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. The main study outcome analysis will be guided by the following hypothesis (which centers on the primary study objective): HIV+ women in the intervention group, when compared to those in the comparison group, will, on average, report greater reductions in unprotected sex acts (i.e., vaginal, anal, oral) at follow-up. The primary analysis of treatment effect on reducing unprotected sex acts will be conducted using logistic regression for dichotomous outcomes, generalized linear model-based analysis for continuous, normally-distributed outcomes and zero-inflated Poisson or Negative-Binomial regression models for zero-inflated, highly skewed frequency data.

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. No locator information, in any form, will be retained after this period. 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. By signing the pledge, study staff acknowledge that they have read, received and had all their questions answered regarding the document entitled, "*Ethical Guidelines for Project Staff*." The "*Ethical Guidelines for Project Staff*" outlines ethical guidelines for staff working with the project, specifically as related to maintaining professional boundaries in staff-participant relationships and general rules of conduct, including demeanor, dress and prohibiting drug and alcohol use. Staff also agree to keep

all information regarding study participants as secure as possible, to the extent permitted by law, and not to disclose the names of participants, information about their personal lives, or the fact that they are study participants to anyone who is not a member of the research staff.

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 privacy 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 privacy 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 the security of participants' personal information 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 privacy 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. These estimates were derived from pilot testing the assessment with 9 HIV+ women. 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	30	$13.45	$404.00

Interview			
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.