Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

Supporting Statement
Part A

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Contact Information

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for a new data collection called "Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South" for three years. The purpose of this information collection is to determine if an adapted version of the original, "Sister to Sister" sexual risk reduction intervention is effective for use with a growing population of HIV-positive women in the southeastern United States, and to study factors associated with risk among women in this region.

Background

Women in the non-urban southeastern U.S, particularly women of color, are disproportionately affected by HIV/AIDS (CDC, 2005). Seven of the 10 states with the highest AIDS case rates among women are in the South (Kaiser Foundation, 2006). HIV-positive women residing in this region face increasing challenges, including stigma, geographic isolation, poverty, inadequate knowledge, and lack of access to adequate medical care and support (Castaneda, 2000). Furthermore, many women diagnosed with HIV remain sexually active (Kline & Van Landingham, 1994; Wilson et al., 1999). Although some women practice safer sex (i.e., use condoms consistently), many do not, thus contributing to the spread of the virus and are at increased risk for STD acquisition and subsequent adverse health outcomes.

The Advancing HIV Prevention: New Strategies for a Changing Epidemic Initiative, announced by CDC in April 2003, emphasizes increased attention to prevention among HIV positive persons. This data collection is a necessary step to assess the efficacy of providing a sexual risk reduction intervention for women living with HIV.

The original intervention called "Sister to Sister" was a brief, single-session, nurse-delivered, individual-level HIV prevention discussion, designed for and tested with HIV-negative, inner-city African American women living in the northeastern U.S. (Jemmott, Jemmott & O'Leary, 2007).

For the present study, the adapted version of "Sister to Sister" has been renamed, "Sister to Sister Positive HOPE." The revised version is also a single-session, brief, nurse-delivered, individual-level discussion with HIV-positive women living in North Carolina. This project will provide participants with the information, motivation, and skills necessary to reduce their risk of contracting an STI (sexually transmitted infection), potentially contracting another strain of HIV, and reducing risk of transmitting HIV to a sexual partner.

This activity is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

Privacy Impact Assessment

Overview of the data collection system

The study design is a randomized controlled trial with a three month follow-up assessment. A randomized controlled trial is a study in which participants are assigned to conditions on the basis of chance and where at least one of the conditions is a control or a comparison condition. The intervention group (consisting of participants completing the one on one intervention counseling session with the nurse) is Group 1 and the control or comparison condition (consisting of participants not exposed to the intervention counseling session) is Group 2. An estimated 550 HIV-positive women will be screened for eligibility, by a data collector, using the Screener Form (Attachment 3a). Study participants will be recruited from health departments, clinics providing healthcare services to HIV-positive women and AIDS Service Organizations in North Carolina. If potential participants are not able to complete screening when they are first approached in the clinic or AIDS Service Organization, they will be asked to provide their name and telephone numbers so that a data collector can follow up to complete screening. This contact information will be documented by the data collector using the Screener Contact Form (Attachment 3b).

A total of 330 eligible HIV-positive women will be scheduled for a baseline assessment visit where they will: 1) complete a Locator Form (Attachment 4) to provide contact information for follow up visits; 2) review and sign a Consent Form (Attachment 7a) and 3) complete the Baseline Assessment (Attachment 5). The data collector, trained in confidentiality procedures, will conduct the combination Computer Assisted Personal Interviewing (CAPI) / Audio-Computer Assisted Self-Interviewing (ACASI) Baseline Assessment (Attachment 5) with the participant. Following the Baseline Assessment, participants will be randomly assigned by computer to the intervention or the comparison condition. Participants enrolled in the intervention condition will then be scheduled to complete the single session, “Sister to Sister Positive HOPE” intervention. “Sister to Sister Positive HOPE” is a brief, one on one, nurse-delivered, sexual risk reduction intervention counseling session designed for HIV positive women. The intervention provides the information, motivation, and skills necessary to reduce HIV positive women’s risk of contracting a sexually transmitted infection, potentially contracting another strain of HIV, and transmitting HIV to a sexual partner by decreasing the number of unprotected sex acts. No data will be collected from participants during the “Sister to Sister Positive HOPE” one on one intervention counseling session.

Three months after completing the intervention, participants assigned to the intervention (comparison) condition will complete a three month follow-up assessment (Attachment 5). Participants assigned to the control condition will return for the follow-up assessment three months after completing the baseline assessment. The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with a few additional questions regarding use of ACASI. The procedures followed for the Follow-up Assessment are the same as those for the Baseline Assessment. The wait list/comparison group will be offered the opportunity to participate in the intervention session after completing the three month Follow-up Assessment. CDC estimates that a sample of 165 participants per condition (intervention and comparison) would provide 80% power to detect various differences between the intervention condition and the comparison condition with a two-sided test and α=.05.
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A subset (N = 25-30) of intervention condition participants will complete the individual In-depth Interviews (Attachment 6) following their completion of the three-month Follow-up Assessment. If the participant agrees to participate, Informed Consent (Attachment 7b) will be obtained and the In-depth Interview will be conducted or scheduled.

Items of Information to be collected

The Screener Form (Attachment 3a) will collect information to ascertain if the study participant meets the following eligibility criteria: 1) female, 2) HIV-positive, 3) 18 years of age and older, 4) reside within the geographic boundaries of the catchment areas, 5) speak and read English, 6) have been sexually active with a man in the past 3 months, and 7) does not intend to get pregnant in the next 3 months. The Screener Form asks participants if they had previously been approached for participation in the study and if they would feel comfortable taking a face-to-face interview. This form also asks if they would feel comfortable participating in a meeting with a nurse that might include discussions about sexuality and drug use. The Screener Form will not be used to collect information in identifiable form. The participant's age will be determined by asking, "How old are you?"

If potential participants are not able to complete screening when they are first approached in the clinic or community based organization, and are willing to be contacted by recruitment staff for screening, they will be asked to provide their name and telephone numbers so that a data collector can follow up to complete screening. She will also be asked to indicate whether a message may be left and if it is okay to identify the caller as from the Sister-to-Sister Positive HOPE Project. If it is not, she will be asked how she would like the caller to identify herself. This information will be documented on the Screener Contact Form (Attachment 3b).

At the baseline office visit, the Locator Form (Attachment 4) will be used by the data collector to collect participant contact information (i.e., names, addresses, telephone numbers). This information will be used to remind participants of follow up visits.

The Baseline and Follow-up Assessment (Attachment 5) contain questions about participants' background, health, health care, sexual activity, substance use, and other psychosocial issues. The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with a few additional questions regarding use of ACASI.

More specifically, the data elements collected in both the Baseline and Follow-up Assessments include the following:

- Self-reported demographics
- Social support (sources, forms, frequency)
- HIV stigma
- Health and well being
- HIV/AIDS status
- Viral load
- CD4 count
- Depression
- Stressful life events
- Physical activity
- Alcohol and drug use behaviors
- Sexual behaviors (main partner, other partner, HIV-positive, negative and unknown status partners)
- Sex exchange
- Self efficacy for safer vaginal sex (how sure you can use a condom during vaginal sex in certain situations)
- Condom use self efficacy (how sure you can get your partner to use a condom)
- Hedonistic outcome expectancies (negative condom beliefs),
- Self evaluative outcome expectancy (how you might feel in certain situations when having sex with an HIV-positive, negative or unknown status partner)
- Partner outcome expectancy (opinions about your partner thoughts/feelings about using condoms)
- Partner HIV status
- HIV disclosure
- Spousal abuse
- Power in relationships
- HIV knowledge
- Female condom use
- Incarceration history
- Medical services and adherence to medication
- Case management services and attitudes towards ACASI.

The Baseline and Follow-up Assessments (Attachment 5) do not collect personally identifiable information. Only the month and year of birth are collected to confirm eligibility.

The In-depth Interview Guide (Attachment 6) consist of open-ended qualitative questions that ask about participant's experiences with the intervention; elicits recommendations for developing risk reduction intervention strategies for HIV-positive women, as well as information on factors that place women at risk for HIV. No information in identifiable form is collected using the In-depth Interview.

Screener Contact Forms (Attachment 3b) will be kept in a locked file cabinet in the research office at the University of North Carolina Chapel Hill, until participants fill out the more detailed

Locator Form (Attachment 4) – at which point Screener Contact Forms will be destroyed. Locator information will be entered into a computer file which will be stored in an encrypted and password protected computer and maintained in the research office at the University of North Carolina, Chapel Hill. Paper copies of the Screener Contact Form and Locator Form will be destroyed immediately after the information is entered into the computer file. This computer file will be destroyed within 6 months after the end of the intervention trial. The screener, baseline and follow-up data will be stored on a computer with only an ID and not with any personal identifier such as name or phone numbers. A file will be created to link the study numbers to participants' names. The ID-name linkage file will be kept in a locked file cabinet in the research office separately from the screening, baseline and follow-up assessment data. All data will be deleted from the data collector computers as soon as the data is successfully transferred to the Data Manager's computer. Weekly, new data (i.e., Baseline and Follow-up Assessment) on the Data Manager's computer will be encrypted and uploaded to CDC via a secure data network based at CDC. No personal identifiers will be sent to CDC.

Identification of website(s) and website content directed at children under 13 years of age

The information collection does not involve use of website(s) or website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

To date, the number of existing interventions with demonstrated effectiveness in reducing risk among HIV-positive women is limited. To our knowledge, no sexual risk reduction interventions have been evaluated for use with HIV-positive women in the urban and rural southeastern U.S., an area disproportionately impacted by the HIV/AIDS epidemic. Increasing the number of evidence-based prevention interventions is a necessary requisite to decreasing HIV/AIDS among women in this region of the United States. This information collection is being collected to provide evidence for effectiveness of a sexual risk intervention delivered by a female nurse, to an HIV –positive woman in an environment that supports confidential discussions between 2 women. Findings from this project will contribute to knowledge about how to design regional and culturally appropriate interventions for HIV-positive women to reduce transmission of HIV.

This project is consistent with CDC's mission, in implementing prevention strategies and promoting healthy behaviors. This information collection will increase scientific expertise in the HIV prevention arena and ultimately provide the information and tools necessary to HIV-positive women to protect their health as well as the health of their sexual partners and communities.

This project is a cooperative agreement between the University of North Carolina-Chapel Hill (UNC-CH) School of Nursing and the CDC and is relevant to the following Goals and Objectives addressed in CDC's HIV Prevention Strategic Plan Through 2010.

1. This project will address the priorities "Among people living with HIV, increase the

proportion of those who consistently engage in behaviors that reduce risk for HIV transmission or acquisition" and "Reduce the disparities in access to prevention and care services that are experienced by communities of color, women, and special-needs populations" by developing and evaluating a provider-delivered sexual risk reduction intervention for HIV-positive women in the southeastern U.S. (who constitute a growing proportion of the epidemic, who are overwhelmingly women of color, and for whom there is limited effective risk reduction interventions).

2. This project will address the priority "To increase the number of evidence-based interventions and the proportion of prevention providers funded by CDC who successfully provide demonstrably effective HIV prevention interventions (including behavioral and biomedical interventions)" by generating an intervention that is evidence-based. A brief and effective risk reduction intervention that is delivered by providers who provide care and treatment to HIV-positive women will be an important addition to CDC's repertoire of evidence-based interventions and would expand the scope of health care providers as prevention providers.

3. This project will address the priority "To integrate prevention services, including adherence to treatment, for persons diagnosed with HIV and AIDS into the delivery of patient care in both public and private sectors". We will link HIV-positive women in the southeastern U.S. to medical care and a brief medical provider-delivered prevention intervention. The intervention is based in understanding the difficulty that many HIV-positive women have in negotiating with sexual partners and disclosure of status to partners. The project would also strengthen provider capacity for providing HIV care and treatment in the Southeastern US.

If the intervention is found to be effective, it may ultimately be packaged for wider dissemination. The CDC's Replicating Effective Programs (REP) identifies and packages HIV behavioral prevention interventions that are tested, science-based, and with demonstrated evidence of effectiveness in reducing risky behaviors, such as unprotected sex, or in encouraging safer ones, such as using condoms. These packages are designed, developed, and field-tested by researchers collaborating with community-based partners. The resulting products can guide prevention providers in replicating effective risk-reduction programs in their own settings and communities. Replicating Effective Programs (REP) works with CDC's Diffusion of Effective Behavioral Interventions (DEBI) project to move effective HIV interventions into program practice. The DEBI project coordinates the dissemination of packaged interventions and provides training and technical assistance. If effective, the goal then would be to have an intervention product that can be used by prevention providers and state and local health departments throughout the United States.

Without the information from this project, CDC would be unable to identify the cost-effectiveness of personal interventions to a vulnerable group in order to reduce transmission of HIV. Without knowing whether personal outreach is acceptable by the vulnerable population, CDC will be unable to establish a credible scientific basis for informing the mechanisms available to reduce HIV transmission risk and improving health of women living with HIV/AIDS. The results from this project will inform policy makers at CDC and other state and

federal agencies, and communities throughout the country about funding, planning, implementing, and evaluating similar efforts.

This study has several limitations. All data collections will be conducted in the state of North Carolina, and, therefore, may not be generalizable to other locations in the Southeastern United States, a region heavily impacted by the HIV/AIDS epidemic. Nevertheless, the findings from this trial could be applicable to other areas because, HIV transmission patterns among women in the southeastern US and the demographics of people residing in this region are similar to other parts of the U.S. Further, generalization to the larger U.S, population may not be possible because, as with any longitudinal cohort study, there is potential for attrition over the course of the study. There is a possibility of differential attrition between treatment conditions.

Privacy Impact Assessment Information
This information is being collected in order to inform CDC of effective person-to-person counseling that can change the HIV risk behaviors of at-risk women in southeastern U.S. eligibility for study participation, collect contact information

Without this data collection, we will not have sufficient data to determine the effectiveness of the nurse delivered counseling in reducing the sexual risk behaviors among HIV-positive women.

In order to get the maximum benefit to the existing HIV/AIDS prevention portfolio, CDC and the University of North Carolina, Chapel Hill will disseminate findings from this study via science-based peer-reviewed scientific publications and presentations/conferences.

Because CDC is not collecting any individually identifiable information from the affected population, the proposed data collection will have little or no effect on the respondent's privacy. No IIF is being collected.

3. Use of Improved Information Technology and Burden Reduction

Data collectors will collect screener information (Attachment 3a) from respondents using a computerized interview program stored on laptops to minimize burden to respondents and interviewers. One hundred percent of the responses provided to the screener form will be entered directly into a computer program by the data collector. This project will also use computer assisted personal interviewing (CAPI) and audio-computer assisted self-interviewing (ACASI) technologies. One hundred percent of responses to the baseline and follow up assessments will be collected utilizing these electronic means (i.e., CAPI, ACASI). There are several ways that these technologies minimize burden on participants and improves data quality. One is that the audio files minimize the difficulty that participants with lower literacy levels may have reading the questionnaire items (Des Jarlais et al., 1999; Turner et al. 1998). Another benefit is that the computer-assisted technology is ideal for in-person data collection because it facilitates the use of highly complex interviewing protocols such as those designed for the current project. Programmed skip patterns will allow for complex question sequencing while substantially reducing the number of questions a participant will have to complete, as the computer program

will automatically skip questions that are not relevant based on responses to previous questions. This will increase the instrument's overall efficiency. Finally, questions can be tailored through the use of specific "fills" that have the function of automatically customizing a given question interview to fit the individual circumstances and previous answers of a study participant. That is, the program will insert an answer provided from a previous question into a later question so the participant will not have to recall how he/she answered that particular question. The CAPI portions of the assessment will be conducted on a laptop computer by an experienced, professionally trained interviewer. For those sections or modules which are designed to be self-administered the participant will be allowed controlled access to the laptop. The interviewer will instruct the participant on how to self-administer the assessment on the laptop computer.

The electronic format of the Screener Form (Attachment 3) and Baseline and Follow-up Assessments (Attachment 5) will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). CDC will conduct training and site visits to provide instructions and technical assistance on how to use the CAPI and ACASI software, archive the collected data, and transfer the data. Individual records (specifically participant responses to the baseline and follow up assessments) will be transmitted to CDC using the Secure Data Network (SDN). No personally identifiable information will be sent to CDC

4. Efforts to Identify Duplication and Use of Similar Information

Several steps have been taken to prevent duplication of efforts. CDC personnel on this project have reviewed the literature on HIV/AIDS among women in the South and in rural areas, performed studies of and reported on HIV in the non-urban South, attended numerous local, national and international conferences, and communicated frequently with both relevant federal (e.g. HRSA) and non-federal colleagues (e.g. at Southern universities and health departments). In addition, multiple search strategies were used to identify published reports of relevant literature and interventions designed to reduce risk among HIV positive women in the South. A comprehensive review of the medical and psychological electronic databases (AIDSLINE, CINHAL, PsychINFO, EMBASE and SocioFile was conducted to review HIV-related research on HIV-positive women in the southeastern United States and the nature of that research. The Computer Retrieval of Information Scientific Projects (CRISP) data base was also searched for federally funded projects involving HIV related research or prevention among HIV-positive women. We also reviewed programs in the branch, to identify potential areas of duplication; however, none were found to exist. To our knowledge, the information that will be collected is unique and has not been collected by another federal or non-federal agency.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

Participants will be contacted twice, once for the baseline study, and once for a 3-month follow-up to assess the effectiveness of the intervention in reducing sexual risk behaviors. This study collection of data at two points is necessary to determine behavioral change and improvements in health status. If the data are collected less frequently study investigators will not be able to determine the efficacy of the proposed intervention in reducing sexual risk of HIV positive women. There are no legal obstacles to reduce the number of times the data are collected. The Screener Forms (Attachment 3a, 3b), Informed Consents (Attachment 7a, 7b) and Locator Form (Attachment 4) are one-time necessary collections.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Related to the Guidelines of CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-Day Federal Register Notice (Attachment 2) was published on July 30, 2008 (Vol. 73. pg. 44270). We did not receive public comments.

The target population for the "Sister to Sister Positive HOPE" intervention is HIV-positive women in the southeastern U.S. A Community Advisory Board (Attachment 11) composed of healthcare providers, as well as members of AIDS service organizations and HIV-positive persons has worked with the principal investigator to ensure that intervention and assessment materials are appropriate for the target population. The board members have provided input into all aspects of the study, most notably recruitment methods, data elements to be collected, clarity of instructions and intervention content. In accordance with congressional mandate (Section 2500 (b),(c), and (d) of the Public Health Service Act, 42, U.S.C. Section 300ee(b),(c)and (d)), all intervention materials and research instruments will be reviewed by a local program review panel to ensure that these materials do not violate community standards.

9. Explanation of Any Payment or Gift to Respondents

Participants in the intervention condition will receive $30 in cash following completion of the Baseline Assessment (Attachment 5) and intervention session and an additional $30 in cash following completion of the 3 month Follow-up Assessment (Attachment 5). Participants in the comparison condition will receive $30 in cash following completion of the Baseline Assessment and $30 in cash following completion of the 3 month Follow-up Assessment. Each participant will also receive bus passes for transportation. The research team conferred with local key informants to determine the appropriateness of reimbursement plans for participation in study activities. This level of gift is the norm for participation in research and contributes to increased

levels of participation in research activities in the localities where the project will be conducted. Additionally, previous research experience by members of the CDC research team has shown that reimbursement to research participants, either in the form of money or other material goods (e.g., bus passes) encourages participation in the data collection process.

Participants of the interviews (Attachment 6), will also receive $30 in cash following completion of the In-depth Interview. If a participant is not able to complete the In-depth Interview immediately following the 3 month assessment (Attachment 6) and must return on another day, she will receive a bus pass to cover transportation costs for the return visit.

Tokens of appreciation for participation is an important tool used in research designs, and is particularly important for the population in this study. This is a marginalized group in society, as women are living with HIV but who also may have additional issues such as drug or alcohol use. It is important to the validity of the study to have as broad a representation of this population as possible. Providing incentives not only indicates to participants that their time is valuable, but also is likely to boost participation and retention rates (Kamb et al., 1998; Greenberg et al., 1998). Thus it is important in a longitudinal study such as this one to use all the methods available to retain as many participants as possible. In addition to having people who will track participants and maintain contact with them during the course of the study, appropriate incentives will be offered to the participants. Many discussions regarding the incentives took place during the development of this study. As the amount of time since the baseline session increases, it becomes more difficult to retain participants in a study. Although we have extensive measures in place to track and retain participants (see Section B.3), providing a monetary reimbursement and bus passes will provide participants additional motivation to continue in the study.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this request.

We do not anticipate that any formal confidentiality protections will be needed for this research. All data will be treated in as secure a manner as legally possible. The University of North Carolina is responsible for carrying out the following procedures including the collection of data using the Screener Form, Screener Contact Form, Locator Form, Baseline and Follow-up Assessment and In-depth Interviews.

The Screener Form (Attachment 3a) will be used to collect information to ascertain if the study participant meets the study eligibility criteria and will not collect information in identifiable form. The Screener Contact Form (Attachment 3b) will be used if a potential participant is not able to complete screening when they are first approached in the clinic or community based organization, and are willing to be contacted by recruitment staff for screening. The potential participant will be asked to provide their name and telephone numbers for this purpose. The Locator Form (Attachment 4) will be used to collect contact information (i.e., name, address, telephone numbers) so that data collectors can follow up with participants to remind participants of follow-up visits. The In-depth Interviews (Attachment 6) will be used to assess participant's

experiences with the intervention and elicit their recommendations for developing risk reduction intervention strategies for HIV-positive women, and to better understand the factors placing women at risk for HIV. The Screener, Baseline and Follow-up Assessment and the In-depth Interview will only have a participant ID numbers and will not collect personally identifiable information. No personal identifiers will be transmitted to the CDC.

The Screener Contact forms (Attachment 3b) for ineligible persons will be destroyed immediately after the trial is completed. The forms for persons who were determined to be ineligible for this intervention are kept until after the trial is complete to ensure that they will not be approached again for recruitment. Screener Contact Forms of eligible participants will be kept until participants complete the more detailed Locator Form (Attachment 4). The Screener Contact Forms will be destroyed when the Locator Forms are completed. The Screener Contact Forms (Attachment 3b) of those who have declined to participate in the study will be destroyed immediately after the trial is completed. The forms for those declining to participate are kept until then to ensure that they will not be approached again for recruitment.

Data collectors will collect identifiable information using the Screener Contact Form (Attachment 3b) and the Locator Form (Attachment 4) and this information will be entered into a computer file which will be stored in an encrypted and password protected computer in the research office at the University of North Carolina, Chapel Hill with access only to the Principal Investigator, Project Manager and Data Manager. A linkage file matching name and ID number will be maintained in a locked file cabinet at UNC Chapel Hill, separate from the screening, baseline and follow-up data. Only the Principal Investigator, Project Manager and Data Manager at UNC, Chapel Hill will have access to either or both file cabinets. Electronic computer files at UNC, Chapel Hill, containing identifying data will be destroyed within 6 months after the end of the intervention trial.

None of these documents will be accessed by CDC staff.
CDC IRB granted approval for this project on 8/12/08 and Local IRB approval on 8/7/08 from the UNC, Chapel Hill (Attachment 9b).

Privacy Impact Assessment Information

A. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply.

B. Screener Contact Forms (Attachment 3b) will be stored in locked file cabinets in the research office at the University of North Carolina until the baseline visit at which time participants can complete the Locator Form (Attachment 4). Paper copies of the Screener Contact Form will be destroyed immediately after the information is entered into a computer file which will be stored in an encrypted and password protected computer in the principal investigator's research office with access only to research team members with work-related needs. The computer file will be destroyed within 6 months after the end of the intervention trial. Data collected from the Screener Contact Form will not be sent to CDC. Information collected via that Locator Forms (name, addresses, telephone numbers) will be entered into a computer file which will be stored in an encrypted and

password protected computer in the research office with access only to the Principal Investigator, Project Manager and Research Data Manager. The paper copies of the Locator Form will be destroyed immediately after the information is entered (on a daily basis) into the computer file on an encrypted and password protected computer in the research office with access only to the Principal Investigator, Project Manager and Research Data Manager. The computer file will be destroyed within 6 months after the end of the intervention trial. Data collected from the Locator Form (Attachment 4) will not be sent to the CDC.

Consent Forms (Attachment 7a, 7b) will also be stored in a separate locked file cabinet in the Principal Investigator's research office at the University of North Carolina, Chapel Hill and will be destroyed 5 years after the study final reports are completed. Only the Principal Investigator, Project Manager and Research Data Manager will have access to the Consent Forms.

The screening, baseline and three month follow-up data will be stored on a computer in the research office at the University of North Carolina, Chapel Hill with only an ID and not with a direct personal identifier such as name or phone number. The linkage file matching name and ID number will be maintained under lock and key in a separate file cabinet from the screening, baseline and follow-up data. Each day, data collectors will transfer and back up the assessments on the data collection computers to the Data Manager's computer by disk. Only the Principal Investigator, Project Manager and Research Data Manager will have access to these disks following their transfer. Data will be deleted from the data collection computers and from the disks as soon as the data is successfully transferred to the Data Manager's computer. Weekly, baseline and follow-up data will be encrypted and uploaded to CDC via a secure data network based at CDC.

Baseline and follow up assessment data will be transmitted to CDC using the Secure Data Network (SDN). Databases submitted through the SDN must be encrypted before being sent to CDC. No personally identifiable information will be sent to CDC

Regarding the In-depth Interviews (Attachment 6), no participant identifying information will be attached to the interviews. The In-depth Interview Consent Form (Attachment 7b) will be destroyed 5 years after the final reports are completed.

Access to the research office at the University of North Carolina, Chapel Hill is limited to research personnel only. All research team members/Project staff will be trained on and adhere to strict ethical guidelines regarding professional conduct and will sign a pledge of confidentiality.

The following safeguards are applied to the data on laptop computers used for interviews. 1) The laptop computers are solely used for the current project activities. 2) All data are encrypted when stored on a laptop computer. 3) Laptop computers are protected by a coded password only known to authorized staff at the University of North Carolina, Chapel Hill. The laptop computers are kept with the staff at all times when in the field; 5) The computer are secured by the data collectors after the last interview each day. 6) When not in use in the field, the laptop computer is to be locked in a drawer or office.

C. All participants interested in participating in the Sister to Sister Positive Hope study will be asked to provide written Consent (Attachment 7a, 7b). The Consent Form provides details of the study procedures, risks, benefits, site contact information, and the nature of confidentiality and voluntary participation. The consent process also covers information on the trial and that the participant will receive a token of appreciation for their time and travel expenses. Participants are also informed on the Consent Form that they can not enroll in the study more than once and that to keep that from happening, we will keep their names. Before a participant signs the Consent Form, staff will thoroughly review the form, ask if the participant understands the content of the Consent Form, and answer any questions they may have. Participants will be given a copy of the Consent Form for their records.

Participants will be informed that their data will be kept as secure as possible and that the data will be reported in aggregate format and that their name will not be in any report about this study. The confidentiality section of the Consent Forms (Attachment 7a, 7b) also explains to the participant that the University of North Carolina Chapel Hill will take all legal steps to protect privacy that no identifying information will be given to the CDC, just the participant ID number. Participants will also be informed that no identifying information will be attached to the assessments, just an ID number. Participants are also informed that information will be stored in locked file drawers in the project office at the University of North Carolina, Chapel Hill. (on a secure computer). Participants are informed that data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The study activities will be conducted by trained staff in a private location where the questions and responses cannot be overheard by others. This project was submitted and approved by the CDC IRB and the local IRB (See Attachment 10a, 10b).

D. All participants will be informed of the voluntary nature of their participation during the consent process. Voluntary participation is also written in both the trial and In-depth Interview Consent Forms (Attachment 7a, 7b). Almost all the questions in the eligibility Screener Form (Attachment 3a) and the assessments allow the respondent the option of refusing to provide a response without a refusal form. Respondents will be advised that summary (aggregate) and not individual information will be shared in CDC reports and used for the purposes of learning if a program developed for HIV- positive women will help HIV-positive women make healthy choices in their lives.

Procedural protocols will be developed in collaboration with CDC detailing data management and security and confidentiality procedures.

11. Justification for Sensitive Questions

This intervention is based on discussion of sexual behaviors and unprotected sex which involves sensitive questions about sexual and drug use activities. Without this information the study would not be able to answer the primary research question of whether the proposed sexual risk reduction intervention is effective for reducing a woman's sexual risk for transmitting and acquiring HIV/STDs. These data on sex and drug use behaviors will increase our understanding of the HIV prevention barriers encountered by women in the Southern US. Participants will be informed that this study involves collecting sensitive information about sexual and drug use behavior among HIV positive women. Participants will be informed at the beginning of the assessments (Attachment 5) of their right to skip questions that they do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs

A. The estimated time needed to complete screening 550 potential participants for eligibility is 10 minutes per participant (Attachment 3a). A total of 330 women will be selected to participate in this study and will spend 45 minutes to complete the Baseline Assessment (Attachment 5) and an additional 45 minutes to complete the Follow up Assessment. The estimated time for obtaining contact information from 330 participants is 3 minutes per participant (Attachment 4). Approximately 25-30 of participants will spend an additional 1 hour to complete the qualitative In-depth Interviews (Attachment 6).

Table A.12.a presents participant burden hours for completion of the study. The total participant burden for this data collection is estimated at 635 hours.

Exhibit A.12a

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Potential Participants	Screener/ Contact Form	550	1	10/60	92
Intervention Participants and Comparison Group	Locator Form	330	1	3/60	17
Intervention Participants and Comparison Group	Assessment – Baseline	330	1	45/60	248
Intervention Participants and Comparison Group	Assessment - Follow-up	330	1	45/60	248
Subset of Intervention Group	In-depth Interview	30	1	1	30
Total					635

B. Annualized cost to respondents

Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of Labor, Bureau of Labor Statistics. Since we do not know a typical job category for study participants, costs for participants are estimated using a median wage for respondents of $13.45 per hour, a figure representing occupational employment and wage estimates with data collected from employers in all industry sectors in metropolitan and nonmetropolitan areas in North Carolina (web address: http://www.bls.gov/oes/current/oes_nc.htm.

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Intervention Participants and Comparison Group - Screener/ Contact Form	92	$13.45	$1,237.00
Intervention Participants and Comparison Group - Locator Form	17	$13.45	$229.00
Intervention Participants and Comparison Group – Baseline Assessment	248	$13.45	$3,336.00
Intervention Participants and Comparison Group – Follow up Assessment	248	$13.45	$3,336.00
Subset of Intervention Group - In-depth Interview	30	$13.45	$404.00
Total	**635**		$8,542.00

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The CDC Project officer is assigned 30% effort and the Co-Project Officer 10% effort. Assuming an annual salary of $90,000 for the Project Officer and $100,000 for the Co-Project Officer and $2,500 for travel, the total cost per year for government personnel is $39,500. CDC travel is related to providing technical assistance and site visits, as well as attending trainings. This grant (cooperative agreement) has been awarded to the University of North Carolina, Chapel Hill-School of Nursing who is responsible for conducting the study. This grant includes costs for salaries, travel, equipment, supplies and incentives. The grant also covers funds for developing IRB protocols, information collection requests, data management and validation systems and to conducting data analysis. The total award for four years is approximated at $964,000. Therefore, the annualized cost for the University of North Carolina, Chapel Hill - School of Nursing is $241,000.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government

The cost of the project to the Federal Government for the 4 years is estimated to be $1,122,000. The annual cost is summarized in Exhibit A.14.

Exhibit A.14

Expense Type	**Expense Explanation**	**Annualized Costs (dollars)**
Centers for Disease Control		
Direct Costs to the Federal Government	CDC Project Officer (GS-13, .30 FTE)	$ 27,000
	CDC Co-Project Officer (GS-14, .10 FTE)	$10,000
Operational	CDC Project Officers - travel (1 trip for 2 Project Officers)	$2,500
	Subtotal, Direct Costs to the Government	**$39,500**
Contractor and Other Expenses	University of North Carolina, Chapel Hill-School of Nursing Cost and Fee	$241,000
	TOTAL COST TO THE GOVERNMENT	**$280,500**

Salary estimates were obtained from OPM salary scale at the following web address: http://www.opm.gov/oca/09tables/index.asp

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Timeline Schedule

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Begin Recruiting Trial Participants	2-3 months after OMB approval
Conduct 3 month follow-up and in-depth interviews)	3 - 8 months after OMB approval
Data management and validation	3- 9 months after OMB approval
Conduct data analysis	10 – 12 months after OMB approval
Dissemination of results	36 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exception is requested. We will display the OMB Expiration date.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

There are no exceptions to certification for Paperwork Reduction Act guidelines of 5 CFR 1320.5.

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

Supporting Statement
Part B

0920-XXXX

Contact Information

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January 26, 2008

B. Statistical Methods

1. Respondent Universe and Sampling Methods

HIV-positive women 18 to 69 years (average 42 years), from several clinics in North Carolina will be screened for participation in this study. The facilities that will serve as the respondent universe, are: Early Intervention Clinic, Durham County Health Department (Durham NC); the Positive Active Women Center, an HIV-related community based organizations (Durham, NC); the Carolina Medical Center HIV Clinic (Charlotte NC); the Mecklenburg County Health Department (Charlotte, NC), the Moses Cone Hospital (Greensboro NC) and the HealthServe Clinic, an HIV community based organization (Greensboro NC). The catchment areas for these sites are Durham County, Mecklenburg County and Guilford County in North Carolina. Women served by these sites are predominantly African-American (~96%) with a much smaller number of Caucasian (~3%) and Hispanic (~1%) women receiving care.

An estimated 550 HIV- positive women will be screened using a Screener Form (Attachment 3a) to determine eligibility for study participation. The Screener Form will collect information to ascertain if the potential participant meets the following eligibility criteria: 1) female, 2) HIV-positive, 3) 18 years of age and older, 4) reside within the geographic boundaries of the catchment areas (i.e., Durham County, Mecklenburg County and Guilford County in North Carolina), 5) speak and read English, 6) have been sexually active with a man in the past 3 months, and 7) does not intend to get pregnant in the next 3 months.

The full intervention trial will be conducted with a total of 330 HIV Positive women with a projected sample size of 165 each, for the intervention group and the wait list/comparison group. A subset of 25-30 women who participated in the Sister to Sister Positive HOPE intervention condition will be recruited following their completion of the trial. Participants will be drawn from the participants in the intervention condition of the trial.

Sampling Procedures: The current study is a randomized controlled trial of HIV-positive women in the southeastern United States. Power and sample size calculations for this study were performed using two outcome measures:

- Frequency of unprotected sexual acts in the past 3 months.
- An HIV preventive psychosocial factor (i.e., condom use self-efficacy).

Estimates of these outcome measures were obtained from the WiLLOW Program (Wingood et al., 2004) which evaluated the efficacy of an intervention to reduce HIV transmission risk behaviors and enhance HIV-preventive psychosocial factors in women living with HIV. For the purpose of these calculations, frequency of unprotected sexual intercourse (UPS) is defined as the number of reported unprotected sexual acts in the past 3 months. Data are assumed to follow a normal distribution. The estimated variability used in these calculations is the pooled variance of estimated UPS at baseline. The sample size calculations presented are the number of participants needed for 80% power to detect various differences between the treatment condition and the control condition with a two-sided test and α=.05. Using estimates similar to those reported in the Sister to Sister Study, Table 1 contains the sample size calculations.

Table 1. Participants per condition needed for 80% power to detect a difference in number of unprotected vaginal sex acts in the past 3 months (α=.05).

Control Condition	Treatment Condition	Difference in Means	N per Condition for 80% Power	N per Condition for 80% Power (15% attrition)	N per Condition for 80% Power (20% attrition)
7.5	4.5	3.0	159	183	210
	4.0	3.5	117	135	155
	3.5	4.5	90	104	119
8.7	5.5	3.2	140	161	185
	5.0	3.7	108	124	130
	4.3	4.0	125	144	150

Table 1 contains sample size calculations for various levels of UPS, treatment differences, and attrition. According to these results, the factor which has the greatest impact on sample size is the difference in the mean UPS between the treatment and control condition. The Willow Study reported a rate difference of approximately 3.9 acts. Using this as a gauge, the projected sample size per condition of approximately 165 is adequate relative to the goals of this study.

2. Procedures for the Collection of Information

Project staff at the University of North Carolina, Chapel Hill includes a Project Manager, Data Collectors, and the Data Manager. The Project Manager will coordinate all aspects of the project, including screening, enrollment, baseline and follow-up assessments, and in-depth interviews. The Project Manager will also be responsible for coordinating all tracking and contact activities including using contact information to locate participants and schedule follow-up visits and will interact as necessary with other staff assisting with maintaining contact with participants.

Prior to beginning data collection, study staff at UNC, Chapel Hill will receive training on confidentiality and scientific ethics, recruitment and facilitation skills, referral resources, and managing adverse events, among other important issues. Data Collectors will be trained to administer the assessment instrument (Attachment 5) using CAPI and A-CASI. The Data Collector will remain accessible to the participant during the ACASI portion in case she needs help or has any questions. Strict ethical guidelines regarding professional conduct will be enforced and signed by all research team members.

Potential participants will be screened for eligibility using the Screener Form (Attachment 3a). If potential participants are not able to complete screening when they are first approached in the clinic or community based organization, but are willing to be contacted by recruitment staff for screening, they will be asked to provide their name and telephone numbers. She will be asked to indicate whether a message may be left. She will also be asked if it is okay to identify the caller as from the Sister-to-Sister Positive HOPE Project. If it is not, she will be asked how she would like the caller to identify herself. This information will be documented on the Screener Contact Form (Attachment 3b). After eligibility is verified, and during the baseline visit, the Data Collectors will explain the study to the potential participant,

review the Consent Form (Attachment 7a), and have the participant sign the form. After consent is obtained, the Data Collector will collect basic contact information from the participant using the Locator Form
(Attachment 4). The purpose of collecting this information is to aid the study staff in locating participants for follow-up visits.

After the screening and study enrollment, participants who meet eligibility requirements will begin baseline procedures: (1) The Data Collector will conduct the combination CAPI (Computer Assisted Personal Interviewing) /ACASI (Audio-Computer Assisted Self-Interviewing) baseline assessment (Attachment 5) with the participant; (2). Following the baseline assessment, participants will be randomly assigned to the intervention or the comparison condition (projected sample size per condition N = 165).The assignment to a condition will occur by computer. Participants enrolled in the intervention condition will then be scheduled to complete the single session, "Sister to Sister Positive HOPE" intervention, a brief, nurse delivered one on one counseling session, will last approximately 45 minutes. No data will be collected from participants during the "Sister to Sister Positive HOPE" one on one intervention counseling session. Three months after completing the intervention, intervention condition participants will complete the follow up assessment (Attachment 5). The follow-up assessment will cover virtually the same content as the baseline assessment with a few additional questions regarding use of ACASI. Participants assigned to the wait list/comparison condition will return for the follow up assessment three months after completing the baseline assessment. The follow up assessment will also take approximately 45 minutes to complete (Attachment 5).

The wait list/comparison group (= control) will be offered the opportunity to participate in the intervention session after completing the follow up assessment, however no data will be collected on this group beyond the three month follow-up assessment. For each condition, participants will be reminded that they have to complete a three month follow up assessment and that they will be sent a card (Attachment 7f) with the date/time of the follow up assessment appointment. Participants will also be reminded that they will receive a reminder phone call (Attachment 7g) the day before their scheduled follow up assessment reminding them of their appointment. Participants will be given a specific "target date" for the follow-up visit (at the baseline visit for the wait list/comparison group and at the intervention visit for the intervention group). All follow-up visits will be scheduled within a two-week target window (i.e., visits may be scheduled either up to one week before or up to 1 week after the target follow-up date). Participants who miss an appointment within the target window or cannot complete the assessment at that time will be scheduled for an appointment outside of the target window, but within the acceptable window period. For the 3-month visit, the acceptable window period will be one week before the start of the target window and two weeks after the target window.

The baseline and follow-up assessment (Attachment 5) will be administered in private offices at all sites. The assessment instrument contains questions about participants' socio-demographic information, health and health care, sexual activity, drug use, and other psychosocial issues. Sensitive questions on the assessments (e.g., sexual activity, drug use) will be asked using A-CASI. The A-CASI system displays each assessment question on a computer monitor while simultaneously playing an audio recording of the question through headphones. Participants

enter their responses to the assessment questions directly on the computer. Use of this method allows not only for direct entry of data into the computer, but this method has also been shown to result in participants reporting higher rates of sensitive behavior than from other survey methods (Turner, Forsyth. O'Reilly et al, 1998). Data Collectors who have been trained in the use of A-CASI will prepare a new data record for the participant. Data Collectors will demonstrate the A-CASI system to each participant and answer any questions about its use. Questions determined not to be sensitive (e.g., socio-demographic information, health care) will be asked using CAPI, where a Data Collector will ask respondents questions face-to-face while inputting the responses into the computer. The CAPI portions of the assessment will be completed by participants at the beginning and the end of the assessment. During administration of the assessment, the Data Collector will remain on-site to answer any additional questions or address any problems.

For the in-depth individual interviews (Attachment 6), a subset of 25-30 women who participated in the intervention condition will be recruited following their completion of the three-month follow-up assessment. Participants will be identified by a random numbers table (generated from a pool of women who were randomized into the intervention arm) prior to the 3-month follow-up assessment. Data collectors will be blinded to who is selected for the in-depth interviews prior to conducting the follow up assessment. Once the follow up assessment is complete, the data collector will open an envelope to determine if the participant has been selected to participate in the in-depth interview (Attachment 6). If yes, then the data collector will read the script describing the qualitative study to determine if participant is interested in participating. If the woman agrees to participate, informed consent (Attachment 7b) will be obtained. After informed consent is obtained, the in-depth interview will be conducted or scheduled. Participants will complete in-depth interviews within 30 days of the follow-up assessment. After 10 interviews, the study investigators will assess this demographic pool of subjects interviewed to see if there is a need to target specific demographic characteristics (e.g. age, race, geography) in subsequent interviews in order to ensure a representative sample. In-depth interviews will be conducted by a trained data collector in a private room in the clinic, agency, or community AIDS organization in which the follow-up assessment took place.

Data quality is ensured by use of computer-assisted interviewing, data collector training and monitoring, site visits, and data editing. Computer-assisted interviewing improves data quality in several ways. Data Collector errors are reduced because interviewers do not have to follow complex routing instructions; the computer does it for them. Respondent errors are also reduced. Consistency checks are programmed into the assessments so that inconsistent answers or out of range values can be corrected or explained while the interview is in progress. Use of computer-assisted interviewing also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and more accurately. A two-day training of local field staff will occur prior to implementation of data collection. This training will cover general interviewing skills, the sampling and recruitment protocol, and a question-by-question review of data collections forms to ensure data collectors understand the purpose of each question and how data collected should be entered on forms and in the computer. Data collectors will have opportunities to practice administering the eligibility screener (Attachment 3a), as well as going through the CAPI/ACASI assessment. The training will also address data collector integrity, underscoring the importance of collecting quality data and the consequences of inappropriate behaviors, including falsification of data. The training will cover how to provide technical assistance to

respondents who have problems with the CAPI/ACASI assessment. During the data collection period, field staff will be monitored by their Principal Investigator or other management staff. Feedback will be provided for areas of improvement or incorrect implementation of the protocol. Supervisors will provide feedback on ways to help improve response rates. CDC will conduct at least one site visit per year. The purpose of the site visit is to monitor adherence to the study protocol and to obtain feedback on study procedures. In addition to the checks provided through the computer-assisted interview program, editing of the data will be performed by CDC, performing extensive checks of the quality of the files and identification of errors in programs or procedures.

HIV preventive psychosocial factors (or mediators) are defined as intermediate factors specifically targeted by the intervention to bring about a change in behavior. Condom use self-efficacy is a common mediator in HIV intervention studies which measures a participant's self-perceived effectiveness at using a condom. In this study, condom use self-efficacy was measured using a 9-item scale that assessed participants' confidence in their ability to use condoms properly (Cronbach's α=0.90). Data are assumed to follow a normal distribution. As with the previous analysis, the sample size calculations presented are the number of participants needed for 80% power to detect differences of varying size between the treatment condition and the control condition with a two-sided test and α=.05. Using estimates similar to those reported in the WiLLOW Study, Table 3 contains the sample size calculations.

Table 3. Participants needed for 80% power to detect a difference in condom use self-efficacy (α=.05)

Rate: Control Condition	Rate: Treatment Condition	Difference in Rates	N per Condition for 80% Power	N per Condition for 80% Power (15% attrition)	N per Condition for 80% Power (20% attrition)
12.5	14.0	1.5	274	315	362
	14.5	2.0	154	177	204
	15.0	2.5	100	115	132

Due to the size of the variability in this estimate, we need a slightly larger sample size than the anticipated 165 per treatment arm in order to detect the one percentage point difference reported in the WiLLOW Study. However, the current study, which aims to recruit approximately 165 participants per condition, has sufficient power to detect a two percentage point difference or greater.

The Sister to Sister study reported approximately 8% attrition among an HIV seronegative population. The WiLLOW Program examined the effectiveness of an intervention on transmission risk among HIV seropositive women and also reported an attrition rate of approximately 8%. For this sample size calculation, we are assuming a 15-20% rate of attrition, thus our sample sizes are very conservative. If the actual rate of attrition is lower than we assume, the sample size needed to detect the specified difference will be smaller.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Participant retention during the intervention trial will be enhanced in several ways. This is particularly important in an intervention trial, where high-levels of follow-up are required for an intervention study to be deemed scientifically rigorous.

In order to reach the number of women needed to participate in the study, we will monitor closely recruitment and retention throughout the course of the study. If we are not reaching the number of women needed, we will expand recruitment efforts by doing the following: 1) locating additional clinics and community based organizations serving HIV-positive women, 2) determining ideal times for recruitment to occur (i.e., when patient flow is maximal), and 3) maximizing study staff available during patient peak periods to increase opportunities to recruit participants for the study. Study staff will also remind participants of follow-up visits and attempt to locate participants who cannot be found. Participants will also receive a phone call (Attachment 7e) the day prior to a scheduled visit (i.e., baseline assessment, intervention and 3 month follow-up) using a reminder script (Attachment 7g). If a participant misses a scheduled visit without prior notification to staff, she will be contacted the day following the missed appointment to try and reschedule the visit.

Another important method for retention is the use of reimbursements for participation. As described in Section A.9, the use of monetary incentives has previously been shown to improve retention of participants in projects similar to this (Kamb et al., 1998; Greenberg et al., 1998). In addition, many of our potential study participants live in rural areas of North Carolina; therefore monetary incentives are necessary, in part, as a token of appreciation for their interest in assisting UNC and CDC. They will also be provided with bus passes to assist with transportation costs.

To maximize reporting of sensitive behaviors in the baseline and follow-up assessments (Attachment 5), we will use ACASI for sensitive portions of the questionnaire (i.e., questions asking about participants' sexual and drug using behaviors and traumatic life events. Research suggests that the A-CASI technology improves reporting of sensitive behaviors (Des Jarlais et al., 1999; Turner et al.). For relatively non-sensitive questions, CAPI will be used where the Data Collector administers the instrument face-to-face and enters responses directly into a computer. As described in the previous section, the Data Collectors will receive extensive training on how to administer CAPI/ACASI assessment. Participants will also receive a mini-practice session from the Data Collector before she starts the ACASI portion of the assessment. The Data Collector will be available to the participant during the ACASI portion in case she needs help or has any questions.

Since this study is a randomized controlled trial of an intervention, the following measures will be taken to minimize potential biases that could be threats to the study's internal validity: 1) use of a computerized randomization program to allocate participants into the immediate intervention group or the wait list comparison group; 2) examination of baseline participants' characteristics (e.g., demographic and risk behavior data) to ensure that the two

groups are equal; if not, make statistical adjustment in the analyses; 3) aim to achieve equal follow-up rates between the two groups; if not, examine potential reasons for differences in follow-up rates.

The Data Manager will develop and maintain databases to track and monitor data collection, enter data and produce reports on the status of data collection. Monitoring of response rates will be done through conference calls on a weekly basis with CDC, offering the opportunity to share strategies for improving response rates.

4. Test of Procedures or Methods to be Undertaken

Individuals who were knowledgeable about the study population (i.e., Principal Investigators and their staff, CDC investigators) and those who shared sociodemographic characteristics similar to the study population (i.e., near peers identified by the Principal Investigators, Community Advisory Board Members) reviewed the data collection instrument and provided verbal feedback on the length of the data collection instruments and readability and comprehension of each question. Based on the feedback, the instruments were further revised and shortened

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The primary persons consulted on statistical aspects of this project and who will be responsible for analyzing the data are Ms. Felicia Hardnett of the CDC and Dr. Michael Weaver of the University of North Carolina-Chapel Hill. The study design and data collection instruments were a collaborative effort between CDC and University of North Carolina-Chapel Hill. UNC-Chapel Hill will be responsible for data collection activities.

Statisticians assigned to the project are as follows:

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Federal staff involved with various aspects of the study are listed below.

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Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 3

Screener/Contact Form

_____ __

Form Approved

OMB No. 0920-XXXX

Exp. Date__xx/xx/20xx

Attachment 3a **ID Number:**

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-XXXX)

Screener Form

Sister to Sister Positive HOPE Project

BEFORE APPROACHING THE POTENTIAL PARTICIPANT VERIFY WITH CLINIC STAFF AND THE PRINCIPAL INVESTIGATOR THAT:

- The potential participant did not participate in the focus group or pilot study
- The potential participant is a resident of NC
- The potential participant does not have severe cognitive impairment

Staff name: _____

Date: _____ Time: _____

Instructions: Read statements in ***bold italics*** to the potential participant. Write responses directly on this form. Do not write the participant's name or contact information on this form. The participant's ID number must be written on this form and contact information must be recorded separately on the Screener Contact Form.

I. APPROACHING THE POTENTIAL PARTICIPANT

Introduce yourself warmly and professionally:

"Hi, I'm _____ with the Sister to Sister Positive HOPE Project and I would like to talk to you about a research study we are conducting at the University of North Carolina Chapel Hill.

Have we already talked to you about being in this study?

_____ ***1) Yes*** **Thank you for your time.**

2) No **Continue reading script.**

Is now a good time to tell you about the project and see if the study might be helpful for you?

_____ 1) Yes ***"Good"*** **– Continue to Section II**

_____ 2) No, this time doesn't work, but person is interested. **Get her phone number. Ask for a good time to call. Ask if it is okay to leave a message OR give her the study phone number and business card. Document this on the Screener Contact Form.**

When calling the person, read Section II Introducing the Trial Study. If you call and do **NOT** reach the person, then call again later or leave a message stating ***"We are calling from the Sister to Sister Positive HOPE Project because you told us that you might be interested in participating in a research study. Please call us back at (919) 966-3119 or our toll free number 1(866) 619-0007 at your convenience or leave us a message telling us the best time to call you."*** **Log this information on the Screener Contact Form.**

_____ 3) Person is not interested in the program. **Thank the person and leave**.

II. INTRODUCING THE TRIAL STUDY

A. ***"I want to thank you for your interest in our study. First, I'm going to tell you a little bit about the study. Then, if you're still interested, I'll ask you some questions to determine if you are eligible to participate in the study."***

"First, about the study: We are a group of nurse researchers from the University of North Carolina Chapel Hill who are working with the Centers for Disease Control and Prevention in Atlanta."

Screener: Read the description below

B. <u>Study Description</u>

Our research team has developed a program for HIV-positive women living in the South. We want to see whether this program can help HIV-positive women make healthy choices in their lives.

If you decide to participate in our study, this is what will happen. First, we'll ask you to take a face-to-face interview with an interviewer in a private office. The interview will ask questions about your health, sexual practices, and drug using behaviors, and should last up to

45 minutes. In addition to questions asked by the interviewer you will also be answering some questions using a computer.

After completing the interview, you will either meet with a nurse in the private office for a 45-minute session to talk about healthy living including discussions about how to protect yourself and others from sexually transmitted infections and then be reinterviewed in three months.

OR after completing the first interview you will be interviewed again in three months.

All information you share will be kept confidential (private) by project staff to the extent allowed by law. There also are laws that require us to tell others if you tell us that you are going to hurt yourself or a specific person, or that a child or older person is being hurt or abused. In these cases, we will have to tell someone (e.g., local police or the child welfare agency) to protect that person. The meeting with the nurse may be audiotaped so that the project supervisors can listen to how the nurse is doing. The interview, the tape, and notes from the tape will be destroyed at the end of the study. If you do decide to participate in the study, your name will not be attached to any of the information you give us in the interviews. In appreciation for your time and effort we will give you $30 and a bus pass for your transportation at each interview.

C. ***"Are you interested in being screened for this study?***
_____ 1) Yes ***"Good."*** Go to **Section III**

_____ 2) No, person is not interested in the program. **Skip to Section III - I**

III. SCREENING - AFTER THE POTENTIAL PARTICIPANT HAS BEEN TOLD ABOUT THE STUDY

"Do you feel comfortable right now answering a few personal questions so that I can determine whether you are eligible to participate?"

_____ 1) Yes ***"Good. Let's start with a few brief questions."***

_____ 2) Not a good time, but later ***"Is it okay of us to call you at a different time?"***
Get her phone number. Ask for a good time to call. Ask if it is okay to leave a message and ask her how she would like the caller to identify herself. Also give her the study phone number. Document this on the Screener Contact Form.

_____ 3) No, doesn't want to be screened – **Skip to Section III – I**

BEFORE ASKING SCREENING QUESTIONS:

You don't have to answer any question you don't want to answer, but if you don't answer a question, I might not be able to tell if you are eligible, and then you won't be able to be in the study.

A. ***What is your HIV status?***
   1) Positive
   2) Negative-INELIGIBLE ***"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time."***
   3) Don't know

B. ***"How old are you?"*** _____Years old (If under 18, say ***"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time." IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON AND LEAVE.)***

C. ***"When was the last time you had sex with a man? By sex I mean vaginal sex where a man put his penis in your vagina, anal sex where a man put his penis in your behind (butt), or oral sex where a man put his penis in you mouth."***
   _____1) Never– **INELIGIBLE** *Keep screening.*
   _____2) More than 90 days ago– **INELIGIBLE** *Keep Screening*
   _____3) 90 days or less

D. ***"Would you feel comfortable taking a face-to-face interview and having a face-to-face meeting with a nurse that might include discussions about sexuality and drug use?"***
   _____1) Yes
   _____0) No - **INELIGIBLE**

E. ***"Do you feel comfortable speaking and reading in English?"***
   _____**1) Yes**
   _____0) No

F. "***Do you intend to get pregnant in the next 3 months***?"
   _____1) Yes **- INELIGIBLE**
   _____0) No

G. Is person eligible?

   _____1) Yes
   _____2) No– doesn't meet study criteria

   A) If NO:

THANK YOU

"I want to thank you for talking with me, but unfortunately, you are not eligible for the study at this time. Due to the nature of this research, we're limited in terms of the numbers of

people we can enroll due to our recruitment criteria. IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON AND LEAVE.

B) If YES:

"It looks like you are eligible for the study. Are you still interested in participating?"

_____1) Yes– *go to question H.*
_____2) No– *go to question I.*

H. Give eligible participants directions to proceed with the study.

"We would like to thank you for helping us with our study. Again, I want to remind you that all of the information that you gave us is confidential to the extent permitted by law."

End screening.

IF PERSON REFUSES TO PARTICPATE:

I. Person decides not to participate at any point: ***"Thank you for taking the time to talk with me today. You don't have to answer the next question if you do not wish, but it would be helpful for us to know why you do not want to participate?" IF ANY COMMUNITY SERVICE RESOURCES ARE AVAILABLE, PROVIDE THEM. THANK THE PERSON.***

_____1) Not interested in study topic
_____2) Study topic too sensitive/personal
_____3) Scheduling difficulties
_____4) Concerned about confidentiality
_____5) Not comfortable participating
_____6) Other: (specify _____)

"Thank you again for your time."

Attachment 3b

Screener Contact Form

Sister to Sister Positive HOPE Project

DATE: _____

NAME: _____

TEL: _____ ALTERNATE TEL: _____

OK TO LEAVE REMINDER MESSAGE? Y: _____ N: _____

BEST TIME TO REACH: _____

HOW WOULD YOU LIKE FOR US TO IDENTIFY OURSELVES WHEN WE CALL YOU:

Sister to Sister Positive HOPE _____

University of North Carolina at Chapel Hill _____

Research Study _____

Other:_____

CONTACT ACTIVITY

Date	Time	Contact Type	Outcome (scheduled date/time?)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

NOTES

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 4

Locator Form

Form Approved
OMB No. 0920-XXXX
Exp. Date __xx/xx/20xx

Attachment 4

Sister to Sister Positive HOPE
Locator Information Form

Public reporting burden of this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-XXXX)

Name: Participant I.D. Number: _____

Recruitment Date:
Telephone numbers where subject can be reached:
Name: Number: ( )
Name: Number: ( )
Name: Number: ( )
Home Address:
County:
Street Address:
City:
Zip Code:

Telephone numbers of other persons (relatives, partners, friends) where subject can be reached:
Name: Number: ( )
Name: Number: ( )
Name: Number: ( )

Home address:
County:
Street Address:
City:
Zip Code:

Mailing address if different:
Frequent Hang Outs:
1.
2.
3.

Services Used:
1.
2.
3.

Health Care Providers Used:
1.
2.
3.

Treatment Agencies Used:
1.
2.
3.

Additional Notes:

RA/Data Collector : _____
Date:
Contact Data Form Rev. 1-17-08

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 5

Baseline/Follow-up Assessment

Form Approved

OMB No. 0920-XXXX

Exp. Date __xx/xx/20xx

Public reporting burden of this collection of information is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-XXXX)

Baseline/Follow-up Assessment Questionnaire

Sister to Sister Positive HOPE Project

(Note: Page numbers referenced throughout the assessment refer only to the assessment document)

Administrative:

Study Site:

_____

Staff ID:

_____

Assessment Point:

_____

Date:

_____

Version of Questionnaire:

Starting Time:

_____

Ending Time:

_____

DEMOGRAPHICS, PART 1

To begin the interview, I'd like to ask you some background questions. This lets us know something about the people who participate in the project.

In what month and year were you born?

_____/____ (mm/yyyy)
month/year
2098 Refuse to Answer

So that makes you _____ *(CALCULATE FROM Q1)* years old**.** If this is not correct please go back to the previous question and change your answer.

Do you consider yourself to be Hispanic or Latina?

1 Yes
0 No → *SKIP TO Q5*
8 Refuse to Answer

IF Q3 = 1, ASK:

4. Which of the following best describes your ethnic background? *(IF MORE THAN ONE COUNTRY NAMED: Which do you feel closest to?)* (Choose One)

01 Puerto Rican
02 Dominican
03 Mexican
04 Cuban
05 Central American
06 South American
07 Spaniard, from Spain
08 Other
98 Refuse to Answer

5. For this question you may select more than one option. Do you consider yourself…

01 Black or African American

02 White
03 Asian
04 American Indian or Alaskan Native
05 Native Hawaiian or other Pacific Islander
06 Other (specify _____)
98 Refuse to Answer

Now some questions about school and work.

What is the highest level of education you have completed? (Choose One)

01 ≤ Grade 8
02 Grades 9 through 11
03 Grade 12 or GED
04 Some college, Associate's Degree, or Technical Degree
05 Bachelor's Degree
06 Any post graduate studies
98 Refuse to Answer

Which of the following best describes your current marital status? (Choose One)

1 Married and living with your husband – *SKIP TO Q10*
2 Married and not living with husband – *SKIP TO Q11*
3 Legally separated
4 Divorced
5 Widowed
6 Never been married
7 Living with someone and not married
98 Refuse to Answer

Do you have a main or primary partner, that is, a partner who you would call your boyfriend, girlfriend, lover, or significant other?

1 Yes
0 No – *SKIP TO Q11*
8 Refuse to Answer – *SKIPT TO Q11*

IF Q8 =1, ASK:
Are you currently living with this person?

1 Yes
0 No - *SKIP TO Q11*
8 Refuse to Answer – *SKIP TO Q11*

IF Q9=1, ASK:
How long have you been living together?

___ ___Weeks
___ ___Months
___ ___Years
98 Refuse to Answer

Have you ever been pregnant?

1 Yes
0 No → *SKIP TO Q14*
8 Refuse to Answer – *SKIP TO Q14*

IF Q11 = 1, ASK:
Have you had a baby in the last 3 months?

1 Yes
0 No
8 Refuse to Answer

Are you currently pregnant?

1 Yes
0 No
8 Refuse to Answer

14. Are you planning to get pregnant in the future? (next # months???)

1 Yes
0 No
8 Refuse to Answer

15. How many children are you currently taking care of?

___ ___ (# of children)
98 Refuse to Answer – *SKIP TO Q17*

16. Of the ___ ___ (Q15) children who are living with you, how many are HIV positive?

___ ___ (# of children)
98 Refuse to Answer

The next few questions are about religion.

17. How important to you is religion or spirituality? (Choose One)

01 Very important
02 Somewhat important
03 Slightly important
04 Not at all important
98 Refuse to Answer

18. How often, if at all, do you attend religious or spiritual services? Would you say never, less than once a year, a few times a year, about once a month, once a week or more, or everyday? (Choose One)

01 Never
02 Less than once a year
03 A few times a year
04 About once a month
05 Once a week or more
06 Everyday
98 Refuse to Answer

HOUSING

1. In the last 3 months, that is since _____ (*CALCULATE THE DATE)* where did you sleep most of the time? (Choose One)

Your own place, a room, apartment, or house that is your home
Temporarily doubled up with others, in someone else's house, apartment, or room
In a temporary or transitional housing program, or a halfway house
In an SRO, that is, a "single room occupancy" facility, or welfare hotel or motel, or a shelter for homeless people
In jail or prison
In drug treatment, a detox unit, or drug program housing
In a hospital, nursing home, or hospice
On the street
Someplace else
98 Refuse to answer

IF Q1 = 09, ASK:
(Some place else: specify) _____

RELATIONAL/SOCIAL CONTEXT

1. About how many close friends and close relatives do you have, people you feel at ease with and can talk to about what is on your mind?

__ __
98 Refused to Answer

2. People sometimes look to others for companionship, assistance, or other types of support. I am going to read you some statements. Please tell me how often each of these are available to you if you need it? (Choose One for each question) (RF = refused to answer)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time	RF
a. Some one to help you if you were confined to bed	1	2	3	4	5	8
b. Someone you can count on to listen to you when you need to talk	1	2	3	4	5	8
c. Someone to give you advice about a crisis	1	2	3	4	5	8
d. Someone to take you to the doctor if you needed it	1	2	3	4	5	8
e. Someone who shows you love and affection	1	2	3	4	5	8
f. Someone to have a good time with	1	2	3	4	5	8
g. Someone to give you information to help you understand a situation	1	2	3	4	5	8
h. Someone to confide in or talk to about yourself or your problems	1	2	3	4	5	8
i. Someone who hugs you	1	2	3	4	5	8
j. Someone to get together with for relaxation	1	2	3	4	5	8
k. Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5	8
l. Someone whose advice you really want	1	2	3	4	5	8
m. Someone to do things with to help you get your mind off things	1	2	3	4	5	8

n.	Someone to help with daily chores if you were sick	1	2	3	4	5	8
o.	Someone to share your most private worries and fears with	1	2	3	4	5	8
p.	Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5	8
q.	Someone to do something enjoyable with	1	2	3	4	5	8
r.	Someone who understands your problems	1	2	3	4	5	8
s.	Someone to love and make you feel wanted	1	2	3	4	5	8

3. The next set of questions asks about some of your experiences, feelings, and opinions about how people with HIV feel and how they are treated. For each one, please tell me if you strongly disagree, disagree, agree, or strongly agree. (Choose One)

	Strongly Disagree	Disagree	Agree	Strongly Agree	RF
a. I feel guilty because I have HIV.	1	2	3	4	8
b. People I know would reject someone with HIV.	1	2	3	4	8
c. I feel I am not as good as others because I have HIV.	1	2	3	4	8
d. People I know would be uncomfortable around someone with HIV.	1	2	3	4	8
e. I never feel ashamed of having HIV.	1	2	3	4	8
f. People I know would not want someone with HIV around their children.	1	2	3	4	8
g. Having HIV makes me feel unclean.	1	2	3	4	8
h. People I know think that a person with HIV is disgusting.	1	2	3	4	8
i. People's attitudes about HIV make me feel worse about myself.	1	2	3	4	8
j. Having HIV makes me feel that I'm a bad person.	1	2	3	4	8
k. People I know would treat someone with HIV like an outcast.	1	2	3	4	8
l. People I know believe that a person who has HIV is dirty.	1	2	3	4	8
m. Having HIV in my body is disgusting to me.	1	2	3	4	8

HEALTH AND WELL-BEING

Now I would like to ask some questions about your health.

1. When did you first learn that you had HIV? If you are not sure, enter your best guess.
__ __ /____(mm/yyyy)
Refused to Answer 2098

2. What was your most recent CD-4 or T-cell count? Was it …
(Choose One)

1 Less than 200
2 200-349
3 350-500
4 501 or greater
5 I have never had my CD-4 or T-cell count measured
6 I don't know
08 Refused to Answer

3. Was the result of your viral load test…[Changed response category] (Choose One)

1 Undetectable, that is, less than 400 or less than 40 depending on the type of test
2 Detectable
3 I have never had my viral load measured
4 I don't know
8 Refused to Answer

4. Has a doctor or other medical provider ever told you that you had Clinically-Diagnosed AIDS? By Clinically-Diagnosed AIDS we mean that you have symptoms or other diseases that were caused by the HIV virus.

1 Yes
0 No
8 Refused to Answer

5. In the past 3 months, has a doctor, nurse, or other health care provider given you a new diagnosis of a sexually transmitted infection other than HIV?

01 Yes
02 No
98 Refuse to Answer

6. In general, would you say your health is...(Choose One)

1 Excellent
2 Very Good
3 Good
4 Fair
5 Poor
8 Refused to Answer

7. The following questions are about activities you might do during a typical day. For each item, rate how much your health limits you in these activities.
(Choose One for each question)

	Limited A Lot	Limited A Little	Not Limited At All	RF
a. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports.	1	2	3	8
b. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or bowling.	1	2	3	8
c. Walking uphill or climbing (a few flights of stairs).	1	2	3	8
d. Bending, lifting or stooping.	1	2	3	8
e. Walking one block.	1	2	3	8
f. Eating, dressing, bathing or using the toilet.	1	2	3	8

8. Does your health keep you from working at a job, doing work around the house or going to school?

1 Yes
0 No
8 Refused to Answer

9. Have you been unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

1 Yes
0 No
8 Refused to Answer

10**.** For the following items, please select the choice that best describes how you have felt during the last week. (Choose One for each question)

	Rarely (<1 day)	Some days (1-2 days)	Occasionally (3-4 days)	Most days (5-7 days)	Refused to Answer
a. During the last week, how often were you bothered by things that usually don't bother you?	0	1	2	3	8
b. During the last week, how often did you have trouble keeping your mind focused on what you were doing?	0	1	2	3	8
c. During the last week, how often did you feel depressed?	0	1	2	3	8
d. During the last week, how often did you feel that everything you did was an effort?	0	1	2	3	8
e. During the last week, how often did you feel hopeful about the future?	0	1	2	3	8
f. During the last week, how often did you feel fearful?	0	1	2	3	8
g. During the last week, how often was your sleep restless?	0	1	2	3	8
h. During the last week, how often were you happy?	0	1	2	3	8
i. During the last week, how often did you feel lonely?	0	1	2	3	8
j. During the last week, how often could you not get "going"?	0	1	2	3	8

AUDIO-CASI SECTION OF INSTRUMENT BEGINS. [DATA COLLECTORS – PLEASE SKIP TO Q1A AND PILOT TEST THIS SECTION USING FACE-TO-FACE INTERVIEW]

ACASI1 An important part of this interview is the sections you will conduct completely on your own using the computer and the headphones. Before you begin, I will help you go through a short practice session to learn how to use the computer. Let me quickly point out the keys you will use. The computerized practice session that follows will go through what each key does in greater detail.

Practice Questions

READ: So that you are comfortable answering these questions using the computer, the first few questions will be for practice. These will give you an idea of the different types of questions you will see during the interview, and will give you a chance to ask your host any questions before you get started. Now, use the mouse to click on the "Next Question" button to begin.

PRA1. Some of the questions will ask you to answer either YES or NO. For example, "Are you wearing blue today?"

1	Yes
0	No

PRA2. Some of the questions will ask you to pick one answer from a list, such as, How much do you agree with this statement? Blue is my favorite color. (Choose one)

1	Strongly Disagree
2	Disagree
3	Neither Disagree nor Agree
4	Agree
5	Strongly Agree
8	Refuse to Answer

PRA3. Some of the questions will ask you to pick one or more answers from a list of choices, such as, what colors do you like the most? Please check all that apply, then click on the "NEXT QUESTION" button. (Check all that apply)

__	Red
__	Blue
__	Green
__	Yellow
__	Purple

PRA4. Some of the questions will ask you to enter a number, such as, how many colors did you choose on the previous question? After entering the number, click on the "NEXT QUESTION" button.

__ __

READ: Sometimes the computer will tell you that the number that you have entered is not a possible response, and that you have to go back and give another answer. For example, on the previous question if you entered the number 6, the computer would tell you that the highest number you could have chosen is 5 since there were only 5 colors listed. Please click on the "NEXT QUESTION" button.

PRA5. So that you see what this screen looks like, enter a number higher than 5 and press "Next Question." A box will appear saying, Number too big. Click OK and then click on the "Clear" button and enter the correct number.

__

PRA6. A few of the questions will ask you to enter a date. In this practice question you will be asked to enter today's date, indicating the year, month, and day. Using the arrow keys on either side of the boxes, indicate today's year, today's month and today's day. After entering the date, please click on the "NEXT QUESTION" button.

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

If PRA6 is not equal to TODAY then READ: "You have entered the date other than today's date. Please re-answer this question." skip to PRA6.

PRA7. Finally, some of the questions will ask you to spell out your answer using a keyboard on the screen that you click with the mouse you are using. Now you try it by answering the question, "My mother's name is." After entering the name, please click "NEXT QUESTION."

__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

PRA8. Has this been enough practice using the computer? If it has been, click YES and you can get started. If not, click NO and you will get a few more practice questions.

1	Yes	*Skip to instruction before A1*
0	No	

READ: Try a few more questions for you to practice getting used to the computer...

PRA9. Do you like watching TV?

1 Yes

0 No

PRA10. My favorite thing about TV is sports. (Choose one)

0 Strongly Disagree

1 Disagree

2 Neither Disagree or Agree

3 Agree

4 Strongly Agree

PRA11. Can you tell me what kinds of food you like? Please check all that apply, and then click "NEXT QUESTION." (Check all that apply)

__ Pasta

__ Salad

__ Steak

__ Sweets

__ Other things not listed here

PRA12. How many things that you don't like about the city did you choose from the list in the previous question? After entering the number, please click on the "NEXT QUESTION" button.

__ __

PRA13. So that you see again what the screen looks like when you enter an answer that is too high or low, try to enter a number greater than 5 for the question. A box will appear saying, Number too big. Click OK and then click on the "Clear" buttton and enter the correct number.

__

PRA14. What is your favorite month and year? After entering the date, please click on the "NEXT QUESTION" button.

__ __ / __ __ __ __ mm / yyyy

(Year)

PRA15. My favorite actor's first name is? After entering the name, please click on the "NEXT QUESTION" button.

— — — — — — — — — — — — — — — — — — — —

PRA16. Is that enough practice on the computer? If so, just click READY TO GET STARTED and the interview will begin. If you would like some more help with the computer, just ask your host to help you. (Choose one)

0 Ready to get started

READ: Great. Now you will answer questions on your own. Remember that your answers are confidential. If you need help, ask your host. Please click on the "NEXT QUESTION" button.

ALCOHOL AND DRUG USE MEASURES

These questions are about drinking alcohol and use of other substances. Remember that all of your answers will be kept strictly confidential and protected, and that you can skip any question you do not want to answer.

1A. Did you ever in your life have a whole drink of any alcoholic beverage like wine, beer or liquor? We are not asking about times when you only had a sip or two from a drink. [shortened from original]

1 Yes
0 No→ *SKIP TO Q8*
8 Refused to Answer – *SKIP TO Q8*

If Q1A =1, ASK:
1B. In the last 3 months, how often did you drink beer, wine, or liquor? (Choose One)

1 Never in the last 3 months → *SKIP TO Q3*
2 Less than once a month
3 Once to 3 times a month
4 Once or twice a week
5 3-4 times a week
6 Everyday or nearly everyday
8 Refused to Answer - SKIP TO Q3

2. On the days when you drank, how many drinks did you usually have? (Choose One)

0 A few sips or less than one drink
1 One drink
2 Two drinks
3 Three drinks
4 Four drinks
5 Five drinks
6 More than five drinks
8 Refused to Answer

3. Have you ever felt that you **should** cut down on your drinking?

1 Yes
0 No
8 Refused to Answer

4. Have you ever been annoyed by people criticizing your drinking?

1 Yes
0 No
8 Refused to Answer

5. Have you ever felt guilty about your drinking?

1 Yes
0 No

8 Refused to Answer

6. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hang over?

1 Yes
0 No – *SKIP TO Q8*
8 Refused to Answer – *SKIP TO Q8*

IF 1B=1 SKIP Q7

7. Has this happened to you more than one time in the last 3 months days

1 Yes
0 No
8 Refused to Answer

Now here are some questions about drug use in the last 3 months. Remember that all of your answers will be kept strictly confidential and protected, and that you can skip any question you do not want to answer.

	Yes	No	RF
8. In the last 3 months have you used marijuana, hashish, weed, pot, or reefer, even one time?	1	0	8
9. In the last 3 months have you used cocaine by itself, even one time?	1	0	8
10. In the last 3 months have you used crack or free-base by itself, even one time?	1	0	8
11. In the last 3 months have you used heroin by itself, even one time?	1	0	8
12. In the last 3 months have you used heroin and cocaine together, sometimes called a speedball, even one time?	1	0	8
13. In the last 3 months have you used methadone without a prescription, or more than a doctor told you, even one time?	1	0	8
14. In the last 3 months have you used sedatives, tranquilizers, or downers without a prescription, or more than a doctor told you to, even one time?	1	0	8
15. In the last 3 months have you used methamphetamines, amphetamines, uppers, speed, crystal or ice even one time?	1	0	8

IF "YES" TO ANY IN Q8-Q15, ASK Q16-Q23 FOR EACH DRUG USED.

IF YES to Q8

16. In the last 3 months, how often did you usually use marijuana, hashish, weed, pot, or reefer? (Choose One)

	Less than	Once to 3	Once or	3-4 time	Every day or	RF

	once a month	times a month	twice a week	s a week	nearly everyd ay	
	05	04	03	02	01	08

IF YES to Q9

17. In the last 3 months, how often did you usually use cocaine by itself? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 time s a week	Every day or nearly everyd ay	RF
	05	04	03	02	01	08

IF YES to Q10

18. In the last 3 months, how often did you usually use crack or free-base by itself? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 time s a week	Every day or nearly everyd ay	RF
	05	04	03	02	01	08

IF YES to Q11

19. In the last 3 months, how often did you usually use heroin by itself? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 time s a week	Every day or nearly everyd ay	RF
	05	04	03	02	01	08

IF YES to Q12

20. In the last 3 months, how often did you usually use heroin and cocaine together, sometimes called a speedball? (Choose One)

	Less	Once	Once	3-4	Every	RF

	than once a month	to 3 times a month	or twice a week	times a week	day or nearly everyday	
	05	04	03	02	01	08

IF YES to Q13

21. In the last 3 months, how often did you usually use methadone without a prescription or more than a doctor told you? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 times a week	Every day or nearly everyday	RF
	05	04	03	02	01	08

IF YES to Q14

22. In the last 3 months, how often did you usually use sedatives, tranquilizers, or downers without a prescription or more than a doctor told you to? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 times a week	Every day or nearly everyday	RF
	05	04	03	02	01	08

IF YES to Q15

23. In the last 3 months**,** how often did you usually use methamphetamines, amphetamines, uppers, speed, crystal or ice? (Choose One)

	Less than once a month	Once to 3 times a month	Once or twice a week	3-4 times a week	Every day or nearly everyday	RF
	05	04	03	02	01	08

24. The next question is about injecting, "shooting," or "skin popping" drugs, including those that you injected into yourself or others injected into you. Do not include drugs for things like allergies and diabetes, or HIV medications. In the last 3 months, did you inject drugs?

1 Yes
0 No
8 Refused to Answer

25. These next questions are about stressful things that sometimes happen to people.
ASK EVERYONE:

a. In the last 3 months, has there been a time when you did not have enough money to pay for the things you needed to live, like food or clothing?

1 Yes
0 No
8 Refused to Answer

b. In the last 3 months, have you had to stop work when you wanted to work, been laid off or fired?

1 Yes
0 No
8 Refused to Answer

c. In the last 3 months, have you had difficulty finding a job?

1 Yes
0 No
8 Refused to Answer

d. In the last 3 months, have you had to stop work when you wanted to work?

1 Yes
0 No
8 Refused to Answer

e. In the last 3 months, have you been in danger of losing your home or not having a safe place to live?

1 Yes
0 No
8 Refused to Answer

f. In the last 3 months, have you experienced a break up with a husband/partner/lover?

1 Yes
0 No
8 Refused to Answer

g. In the last 3 months, has your child had serious health problems?

1 Yes
0 No

8 Refused to Answer

h. In the last 3 months, have you experienced change in childcare arrangements?

1 Yes
0 No
8 Refused to Answer

i. In the last 3 months, have you lost custody of a child?

1 Yes
0 No
8 Refused to Answer

Now I'd like to ask you some questions about any experience you have had with violence or abuse

j. Did you ever experience a sexual assault or rape as a child or teenager, that is, when you were 17 years of age or younger?

1 Yes
0 No
8 Refused to Answer

k. In the last 3 months, have you experienced sexual assault or rape?

1 Yes
0 No
8 Refused to Answer

l. Did you ever experience a physical assault or abuse as a child or teenager, that is, when you were 17 years of age or younger?

1 Yes
0 No
8 Refused to Answer

m. In the last 3 months, have you experienced physical assault or abuse by someone other than your partner?

1 Yes
0 No
8 Refused to Answer

Now I'd like to ask you some questions about any experiences you may have had with losing someone close to you.

n. Have you ever experienced losing a child through death?

1 Yes
0 No
8 Refused to Answer

o. In the last 3 months, have you experienced losing a spouse/partner, family member or friend through death? By losing, we mean when someone dies, moves away, or is no longer available.

1 Yes
0 No
8 Refused to Answer

p. In the last 3 months, has your spouse/partner or family member (other than your child) had serious health problems?

1 Yes
0 No
8 Refused to Answer

q. In the last 3 months, have you became pregnant but did not want to be pregnant?

1 Yes
0 No
8 Refused to Answer

r. In the last 3 months, have you terminated a pregnancy?

1 Yes
0 No
8 Refused to Answer

s. In the last 3 months, have you experienced a miscarriage or stillbirth?

1 Yes
0 No
8 Refused to Answer

Now we are going to talk about your HIV status

t. In the last 3 months, have you told a family member or friend your HIV status?

1 Yes
0 No
8 Refused to Answer

u. In the last 3 months, was your HIV status revealed against your wishes?

1 Yes
0 No
8 Refused to Answer

v. In the last 3 months, have you experienced changes or difficulties having sex?

1 Yes

0 No
8 Refused to Answer

26. At any time have you been concerned about the following when disclosing your HIV status? (Check all that apply)

1 Rejection
2 Stigma
3 Fear of violence
4 Accused of being unfaithful or sleeping around
5 Implying that your partner is unfaithful or sleeping around
6 Fear of being cut off from financial resources
7 State laws
8 Other (specify _____)

27. Which of the following best describes you? (Choose One)

01 Heterosexual or straight
02 Homosexual, gay, queer, or lesbian
03 Bisexual
04 Not sure/questioning
05 Other (Specify _____)
08 Refused to Answer

SEXUAL BEHAVIOR MEASURES [*TO DATA COLLECTORS* – Please remember in the actual trial this section will be done by A-CASI. So you may feel that some of the questions are worded awkwardly ("please enter…") – but please leave the questions as they are worded when pilot testing.]

The next section is about the sex that you have had over the last 3 months, that is, since (*CALCULATE THE DATE*).
Different people have different definitions of "sex." In this study, by sex we mean
vaginal sex, which is when a man puts his penis in a woman's vagina,
anal sex, which is when a man puts his penis in a woman's rectum or butt, or
oral sex, which is when a man puts his penis in a woman's mouth, or when a person puts his or her mouth on a woman's genitals.

1**.** According to the definition of sex we are using for this study, did you have sex in the last 3 months, that is, since (*CALCULATE THE DATE*)?

1 Yes
0 No *SKIP TO HEDONISTIC OUTCOME EXPECTANCIES* (page 57 Q9)
8 Refused to Answer *SKIP TO HEDONISTIC OUTCOME EXPECTANCIES* (page 57 Q9)

SEX WITH MAIN PARTNER

IF Q1=1 , ASK:
2**.** In the last 3 months, that is, since (CALCULATE THE DATE) did you have a main or a primary sex partner; that is, a partner who you would call your boyfriend, girlfriend, husband, wife, lover, or significant other?

1 Yes
0 No *SKIP TO page 34 Q1-B*
8 Refused to Answer *SKIP TO page 34 Q1-B*

If Q2 =1, ASK:
3**.** Please give initials for your main partner so that we can be clear which partner we're talking about in the following questions. If you had more than one main partner in the last 3 months, select the one person that you feel closest to. Please enter initials for your main partner now. Then press "ENTER" to continue. If you have any questions about how to do this, please ask the interviewer for assistance. _____

3a. Shortly, you will be asked questions about your main partner. By main partner we mean the person whose initials you entered into the computer. That person's initials appear on this screen. Enter "1" and then the ENTER key to continue.

4**.** Is your main partner male or female?

01 Male
02 Female *SKIP TO page 34 Q1-A*

5. How many times did you have vaginal sex with your main partner in the past 3 months?

_____ times vaginal sex
998 Refuse to Answer

6**.** Think about all of the times you had vaginal sex with your main partner in the last 3 months. How many times did you have vaginal sex when he was <u>not</u> wearing a condom?

____ times without a condom
998 Refuse to Answer

7. How many times did you have anal sex with your main partner in the past 3 months?

_____ times anal sex
998 Refuse to Answer

8**.** Think about all of the times that you had anal sex with your main partner in the last 3 months. How many times did you have anal sex with him when he was <u>not</u> wearing a condom?

____ times without a condom
998 Refuse to Answer

9. How many times did you perform oral sex on your main partner in the past 3 months?

_____ times oral l sex
998 Refuse to Answer

10**.** In the last 3 months, how many times did you perform oral sex on your main partner when he was <u>not</u> wearing a condom?

____ times without a condom
998 Refuse to Answer

11. In the last 3 months, did you have sex with your main partner to get money, drugs, or something else you needed like a place to stay?

1 Yes
0 No
8 Refused to Answer

12. What was your HIV status when you started having sex with your main partner? Were you HIV positive or HIV negative or did you not know your HIV status? (Choose One)

1 I was HIV Positive
2 I was HIV Negative → *SKIP TO Q14*
3 I didn't know my status → *SKIP TO Q14*

13**.** Did you tell your main partner that you were HIV positive before you had sex with him for the first time?

1 Yes→ *SKIP TO Q15*
0 No
8 Refused to Answer – *SKIP TO Q15*

14. Since then, have you told your main partner that you are HIV positive?

1 Yes
0 No
8 Refused to Answer

15. Has your main partner told you whether he is HIV+ or HIV- (Choose One)

01 My main partner is HIV Positive.
02 My main partner is HIV Negative.
03 My main partner does not know his HIV status.
04 My main partner has never told me about his HIV status.
08 Refused to Answer

16. In the last 3 months, did you talk to your main partner about safer sex or using condoms?

1 Yes
0 No→ *SKIP TO Q17-2*
8 Refused to Answer – *SKIP TO Q17-2*

17**.** In the last 3 months, did you ask your main partner to use a condom?

1 Yes
0 No
8 Refused to Answer

17-2. In the last 3 months, how often did you use alcohol or drugs before or during sex with your main partner? (Choose One)

1 Everytime
2 Most of the time
3 Sometimes
4 Almost never
5 Never
8 Refused to Answer

PARTNER OUTCOME EXPECTANCIES SCALE

READ: These next questions are about [MAIN PARTNER'S INITIAL]'s thoughts and feelings about using condoms. Please tell us how strongly you agree or disagree with the following statements.

18. I think that [MAIN PARTNER'S INITIAL] would be mad at me if I asked him to use condoms. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

19. I think [INITIAL] would be proud of me if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

20. I think that [INITIAL] would hit me if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

21. I think that [INITIAL] would break up with/**leave me** if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

22. I think that [INITIAL] would be supportive if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

23. I think that [INITIAL] would think I have other partners if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

24. I think that [INITIAL] would appreciate it if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

25**.** I think that [INITIAL] would be jealous if I asked him to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

SELF EFFICACY FOR SAFER VAGINAL SEX

READ: Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you can use a condom for vaginal sex with [MAIN PARTNER'S INITIAL], even if you have never been in that exact situation?

26**.** When you have vaginal sex with [MAIN PARTNER'S INITIAL], you can convince him to use a condom even if he does not want to. (Choose one)

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

27. When you have vaginal sex with [INITIAL], you can convince him to use a condom **absolutely every time** you have sex with him.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

28. When you have vaginal sex with [INITIAL], you can use a condom even if you both really want to feel close.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can

8	Refused to Answer

29. When you have vaginal sex with [INITIAL], you can use a condom even if you are making up after a fight.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

30. When you have vaginal sex with [INITIAL], you can use a condom even if he wants to have a baby.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

31. When you have vaginal sex with [INITIAL], you can use a condom even if he might lose his erection.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

32. When you have vaginal sex with [INITIAL], you can use a condom even if you have not used them before.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

33. When you have vaginal sex with [INITIAL], you can use a condom even if you are very turned on.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

34. When you have vaginal sex with [INITIAL], you can use a condom even if you have been high or drinking alcohol.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot

3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

CONDOM USE SELF-EFFICACY

The next questions are about how likely it is that you could do each of these following things with [MAIN PARTNER'S INITIAL], your main partner. Your choices are very unlikely, somewhat unlikely, somewhat likely, and very likely. How likely is it that:
(Choose One for each question)

	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	RF
35. You could think up a good way of talking about using condoms with [INITIAL]?	1	2	3	4	8
36. You could actually talk to [INITIAL] about using condoms?	1	2	3	4	8
37. You could get [INITIAL] to agree to use a condom?	1	2	3	4	8
38. If [INITIAL] said no, how likely is it that you could bring it up again?	1	2	3	4	8

PARTNER NORM MEASURE

READ: Please tell us how strongly do you agree or disagree with the following statements

39. My main partner thinks a condom should be used when we have vaginal sex. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refuse to Answer

40. When it comes to safer vaginal sex with my main partner, I want to do what he thinks I should do.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refuse to Answer

INDEX OF SPOUSE ABUSE SCALE

These next questions are about how [MAIN PARTNER'S INITIAL], your main partner may have treated you in the last 3 months. Please tell us how often each of the following happened. Your options are never, rarely, sometimes, frequently, and very frequently.

Your main partner…(Choose One for each question)

[DELETED N/A OPTION]

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
41.Belittled you (made fun of you)	1	2	3	4	5	8
42. Demanded obedience to his desire	1	2	3	4	5	8
43. Became angry if you tell him he is drinking too much.	1	2	3	4	5	8
44. Made you perform sex acts that you do not enjoy or like.	1	2	3	4	5	8
45. Became very upset if dinner, housework, or laundry was not done when he thought it should be.	1	2	3	4	5	8
46. Was jealous and suspicious of your friends.	1	2	3	4	5	8
47. Punched you with his fists.	1	2	3	4	5	8
48. Told you that you are ugly and unattractive.	1	2	3	4	5	8
49. Told you that you could not manage or take care of yourself without him.	1	2	3	4	5	8
50. Acted like you are his personal servant	1	2	3	4	5	8
51. Insulted or shamed you in front of others.	1	2	3	4	5	8

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
52. Became very angry if you disagreed with his point of view.	1	2	3	4	5	8
53. Threatened you with a weapon.	1	2	3	4	5	8
54. Was stingy in giving you enough money to run your home.	1	2	3	4	5	8
55. Belittled you intellectually.	1	2	3	4	5	8
56. Demanded that you stay at home to take care of the children.	1	2	3	4	5	8
57. Beat you so badly that you had to see a doctor.	1	2	3	4	5	8
58. Felt that you should not work or go to school.	1	2	3	4	5	8
59. Was not a kind person. (was an unkind person).	1	2	3	4	5	8
60. Did not want you to socialize with your female friends.	1	2	3	4	5	8
61. Demanded sex whether you wanted it or not.	1	2	3	4	5	8
62. Screamed or yelled at you.	1	2	3	4	5	8
63. Slapped you about the face and head.	1	2	3	4	5	8
64. Became abusive when he drank.	1	2	3	4	5	8
65. Ordered you around.	1	2	3	4	5	8
66. Had no respect	1	2	3	4	5	8

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
for your feelings.						
67. Acted like a bully towards you.	1	2	3	4	5	8
68. Frightened you.	1	2	3	4	5	8
69. Treated you like you are stupid	1	2	3	4	5	8
70. Acted like he would like to kill you.	1	2	3	4	5	8

Relationships Sexual Relationship Power Scale

Now I would like to ask you some more questions about your relationship with [MAIN PARTNER'S INITIAL], **your main** partner in the last 3 months. For each of the following statements, tell me whether you strongly agree, agree, disagree, or strongly disagree with it. (Choose One for each question)

	Strongly agree	Agree	Disagree	Strongly disagree	RF
71. Most of the time, you do what [MAIN PARTNER'S INITIAL] wants to do.	1	2	3	4	8
72. [INITIAL] will not let you wear certain things.	1	2	3	4	8
73. When you and [INITIAL] are together, you are pretty quiet.	1	2	3	4	8
74. [INITIAL] has more say than you do about important decisions that affect both of you.	1	2	3	4	8
75. [INITIAL] tells you who you can spend time with.	1	2	3	4	8
76. You feel trapped or stuck in your relationship	1	2	3	4	8
77. [INITIAL] does what he wants, even if you do not want him to.	1	2	3	4	8
78. You are more committed to your relationship than [INITIAL] is.	1	2	3	4	8
79. When you and [INITIAL] disagree, he gets his way most of the time.	1	2	3	4	8

80. [INITIAL] gets more out of your relationship than you do.	1	2	3	4	8
81. [INITIAL] always wants to know where you are.	1	2	3	4	8
82. [INITIAL] may be having sex with someone else	1	2	3	4	8

For each of the following statements, please tell me who made these decisions in your relationship with [MAIN PARTNER'S INITIAL], your main partner in the last 3 months. Your choices are your main partner, both of you equally, or you. (Choose One for each question)

	Your main partner	Both of you equally	You	RF
83. Who usually had more say about whose friends you went out with?	1	2	3	8
84. Who usually had more say about whether you had sex?	1	2	3	8
85. Who usually had more say about what you did together?	1	2	3	8
86. Who usually had more say about how often you saw each other?	1	2	3	8
87. Who usually had more say about when you talked about serious things?	1	2	3	8
88. In general, who do you think had more power in your relationship?	1	2	3	8
89. Who usually had more say about whether you used condoms?	1	2	3	8
90. Who usually had more say about what types of sex you had?	1	2	3	8

SEX WITH **OTHER** PARTNERS. - (All Respondents)

1-a. The next questions are about **other** sex partners, that is partners other than [MAIN PARTNER'S INITIAL] that you already told me about. In the last 3 months, did you have sex with anyone other than [INITIAL]?

1 Yes
0 No→*SKIP TO HEDONISTIC OUTCOME EXPECTANCIES* page 57 Q9

IF MAIN PARTNER WAS NOT REPORTED BUT PARTICIPANT REPORTED HAVING SEX
1-b. You told me that you had sex in the last 3 months but did not have a main partner. This means that you had sex with partners other than a main partner in the last 3 months. If this is correct please click on the "YES" button. If this is not correct please click on the "NO" button.

YES – GO TO Q2
NO – GO BACK TO Q1 ON PAGE 22

The next questions are about your other sex partners you had in the last 3 months.

2. How many of these other partners were male?

_____

2-2. How many of these other partners were female?

_____

[CREATE A LOGIC CHECK Q2+Q2-2>0]

ASK IF Q2 (# OF OTHER MALE PARTNERS) >0
3. Earlier you told me that you had __ other male partners in the last 3 months. How many of these partners were HIV positive? If you don't know their HIV status, please enter 0. ___

4. How many of your other male partners were HIV negative? If you don't know their HIV status, please enter 0. ___

Q2 MIUUS Q3 MINUS Q4 = Q5 [INSERT THE NUMBER BELOW]

5. This means that you had __ other male partners whose HIV status was unknown. If this is not correct please go back to the previous questions and change your answers.

IF Q3 (# OF HIV+ OTHER MALE PARTNERS)>0
6-1. You told me that you had __ other partners who were HIV positive in the last 3 months. In the last 3 months, did you have vaginal sex with these __ HIV positive other partners?

1 Yes
0 No – *SKIP TO 6-4*
8 Refused to Answer – *SKIP TO 6-4*

6-2. How many times did you have vaginal sex with HIV positive other partners in the last 3 months?

____ times vaginal sex
998 Refuse to Answer

6-3. Think about all of the times you had vaginal sex with these __ HIV positive other partners in the last 3 months. How many times did you have vaginal sex when they were not wearing a condom?

_ ___ times without a condom
998 Refuse to Answer

6-4. In the last 3 months, did you have anal sex with these __ HIV positive other partners? By anal sex we mean that he put his penis in your rectum or butt.

1 Yes
0 No – *SKIP TO 6-7*
8 Refused to Answer – *SKIP TO 6-7*

6-5. How many times did you have anal sex with HIV positive other partners in the last 3 months?

____ times anal sex
998 Refuse to Answer

6-6. Think about all of the times you had anal sex with these __ HIV positive other partners in the last 3 months. How many times did you have anal sex when they were not wearing a condom?

____ times without a condom
998 Refuse to Answer

6-7. In the last 3 months, did you have oral sex with these __ HIV positive other partners? By oral sex we mean when he put at least the head of his penis in your mouth.

1 Yes
0 No – *SKIP TO 6-10*
8 Refused to Answer – *SKIP TO 6-10*

6-8. How many times did you have oral sex with HIV positive other partners in the last 3 months?

____ times oral sex
998 Refuse to Answer

6-9. Think about all of the times you had oral sex with these __ HIV positive other partners in the last 3 months. How many times did you have oral sex when they were not wearing a condom?

6-10. In the last 3 months, did you have sex with any of the ___ HIV positive other partners to get money, drugs, or something else you needed like a place to stay?

1 Yes
0 No
8 Refused to Answer

6-11. Have you told these ___ HIV positive other partners that you are HIV positive? (new question) (Choose One)

1 I told none of them that I am HIV positive
2 I told some of them that I am HIV positive
3 I told all of them that I am HIV positive
8 Refused to Answer

6-12. In the past 3 months, how often did you use alcohol or drugs before or during sex with these ___ HIV positive other partners? (new question from INSPIRE) (Choose One)

1 Everytime
2 Most of the time
3 Sometimes
4 Almost never
5 Never
8 Refused to Answer

PARTNER OUTCOME EXPECTANCIES SCALE

READ: These next questions ask your opinion about what your ___ HIV positive other partners' thoughts and feelings about using condoms. Please tell us how strongly you agree or disagree with the following statements.

6-13. I think that my ___ HIV positive other **partner**(s) would be mad at me if I asked **them** to use condoms. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-14. I think that my ___ HIV positive other partner(s) would be proud of me if I asked **them** to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-15. I think that my ___ HIV positive other partner(s) would hit me if I asked **them** to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-16. I think that my ___ HIV positive other partners would break up with me if I asked **them** to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-17. I think that my ___ HIV positive other partners would be supportive if I asked **them** to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-18. I think that my ___ HIV positive other partners would think I have other partners if I asked **them** to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-19. I think that my ___ HIV positive other partners would appreciate it if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6-20. I think that my ___ HIV positive other partners would be jealous if I asked them to use condoms.

1	Strongly disagree
2	Disagree

3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

SELF EFFICACY FOR SAFER VAGINAL SEX

READ: Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you can use a condom for vaginal sex with your ___ HIV positive other partners, even if you have never been in that exact situation?

6-21. When you have vaginal sex with the __ HIV positive other partners, you can convince them to use a condom even if they do not want to. (Choose one)

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

6-22. When you have vaginal sex with the __ HIV positive other partners, you can convince them to use a condom absolutely every time you have sex with them.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

6-23. When you have vaginal sex with the __ HIV positive other partners, you can use a condom even if they might lose his erection.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

6-24. When you have vaginal sex with the __ HIV positive other partners, you can use a condom even if you have not used them before.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

6-25. When you have vaginal sex with the __ HIV positive other partners, you can use a condom even if you are very turned on.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

6-26. When you have vaginal sex with the __ HIV positive other partners, you can use a condom even if you have been high or drinking alcohol.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

CONDOM USE SELF-EFFICACY

Now I am going to ask you about how likely it is that you could do each of these following things with your ___ HIV positive other partners. Your choices are very unlikely, somewhat unlikely, somewhat likely, and very likely. How likely is it that: (Choose One for each question)

	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	RF
6-30. You could think up a good way of talking about using condoms with your HIV positive other partners?	1	2	3	4	8
6-31.You could actually talk to your HIV positive other partners about using condoms?	1	2	3	4	8

6-32.You could get your HIV positive other partners to agree to use a condom?	1	2	3	4	8
6-33.If your HIV positive other partners said no, how likely is it that you could bring it up again?	1	2	3	4	8

PARTNER NORM MEASURE

READ: Please tell us how strongly do you agree or disagree with the following statements

6-34. Most of my ___ HIV positive other partners think a condom should be used when we have vaginal sex. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

6.35. When it comes to safer vaginal sex with these __ HIV positive other partners, I want to do what they think I should do.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

INDEX OF SPOUSE ABUSE SCALE

These next questions are about how your HIV positive other partners may have treated you in the last 6 months. Please tell me how often each of the following happened. Your options are never, rarely, sometimes, frequently, and very frequently.
Your HIV positive other partners…(Choose One for each question)

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
6-36. Made you perform sex acts that you do not enjoy or like.	1	2	3	4	5	8

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
6-37Punched you with his fists.	1	2	3	4	5	8
6-38Told you that you are ugly and unattractive.	1	2	3	4	5	8
6-39Threatened you with a weapon.	1	2	3	4	5	8
6-40Beat you so badly that you had to see a doctor.	1	2	3	4	5	8
6-41Was not a kind person. (was an unkind person).	1	2	3	4	5	8
6-42Demanded sex whether you wanted it or not.	1	2	3	4	5	8
6-43Screamed or yelled at you.	1	2	3	4	5	8
6-44. Slapped you about the face and head.	1	2	3	4	5	8
6-45Became abusive when he drank.	1	2	3	4	5	8
6-46Acted like a bully towards you.	1	2	3	4	5	8
6-47Frightened you.	1	2	3	4	5	8
6-48Acted like he would like to kill you.	1	2	3	4	5	8

IF PAGE 22 Q4= 0 GO TO INSTRUCTION BEFORE PAGE 49 Q8-1
IF PAGE 22 Q4 (# OF HIV-NEGATIVE OTHER MALE PARTNERS)>0 ASK

7-1. You told me that you had __ other partners who were HIV negative in the last 3 months. In the last 3 months, did you have vaginal sex with these __ HIV negative other partners?

1 Yes
0 No – *SKIP TO 7-4*
8 Refused to Answer – *SKIP TO 7-4*

7-2. How many times did you have vaginal sex with HIV negative other partners in the last 3 months?

____ times vaginal sex
998 Refuse to Answer

7-3. Think about all of the times you had vaginal sex with these __ HIV negative other partners in the last 3 months. How many times did you have vaginal sex when they were not wearing a condom?

____ times without a condom
998 Refuse to Answer

7-4. In the last 3 months, did you have anal sex with these __ HIV negative other partners? By anal sex we mean that a man put his penis in your rectum or butt.

1 Yes
0 No – *SKIP TO 7-7*
8 Refused to Answer – *SKIP TO 7-7*

7-5. How many times did you have anal sex with HIV negative other partners in the last 3 months?

____ times vaginal sex
998 Refuse to Answer

7-6. Think about all of the times you had anal sex with these __ HIV negative other partners in the last 3 months. How many times did you have anal sex when they were not wearing a condom?

____ times without a condom
998 Refuse to Answer

7-7. In the last 3 months, did you have oral sex with these __ HIV negative other partners? By oral sex we mean when he put at least the head of his penis in your mouth.

1 Yes
0 No – *SKIP TO 7-10*
8 Refused to Answer – *SKIP TO 7-10*

6-2. How many times did you have oral sex with HIV negative other partners in the last 3 months? -

____ times vaginal sex
998 Refuse to Answer

7-9. Think about all of the times you had oral sex with these __ HIV negative other partners in the last 3 months. How many times did you have oral sex when they were not wearing a condom?

____ times without a condom
998 Refuse to Answer

7-10. In the last 3 months, did you have sex with any of the ___ HIV negative other partners to get money, drugs, or something else you needed like a place to stay?

1 Yes
0 No

8 Refused to Answer

7-11. Have you told these ___ HIV negative other partners that you are HIV positive? (Choose One)

1 I told none of them that I am HIV positive
2 I told some of them that I am HIV positive
3 I told all of them that I am HIV positive
8 Refused to Answer

7-12. In the past 90days, how often did you use alcohol or drugs before or during sex with these ___ HIV negative other partners? (Choose One)

1 Everytime
2 Most of the time
3 Sometimes
4 Almost never
5 Never
8 Refused to Answer

PARTNER OUTCOME EXPECTANCIES SCALE

READ: These next questions ask your opinion about what your ___ HIV negative other partners' thoughts and feelings about using condoms. Please tell us how strongly you agree or disagree with the following statements.

7-13. I think that my ___ HIV negative other partners would be mad at me if I asked them to use condoms. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-14. I think that my ___ HIV negative other partners would be proud of me if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-15. I think that my ___ HIV negative other partners would hit me if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-16. I think that my ___ HIV negative other partners would break up with me if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-17. I think that my ___ HIV negative other partners would be supportive if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-18. I think that my ___ HIV negative other partners would think I have other partners if I asked them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-19. I think that my ___ HIV negative other partners would appreciate it if I them to use condoms.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-20. I think that my ___ HIV negative other partners would be jealous if I asked them to use condoms.

1	Strongly disagree
2	Disagree

3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

SELF EFFICACY FOR SAFER VAGINAL SEX

READ: Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you can use a condom for vaginal sex with your ___ HIV negative other partners, even if you have never been in that exact situation?

7-21. When you have vaginal sex with the __ HIV positive other partners, you can convince them to use a condom even if they do not want to. (Choose one)

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

7-22. When you have vaginal sex with the HIV negative other partners, you can convince them to use a condom absolutely **every time** you have sex with them.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

7-23. When you have vaginal sex with the __ HIV negative other partners, you can use a condom even if they might lose their erection.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

7-24. When you have vaginal sex with the __ HIV negative other partners, you can use a condom even if you have not used them before.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

7-25. When you have vaginal sex with the __ HIV negative other partners, you can use a condom even if you are very turned on.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

7-26. When you have vaginal sex with the __ HIV negative other partners, you can use a condom even if you have been high or drinking alcohol.

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

CONDOM USE SELF-EFFICACY

Now I am going to ask you about how likely it is that you could do each of these following things with your ___ HIV negative other partners. Your choices are very unlikely, somewhat unlikely, somewhat likely, and very likely. How likely is it that: (Choose One for each question)

	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	RF
7-30. You could think up a good way of talking about using condoms with your HIV negative other partners?	1	2	3	4	8
7-31.You could actually talk to your HIV negative other partners about using condoms?	1	2	3	4	8

7-32.You could get your HIV negative other partners to agree to use a condom?	1	2	3	4	8
7-33.If your HIV negative other partners said no, how likely is it that you could bring it up again?	1	2	3	4	8

PARTNER NORM MEASURE

READ: Please tell us how strongly do you agree or disagree with the following statements

7-34. Most of my ___ HIV negative other partners think a condom should be used when we have vaginal sex. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

7-35. When it comes to safer vaginal sex with these __ HIV negative other partners, I want to do what they think I should do.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refused to Answer

INDEX OF SPOUSE ABUSE SCALE – ADAPTED

These next questions are about how your HIV negative other partners may have treated you in the last 3 months. Please tell me how often each of the following happened. Your options are never, rarely, sometimes, frequently, and very frequently.

Your HIV negative other partners…(Choose One for each question)

[DELETED N/A OPTION]

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
7-36. Made you perform sex acts that you do not enjoy or like.	1	2	3	4	5	8
7-37 Punched you with his fists.	1	2	3	4	5	8
7-38 Told you that you are ugly and unattractive.	1	2	3	4	5	8
7-39 Threatened you with a weapon.	1	2	3	4	5	8
7-40 Beat you so	1	2	3	4	5	8

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
badly that you had to see a doctor.						
7-41 Was not a kind person. (was an unkind person).	1	2	3	4	5	8
7-42 Demanded sex whether you wanted it or not.	1	2	3	4	5	8
7-43. Screamed or yelled at you.	1	2	3	4	5	8
7-44. Slapped you about the face and head.	1	2	3	4	5	8
7-45 Became abusive when he drank.	1	2	3	4	5	8
7-46 Acted like a bully towards you.	1	2	3	4	5	8
7-47 Frightened you.	1	2	3	4	5	8
7-48 Acted like he would like to kill you.	1	2	3	4	5	8

IF PAGE 34 Q5=0 GO TO HEDONISTIC ON PAGE 50 Q9
IF Q5 (# OF UNKNOWN STATUS OTHER MALE PARTNERS)>0 ASK

8-1. You told me that you had __ other partners whose HIV status was unknown in the last 3 months. We will call them "unknown status other partners." In the last 3 months, did you have vaginal sex with these __ unknown status partners?

1 Yes
0 No – *SKIP TO 8-4*
8 Refused to Answer – *SKIP TO 8-4*

8-2. How many times did you have vaginal sex with unknown status other partners in the last 3 months?

____ times vaginal sex
998 Refuse to Answer

8-3. Think about all of the times you had vaginal sex with these __ unknown status other partners in the last 3 months. How many times did you have vaginal sex when they were not wearing a condom?

8-4. In the last 3 months, did you have anal sex with these __ unknown status other partners? By anal sex we mean that a man put his penis in your rectum or butt.

1 Yes
0 No – *SKIP TO 8-7*

8 Refused to Answer – *SKIP TO 8-7*

8-5. How many times did you have anal sex with unknown status other partners in the last 3 months?

____ times anal sex
998 Refuse to Answer

8-6. Think about all of the times you had anal sex with these __ unknown status other partners in the last 3 months. How many times did you have anal sex when they were not wearing a condom?

8-7. In the last 3 months, did you have oral sex with these __ unknown status other partners? By oral sex we mean when a man put at least the head of his penis in your mouth.

1 Yes
0 No – *SKIP TO 8-10*
8 Refused to Answer – *SKIP TO 8-10*

8-8. How many times did you have oral sex with unknown status other partners in the last 3 months?

____ times oral sex
998 Refuse to Answer

8-9. Think about all of the times you had oral sex with these __ unknown status other partners in the last 3 months. How many times did you have oral sex when they were not wearing a condom?

8-10. In the last 3 months, did you have sex with any of the ___ unknown status other partners to get money, drugs, or something else you needed like a place to stay?

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0 No
8 Refused to Answer

8-11. Have you told these ___ unknown status other partners that you are HIV positive? (Choose One)

1 I told none of them that I am HIV positive
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8-12. In the past 90days, how often did you use alcohol or drugs before or during sex with these ___ unknown status other partners? (Choose One)

1 Everytime
2 Most of the time
3 Sometimes
4 Almost never
5 Never

8 Refused to Answer

PARTNER OUTCOME EXPECTANCIES SCALE

READ: These next questions ask your opinion about what your ___ unknown status other partners' thoughts and feelings about using condoms. Please tell us how strongly you agree or disagree with the following statements.

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8-14. I think that my ___ unknown status other partners would be proud of me if I asked them to use condoms.

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8-15. I think that my ___ unknown status other partners would hit me if I asked them to use condoms.

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SELF EFFICACY FOR SAFER VAGINAL SEX FROM INSPIRE

READ: Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you can use a condom for vaginal sex with your ___ unknown status other partners, even if you have never been in that exact situation?

8-21. When you have vaginal sex with the __ unknown status other partners, you can convince them to use a condom even if they do not want to. (Choose one)

1	Absolutely Sure I Cannot
2	Pretty Sure I Cannot
3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

8-22. When you have vaginal sex with the __ unknown status other partners, you can convince them to use a condom absolutely every time you have sex with them.

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4	Pretty Sure I Can
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4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

8-25. When you have vaginal sex with the __ unknown status other partners, you can use a condom even if you are very turned on.

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3	Not Sure
4	Pretty Sure I Can
5	Absolutely Sure I Can
8	Refused to Answer

8-26. When you have vaginal sex with the __ unknown status other partners, you can use a condom even if you have been high or drinking alcohol.

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CONDOM USE SELF-EFFICACY

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	Very unlikely	Somewhat unlikely	Somewhat likely	Very likely	RF
8-30. You could think up a good way of talking about using condoms with your unknown status other partners?	1	2	3	4	8
8-31.You could actually talk to your unknown status other partners about using condoms?	1	2	3	4	8
8-32.You could get your unknown status other partners to agree to use a condom?	1	2	3	4	8
8-33.If your unknown status other partners said no, how likely is it that you could bring it up again?	1	2	3	4	8

PARTNER NORMS

READ: Please tell us how strongly do you agree or disagree with the following statements

8-34. Most of my ___ unknown status other partners think a condom should be used when we have vaginal sex. (Choose one)

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refuse to Answer

8-35. When it comes to safer vaginal sex with these __ unknown status other partners, I want to do what they think I should do.

1	Strongly disagree
2	Disagree
3	Neither disagree nor agree
4	Agree
5	Strongly agree
8	Refuse to Answer

INDEX OF SPOUSE ABUSE SCALE

These next questions are about how your unknown status other partners may have treated you in the last 6 months. Please tell me how often each of the following happened. Your options are never, rarely, sometimes, frequently, and very frequently.
Your unknown status other partners…(Choose One for each question)

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
8-36. Made you perform sex acts that you do not enjoy or like.	1	2	3	4	5	8
8-37Punched you with his fists.	1	2	3	4	5	8
8-38Told you that you are ugly and unattractive.	1	2	3	4	5	8
8-39Threatened you with a weapon.	1	2	3	4	5	8
8-40Beat you so badly that you had to see a doctor.	1	2	3	4	5	8

	Never	Rarely	Sometimes	Frequently	Very Frequently	RF
8-41Was not a kind person. (was an unkind person).	1	2	3	4	5	8
8-42Demanded sex whether you wanted it or not.	1	2	3	4	5	8
8-43. Screamed or yelled at you.	1	2	3	4	5	8
8-44. Slapped you about the face and head.	1	2	3	4	5	8
8-45Became abusive when he drank.	1	2	3	4	5	8
8-46Acted like a bully towards you.	1	2	3	4	5	8
8-47Frightened you.	1	2	3	4	5	8
8-48Acted like he would like to kill you.	1	2	3	4	5	8

HEDONISTIC OUTCOME EXPECTANCIES SCALE
ASK EVERYONE

READ: The next several statements are about how you might feel about condoms. For each item, please indicate how much you agree or disagree with the statement.

9. Condoms ruin the mood. (Choose one)

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

10. Sex doesn't feel as good when you use a condom.

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

11. Sex with condoms doesn't feel natural.

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

12. Using condoms breaks up the rhythm of sex.

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

13. Condoms can make my partner lose his hard on.

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

14. Condoms rub and cause irritation

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

15. Condoms cost too much

1 Strongly disagree
2 Disagree
3 Neither disagree nor agree
4 Agree
5 Strongly agree
8 Refused to Answer

READ: The next several statements are about getting condoms.

15. Do you know where to get condoms in your community?

1 Yes
0 No
8 Refused to Answer

16. Do you have problems getting transportation to go and buy or get condoms?

1 Yes
0 No
8 Refused to Answer

SELF EVALUATIVE OUTCOME EXPECTANCIES SCALE

READ: The next several statements are about how you might feel in certain situations when having sex with someone whose HIV status is unknown or who you know is HIV negative. For each item, please indicate how much you agree or disagree with the statement. If a question does not apply to you,think about how you would feel if you were in that situation.

17. If I had sex without a condom with an HIV negative or unknown status partner, I would regret it or feel guilty the next day. (Choose one)

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

18. I would feel good about myself if I had safer sex with an HIV negative or unknown status partner.

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

19. I would feel good about myself if I used a condom with an HIV negative or unknown status partner.

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

20. Having sex with an HIV negative or unknown status partner without a condom would make me feel bad about myself.

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

21. I would be pretty hard on myself if I had unsafe sex with an HIV negative or unknown status partner.

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

22. If I had unsafe sex with an HIV negative or unknown status partner, I would not feel bad about it.

1 Strongly Disagree
2 Disagree
3 Neither Disagree or Agree
4 Agree
5 Strongly Agree
8 Refused to Answer

KNOWLEDGE QUESTIONS

READ: Please tell us if the following statements are true or false. If you don't know the answer, please enter unsure.

23. Once you have H.I.V., you cannot get infected with another strain of H.I.V. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

24. Anal sex and vaginal sex are riskier than oral sex for transmitting H.I.V. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

25. An H.I.V. positive person only needs to go to the doctor when they feel bad. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

26. It is possible to transmit H.I.V. through oral sex. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

27. H.I.V. is cured when the viral load test comes back undetectable. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

28. Becoming infected with another sexually transmitted disease can cause an HIV positive person to get sick quicker

1 True
2 False
3 Unsure
8 Refuse to Answer

29. Using a latex condom is highly effective in reducing the risk of transmitting H.I.V. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

30. It is important to take your H.I.V. medications the way your provider says you should. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

31. If an H.I.V. positive person has another sexually transmitted disease, it is easier for them to transmit H.I.V. to others. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

32. Regular medical care is important for anyone who is H.I.V. positive. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

33. If you keep missing doses of your H.I.V. medicines, the virus can become resistant to the medicines. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

34. Once you have H.I.V., getting other sexually transmitted diseases cannot hurt you. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

35. When lab tests tell you the virus is undetectable then you can stop taking your medications. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

36. If your CD4 or T cell count goes up, your immune system is getting stronger. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

37. You can still transmit H.I.V. even when your viral load is undetectable. (Choose one)

1 True
2 False
3 Unsure
8 Refuse to Answer

38. Have you ever used a female condom?

1 Yes
0 No –SKIP TO Q42
8 Refused to Answer – SKIP TO Q42

IF YES

39. How easy was it for you to use a female condom? (Choose One)

1 Very easy
2 Easy
3 Difficult
4 Very difficult
8 Refused to Answer

40. Would you use a female condom again?

1 Yes
0 No
8 Refuse to answer

41. Would you recommend that other women use a female condom?

1 Yes
0 No
8 Refuse to answer

42. Have you ever put a condom on a man's penis?

1 Yes
0 No –SKIP TO Q1
8 Refused to answer – SKIP TO Q1

43. How easy was it to put a condom on a man's penis? (Choose One)

1 Very easy
2 Easy
3 Difficult
4 Very difficult
8 Refused to Answer

44. Have you ever put a condom on a man's penis using your mouth?

1 Yes
0 No – SKIP TO Q41
8 Refused to Answer – SKIP TO Q41

IF YES

45. How easy was it for you to put a condom on a man's penis using your mouth? (Choose One)

1 Very easy
2 Easy
3 Difficult
4 Very difficult
8 Refused to Answer

That concludes this section of the questionnaire. Please let your interviewer know that you are finished with this section.

[AUDIO-CASI SECTION OF THE ASSESSMENT IS COMPLETE. REMAINDER OF INTERVIEW IS INTERVIEWER-ADMINISTERED VIA CAPI.]

DEMOGRAPHICS, PART 2

The next few questions are about any work you may have done for money.

1. What best describes your current employment status? (Choose One)

1 Employed full-time
2 Employed part-time
3 Unemployed
08 Refuse to Answer

2. I am going to read you a list of various ways people bring in money or get support for living expenses. For each item, please tell me if it has been a source of money or support for you at any time in the last 3 months.

Was this a source of money or support for you at any time in the last 3 months?	Yes	No	RF
A. Income from a regular full or part-time job	1	0	8
B. Money from occasional work	1	0	8
C. Money from activities that could get you arrested (e.g., commercial sex work, selling illegal drug)	1	0	8
D. Public assistance (e.g., Social Security Disability Income or SSDI, Food Stamps, welfare payments)	1	0	8
E. Other	1	0	8

2-2. If Other, please specify (Record answer verbatim)_____

3. Over the last 30 days, that is, since (REFERENCE DATE) what was your total household income from all sources mentioned in the previous questions?

(READ IF NECESSARY): By household income we mean any money that you made over the last 30 days, plus any money that anyone else made who has lived with you over the last 30 days.) (Choose One)

1 Less than $500
2 $500-$999
3 $1000-$1499

4 $1500-$1999
5 $2000 and above
8 Refuse to Answer

4. Do you currently have health insurance coverage? This includes Medicaid or Medicare?

1 Yes
2 No
98 Refuse to Answer

5. What kind of health insurance do you currently have, if any? (Choose all that apply)

1 Private Insurance
2 Medicaid
3 Medicare
4 ADAP/ADAP+
5 Other public insurance
6 None
8 Refused to Answer

Next, I would like to ask you a few questions about your incarceration history. Remember, that all of your answers will be kept strictly confidential and protected, and that you can skip any question you do not want to answer.

6. Have you ever spent at least one night in jail or prison?

1 Yes
0 No→ *SKIP TO Q1*
8 Refused to Answer – *SKIP TO Q1*

7. In the last 3 months, how much time were you in jail or prison? *(R can answer in DAYS, WEEKS, or MONTHS, but answer cannot exceed equivalent to 90 days, and answer cannot be in YEARS.)*

Number of Days/Weeks/Months

___ ___ Days
___ ___Weeks
___ ___Months
98 Refused to Answer

MEDICAL SERVICES AND ADHERENCE TO MEDICATIONS

Next are some questions about different services you may have received.

1. Where do you usually go to get medical care? (Choose One)

01	No regular source of care →*SKIP TO Q7*
02	Emergency Room/Department →*SKIP TO Q6*
03	Urgent Care Clinic
04	Health Department Clinic
05	Hospital Clinic
06	Private Physician's Office
07	Other
08	Refused to Answer

IF Q1=7, ASK:

Other *(specify)* _____

2. Where do you usually go to get HIV medical care? (Choose One)

01	No regular source of care →*SKIP TO Q7*
02	Emergency Room →*SKIP TO Q6*
03	Urgent Care Clinic
04	Health Department Clinic
05	Hospital Clinic
06	Private Physician's Office
07	Other
08	Refused to Answer

IF Q1=7, ASK:

Other *(specify)* _____

IF Q1=3-7, ASK

3. How long have you been receiving HIV medical care at this place?

Number of Weeks/Months/Years

___ ___	Weeks
___ ___	Months
___ ___	Years
98	Refused to Answer

IF Q=3-7, ASK:

4. In the last 3 months, that is since (*CALCULATE DATE*), did you miss any HIV medical appointments that were scheduled for you?

Yes	
00	No
02	Not relevant, no medical appointments were scheduled
08	Refused to Answer

Now I'd like to ask you a couple of questions about how you get from place to place.-
IF Q1 =3-7, ASK:

5. How do you usually get to your doctor for HIV medical care? (Choose One)

01 Drive my own car
02 Drive some one else's car
03 Friend or family member drives me
04 A cab or car service I pay for
05 A van, cab or car service that is free to me
06 Public transportation like a bus
07 Walk
08 Other
98 Refused to Answer

If Q5= 8, ASK:
Other *(*specify*)* _____

IF Q=2-7 ASK
6. How long does it take you to get to your doctor or to the place where you usually go to get HIV medical care?

___ ___ Minutes
___ ___ Hours
98 Refused to Answer

ASK EVERYONE
7. Have you ever taken medication for depression?

1 Yes
0 No – *SKIP TO Q9*
8 Refused to Answer – *SKIP TO Q9*

8. In the last 3 months, did you take medication for depression?

1 Yes
0 No
8 Refused to Answer

This next section of the interview is about medications.
ASK EVERYONE:
9. Have you <u>ever</u> taken HIV medications?

1 Yes
0 No → *SKIP TO Q13*
8 Refused to Answer – *SKIP TO Q13*

IF Q9 =1, ASK:
10. Are you <u>currently</u> taking any HIV medications?

1 Yes
0 No→ *SKIP TO Q21*
8 Refused to Answer – *SKIP TO Q26*

11. How long have you been taking HIV medications?

___ ___Weeks
___ ___ Months
___ ___ Years
98 Refused to Answer

12. Who helps you pay for your prescription drugs? (Choose All that Apply)

1. Medicaid
2. Private Insurance
3. ADAP (including Ryan White funds)
4. Clinical Trials
5. Medicare
6. Other
7. No one [CREATE A LOGIC CHECK] – *SKIP TO Q24*
8. Refused to Answer – *SKIP TO Q24*

ASK EVERONE

13. The next set of questions ask how you feel about taking HIV medications whether or not you have ever taken HIV medications in the past. I would like to know how you feel about taking HIV medications. Please indicate how strongly you agree or disagree with the following statements.

13-1. The side effects of HIV medicines are not as bad as people think.

01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
04 Agree
05 Strongly Agree
08 Refused to Answer

13-2. Taking HIV medicines makes people sicker.

01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
04 Agree
05 Strongly Agree
08 Refused to Answer

13-3. The side effects of HIV medicines are worse than not taking them.

01 Strongly Disagree

2 Disagree
3 Neither agree nor disagree
4 Agree
5 Strongly Agree
08 Refused to Answer

13-4. People who take HIV medicines are taking good care of themselves.
01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
4 Agree
5 Strongly Agree
08 Refused to Answer

13-5. People who take HIV medications feel better when they stop taking them.
01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
4 Agree
05 Strongly Agree
08 Refused to Answer

13-6. Taking HIV medicines could mean that people will find out that a person has HIV.
01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
4 Agree
5 Strongly Agree
08 Refused to Answer

13-7. I believe that my health will be better if I take HIV medicines.
01 Strongly Disagree
2 Disagree
3 Neither agree nor disagree
4 Agree
5 Strongly Agree
08 Refused to Answer

13-8.Taking HIV medications makes people feel better in the long run.
01 Strongly Disagree
02 Disagree
3 Neither agree nor disagree
4 Agree
05 Strongly Agree
08 Refused to Answer

14. During the last 3 months, has any case manager, social service agency or paid provider worked with you in any of the following ways?

	Yes	No	RF
A. Developing or revising a plan for dealing with your needs?	1	0	8
B. Helping you get or refer you to specific medical services?	1	0	8
C. Helping you to get HIV medications or to pay for HIV medications?	1	0	8
D. Helping you get or refer you to specific social services such as housing, meal program, transportation services?	1	0	8
E. Escorting you or going with you to your medical appointments?	1	0	8
F. Periodically checking on how you are doing or asking whether you are getting the services you need?	1	0	8
G. Filling out forms for benefits?	1	0	8
H. Talking with you or giving you advice about your personal life or problems you are having?	1	0	8
I. Talking to you or giving you advice about drug or alcohol use?	1	0	8
J. Talking to you or giving you advice about practicing safer sex?	1	0	8
K. Talking to you or giving you advice about taking your HIV/AIDS medication?	1	0	8
Talking to you or giving you advice about domestic violence assistance?	1	0	8
Talking to you, giving you advice or referring you to mental health, emotional or psychological services?	1	0	8
Talking to you or giving you advice about partner notification?	1	0	8

15. Here are some questions about different types of problems people sometimes have in getting medical care.

ASK EVERYONE:

At any time in the last 3 months, that is since (*CALCULATE DATE*), did you delay or not get the medical assistance you thought you needed because…	Yes	No	RF
A. It cost too much or it wasn't covered by insurance?	1	0	8
B. You were concerned that your HIV status might be disclosed?	1	0	8
C. The staff at the office or clinic were not competent to deal with your problem?	1	0	8
D. You didn't know or weren't sure where to go?	1	0	8
E. You had transportation problems and it was difficult to get to the clinic or agency?	1	0	8
F. The staff at the office or clinic were often not polite, were disrespectful, or were insensitive to your needs?	1	0	8
G. You weren't sure that the staff at the office or clinic would understand your problems?	1	0	8
H. The staff did not listen to your problems or needs?	1	0	8
I. You had childcare problems or you needed someone to take care of your children?	1	0	8
J. You were nervous or afraid of what the doctor or service provider might say?	1	0	8
K. It takes too long to get an appointment or to see someone who might help you?	1	0	8

16. In the past year, are they any HIV programs or classes or groups that you have attended?

Yes 1
No 0
Refused to Answer 8

17. IF YES, what is the name of the program? _____

That was the last question in the interview. Now I'd like to ask you a question that you can answer any way you like.

18. If you could change one thing about help that is or is not available to persons living with HIV what would that be?

_____

_____

Attitudes toward A-CASI Questions (Use at 3month Follow-up Assessment Interview ONLY)

In this survey, you answered some questions asked by a person and other questions asked by a computer. The following questions ask you about your experience with using the computer for this survey. Please indicate how much you agree or disagree with each of the following statements.

I felt comfortable using the computer. (Choose one)

1 Strongly disagree

2 Disagree

3 Neither disagree nor agree

4 Agree

5 Strongly agree

8 Refuse to Answer

I prefer to do the survey with a person rather than a computer. (Choose one)

1 Strongly disagree

2 Disagree

3 Neither disagree nor agree

4 Agree

5 Strongly agree

8 Refuse to Answer

Overall, I could not understand the questions I heard on the computer. (Choose one)

1 Strongly disagree

2 Disagree

3 Neither disagree nor agree

4 Agree

5 Strongly agree

8 Refuse to Answer

Compared to an interview with a person, the computer made it harder for me to be open and honest about my sexual and drug using behavior. (Choose one)

1 Strongly disagree

2 Disagree

3 Neither disagree nor agree

4 Agree

5 Strongly agree

8 Refuse to Answer

How much computer experience did you have before you participated in this study? (Choose one)

1 None

2 Some

3 A lot

8 Refuse to Answer

130

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 7b

Consent-In-depth Interview

Consent Form In-depth Interview

University of North Carolina, Chapel Hill
School of Nursing
CONSENT TO PARTICIPATE IN A RESEARCH PROGRAM
SISTER TO SISTER POSITIVE HOPE PROJECT
STUDY
University of North Carolina-Chapel Hill
Sister-to-Sister Positive HOPE
Informed Consent Form

IRB Study #: 07-1016
Consent Form Version Date: 1-06-08
Title of Study: Reducing Sexual Risk in Southern HIV-Positive Women

Principal Investigator: Catherine Ingram Fogel, PhD, RNC, FAAN
UNC-Chapel Hill Department: Nursing
UNC-Chapel Hill Phone number: 966-3590 or 966-3119
Email Address: cfogel@email.unc.edu

University of North Carolina-Chapel Hill
David Wohl, MD Co-Investigator
Mark Weaver, PhD, Co-Investigator
Margarete Sandelowski, PhD, RN
Nurse Interventionists (2) to be named later
Research Assistants (3) to be named later

CDC-PRB, DHAP, NCHSTP, CCID
Kim Williams, Ph.D., Project Officer
Yuko Mizuno, Ph.D., Co Project Officer
Ann O'Leary, Ph.D., Consultant
Dale Stratford, Ph.D., Consultant

Consultants
Loretta Sweet Jemmott, PhD
Lynette Gueits, MPH

Name of funding source or sponsor:
Federal: The Centers for Disease Control and Prevention
Funding Mechanism: Cooperative Agreement
Funding Number: U01 PS000100-01

FWA Number: FWA00004801
Study Contact telephone number: 919-966-3119
Study Contact email: cfogel@email.unc.edu or nabrown@email.unc.edu [Author ID1: at Fri Feb 1 14:21:00 2008]
Flesch - Kincaid Reading Level: 7.1

These are some things that we want you to know about research studies.
You are being asked to be in a research study. You don't have to be in this study if you do not want to answer. You may stop being in the study at any time. If you decide to stop, it will not change the way you receive care.

We do research studies to learn new information.
This new information may help people in the future. Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

We will tell you more about this research study in the next part. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who help them, any questions you have about this study at any time.

What is the purpose of this study?
The reason we are doing this research study is to learn if a program our research team created for HIV positive women living in the South will help HIV-positive women make healthy choices in their lives. You are being asked to be in the study because you are an HIV-positive woman living in the South

Are there any reasons you should not be considered for this study?
You should not be in this part of the Sister to Sister Positive HOPE study if you are not willing to talk with one of the interviewers about your experiences as an HIV-positive woman and about Sister to Sister Positive HOPE intervention.

How many people will take part in this study?
If you choose to be in this study, you will be one of about 25-30 women in this research study.

How long will your part in this study last?
After you agree to be in this part of the study you will be asked some questions. This part will take about 45 minutes.

What will happen if you take part in the study?

You will be interviewed by someone on our research team in a private room in the place where you were asked to participate in the first part of the study. The interview will be audio taped. The interview will be about how you became infected, any ways you have tried to lower your risks, your experiences with using protection, and any experiences you may have had when/if you told people about your HIV status. You will also be asked to tell us what you think about the Sister to Sister Positive HOPE intervention.

What are the possible benefits from being in the study?

People may have good things happen to them because they are in research studies. These are called "benefits." The benefits to you of being in this study may be what you learn from the healthy living session. We believe that this study can help women living with HIV learn ways to take good care of themselves and those they care about. You may also benefit from meeting with the nurse and learning ways to protect you and your partner from infections you can get from sex

What are the possible risks from being in the study?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks." These are the risks of this study. Some of the questions you answer in your talk may make you feel uneasy or uncomfortable. We respect your right not to answer any questions. Taking part in the study is up to you. You can stop taking part in the study at any time. If you do not want to be in the study, it will not change your right to services at the (fill in the blank with the name of the place you are getting this form). Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the Sister-to-Sister Positive HOPE study team.

How will your privacy be protected?

We will do everything we can to make sure no one knows you are in this study. Your name will not be in any report about this study. Our research staff has been trained to keep your information private. There may be times when federal or state law can make us give them records that could tell them that you were in the study. This is very unlikely, but if we have to do this, The University of North Carolina, Chapel Hill will take all legal steps to protect your privacy. Sometimes, your information may be looked at by the University, research sponsors, or government agencies. This would be done to make sure the quality and safety of the research is the best that it can be. There are also laws that require us to tell others if you tell us that you are going to hurt yourself or anyone else, or that a child or older person is being hurt. If this happens, we will have to tell someone for example: local police or the child welfare agency) to protect that person.

The information that you share with us will be kept private. The interview and tapes will have a study number, not your name. A single sheet will be used to link your name with the study number. Only the Principal Investigator (PI), Project Manager and Research Data Manager will have access to this sheet. This sheet, consent forms, and tapes will be kept in separate locked file drawers. This file drawer will be in the Principal Investigator's (Catherine I. Fogel) research office in the School of Nursing at the University of North Carolina, Chapel Hill. The survey answers will be stored in a secure computer in the Principal Investigator's research office.

You cannot enroll in this study more than once. To keep that from happening, we will keep your name and contact information. Only project staff will have access to information about you, including your name, study number, and contact information. This information will be kept in a secure computer that is different from the one used to record your answers in the Principal Investigator's office and destroyed 6 months after the end of the study. The tapes and consent form will be destroyed 5 years after the final reports are completed.

Will you receive anything for being in the study?

We will give you $30 in cash and a bus pass when you finish your talk for your time and effort.

Will it cost you anything to be in the study?

There are no costs for being in the study.

Who should you ask if you have any questions?

You can ask and have answered any questions you may have about this study. If you have questions call Cathie Fogel, the Principal Investigator or Niasha Brown, the Project Manager at the toll free number (866) 619-0007.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. You do not have to tell them who you are when you call.

Participants Agreement:

I agree to be in this research study. I have been given a chance to ask questions. I feel that all of my questions have been answered. I know that being in this study is my choice. I know that after choosing to be in this study, I may leave at any time. I have been told that the discussion will be audio taped.

I have been given a copy of this consent form to keep.

Signature of participant

Date

Investigator

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 7b

Consent-In-depth Interview

Consent Form In-depth Interview

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School of Nursing
CONSENT TO PARTICIPATE IN A RESEARCH PROGRAM
SISTER TO SISTER POSITIVE HOPE PROJECT
STUDY
University of North Carolina-Chapel Hill
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Informed Consent Form

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UNC-Chapel Hill Department: Nursing
UNC-Chapel Hill Phone number: 966-3590 or 966-3119
Email Address: cfogel@email.unc.edu

University of North Carolina-Chapel Hill
David Wohl, MD Co-Investigator
Mark Weaver, PhD, Co-Investigator
Margarete Sandelowski, PhD, RN
Nurse Interventionists (2) to be named later
Research Assistants (3) to be named later

CDC-PRB, DHAP, NCHSTP, CCID
Kim Williams, Ph.D., Project Officer
Yuko Mizuno, Ph.D., Co Project Officer
Ann O'Leary, Ph.D., Consultant
Dale Stratford, Ph.D., Consultant

Consultants
Loretta Sweet Jemmott, PhD
Lynette Gueits, MPH

Name of funding source or sponsor:
Federal: The Centers for Disease Control and Prevention
Funding Mechanism: Cooperative Agreement
Funding Number: U01 PS000100-01

FWA Number: FWA00004801
Study Contact telephone number: 919-966-3119
Study Contact email: cfogel@email.unc.edu or nabrown@email.unc.edu [Author ID1: at Fri Feb 1 14:21:00 2008]
Flesch - Kincaid Reading Level: 7.1

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You should not be in this part of the Sister to Sister Positive HOPE study if you are not willing to talk with one of the interviewers about your experiences as an HIV-positive woman and about Sister to Sister Positive HOPE intervention.

How many people will take part in this study?
If you choose to be in this study, you will be one of about 25-30 women in this research study.

How long will your part in this study last?
After you agree to be in this part of the study you will be asked some questions. This part will take about 45 minutes.

What will happen if you take part in the study?

You will be interviewed by someone on our research team in a private room in the place where you were asked to participate in the first part of the study. The interview will be audio taped. The interview will be about how you became infected, any ways you have tried to lower your risks, your experiences with using protection, and any experiences you may have had when/if you told people about your HIV status. You will also be asked to tell us what you think about the Sister to Sister Positive HOPE intervention.

What are the possible benefits from being in the study?

People may have good things happen to them because they are in research studies. These are called "benefits." The benefits to you of being in this study may be what you learn from the healthy living session. We believe that this study can help women living with HIV learn ways to take good care of themselves and those they care about. You may also benefit from meeting with the nurse and learning ways to protect you and your partner from infections you can get from sex

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Signature of participant

Date

Investigator