who will be trained on gender equity community mobilization strategies. Priorities of mobilization efforts will be identified by the ESTIMA collectives, facilitated by the election of collective leaders, and guided by the findings of Aim 1. Notably, our preliminary work in this area (communication with FSW involved in ongoing UCSD research projects) indicate that women are very interested in ESTIMA; many women reported that they initiated sex work to save money to start a business. Women will be provided with a loan of up to $2,500 pesos each. (See Appendix I for details on the ESTIMA program, see also section 15 for managing risks associated with taking out loans). Women are required to repay the loan within 4 months at 15% interest, which means paying back a total of $2,875 pesos or the equivalent which is a payment of $179.69 pesos per week for 4 months: $23.44 pesos fee for the loan per week as interest and $156.25 pesos to pay back the loan. The loans are at a standard flat rate of 15% over the course of 4 months. While we recognize that this is high, this is lower compared to other existing programs in Mexico, (e.g. Comportamos, which is the largest microfinance program in Mexico, provides loans at higher rates), and is consistent with microfinance programs abroad, including the program from which the ESTIMA project is modelled, called IMAGE: Intervention with Microfinance for AIDS and Gender Equity. The IMAGE project in South Africa offers loans at a flat rate of about 14% (personal communication with Lufuno Muvhango, project director of IMAGE). IMAGE was successfully implemented and produced significant reductions in partner violence as well as HIV risk behaviors among women in South Africa, and has been sustained and scaled up for the past 6 years to reach over 25,000 women.

The initial loan of $2,500 pesos is a small amount to be repaid within 4 months, and thus, this has largely not been a difficult task for women who have participated in the Via program in the past. Women will do all their training in a group format. Also, see figure below for the conceptual framework which will guide the analyses and outcomes of focus for this preliminary study. Notably, our preliminary data among this population (from the parent study, MAPA de Salud, PI: Dr. Brouwer, protocol 100148) has shown that at any given time 50% of women from our sample are in debt and that they tend to pay these debts back within 6 months. Thus, debt and repayment is a familiar concept in this population. _

Figure 1 provides the theoretical basis of the proposed project. *Via* provides training for women to initiate a business, promoting their economic security and decreasing their economic reliance on sex trade or on male partners. Gender equity mobilization aims to improve women's status and power within social and community contexts. Together, these components aim to 1) improve women's capacity and effectiveness as food vendors, 2) decrease GBV, 3) increase women's power to negotiate sexual engagements with male partners and clients, reducing HIV risk behaviors, and 4) reduce women's HIV risk as well as other health benefits to women and their children



The proposed mixed methods study will be paired with a 5-year study led by Dr. Brouwer (R01 DA028692; UCSD Protocol # 100148) that aims to explore the spatial dimensions of HIV risk among FSW in Tijuana. This paired study has recruited 400 FSW (18 or older using venue based sampling), with quantitative assessment at 6, 12 and 18 months follow-up. Recruitment and follow-up for the proposed ESTIMA study will coincide with the follow-up periods of the parent study. *The baseline data collection for the parent study will be used to recruit for Aim 1 of the ESTIMA study, and the 18 months follow-up of the parent grant will coincide with the ESTIMA study baseline (Aim 2).* In addition, we will implement a supplemental survey at the time of recruitment for ESTIMA among eligible and interested women. This supplemental survey (which will take approximately 5-10 minutes) will ask more details regarding women's alcohol use frequency as well as experiences of discrimination, given that these have not been asked in the parent study survey and will be

important to examine in terms of assessing intervention impact. In the parent study, women were recruited via *time-location sampling*, based on the time and location they engage in sex work.[97-100] The parent study developed maps of bars, brothels, hotels, alleys and street corners with sex work activity in Tijuana. Trained outreach workers familiar with these establishments and their clientele conducted all recruitment. Five recruits per establishment and geographical stratification was employed to ensure a diverse sample. Women who appear eligible and are interested in participating will be given a study card and asked to present it when they visit the study office. Informed consent, laboratory testing (e.g. women will provide a venous blood sample and vaginal swab to permit testing for syphilis, Chlamydia, gonorrhea, and HIV), and interviews/surveys will occur in the study office and adjoining clinic space to avoid logistical problems in the workplace. Eligibility criteria included being: (i) biologically female; (ii) Spanish or English speaking; (iii) aged 18 years or older, (iv) reporting having exchanged sex for money, drugs, shelter or goods in the last 30 days, (v) agreeing to receive antibiotic treatment for Chlamydia, gonorrhea, and syphilis if they test positive; and (vi) not be a part of a recent behavioral intervention (*Mujer Segura*).

The Phase I interviews will be implemented specifically for program development related to the current study. Phase 2 evaluation (surveys) will be implemented primarily by the parent study, which is already approved (Protocol # 100148). However, given that the parent study will not collect data past our 6 month data collection for participants, we will collect our own data at 12 months follow-up (corresponding to one additional assessment after the 18 months assessment of the parent study) independent of the parent study, but using the same methodology and quantitative survey that has already been approved for the parent study. The ESTIMA project is funded by a mechanism that allows the PI training to implement this small RCT evaluation of ESTIMA, and thus, the PI will be on-site during much of study procedures and work closely with the parent PI as well as other co-investigators on the parent grant.

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Phase I

Specific Aim 1 To identify key priorities and strategies for a program focused on promoting gender equity to be incorporated within the *Via* microfinance program in Tijuana, Mexico.

Recruitment of Participants: Women (n=30) from the parent study indicating willingness to be considered for participation in a sub-study during regular follow-up phone calls (the parent grant staff call women to schedule follow-up visits as well as to maintain their current contact information, given that the parent study is a longitudinal study, collecting data at 6, 12, and 18 months follow-up after baseline), and who report interest in becoming participants in the ESTIMA intervention (Specific Aim 2) will be contacted to participate. Additional eligibility will include: having no plans to move in the immediate year, and having no issues with cognitive impairment that may interfere with their decisions to participate in the ESTIMA Project.[101]

Qualitative Interview Development: The semi-structured interview instruments will include themes identified via existing empirical literature as well as our previous work (See interview instrument).[1,2,7,66] Interviews will explore a broad range of factors pertinent to women's life contexts, particularly those contributing to women's risk for GBV and HIV, including economic stability (head of household, who they support, financial help from others, debts), living situation, parenting (e.g. if they have children, challenges related to parenting), experiences of violence (e.g. from clients, police, male partners etc.), social support, as well as questions to understand women's life contexts (e.g. day to day activities, challenges, responsibilities, health needs). A set of questions will also focus on needs related to mobilization efforts that would engage men (e.g. police, male partners, clients), primarily to address high levels of gender-based violence perpetrated by police and male partners, with recognition that such violence, like other structural level factors, is rooted in societal-level influences, namely gender norms and attitudes, and requires community-driven prevention approaches (e.g. examples of previous community mobilization strategies among FSW that engaged men include trainings for the police to sensitize them to life challenges of FSW and to dispel myths that result in discriminatory practices against FSW). Questions will also focus on how to engage and maintain women in ESTIMA (e.g. best times for business trainings, frequency of trainings, how to ensure women feel comfortable and safe participating in these groups with other FSW). Using the expertise of collaborators and *Via* microfinance, the interview instrument will be adapted to be most appropriate for and sensitive to this population of women and to best guide program development. The interview protocols will be piloted with three participants prior to initiation of the remaining qualitative interviews and adapted as appropriate.

Interview Facilitation: If possible, interested and eligible women will be scheduled for the interviews when they return to receive their test results (interviews will be conducted prior to receiving test results). Women receive an incentive ($5) to return for these results, and will receive $20 for completing the interview. Interviews will be 60-90 minutes in length and conducted privately by a trained interview facilitator at the parent study office in Tijuana. We will probe to ensure that participants are not under any excessive interview-related stress, following protocols from our previous work.[1,66] . Interviews will be audio-taped, translated, and transcribed. Transcripts will be reviewed for accuracy.

Data Analysis: Qualitative analysis will involve content analysis[102] utilizing Atlas-TI Version 7 software. Coding schema will be developed to identify themes a priori and modified to reflect emerging patterns. Coding for each interview will be conducted by two research staff members and inter-rater reliability will be verified. Any conflicts in coding will be discussed amongst the coding team and a final decision made by the principal investigator based on this advisory.

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Program Development: Developing the gender equity mobilization component will include: 1) Key components of the IMAGE program will be identified by Dr. Charlotte Watts (IMAGE senior investigator); these will be retained in the adapted model. As with the original IMAGE implementation, all sessions will be conducted in a group setting with microfinance business training. 2) The identification of priority areas identified via key findings from the formative work (Aim 1) and with feedback on how to address these from the investigative team (all mentors and collaborators). 3) Revision of original curriculum based on formative research recommendations and comparison to key components with alterations from the original curriculum highlighted and explanations for those alterations provided (by the PI), 4) Review of the curriculum structure and approach with consultation from the community advisory board (CAB) (developed as part of the parent grant), as well as from discussion with FSW collectives and elected leaders. Feedback will be obtained either via discussion or as a written response, and incorporated for pilot testing. 5) Finalization of the curriculum for pilot testing. This adaptation approach has been used by Dr. Raj (primary mentor, co-investigator) for other HIV prevention studies for use in low and middle income nations.

Phase II

Specific Aim 2: To assess preliminary outcomes of ESTIMA

Recruitment and Random Assignment. We will recruit ESTIMA participants from those who are completing 12 month follow-up for the parent study, using the same eligibility criteria and recruitment in Specific Aim 1 (assessing interest among those who indicate willingness to be recruited into a sub-study and based on responses in their surveys from the parent study), with an additional criteria related to women's drug use frequency; the specific criteria will be determined based on Aim 1 findings, consultation from the CAB and *Via* microfinance (drug use data will be retrieved from the parent survey; 41% and 53% of participants from the parent study report using drugs and alcohol less than once per week respectively). *Those who participated in Aim 1 and who fall within these eligibility criteria will be eligible for participation*. Research staff of the K01 and parent grant will work jointly to identify those willing and eligible during the 12 months follow-up data collection of the parent grant. From the parent study, we will recruit a total of 120 participants in expectation to afford a final sample size of at least 48 in each group (using a conservative estimate of 80% retention). Eligible and willing participants will be randomized to treatment assignment (ESTIMA or wait-list control group) using a randomizer software package, after enrollment. The microfinance groups of women (approximately 6-10 per group) will be formed and randomized to intervention or wait-list control condition. The wait-list control group will be provided with referrals to local FSW support organizations, as the standard of care (STI/HIV testing and referrals), and will receive ESTIMA subsequent to the 12 month follow-up data collection. ESTIMA will involve groups of approximately 6-10 women each; groups will initiate once sufficient numbers are enrolled (i.e. groups will be staggered in terms in initiation).

At the point when we have recruited all eligible and interested participants from the parent study (MAPA de Salud, PI: Dr. Brouwer, protocol 100148), if we have not obtained at least 120 participants from the parent study, we will follow the same recruitment protocol as the parent study until we obtain at least 60 participants in each group. We will recruit female sex workers aged 18 years old or older in Tijuana, and who meet other eligibility criteria as described in section 10. Recruitment will be conducted by trained study staff who have worked previously for the parent study and who have experience working in these contexts with this population for a number of years. We will follow time-location sampling to ensure a diverse sample – with recruitment venues and the times at which these sites are frequented changing as the study proceeds. With the help of trained study staff, we will update our existing maps of bars, brothels, hotels, alleys and street corners with sex work activity. We may also choose to allow participants of the study to help identify new sites for recruitment as well as to refer potentially eligible FSW who are interested in the study by providing the study phone number. (See section 11 for more details).

Screener: Trained outreach workers will follow recruitment procedures and invite women interested in the ESTIMA program to visit the study's offices. The trained outreach worker will go through the informed consent process with all potential participants before screening for eligibility. Please refer to informed consent procedures elsewhere in the research plan for more details regarding the consent process. Women interested in participating after the informed consent process will be invited by the outreach worker to determine if they are eligible to participate via a 10 minute screener. The outreach worker would make a statement which would include the following: "If you are interested in answering some personal questions about your health and behaviors to see if you qualify for this study, you will receive the in-kind equivalent of $5 USD for being screened. The questions will take approximately 5-10 minutes of your time. Your answers will not be linked with your name and will be kept private". Personal contact information collected during screening will be kept separate from the screener form and will be kept under lock at our offices, accessed only by staff that need the information to set up

appointments. Screening questions include age, agency over earnings, engaging in exchange of sex for money, drugs, goods or shelter; date of last exchange; intention to move in the next year, drug use, and debt. We will add a few non-related 'red herring' questions (e.g. marital status, place of work) to prevent women from guessing eligibility criteria. Screening will take place in a confidential area where the potential participant feels safe to answer freely.

Survey/Specimen Data Collection. They survey is expected to take approximately 45 minutes and approximately 30 minutes for STI/HIV testing; overall, with waiting times, we expect this aspect of study participation to take approximately 90 minutes. For the baseline ESTIMA survey and HIV/STI testing, we will use data collected from the parent study's 18 months follow-up survey and specimen collection. Participants recruited outside of the parent study will be provided with the survey and STI testing, and reimbursed for their time in the amount of $30 (at baseline and 12 month follow-up) and $20 at 6 month follow-up (survey but no STI testing). All participants will also complete a 5-10-minute supplemental survey during informed consent or at another time preferred by the participant and will measure greater details on women's alcohol use frequency and experiences of discrimination; these measures were not asked in the parent study survey but will be important to examine in terms of assessing intervention impact. For the ESTIMA 6 month follow-up, we will use survey data collected from the same survey as implemented at baseline (including the additional questions on alcohol use frequency and experiences of discrimination). Final 12 month follow-up for ESTIMA will be conducted independently of the parent study.. (We have budgeted for the costs associated with testing of ESTIMA participants for the 6 and 12 month follow-up, whereas the baseline will be conducted under the parent study. Trained research assistants arrange a follow-up interview time to be conducted at the study office via contact information collected as part of the parent grant. After providing informed consent, participants complete a 60 minute interviewer-administered survey using computer assisted personal interviewing (CAPI) (NOVA software, MD, USA). The survey (and any new items for the ESTIMA project) will be translated into Spanish, back-translated to English and reviewed for accuracy by the bilingual project coordinator and project consultants, who have also reviewed questions for cultural and linguistic appropriateness. Women will be reimbursed $30 for the survey and testing (at baseline and 12 month follow-up) and $20 at 6 month follow-up (survey but no STI testing). Data collection interviewers will not be aware of women's treatment assignment. Women who test positive for any HIV/STI test will be provided with appropriate treatment and/or referral to HIV care services. A participant tracking system will be developed during enrollment for the ESTIMA project in order to collect follow-up data (which will take place at the same study office) and kept up to date with information on address, phone number, etc., and all contact attempts. Permission to use different tracking methods (e.g. contacting friends) will be obtained at enrollment and kept current in order for us to collect the additional assessment after participants' involvement in the parent study ends (our 12 month follow-up). A key study aim is to identify retention challenges, which will be monitored quantitatively and qualitatively (Aim 3). *Given that we are recruiting from the 18 month follow-up of the parent study, we also expect to recruit women who have a low probability of attrition, given that they were already among those not lost to follow-up for the 18 month data collection of the parent study.* While we will use the parent study's 18 month follow-up data, we do not expect to see reductions in our outcome measures of interest until 12 months follow-up. However, 6 month follow-up may be useful to conduct mediational analyses to understand patterns in or variations of change in the outcome variables.

Outcome Measures. Measures on GBV, gender, HIV, and health were drawn from Demographic Health Surveys (DHS),[104] multiple instruments previously used by investigators,[1,7] as well as items from the IMAGE study adapted for use in this Mexican context.[43-45] *New items will be added to parent grant surveys (e.g. collective efficacy, additional economic stability variables, women's status indicators) based on Aim 1 findings.* Measures will include relevant demographic variables (e.g. age, education, living situation and evictions, other employment, head of household, economic support, number of children). We will include assessments on collective efficacy/power (e.g. perceptions of power in addressing GBV and gender inequity collectively)[7,45] and women's economic stability using several variables (assessing debts, income, number of sex trades and income from sex trades, other income generating efforts, income independence, economic mobility, self-efficacy and confidence in maintaining financial security, variables measuring consumption-including monies spent on children's needs and education).[1,104] We will also measure knowledge of gender inequity issues, HIV, and interactions between GBV and HIV,[105] gender equitable attitudes,[45] attitudes around GBV (7 items assessing justification of violence against women),[104] and women's status indicators (including women's economic and social decision-making in household, women's economic mobility, e.g. gender-based challenges in engaging in business or managing finances).[104] GBV will be measured as physical, sexual and psychological acts of violence perpetrated by clients, male partners, and other men in the community, using an internationally adapted Conflict Tactics Scale. Frequency of unprotected sex will be constructed from items assessing the number of times participants had vaginal or anal sex with clients and male partners in the past 90 days and the number of times they used a condom during sex.[1] Measures on alcohol use in the supplemental survey were drawn from recommendations from the World Health Organization and the National Institute on Alcohol Abuse and Alcoholism. Measures on discrimination were adapted from a variety of scales frequently used in social psychology, including the Perceived Discrimination scale and Schedule of Sexist Events scale.

Description of Parent Study Survey (that will be implemented by our study at 6 and 12 months follow-up): Domains are as

follows: Sociodemographics (age, marital status, nationality, place of birth, education, first language, income, employment beyond sex work, family ties, # children and other dependents, living situation, mobility patterns). Financial need is assessed by several items that ask about the participant's earning from sex work, other sources, number of people who are financial dependents, other people who help support the participant and/or her household, whether the participant is in debt and who she owes money to, the nature of relationships with financial dependents, other financial challenges (including housing eviction due to lack of rent money), as well as her interest in future programs to promote women's financial stability. Knowledge of HIV and STIs: General knowledge and attitudes regarding HIV/AIDS and STIs will be assessed through a series of questions (e.g., heard of HIV/AIDS, can list transmission routes and preventive behaviors); Drug use and practices: (age at first use of specific drugs, types of drug used and routes of administration, reasons for drug use, injection drug use (for those injecting, questions on syringe re-use, receptive and distributive syringe sharing, frequency of injection, syringe cleaning, abscesses, sources and cost of syringes, barriers to syringe purchase at pharmacies, shooting gallery attendance, and frequency of arrest and incarceration for charges related to drug possession and paraphernalia will be elicited). FSWs will also be asked to report their use of alcohol and specific drugs preceding and during sex with regular, casual and client partners over the past month; Sexual history and current behaviors: Age at initiation into sex work and current patterns of sex work including number and frequency of unprotected vaginal and anal sex with clients, spouse or steady partner and casual male partners in the past month, number of partners who inject drugs, and use of the male and/or female condoms. Since the proposed study focuses on HIV sexual risk behaviors, we will use the Sexual Relationship Power scale which includes items such as "when you and your partner argue, your partner gets his way most of the time."; Entry into sex work: Women who report underage or forced/coerced entry into sex work will be asked questions regarding entry into sex work and HIV risks during the first 30 days in sex work. These will include place of recruitment, relationship to recruiter, and modes of transportation used, physical and sexual abuse, condom use, coerced/forced drug use, injuries, deprivation of food or clean water, and threats of violence; Second-Generation sex work: including if participants had a parent involved in sex work (i.e. second-generation sex work)**;** Contextual factors include working conditions: work setting (e.g., brothel, street, bar; public vs. isolated), registration status, nature of relationship with pimp or manager (if applicable, including degree of financial independence, control over client selection), degree of protection from drunk or aggressive clients, client characteristics (age, age difference, language, ethnicity, duration of relationship [e.g., stranger], country of origin, demands for unprotected sex, aggression or violence, amount received for protected vs. unprotected vaginal and anal sex), availability of condoms and sterile syringes, commodity and value exchanged. We will also ask about interactions with the legal system including arrest history and reasons, incarceration, current interactions with police. Mental Health, including exposure to violence, will be assessed by a number of scales. *Depressed mood* will be assessed using the 21-item Beck Depression Inventory. Questions on community violence scale developed by Steve and O'Donnell (e.g. hearing gunfire, seeing drug deals, witnessing someone being killed) will also be asked. Access to services (past HIV and STI prevention, testing and treatment, drug treatment (e.g. access to methadone maintenance, buprenorphine maintenance, detoxification, social support programs), usage of medical services in the past 6 months, health insurance status and type of insurance (e.g. IMSS)); Changes in the Risk Environment: Specifically, at baseline, women are asked whether the following has increased, decreased or remained the same in the last year: perceived changes in the total number of clients, US clients, other foreign clients, Mexican clients, presence of municipal police, federal police, army; level of community-, cartel- and client-related violence; access to sterile syringes, condoms, HIV/STI testing and drug treatment.

Data Management. Data collected during the additional assessment (12 months follow-up) conducted by our study will be managed in the same way as the parent study. The DMC will be responsible for questionnaire development and coding. Laptops will be used for CAPI data collection using the QDS™ software. Each CAPI interview file will be saved with a name indicating the QDS version, visit month, laptop number, language used (Spanish or English) and date of interview; all computer files in the field will have daily backups. The Project Coordinator will extract and compile CAPI files into QDS warehouses; these encrypted, password protected files will be backed up during the data collection period. Each study participant will be assigned a unique identifier. For confidentiality reasons, no personal information, such as name or address, will be recorded in the surveys. The Project Coordinator who is fluent in both Spanish and English will be responsible for training the site staff to record, extract, and compile data and also for addressing all technical assistance needs. The Project Coordinator will merge all QDS warehouses together, reconcile them into a standard version, and export a final QDS warehouse into SAS or SPSS data sets that are instantly ready to use by any statistical software. Lab data will be received from paper forms and will be entered via SPSS Data Entry Station.™ A clean SPSS data set can be ready for analysis right after the data entry is finished. All lab data will be double entered using the SPSS_DE double entry mode. To ensure quality of the data collection, the Project Coordinator will make accrual and retention reports, tracking reports and missing data reports at least bi-weekly. All data managed by the Project Coordinator will be backed up daily and password protected.

Quantitative Data Analyses and Power Calculations. Descriptive statistics (means, frequencies etc.) will be examined to characterize and compare the control and intervention participants on various relevant measures (demographics, GBV,

sexual health risk indicators). The distributional properties and reliability of continuously scaled variables will be examined. Effects of the intervention on both intermediate and long-term outcomes (see Figure 1) will be examined using logistic regression analyses for dichotomous variables (e.g. GBV, consistent condom use) and ANCOVA for continuous variables (e.g. collective efficacy scales, income, number of sex trades). Analyses will focus on outcomes at the 12 month follow-up. ANCOVA using ranks will be used to examine outcome variables with non-normal distributions, such as income. While ESTIMA is powered to focus on intermediate outcomes, we will also investigate trends on longer term outcomes as well (Figure 1). We expect low rates of loss to follow-up, as ESTIMA is incorporated into existing *Via* trainings; however, we will track any participants who drop out of the program (Aim 3), as well as loss to follow up. If there is more than a trivial amount of missing data, we will examine whether there are any patterns in missing data by relevant study variables (e.g. violence experiences, demographic characteristics etc). Power calculations were performed using a significance level of 0.05 and 80% retention (n=48 in each group), with focus on ***primary intermediate outcome variables*** (economic security and collective power variables) (Figure 1). For analysis focused on variables of income and debt, number of sex trades, as well as the scales measuring women's collective power,[107] we will have 80% power to detect a standardized effect size of 0.5, which is considered a moderate effect size based on work from Cohen (1988).[108] We believe that a moderate effect size would be needed in order to ensure that the effect of the intervention is significant for wide-scale adoption and sufficient impact. However, because we will have small numbers for this pilot of the ESTIMA project, we recognize that we may only be able to find trends to report, and which will be used to secure further funds to run a full-scale trial. While we have not powered the trial to detect a significant effect on GBV, HIV risk behaviors, or HIV/STI, we anticipate a trend toward decreased reports of these in the intervention group compared to the control arm. Furthermore, collecting information on GBV, HIV risk, and HIV/STI will also provide information to power a subsequent larger-scale evaluation.

Laboratory Testing

HIV and STI Testing: All methodology will be used from the parent study in order for us to conduct additional STI/HIV testing (after their participation with the parent study ends) with participants for our 12 month follow-up assessment and participants recruited outside of the parent study. We will use the Determine® test (Abbott Pharmaceuticals), which is licensed in Mexico.[22] Blood specimens will be obtained by venipuncture, and centrifuged on site. A vaginal swab will be obtained by a trained nurse. We plan to use the same methodology, infrastructure (procedures for sending samples to the lab etc.), and staff as the parent study by providing funding to extend both infrastructure and staff of the parent study until our study has been completed. Notably, there will be some overlap, as the parent study will still be actively testing their final participants during some of our 12 month follow-up data collection (data collection took place over 12-14 months for the parent study cohort), and thus, the parent study staff will be actively conducting data collection.. Vaginal swabs will be batched and sent for gonorrhea and Chlamydia testing, since rapid tests for these pathogens lack sensitivity. All specimens will be labeled with the subject's ID# and date, batched and stored at –20 C in on-site freezers before being shipped weekly on ice to the San Diego for further STI testing. Staff have a 'Fastpass' and CDC border permit to facilitate shipping. Two serum aliquots will be shipped to the UCSD CFAR repository where they will be retained for potential future testing. Syphilis serology will be conducted using the rapid plasma reagin (RPR) test (Macro-Vue, Becton Dickenson, Cockeysville, MD, USA). All RPR-positive samples will have confirmatory testing using the *Treponema pallidum* hemagglutinin assay (TPHA) (Fujirebio, Wilmington, DE, USA). *Neisseria gonorrhea* and *Chlamydia trachomatis* will be detected from vaginal swabs using Aptima® Combo 2 (Gen-probe, San Diego, CA), a direct target-amplified nucleic acid probe test. Reactive tests will be confirmed by a re-test.

Pre- and Post-test counseling and referrals: As detailed above and in the sections below, we will follow the same protocols as the parent study in terms of the counseling and referrals conducted during the additional specimen collection (Participants from the parent study which are part of our study participate in one additional survey and specimen collection after their participation in the parent study ends. In comparison, participants recruited outside of the parent study participate in two additional survey and specimen collection.).Also, as described above, parent study staff trained in providing counseling and referrals will be hired to implement these activities for this additional assessment carried out for our study (at 12 months follow-up, which will correspond to a 24 month follow-up assessment for parent study participants). The same staff from the parent study will also conduct the additional assessments required for participants recruited outside of the parent study.

All participants will receive pre- and post-test counseling before and after their HIV and STI tests. Rapid test results for HIV will be ready within 20 minutes, at which time they will be read by a trained counselor and shared with the participant in a private room. Specimens testing HIV+ will be repeated with a second rapid test. All women will receive post-test counseling and those testing positive will be referred to a medical doctor at the local Municipal Health Clinic for follow-up, where free ARVs are provided for those with CD4 counts <300. Participants will be asked to return within one month to receive the remainder of their STI test results. If a participant does not return for her one month follow-up to receive test results, our team of outreach workers who are familiar with the target population will continue to follow-up with the

participant and try to locate the project participant based on the information provided on their locator form. Parent study staff (who will be hired to work with us for this final assessment) have been trained to be discrete in communicating with those listed on participants' locator forms, never mentioning specific results or eligibility criteria for participating in the health study. In cases of active syphilis (e.g., titers >1:8), gonorrhea, or Chlamydia, all subjects are eligible under Mexico Ministry of Health guidelines for free on-site treatment. Mexican guidelines for post-test counseling and STI treatment are identical to that of the CDC. New CDC guidelines recommending cephalosporins for gonorrhea treatment will be adhered to. We will provide referrals to municipal clinics when urgent medical attention is warranted. At each visit, women will be counseled to avoid self-medicating STI symptoms to avoid promoting resistance. Women will be encouraged to refer their sex partners (including clients) for free STI testing and treatment at the Municipal Health Clinics or other local clinics. To encourage women to return for STI treatment, women be given the choice of non-cash incentives, including toiletry items (e.g., shampoo, soap, sewing kits, feminine hygiene products), small toys for their children, baby food, taxi vouchers, not to exceed $5 USD per visit.

Specific Aim 3: To assess ESTIMA in terms of quality of implementation, receptivity by participants, and capacity to be maintained by *Via* microfinance efforts

ESTIMA will be monitored for satisfaction, receptivity, fidelity, and quality of program implementation. Because this is a preliminary implementation and assessment, Aim 3 will be extremely important for providing recommendations for future refinement and delivery of the ESTIMA project. Evaluation of satisfaction and receptivity will include: 1) post-training evaluation forms among staff (to be completed after implementation of each participant training session) to assess challenges or barriers during implementation of the trainings, aspects that went particularly well, overall satisfaction with the training, as well as any issues in the ethical conduct of the study, and 2) qualitative data collection (approximately 2 focus groups with 10 women in each per intervention group, and approximately 5 individual interviews per intervention group), as well as quantitative assessments (conducted during follow-up survey) among participants on satisfaction and response to program. During the last session, participants will be asked if they are interested to participate in a focus group as well as individual interviews that will ask about their satisfaction with the program. Focus group and individual interviews will take approximately 60-90 minutes; responses will be transcribed and translated. All data will be reviewed for themes specific to receptivity, barriers or challenges, quality, feasibility, and appropriateness. Reports will summarize both qualitative and quantitative findings.

Monitoring and evaluation of recruitment, random assignment, adherence to intervention design, retention of participants, contamination across arms, and the incidence of adverse events will include: 1) standard training and periodic observations for all intervention staff; 2) weekly meetings between intervention staff and the Program Director, in which intervention staff review difficult situations that have arisen and discuss these and possible solutions; and 3) quantitative data collection on program recruitment, delivery (e.g. whether all segments of the curricula were covered), potential contamination (e.g. number of control participants who report knowing women in the ESTIMA intervention) and retention. A final report will be developed based on this review to provide future recommendations regarding best approaches for program implementation as well as appropriateness of the intervention content.

10. HUMAN SUBJECTS

The proposed mixed methods study will be paired with a 5-year study led by Dr. Brouwer (R01 DA028692) that aims to explore the spatial dimensions of HIV risk among FSW in Tijuana. This parent study has recruited 400 FSW (18 or older using venue based sampling), with quantitative assessment at 6, 12 and 18 months follow-up. Recruitment and follow-up for the ESTIMA study will coincide with the follow-up periods of the parent grant. The baseline data collection for the parent grant will be used to recruit for formative research of ESTIMA (Aim 1), and the 12 and 18 months follow-up of the parent grant will coincide with the ESTIMA baseline and 6 month follow-up (Aim 2).

Characteristics of the sample
We anticipate that female participants will range in age from 18 to 48 years (mean approx. 31); mean level of educational attainment will be 7 years; 5% will be illiterate; 67% will be single; 87% will have children; 30% will be from Central America; and 70% will be of Mexican origin.

Eligibility criteria for the current study include:
- Biologically female,
- At least 18 years old,
- Ability to Speak English or Spanish
- Report having agency over their earnings (i.e. women that do not have pimps, brokers, or others who may try to take control over the money and/or women's business initiation)

- No reported use of marijuana on a daily basis or more and no reported use of other hard drugs (i.e. heroin, cocaine, crystal, crack, amphetamines, etc.) weekly or more
- Report having exchanged sex for money, goods, shelter or drugs within the last month,
- Live in Tijuana or its suburbs and have no plans to permanently move over the next 18 months
- Willing and able to provide informed consent
- Agree to receive antibiotic treatment for Chlamydia, gonorrhea and syphilis if they test positive
- Not be a part of a recent behavioral intervention (*Mujer Segura* or *Mujer Más Segura*).

For Phase 1 (Aim 1), women from the parent study (n=30) (see recruitment details below) who report interest in becoming participants in the ESTIMA intervention (Specific Aim 2) will be contacted to participate. Additional eligibility will include: having no plans to move in the immediate year, and having no issues with cognitive impairment that may interfere with their decisions to participate in the ESTIMA Project (see section 26).[101]

For Phase 2 (Aims 2-3), using a two-armed randomized controlled design, we will recruit FSW (n=120, 60 in each arm) from the parent study as well as via venue-based sampling methods similar to the parent study if needed (i.e. if we do not obtain sufficient numbers from the parent study to recruit) who will be randomized to: 1) the ESTIMA intervention (gender equity program and Via microfinance program) or 2) a wait-list control group. Women will be part of groups of approximately 10 women each, and each group will be randomized to intervention or control conditions. We will recruit ESTIMA participants from those who are completing 12 month follow-up for the parent study, using the same eligibility criteria and recruitment in Specific Aim 1 (assessing interest among those who indicate willingness to be recruited into this study), with an additional criteria related to women's drug use frequency; the specific criteria will be determined based on Aim 1 findings, consultation from the CAB and *Via* microfinance (drug use data will be retrieved from the parent survey; 41% and 53% report using drugs and alcohol less than once per week respectively). Those who participated in Aim 1 and who fall within these drug-related eligibility criteria are also eligible for participation. Research staff of ESTIMA and the parent grant will work jointly to identify those willing and eligible during the 12 months follow-up data collection of the parent grant, and explain the ESTIMA study to further assess interest. If we do not obtain at least 120 participants from the parent study we will conduct additional recruitment following the same recruitment protocol as the parent study (MAPA de Salud, PI: Dr. Brouwer, protocol 100148).

11. RECRUITMENT

Recruitment for Phase I and II will be done via follow-up phone calls conducted by the parent study (the parent grant staff call women to schedule follow-up visits as well as to maintain their current contact information, given that the parent study is a longitudinal study, collecting data at 6, 12, and 18 months follow-up after baseline). When called, if participants indicated interest in being told about future studies in which they may be eligible in their consent form, participants will be told about this interview study, and those indicating willingness to be considered for participation. *The parent study has incorporated this recruitment procedure into their protocol. Parent study participants will complete an addendum to their consent form at 6 months follow up which describes this study, asks about their interest in being contacted about this study, and if they agree to having their data shared with this study. Only those indicating agreement with these aspects will be contacted to ascertain interest in participation.*

Phase I (Aim 1)
Women (n=30) from the parent study indicating willingness to be considered for participation in a sub-study during regular follow-up phone calls, and who report interest in becoming participants in the ESTIMA intervention (Phase II) will be contacted to participate in qualitative interviews.

Phase II (Aims 2-3)
From the parent study, we will recruit a total of 120 participants in expectation to afford a final sample size of at least 48 in each group (using a conservative estimate of 80% retention). The microfinance groups of women (approximately 10 per group) will be formed and randomized to intervention or wait-list control condition using a randomizer software package, after baseline data collection for ESTIMA. The wait-list control group will be provided with referrals to local FSW support organizations, as the standard of care, and will receive ESTIMA subsequent to the 12 month follow-up data collection. ESTIMA will involve groups of approximately 10 women each; groups will initiate once sufficient numbers are enrolled (i.e. groups will be staggered in terms in initiation).

Additional recruitment, using the same venue-based sampling protocol as the parent study, will be conducted as needed in order to meet final sample size expectations. Briefly, participants will be recruited from areas in which sex work occurs

in Tijuana. They will be recruited based on information gained through informal conversations with participants on where to recruit other female sex workers (FSWs) and the knowledge of our study staff, who are familiar with the FSW population. We will recruit female sex workers aged 18 years old or older in Tijuana. Recruitment will be conducted by trained study staff who have worked previously for the parent study and who have experience working in these contexts with this population for a number of years. Furthermore, a minimum of two staff members will go together for recruitment at any time in order to ensure safety. Recruitment staff will also carry identification badges and use identifying shirts to decrease risks, which has shown to be helpful in recruitment for the parent study as well. We will follow time-location sampling to ensure a diverse sample – with recruitment venues and the times at which these sites are frequented changing as the study proceeds. With the help of trained study staff, we will update our existing maps of bars, brothels, hotels, alleys and street corners with sex work activity. We may also choose to allow participants of the study to help identify new sites for recruitment as well as to refer potentially eligible FSW who are interested in the study by providing the study phone number. (Some participants have asked if they can tell their friends about the ESTIMA program and study as well.) In addition, we may provide some incentives (up to an equivalent of $5 per person recruited) for ESTIMA participants to tell other FSW about the study as a means to recruit additional women. All participants will go through the same screening procedures, informed consent and randomization. Participants will not know the details about the eligibility criteria. We will remind participants to not share details about their participation in ESTIMA or anyone else's participation in ESTIMA with friends or anyone else in a way that would compromise the identity of any participant.

In addition to the baseline assessment (which involves a separate survey at baseline for those recruited outside of the parent study and the extraction of data from the parent study 18 month follow-up from those recruited from the parent study), we will ask participants to fill out a supplemental survey (to collect greater detail on alcohol use frequency and experiences of discrimination that is not collected in the parent study survey, but important to measure in terms of the impact of ESTIMA) which will take an additional 5-10-minutes and will be implemented at the time of informed consent or at another time as preferred by the participants. We will collect these additional assessments using the same survey (including these additional measures) at 6 and 12 months follow-up independent of the parent grant. We will also collect these same assessments for those participants recruited outside of the parent study. The assessments will be incorporated into the larger survey for their baseline assessment.

Participant Follow-up and Tracking: Similar to the parent study, this last follow-up assessment will also be conducted at the study site. We expect that since we recruited participants at the 18 month follow-up from the parent grant that they may be among those who were most available for follow-up (since they were not lost to follow-up in the parent grant by 18 months). Other important suggestions from the parent grant for ensuring good follow-up include participant reimbursement for participation, a non-coercive approach, and easy access to the clinic for FSWs from their place of work/residence.

1. The participant recruited during baseline will be advised in her first contact that she will be followed for 2 additional follow-up surveys and STI/HIV testing. She will be told that she is expected to undergo an interview and a free gynecological exam and blood test at this visit, similar to how she has participated in the parent study.
2. The participant will also be asked at her first visit to provide us with the name and telephone number of a contact (girlfriend, fellow worker, bar manager) whom we may contact if we have difficulty locating her for this additional survey and STI/HIV testing. We will provide a small reimbursement (in-kind goods valued at $5) for her to return in between study visits to update or confirm this information.
3. It is critical when working with this population to develop strong bonds of trust and confidence. To this end, project staff in each research site have been carefully chosen for their sensitivity, discretion, and understanding of the needs of the target population. As possible, we will hire the same staff from MAPA de Salud to conduct the final survey and STI/HIV testing protocol.

FSWs will be advised at their first visit that if they move away, they will be provided with a bus ticket or voucher to get them back to the US-Mexican Border Health Commission for their follow-up visit (if they have moved 100 miles or less from the agency's site).

12. INFORMED CONSENT

We will apply for Federal Certificates of Confidentiality which allow us to protect participant information from outside requests and subpoenas in the U.S. There are limits to this protective strategy (e.g., data cannot be protected from Mexican authorities); however, to date, Mexican police have respected this document and the parent study has not experienced a breach in confidentiality while working in this setting.

Phase I

Upon being eligible, interview staff will then explain the project in more detail, obtain written consent from interested individuals, and arrange a time for each member to complete the interview. Prior to the interview, and if an appointment is made to complete the interview at a later time, all information in the consent form will be verbally stated and repeated, including that participation in the study is voluntary, that participants may choose not to answer any questions, and that participants can withdraw from the study at any time. The consent process will take place in private rooms in study offices in Tijuana, Mexico. The consent forms will be translated into Spanish and use language specifically tailored to this population. It will also be emphasized that no persons other than the investigators will have access to any survey interview materials.

Adequate time will be allowed for participants to ask questions. Survey interviews will be conducted in a private location. We will also probe to ensure that the participant is not under any interview-related stress after completing the interview. In our previous work, we did not find survey interviews or qualitative interviews to cause any participants to stop the interview or report excessive interview-related stress. (See general consent procedures below).

Phase II (Aims 2-3)

If participants are eligible and interested to participate in the ESTIMA study, we will implement informed consent procedures. Their involvement in the ESTIMA program (microfinance and gender equity program) and evaluation (survey and STI/HIV testing) will be described fully, with the general consent procedures described below. We will provide participants with information about the ESTIMA program as well as associated risks. We will explain to participantsthat the evaluation will involve allowing our access to their baseline data as well as additional data collection points, taken 6 and 12 months after theirinitiation in ESTIMA. We will also explain to participants that they will be completing a supplemental 5-10-minute survey at baseline, which can be completed during the time of informed consent or at another time of their choosing. (These questions will subsequently be implemented with in the full survey at 6 and 12 months follow-up). For participants recruited outside of the parent study, we will provide them with similar information, with the exception that their baseline data will be collected through a survey and STI testing prior to their participation. The informed consent form and description of study involvement for these participants recruited outside of the parent study will reflect this minor difference.

For baseline data collection on participants recruited from the parent study, data will be obtained from the parent study, with the exception of the 5-10-minute supplemental survey. For the 6 and 12 month follow-up and for participants recruited outside of the parent study, we will administer the survey and STI/HIV testing using the same protocol as the parent study, and therefore, we will implement informed consent again prior to this data collection. General consent procedures are described below.

Consent Procedures:

The consent process will take place in private rooms in study offices in Tijuana, Mexico. Our informed consent procedure will be designed to maximize the potential participant's comprehension of study procedures and to ensure that participation is voluntary. Before a participant is enrolled in a study, the purpose, the procedures to be followed, and the risk and benefits of participation will be explained by the clinic staff (i.e., the interviewer), and signed informed consent from the study participant will be obtained. The description of the study will include information on the content of the interview and reimbursements. During the informed consent process, study procedures will be thoroughly and clearly explained in simple language (i.e., at a fifth-grade reading level), and participants will have the opportunity to ask questions and demonstrate their comprehension of study procedures prior to participating. If it is apparent that a participant does not understand study procedures, the interviewer will be trained to go over the information again in a different way with the participant to ensure comprehension prior to continuing. In addition to explaining study procedures, equally important is the need to explain what we *cannot* do (i.e., directly offer victim assistance), to ensure that participants fully comprehend the nature of the interview and our role as researchers. Interviewers will also clarify that referral or access to services or treatment is in no way contingent upon participation. In the case of women who are illiterate, a two-step solution was suggested by the Director of the UCSD IRB (Dr. Michael Caligari): 1). Consent forms are read out loud; 2) A simple test is given wherein participants are questioned about points made in each paragraph of the consent. When errors are encountered, the paragraph is reread and participants are encouraged to ask questions to clarify. They will be retested to ensure they understand all passages.

A copy of the consent form, which includes a description of the study, will be provided to all participants, which includes telephone numbers of the PIs in Mexico and the U.S., and the 0-800 number of the study, where participants can call 24 hours a day if they have questions or concerns. The interviewers will be trained to respond to the participant's questions and concerns. The field coordinator will also be available to answer any questions raised by a participant. Details of study participation, including the need for follow-up contact, will be described in the consent form and explained verbally. The research staff who will be responsible for obtaining informed consent will assess whether the potential participant has

understood the study and consent form by asking key questions (e.g., “How much time will this take you?”; “What are the possible benefits for you?”). Because it is possible that some of our participants may be cognitively impaired, we have outlined procedures for assessing decisional capacity in item 26 below. If a potential participant decides she does not wish to participate, her decision will be honored and the full complement of referral materials will be provided. Participants will be given a copy of the consent document, which will include contact information for the PIs and the SDSU and Mexico-based Human Subjects Committees, should any concerns or questions arise subsequent to their involvement in the study. Although children based on the NIH definition of children (i.e., <22 years) are included in this study, as women aged 18-21 are eligible to participate, we view these women as adults sufficiently mature to provide consent without parental involvement. Documentation of consent will be indicated on the screener based on a check by the researcher staff member; the study ID number for the individual will be generated and placed on the screener.

13. ALTERNATIVES TO STUDY PARTICIPATION

The alternative to participation is non-participation.

14. POTENTIAL RISKS

Overall, The potential risks to study participants are: 1) disclosing personal information to members of the research team, or 2) the inadvertent disclosure of sensitive information about subjects (e.g. sexual risk information, history of STI, gender-based violence, GBV). During Phase II, HIV/STI testing may pose some risk to participants as well. However, we have taken needed steps to reduce these risks.

Interviews and quantitative surveys may contain topics that are embarrassing or emotionally upsetting to participants as they cover a number of sensitive subjects, including sexual risk topics, STI history, and exposure to violence. It is possible that some participants may become anxious, depressed, or angry due to this content. Survey interview participants are at the greatest risk for becoming emotionally distressed as they are being asked to disclose information about their personal life to another person. There is also a small risk that participants may become upset or angry by the content of research questions that they may become at risk of harming themselves or others.

As a result of participating in this study, it is possible that women may be identified by others as a FSW. (Also, see section on confidentiality below for a detailed description of risks related to a loss of confidentiality). There is a small risk of violence or harassment related to the conduct of the protocol, for example, if the participants’ status as a sex worker becomes known. Violence unrelated to the protocol that is incidentally communicated during the information gathering associated with the protocol may be reportable to civil authorities under applicable Mexican local law if the woman so chooses, but would not be reportable as a research-related adverse event. There is some risk that interviewers or counselors will receive reports of physical abuse and violence perpetrated against FSW by clients or other sex partners.

Additionally, learning of a positive HIV/STI test result would also likely be emotionally upsetting to a participant. It is possible that some participants may become anxious, depressed, or angry due to these experiences, and there is a very small possibility this may result in their becoming a risk to themselves or someone else. Our experience from our previous work, which used similar survey items and approach, elicited no such responses. However, to ensure the safety of our participants and staff, precautions will be taken to minimize participants’ risk of emotional distress.

Finally, because study participation involves being part of a microfinance program, women will take on risks associated with being part of this program, namely, those associated with taking out a loan. The Via Microfinance program will support women as much as possible so that they are successful. However, women are responsible for repaying the loan and some participants may face challenges repaying their loan due to personal circumstances. It could be that some participants will use their work in sex trade to repay the loan. This could heighten the urgency of women’s work in sex trade and reduce negotiating power with clients (e.g. in terms of condom use). It could also increase the frequency of women’s work in sex trade, e.g. by taking more clients in order to repay this small loan. Taking on more clients could introduce risks related to new clients (such as risks related to violence or exposure to HIV or other STIs). Furthermore, taking out a loan may be risky if women have pimps, money lenders, male partners or others who control their work and find out that women are participating in this program. This could result in women’s loss of the loan money (e.g. if these people retrieve the loan money from the women).

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Minimizing Psychological risks and distress. The use of trained and sensitive staff will minimize embarrassment or discomfort among participants during the survey or interview. The Research Director and PI will work closely with research staff to ensure there is close oversight, support, and monitoring of the data collection process. Research staff conducting all interviews will clarify at consent all requirements of confidentiality from all individuals, staff and participants,

involved in this study. Due to greater risk for psychological stress rather than physical risk from this largely behavioral study, we have undertaken additional precautions to minimize emotional distress to participants. Survey or interview participants who become emotionally distressed will be reminded that they can skip any questions they prefer not to answer, that the survey or interview can be stopped at any time. The facilitator will stay alert for any signs that the participant is becoming emotionally distressed by the survey or interview. At the conclusion of the survey or interview, all participants will be screened for emotional distress in the following way: "These questions can make some people feel sad, anxious, or angry. How are you feeling now?" At study entry, participants will be clearly informed through the consent process that they may terminate their participation at any point.

Interviewers will be carefully trained to approach questions with sensitivity and in a supportive manner and to provide appropriate referrals when needed. In particular, they will be trained in specific tactics such as carefully monitoring body language to ensure that a participant feels comfortable and safe, not pressing for answers, and avoiding questions that have the potential to elicit significant psychological distress. In-depth interview techniques will be highly adaptable to the specific interview context (i.e., loosely structured to facilitate adaptation, depending on a participant's level of comfort, openness, and experiences), and interviewers will be trained to mainly listen to participants tell what they choose to disclose, rather than press for distressing information. Interviewers will be trained to create non-judgmental and open interview atmosphere through techniques such as friendly and open body language, understanding and concerned (*not* pitying) responses, strong listening skills, and the avoidance of strong language, stereotypes, or assumptions. We will ask our community advisory board (CAB) and *Via* staff to review the instrument and comment on any questions that may be sensitive for participants as well as ways to approach sensitive topics. We have created this instrument from our previous work with FSW in Tijuana as well as other contexts, and will use the feedback from the CAB and *Via* to ensure that it is refined to be most sensitive to this population of women.

Pre- and post-test counseling for HIV will be performed as per guidelines from the U.S. Centers for Disease Control and Prevention, which has been slightly modified for use in Mexico. Participants testing positive for HIV will be encouraged to refer their sex partners for testing and treatment at a local clinics.

In addition to a brief check-in with the survey/interview facilitator, all participants will be provided with information about services related to health assistance for violence, sexual health, and related support issues. Women who report high levels of stress or who indicate they may harm themselves can be walked over immediately for referral services (e.g. counseling services). For example, any participant who is seriously depressed and threatening to harm herself will be immediately interviewed by the on-site manager and appropriate treatment or referral will be immediate; the clinic has an on-site psychologist. All such potentially adverse events or serious problems will be reported within 24 hours on a standard form to the SDSU IRB with a copy to the corresponding Office of Human Subjects in Mexico (COLEF).

With recognition that all individuals who come into contact with this study are likely at increased social and health risks as a consequence of their residence in low income urban communities, we will provide social and health referrals to all individuals with whom we come in contact subsequent to screening, for ineligible or uninterested women, or baseline assessment, for study participants. (These will also be provided by the parent study, but we will not assume that any participants we have come into contact with have already received such services from the parent study). These referrals will include general health services for women, additional HIV and STI counseling and testing, and other counseling services. Direct referrals to HIV or drug use-related care will also be available.

Addressing issues of GBV. Regarding women who report GBV, we will follow the guidelines provided by the World Health Organization's (WHO) report, "Putting women first: Ethical and safety recommendations for research on domestic violence against women." This document outlines the recommendations developed by the World Health Organization regarding the ethical and safety issues associated with planning and conducting domestic violence research. These guidelines have worked well in our previous research among FSW in Mexico, as well as other vulnerable populations of women elsewhere (e.g. these have all been incorporated and found effective in Dr. Blankenship, Dr. Raj, Dr. Brouwer, and Dr. Silverman's previous studies). We have found that women are not only willing to talk about their experiences of violence, but are often grateful for the opportunity to tell their stories. Training of survey facilitators in issues pertinent to GBV will be critical to ensure that they are able to provide a non-judgmental and empathetic environment for women during the interviews.

Risks and Protections associated with HIV/STI Testing: There is a possibility that problems may arise as a result of HIV/STI testing. As HIV and STI counseling and testing are part of this study and can include blood draws, there are risks attached to acquisition of blood from participants. As with any blood testing procedure, it is possible that participants may be exposed to diseases when tested if sterile testing procedures are not followed. It is also possible that confidentiality may be breached if proper procedures are not followed to maintain confidentiality of test results (i.e. delivering test result information over the phone in a public setting. To reduce these risks, for the parent grant and the proposed work, we will

be collaborating with trained clinicians to conduct all testing to ensure it is of the highest quality, and the testing process will be closely monitored by our research staff. We will ensure support follow-up notification of participants of their STI+ status and to support their linkage to HIV/STI treatment; research staff, including the director, will track this process to ensure we have documentation of its occurrence. The research staff will obtain test results so they can be added into the data set, which will be compiled at the study offices in Tijuana and sent to UCSD via a secure server. Women who test positive for any STI test will be provided with appropriate treatment and/or referral to HIV care services. It will be important for research staff to ensure that all participants receive the testing results, and our research staff will work to track participants to ensure that they are offered treatment and/or necessary referral. (see below as well for more details on maintaining confidentiality during this process). (Also see precautions above related to minimizing distress above).

Process evaluation data & protection against risks. In terms of the informal focus groups on participant satisfaction of the program, given that the nature of these focus groups (for the process evaluation) is solely to gain information regarding participant satisfaction and feedback on the program, we do not expect that this involvement will carry the same level of risks as the survey interviews; however, after the brief informal focus groups with participants, we will have facilitators ask them how they are doing and assess for any level of stress caused by the interview; facilitators will take the same precautions with participants regardless of type of data collected and any participant who feels upset or stressed will be offered support services.. Further, we will provide information to all participants regarding related support, counseling, and services as well as a broad spectrum of applicable social services in their area. Participants will also be given contact information of the study director as well as principal investigator in case they have any questions about the study.

Risks associated with taking out a microfinance loan: Our microfinance partner, Via Microfinance, provides over 300 loans a year to poor women in Tijuana to support them to start a business. The repayment rates are 90% or greater. If women need more time to pay loans back, they will be able to work with the lender to develop a schedule for paying the loans back. Loans that are not paid in full, even in cases when more time is provided for pay-back, will result in higher interest charges on subsequent loans to the group or denial of requests for subsequent loans. If a participant defaults on repayment, they will face high interest rates if they proceed to take out more loans. We do not expect that the initial $2,500 pesos will be difficult for women to repay. Women may also use sex work to supplement their income if they are having trouble paying these loans back as well, which could increase the frequency of their sex trades. To address these issues, Via microfinance will support women on all aspects. Via has a strong record for supporting women in their microfinance groups and they have extremely high rates of repayment. Via has the capacity to work with women to manage their repayment schedules as well. Finally, women can choose to take out less than the $2,500 pesos amount if they feel concerned and they can take out more as they see fit (after they pay back the initial loan). Women may also fear that pimps, male partners, or others may learn of their involvement in this program and try to take the loan money away from them or require that they use the money for some other purpose. To further address these risks, we will include these issues in our formative work in Aim 1, Phase I interviews and we will also consult our community advisory board as we prepare to initiate the ESTIMA program. We will be able to recruit women who do not report pimps and who report having control over their money earned (e.g. women who do not report having to give some portion of their salary to brokers or pimps), based on responses to items in the quantitative survey (from the MAPA de Salud study). Finally, we will address this issue during study initiation, trainings, and upon provision of the loan money to women. We will encourage women not to discuss their study involvement and access to this loan money with others, especially with pimps, brokers, or others who may try to take control over the money and/or women's business initiation. Notably, only 4% of women from the study sample reported having pimps or managers who make money from their earnings. We will also monitor the repayment on these loans closely. By staggering these groups over time, we will also be able to alter the program in ways to best address this issue over time (i.e. if this is an issue at all for the first group of 6, we will implement changes to address this prior to initiating the next group of 6). Given that *Via* has had over a decade of experience working with poor women in Tijuana and providing loans, they have experience in helping women develop schedules for paying these loans back.

*see section below on minimizing loss of confidentiality

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

We will request a U.S. Federal Certificate of Confidentiality to allow us to protect participant information from outside requests and subpoenas in the U.S. The consent form will outline the limits of this protective strategy (e.g., data cannot be protected from Mexican authorities); however, to date, Mexican police have respected this document and the parent study PI (Dr. Brouwer) has experienced no breach in confidentiality in the five years working in these settings. Furthermore, the current study is a qualitative study focused on the economic situation of women. While we have some focus on police actions and how that may impact women's economic situation (e.g. bribery), this is a topic covered in the parent study as well, and has not been an issue. The purpose of assessing this topic is to inform future intervention

efforts to work with police to reduce bribery and other types of harassment. The police do not have any rights to these data, nor could they require us to breach confidentiality of participants by releasing any data related to police actions. Notably, the parent study has not experienced any issues with the police harassing participants as a result of being part of the study. The PI has included these same items in surveys and interviews in a similar study conducted in India over the course of a seven year study and never had any issues with police. (Erausquin, J.T., **Reed**, E., Blankenship, K.M. Policing and HIV risk among female sex workers in Andhra Pradesh, India. *Journal of Infectious Diseases.* 2011; 204 Suppl 5:S1223-8.)

As a result of participating in this study, it is possible that women may be identified by others as a FSW or being HIV-positive. We will safeguard against this by conducting interviews/surveys and providing pre- and post-test counseling in private locations, i.e., storefront offices or mobile clinic in each city, where people may be attending the building for myriad reasons. The clinic provides a variety of health services for free and anyone who wants to access the services can do so (not just FSWs or those at-risk for HIV). There is also a slight risk that confidentiality may be breached in the management of data, although multiple safeguards will be implemented to avoid this risk (see below). Participants will be made aware of this risk during the consent procedure. To date, the parent study PI has not had a single breach of confidentiality. While unlikely, if a woman's status as a sex worker were revealed through participation in this study and she becomes endangered as a result, we will refer her to the DIF (Family Integral Development), the Mexican institution that helps people in need, including victims of violence and sexual abuse. DIF offices are located in each of the major cities along the U.S.-Mexico border. DIF provides support and counseling to abused women and has a Center for Social Support to Women, shelters for victims of abuse and sexual violence, a hotline for crisis intervention, and programs that offer psychological, social, and economic support as well as health care. Although unlikely, if a woman's HIV status were compromised as part of this study and she thus becomes endangered or loses her employment, she will be referred to DIF or a number of local NGOs that provide economic and emotional assistance to those living with HIV/AIDS. The participating clinics also have psychologists on staff who will be available to counsel FSWs who may need support and assistance on how to cope with their sex work or HIV status becoming disclosed.

Phase I

Strict ethical procedures regarding confidentiality will be followed, and thus we expect minimal risk of disclosure of personal information. Participants will be asked not to reveal any information that may reveal their identity or the identity of others (e.g. names); however, if they do, it will be removed or replaced with an anonymous name from all transcripts. Efforts will be made to ensure that participation in the interview as well as the nature of the interview will be kept confidential. Initial screening, recruitment, and description of the study will be conducted privately. In the transcription process, pseudonyms will be assigned to each participant. Other names, locations, and other potentially identifying information will be replaced by generic terms in brackets, e.g. [male client], [health care worker], [home city/town]. Consent forms as well as signed reimbursement receipts will be kept in a locked file cabinet and will be used only to verify that written consent has been obtained. All other study materials will be identified with a research ID number only. All electronic files containing interview data will be password-protected and stored in electronic folders accessible to study personnel only. Furthermore, all electronic recordings of interviews will be destroyed upon translation and checking recordings for accuracy. All study materials will only be accessible to the PI and research staff. Audio-recordings will be identified by study ID only. The audio recording will be transcribed in study offices in Tijuana, Mexico and destroyed after the transcript has been reviewed for accuracy. Only de-identified interview transcripts will be transferred from the study offices in Tijuana to UCSD offices through a secured server. Participants will be provided with their study ID number along with a copy of their consent form and told that they can choose to erase any part or all of their transcript at any time by calling study staff and providing staff with their ID number.

Participants will be provided their ID upon participation in the interview. In this way, participants will be able to retract consent by referring to their ID number; researchers will not need to know the identity of the participant. If a participant withdraws from the study, her data will also be deleted from the study using the unique ID.

There is potential that researchers may be required to breach confidentiality if participants disclose any intentions to hurt themselves or others. Our survey does not ask this information, so there should be minimal risk in eliciting such a response from the participant. However, it is possible that subjects may disclose this information following survey completion and during our debriefing which involves screening for emotional distress. All participants will be informed that any disclosure requiring our mandated reporting (e.g., suicidality; homicidal intentions) will require that we contact authorities and immediately take them to mental health services care if they disclose that they are suicidal or thinking to harm someone else.

Phase II

Every effort will be made to minimize risk of participants' loss of confidentiality given the highly sensitive issues covered by this study. No study documents will contain personal identifiers. All participants will be informed that their responses will be kept anonymous unless they are eligible and choose to participate in the intervention study; if they are eligible and wish to participate, their participation will be confidential and only the research team will have access to the information they provide through the study. All electronic files containing contact information or survey interview data will be password-protected and stored in electronic folders accessible to study personnel only. Survey data will only be identified through a unique ID. Contact information will be stored in a separate file.

No identifying information will be collected from screening participants unless they are eligible and willing to participate in the study. If the participant is eligible and willing to participate, we will obtain contact information from them and a unique study ID number (from the parent study or a new ID will be generated for participants recruited outside of the parent study) will be used to link their screening data to their contact information, and subsequently to their survey, HIV/STI testing data, and, when appropriate, in-depth interviews. These lists linking subject ID number to data will be destroyed upon study completion. Research staff members working with this study will be required to maintain confidentiality of all research participants and will be required to sign a pledge agreeing to do so upon joining the study. Additionally, to further protect participant confidentiality, only research staff involved with tracking and follow-up will have access to the list of participant names and their unique identifiers.

Individuals recruited for this component of the study will be required to give us contact information so that we can link their data and contact them should there be changes in date or time for the intervention. Contact information will be linked to their data via a unique study identifier. Only the PI and research staff supporting tracking and follow-up, will have access to the list linking unique identifiers to contact information. This information will be stored in locked file cabinets in locked offices at the clinic, and will be destroyed once follow-up is completed. Unique identifiers will be used to link screening data to survey data and HIV/STI data, as well as in-depth interview data (Phase I), collected from the same participant.

There is potential that researchers may be required to breach confidentiality if participants disclose any intentions to hurt themselves or others. Our survey does not ask this information, so there should be minimal risk in eliciting such a response from the participant. However, it is possible that subjects may disclose this information following survey completion and during our debriefing which involves screening for emotional distress. All participants will be informed that any disclosure requiring our mandated reporting (e.g., suicidality; homicidal intentions) will require that we contact authorities and immediately take them to mental health services care at Tijuana General Hospital if they disclose that they are suicidal or thinking to harm someone else.

Risks and Protections related to Stigma and Confidentiality within the group setting among FSW. Women's confidentiality will be prioritized, in terms of providing information and specimen samples to research staff, but also in terms of their participation in a group among FSW. Particular items in the formative interviews will focus on women's comfort and willingness to participate in a group setting with other FSW. In such a setting, women will identify themselves as conducting sex work. We will ensure that the group understands that they must keep the participation in this group confidential, as some women may not want others in the community to know about their work as sex workers. We will take all steps and efforts to ensure that women's safety is not jeopardized in this group setting. The formative work (phase I, specific aim 1) will be helpful for guiding this process. We have found that in the formation of other sex work collectives, while some women prefer to remain "secret" sex workers and participate in the collective confidentially, others are excited to engage in rallies, trainings, or conferences for FSW – making their identity as a sex worker known within the community. While women will be recruited who would be *willing to be part of a group of FSW* training in microfinance and supporting each other in a collective group, we will also take necessary steps to ensure all women's comfort and safety in the program by prioritizing confidentiality.

Notably, the *Via* Microfinance program currently serves women vulnerable to GBV and HIV, but who are not necessarily FSW. Thus, this program is not recognized in the community as a program that serves FSW. We will take further efforts to ensure that in no way is the *Via* program ever recognized as such by the community; this will be critical to ensure women's safety, confidentiality, as well as success in their new businesses. Every effort will be made to ensure women's confidentiality in terms of her status as a sex worker, her participation in the study, as well as any of the data collected as part of such study participation.

Furthermore, we will plan to limit initial recruitment and implementation to a small group of women (n=10). During this initial implementation, we will monitor carefully for any issues related to confidentiality loss among women. Based on this first cohort of ten women, we will make necessary revisions during and after this first wave of participants, and will continue to monitor these aspects carefully (and make needed revisions in implementation) throughout the study process.

Only after this first cohort of women and subsequent refinement, will we initiate recruitment of the remaining participants. For implementation of the ESTIMA program among the remaining participants, women will be recruited into groups of 10 to receive the SAGE intervention, and thus, program implementation will be staggered based on recruitment time. (As the recruitment process is implemented, women will be randomly assigned to either the intervention or control groups and thus, approximately 20 women will be needed to have a final n=10 to initiate each ESTIMA intervention group). This staggering of ESTIMA intervention group initiation will allow for us to continue to carefully monitor each group. Program refinement will be informed by this close monitoring and continue on an ongoing basis throughout the study.

Risks and Protections associated with HIV/STI Testing (loss of confidentiality for test results, exposure to disease): There is a possibility that problems may arise as a result of HIV/STI testing. As HIV and STI counseling and testing are part of this study and can include blood draws, there are risks attached to acquisition of blood from participants. As with any blood testing procedure, it is possible that participants may be exposed to diseases when tested if sterile testing procedures are not followed. It is also possible that confidentiality may be breached if proper procedures are not followed to maintain confidentiality of test results (i.e. delivering test result information over the phone in a public setting. To reduce these risks, for the parent grant and the proposed work, we will be collaborating with trained clinicians to conduct all testing to ensure it is of the highest quality, and the testing process will be closely monitored by our research staff. We will ensure support follow-up notification of participants of their STI+ status and to support their linkage to HIV/STI treatment; research staff, including the director, will track this process to ensure we have documentation of its occurrence. The research staff will obtain test results so they can be added into the data set, which will be compiled at the study offices in Tijuana and sent to UCSD via a secure server. Women who test positive for any HIV/STI test will be provided with appropriate treatment and/or referral to HIV care services. It will be important for research staff to ensure that all participants receive the testing results, and our research staff will work to track participants to ensure that they are offered treatment and/or necessary referral.

Data Safety Monitoring and Adverse Event Reporting

SDSU is the lead institution on this project and where the PI is located. Although no direct contact with participants will occur at this institution, SDSU will be responsible for all regulatory matters. This includes coordination of all IRB approvals, quality assurance, data safety and monitoring and protocol development. Some data analyses of de-identified data shared through secure servers will be conducted by collaborators to the study at the UCSD School of Medicine, Division of Global Public Health.

a. Access and Storage of Data: In-depth interviews will be transcribed and translated. All unique identifiers (e.g., names) will be removed during transcription to ensure that participants' identities remain confidential. In-depth interview transcripts will be double-checked against original notebooks and tapes at UCSD will be identified only by code numbers to safeguard confidentiality.

Questionnaire data gathered through interviews (collected by this study after the parent study ends) will be shipped to San Diego. In San Diego, computer records will be protected by standard measures that limit access to the data to research project personnel. All computer files will be identifiable only by the participant’s code number. Computer files are kept in locked rooms accessible only to authorized personnel. Any paper records that reflect electronic data are kept in locked file cabinets.

Blood and urine specimens will be stored at the San Diego County Health Department. Computer files will be password protected, backed up, and stored in a locked office. No data that could identify participants will be stored on computer. Electronic files containing the raw qualitative and quantitative data stripped of personal identifiers will be made available to Co-Investigators, who will work closely with the PI and research coordinator to examine the qualitative findings as they emerge. The Co-PIs, Co-investigators, and Research Coordinator will have data access stripped of identifying information. The only individuals with access to participants’ identifying information are the research coordinator and PI. A committee of U.S. and Mexican researchers (including Drs. Reed and Brouwer, parent study PI) will review all requests for data analyses, and all data will be analyzed in San Diego. The same committee will also review all manuscripts for quality control. Research staff in Mexico will not have access to the data because it will be stored in San Diego. The data manager will be the only staff member in San Diego to have access to these data. All of the investigators are experienced researchers who have received training in data collection and analysis, including privacy and confidentiality protocols in accordance with NIH policy, and have completed the UCSD human subjects’ research tutorial. Upon completion of the study, transcripts, field notes, and field materials will be archived in a locked filing cabinet in a locked office. Audio tapes and digital recordings of interviews will be destroyed upon accurate transcription. If a participant withdraws from the study, data from their interview will be destroyed immediately. Electronic files containing the raw data stripped of personal identifiers will be made available to Co- Investigators, who will work closely with the Co-PIs and research coordinator to examine findings as they emerge.

b. Responsible Entities: In each research site, project staff will report emotionally distressed participants to the site manager (a physician) who will be responsible for ensuring the FSWs mental health care. The site manager will refer the participant to the clinic's on-site psychologist. The project staff, and clinical coordinator at each research site will be responsible for immediately reporting any breaches of protocol, breakdowns in the consent process, violations of confidentiality of the data, complaints by participants or any serious problems or adverse events to the on-site manager who will file an incident report with Dr. Rangel at the Tijuana General Hospital and to Drs. Brouwer/Reed at the University of California, San Diego. Procedures for these events will be outlined in a manual (described below). Any ethical issues relevant to the research protocol and consent process will be discussed during regular staff meetings with the PI and research staff. Furthermore, we have incorporated an evaluation of the ethical conduct of the study within the process evaluation of our study (see Aim 3 above). Supervisory staff will be trained to monitor any issues related to breaches of confidentiality and any complaints by participants will be brought to the attention to supervisory staff as well as the PI of both the parent study and the ESTIMA study. In turn, Drs. Brouwer/Reed will make an incident report to the SDSU IRB and the Human Research Protection Program. The IRB in San Diego will report to NIDA and DHHS if warranted. Requests for the use of these data by persons outside of the project will be decided upon by the PI, Dr. Reed and a committee comprised of U.S. and Mexican co-investigators. The IRB board will be informed, and any concerns will be addressed before data are released.

c. Policies and Procedures: A policies and procedures manual for the project will specify immediate data monitoring and response. Participants will be informed during the consent procedure that confidentiality may be breeched under certain circumstances. In cases where a breach of confidentiality is necessary, project staff will be instructed to report to the on-site manager who will file an incident report with Drs. Brouwer and Reed and Dr. Rangel (Mexico) within 24 hours. The incident report requires a detailed account of the problem, date of occurrence, date it came to the PI's attention, impact on participant, and corrective action taken. An investigation will occur in both Mexico and San Diego. In San Diego, the SDSU IRB will make a determination if the event was related to research, directly or indirectly, and, if so, require revisions of protocol or consent, as applicable, and re-review of these procedures by the IRB, with copies to the Office of Human Subjects for any necessary further action.

Project staff at each research site will be required to obtain certification from the Tijuana General Hospital so that they are aware of the type of adverse events that may warrant a breach of confidentiality. Monitoring of potential adverse events or serious problems will be given high priority by project staff and researchers. For example, any participant who is seriously depressed and threatening to harm herself will be immediately interviewed by the on-site manager and appropriate treatment or referral will be immediate; clinics have an on-site psychologist. All such potentially adverse events or serious problems would be reported within 24 hours on a standard form to the SDSU IRB with a copy to the Office of Human Subjects. All project staff will receive verbal and written instructions pertaining to the rules governing the maintenance of confidentiality upon completion of the study or if they leave the study before its completion.

17. POTENTIAL BENEFITS

This study is likely to benefit women's health in that it will provide a greater and broader understanding of the contexts of HIV risk and GBV within women's lives. Such findings will be essential in order to refine future programming, including future implementation of the ESTIMA project, to address these issues as well as to identify the necessary and most appropriate strategies for designing intervention efforts.

18. RISK/BENEFIT RATIO

Study findings will impact the practice of public health: 1) through providing the necessary information for program refinement to address issues of gender-based violence, HIV, and gender equity issues among FSW in Tijuana, Mexico, 2) by providing information generally to help inform both researchers and practitioners working with this population in Tijuana, 3) by providing implications for new approaches for existing economic intervention efforts in Mexico and elsewhere, and 4) by contributing to the advancement of novel peer-driven public health prevention interventions to reduce gender-based violence and HIV.

Due to the expected benefits of this study to women's health, potential benefits to individual participants, and the extensive precautions that will be taken to minimize the risk of harm to participants, we believe that the anticipated benefits of this study far outweigh the potential risks.

19. EXPENSE TO PARTICIPANT

There will not be any study related costs to the participants; however, participants will be those who are interested in being part of a microfinance program, which will involve taking out a small loan. Via has had success with similar populations of women in Tijuana, with high rates of repayment on these loans. Notably, debt is reported by 50% of FSW in the parent

study, and thus, taking out loans is commonly reported by women in this sample. We do not expect that there will be any study-related illnesses or injury as a result of participation. All STI testing will be covered by the study.

20. COMPENSATION FOR PARTICIPATION

The Research Plan and the consent documents describe the compensation plans in detail, including the provision of STI testing and treatment, and monetary reimbursement. Participants will receive $20 for participating in Phase 1 and Phase II 6 month follow-up (V6 consists of a survey but no STI tests), $30 if they participate in Phase II survey and STI testing (at baseline and at 12 month follow-up). This is the amount FSW typically earn for similarly involved research participation. For participants of Phase II, (similar to what is being done for the parent study) as part of tracking for the additional survey and STI/HIV testing (after the parent grant ends), participants will be reimbursed the equivalent of $5 each when they complete locator forms. Also, similar to the parent study, when participants return for their results one month after the survey, they will receive $5 in cash or goods for returning for their results. For intervention participants who complete an in-depth interview to provide feedback on program appropriateness, satisfaction, and benefits/challenges, we will reimburse $20.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

Elizabeth Reed (PI) is an Assistant Adjunct Professor at the University of California, School of Medicine, Division of Global Public Health in San Diego. Her work in the areas of HIV and gender-based violence prevention research as well as program evaluation for over the past decade has prepared her well for this work. She has training and experience in the evaluation of *structural* interventions in an Indian context, and specifically among populations of women at high risk for GBV and HIV. As part of her postdoctoral work, she directed the evaluation (e.g. overseeing data collection, management, and analyses) of a Gates-funded structural intervention in South India aimed to reduce HIV risk among women working as sex workers. She has also written several manuscripts related to structural and environmental factors that contribute to increased experiences of violence as well as HIV risk among women working as sex workers in South India. This work has included a focus on economic debt and how the context of economic insecurity increases women's vulnerability to HIV and GBV. Dr. Reed will serve as the principal investigator. The current grant proposal includes both training and research. The proposed training activities include the following components: (1) formal and/or informal coursework in economic development and structural interventions; (2) practical experience in the implementation and evaluation of structural interventions in India; and (3) a period of mentored research. In terms of the proposed research, Dr. Reed's responsibilities will include oversight and supervision of staffing, program development, implementation, and scientific evaluation, as well as data management, analyses, and dissemination. During the project development and implementation, she will be located on-site in India and oversee program and curriculum development as well as recruitment of participants and program implementation. While not on site, Dr. Reed will also be available for addressing any potential issues. She will keep in close contact with project staff throughout program implementation and evaluation. Dr. Reed will also be on-site in India to oversee project closing and to discuss preliminary findings. Overall, she will direct the study on all aspects and whether on-site or off-site, she will be available for contact to help address and resolve any potential problems or conflicts. Dr. Reed will spend a significant amount of time on-site throughout the duration of the grant.

Anita Raj, Ph.D. (primary mentor) is a Professor at the University of California, School of Medicine, Division of Global Public Health in San Diego. She is an internationally recognized expert on evaluation of gender and context-specific sexual health interventions for vulnerable populations, and intersection of multigenerational forms of gender-based violence against women as a public health concern for India. Among the multitude of research programs she has initiated in India, one of the most relevant to the current proposal involves the development and evaluation of a gender equity family planning intervention addressing gender-based power imbalances that compromise women's reproductive health (put in grant number). Also very relevant to the proposed research, her RHANI Wives intervention among women from high HIV/STI prevalence Mumbai neighborhoods, has provided initial evidence that women-centered HIV/STI prevention interventions can be effective in India.[8] Dr. Raj has led or co-led over 40 federally funded research projects; in the past three years, she has been involved as a lead investigator or co-investigator, on five separate sexual health intervention studies in multiple national contexts, including the US, Russia, and India. Dr. Raj has over 100 peer-reviewed publications in prestigious journals such as Lancet, Journal of the American Medical Association, New England Journal of Medicine and British Medical Journal. I continue to meet with Dr. Raj on a regular basis, working on manuscripts as well as future grant collaborations, and Dr. Raj has provided significant mentorship for the development of the proposed training and research. However, to date, this work has not involved training on RCTs and STI interventions. I expect that my training on economic interventions will lead to increased collaborative opportunities with Dr. Raj, as I will be better equipped to lead efforts related to integrating economic interventions into existing gender equity programs.

Craig McIntosh, PhD, MA (mentor) is Associate Dean and Associate Professor in the Graduate School of International Relations and Pacific Studies, at the University of California, San Diego. He also serves as Director of the International Development and Non-Profit Management Career Track, and is an Associate Editor of the American Journal of Agricultural Economics. Dr. McIntosh is a development economist whose work focuses on program evaluation methodologies. His main research interest is related to efforts designed to promote micro-entrepreneurs. He is currently working on research projects investigating how to boost savings among the poor, on whether schooling can be used as a tool to fight HIV/AIDS in Sub-Saharan Africa, and on mechanisms to improve the long-term viability of Fair Trade markets. His work has been published in leading academic journals in the fields of economics and public health, including the Journal of Economic Development, Health Economics, and the Lancet. Dr. McIntosh will be instrumental in advising on my training pertaining to economic interventions and tailoring the design of such interventions for application to improve health outcomes related to HIV, as well as provide expertise on the development of randomized field trials.

Dr. Jay Silverman, (mentor), is a Professor at the University of California, School of Medicine, Division of Global Public Health in San Diego. Dr. Silverman is a public health researcher whose work is focused on understanding and improving gender-based aspects of women's health, particularly regarding the implications of violence and trauma for heterosexual HIV/STI infection. Dr. Silverman has been PI on multiple federally-funded studies of sex work, violence, trauma and HIV across South and Southeast Asia, with resulting work published in premier scientific journals (15 peer-reviewed publications on sex work, violence and HIV; over 100 peer reviewed publications total). He is also PI or Co-I on multiple currently-funded NIH studies which focus on the development and testing of behavioral interventions, all in the area of reducing women's risk for heterosexual HIV infection. Specifically, Dr. Jay Silverman brings substantive and methodological knowledge on the study of gender-based violence in multiple global contexts. He also has a current NIH R01 in this border region, examining the prevalence, nature, and impact of sex trafficking in this region. Given his research record and experience as a principal investigator, he will be instrumental in providing necessary advice on these topics of research as well as project/study logistics.

Kim M. Blankenship, **Ph.D.** (**mentor**) is Professor and Chair in the Department of Sociology and Director of the Center on Health, Risk and Society at American University in Washington, DC; she also is a member of the District of Columbia Developmental Center for AIDS Research based at George Washington University School of Public Health. As Chair, she has taken a lead mentorship role providing guidance to doctoral-level and early research investigators, and has mentored over 20 successful researchers throughout her career, particularly at the Yale Center for Interdisciplinary Research on AIDS, where she was highly involved in the postdoctoral training program. Her research and publications focus on race, class, and gender analyses of health, with an emphasis on HIV/AIDS. She has received funding from NIDA, NIMH, CDC, and the Bill & Melinda Gates Foundation. Her current research includes a mixed methods study of the implementation and impact of structural interventions for HIV prevention among female sex workers in India (Project Parivartan). Dr. Blankenship is a key leader in the field on structural interventions to address HIV. She has written the critical publications for advancing this work, including those cited in recent NIH requests for proposals on structural interventions.[3,4] I currently attend Dr. Blankenship's seminars weekly at her Center for Health, Risk, and Society, and meet with her on a regular basis, which will be ongoing during the K01 training period. Dr. Blankenship will provide primary training and mentorship on all award aspects, and particularly will provide specific guidance on the development, implementation, and evaluation of structural interventions addressing HIV risk among FSW in this Indian context.

Charlotte Watts, Ph.D. (mentor) is the founding Director of the Social and Mathematical Epidemiology Group in the Department of Global Health and Development of the London School of Hygiene and Tropical Medicine. Dr. Watts has conducted research on HIV since the 1990s. She combines a focus on women's vulnerability to HIV and violence with innovation in mathematical modelling to project epidemiological and other outcomes. Most relevant to the proposed work, Dr. Watts was a senior researcher on the IMAGE violence prevention study in South Africa. Other examples of her numerous senior research and advisory positions most relevant to the proposed work include roles within: the World Bank, advisor on economic interventions to address HIV/AIDS; the WHO Multi-country Study on Women's Health and Domestic Violence; WHO's Gender Violence and Health Centre; WHO and UNAIDS expert consultations on HIV, violence against women, HIV resource projections; the Global Burden of Disease Working Group, as Chair; and the UK Consortium on AIDS and International Development. Dr. Watts has more than 120 publications in peer reviewed journals on topics related to women's vulnerability to HIV and to GBV, and addressing the structural forces that help shape vulnerability, including various publications on economic influences and the evaluation of economic interventions. Her current research projects span many aspects of violence and HIV, and include randomized controlled trials of violence and HIV prevention programs in Uganda, Tanzania, and Cote DIvoire, global assessments of the health burden of

interpersonal violence, mathematical modelling of HIV and rape in conflict affected settings, economic evaluations of the integrated delivery of HIV and reproductive health services in Kenya, Swaziland and Malawi, and modelling analyses of the potential impact and optimal introduction strategies for new female initiated HIV prevention technologies, such as microbicides. Dr. Watts will be instrumental in providing expertise on the development and evaluation of economic programs to address GBV and HIV, and particularly the use of randomized controlled designs.

María Gudelia Rangel Gómez, Ph.D. (mentor) is a Professor of Statistics and Epidemiology at the Universidad Autónoma de Baja California, Gradúate School of Medicine and Public Health; Research Associate and Professor at El Colegio de la Frontera del Norte, Tijuana, Mexico; and the Baja California State Coordinator of the US-Mexico Border Health Commission. Dr. Gudelia Rangel has expertise in conducting HIV research and prevention work in Mexico, and has been working in this area for 30 years. She has collaborated with the Division of Global Public Health on a number of HIV research studies, including numerous studies among female sex workers (FSW). As a consultant on the proposed work, she will be instrumental in providing expertise on cultural influences as well as other factors particular to working in this context with FSW.

Dr. Kimberly Brouwer, Co-Investigator, is a Spanish speaking epidemiologist and Associate Professor at UCSD. She has been working over the past 7 years on studies of sex work, injection drug use, and HIV transmission along the Mexico/U.S. border. In addition to being PI on Mapa de Salud (R01-DA 028692; the parent grant for the proposed study), Dr. Brouwer is also PI of an R01 grant from NIDA (R01DA029899) employing qualitative, quantitative and phylogeographic methods to explore HIV and STI transmission among substance using FSWs and other at-risk populations along the Mexico/Guatemala border. She will advise and assist Dr. Reed and other study staff to integrate the proposed study into her existing project in Tijuana, as well as assist in development of assessments, interpretation of results, and development of manuscripts. She will be instrumental in guiding the proposed work in terms of working with FSW in Tijuana. Given her longstanding relationships among local organizations and other researchers conducting work with this population in Tijuana, she will also be extremely involved in the dissemination of findings to inform future program efforts

Marissa Salazar (Project Coordinator) Marissa is a second-year psychology Masters student at San Diego State University. She is currently the Project Coordinator on another study being conducted by faculty in the Department of Psychiatry and the Division of Global Public Health at University of California, San Diego. Previous work includes research focused on stereotype threat, gender-based violence, and dating violence. Her experience in qualitative and quantitative methods, data collection and analysis, as well as grant management will help ensure all aspects of the project are implemented efficiently.

Ricardo Vera (Project Coordinator) Ricardo has a BA in Mathematics from Dartmouth. He has experience in qualitative and quantitative data analysis and management, as well as project coordination, Relevant to the aims of this project, he also has experience working on programs aimed to promote economic well-being. He will be overseeing project implementation and evaluation, including coordinating all aspects of the IRB.

Rosa Isaela Tehozol Torres (Recruiter & Interviewer) Rosa has a degree in Psychology from the *Universidad Autónoma de Baja California.* For this project she will recruit and interview female sex workers like she did in her previous work for the parent grant, MAPA de Salud. Rosa has been working with ESTIMA since the research begun and she previously worked with the parent study as a recruiter and interviewer for more than 2 years. Rosa's experience and academic training make her acutely sensitive to issues, including violence that affect women working in sex work in Tijuana, Mexico. Rosa has implemented the same survey over the past 4 years with female sex workers in Tijuana so she is well-prepared to deal with any situation that may arise.

Maria Teresa Hernandez Garcia (Group Facilitator) Maria has extensive experience as a group facilitator for Via International. She has worked with many groups of marginalized women in Tijuana coordinating micro-loans and facilitating community development. For this project Maria will be facilitating group sessions and coordinating micro-loan lending and repayment.

Marianna Torreblanca (Research Assistant) Marianna has a BA in psychology from the University of California, San Diego. She has completed her Biomedical Conduct of Research training through CITI and she will assist with qualitative data analysis of de-identified participant interviews.

Estela Delgado Rodriguez (Research Assistant) Estela is a Public Health undergraduate student at Southwestern College and a part-time employee at the University of California, San Diego. For this project Estela will mainly assist with recruitment but could potentially also help with other research tasks involving de-identified participant data. Estela completed her Biomedical Conduct of Research training through the CITI program on June 22th, 2016.

Dulce Arementa (Community Advocate) Dulce is a community member who wants to help with the ESTIMA program. Dulce will work part-time for Via International and her job will be to refer potential candidates to ESTIMA research staff for screening and other study protocols. Dulce will also help with administrative office duties but will have no access to any participant data. Dulce completed her Biomedical Conduct of Research training through the CITI program on October 22th, 2016.

Dr. Manuel Ma (Physician, Clinical Researcher) Manuel graduated from Universidad del Valle de Mexico with a medical degree in 2012. He is licensed to practice medicine in Mexico and his medicine license number is 09683238. He works under the general supervision of Dr. Jose Luis Burgos, clinical director of Health Frontiers in Tijuana, a program sponsored by the UCSD School of Medicine. Manuel completed his Good Clinical Practices certification from NIDA Clinical Trials Network on April 26th, 2016.

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23. FUNDING SUPPORT FOR THIS STUDY

This proposal (number 1K01MH099969-01A1) scored 11 upon NIH review. IRB approval from UCSD and the Colegio de la Frontera Norte, as well as state department clearance, is required before full funding is released.

24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

Biological specimens (i.e., blood, vaginal swabs) will be maintained by the institutions mentioned in this application and used solely for the purposes of this study

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

No investigational drugs to be used

26. IMPACT ON STAFF

None anticipated. Study staff, including clinic staff, will be hired specifically for this study.

27. CONFLICT OF INTEREST

none

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

Not applicable

29. OTHER APPROVALS/REGULATED MATERIALS

We will apply for appropriate approvals in Mexico upon UCSD approval.

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

The research staff who will be responsible for obtaining informed consent will assess whether the potential participant has understood the study and consent form by asking key questions (e.g., “How much time will this take you?”; “What are the possible benefits for you?”). Because it is possible that some of our participants may be cognitively impaired, or they may not initially understand the consent process, we will test all potential participants for their comprehension of critical points in the consent form. Errors will be corrected and these potential participants will then be asked if they need further clarification. Any participants who appear inebriated or high will be rescheduled for the next day. If, after further attempts to clarify any misunderstandings, we determine that they may not fully comprehend the critical aspects of the study, they will not be enrolled. If a potential participant decides she does not wish to participate, her decision will be honored and the full complement of referral