Request for OMB Review and Approval

An assessment of the determinants of HIV risk factors for African American and Hispanic women in the southeastern United States

April 17, 2007

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The respondent universe is African-American women in three rural counties in northeastern Alabama, two contiguous rural counties in eastern North Carolina, and Hispanic women in Miami-Dade County Florida. A total of 1350 (850 African-American and 500 Hispanic) sexually-active women will be enrolled. These sample sizes provide substantial statistical power to make reliable comparisons of sexual risk behaviors between these two groups of women and to examine variables associated with those behaviors (Appendix Number 14.1).

The eligibility criteria for enrolling for each site:

Site	Female	18-59 yrs of age	African American (regardless of ethnicity)	Latina (regardless of race)	English Speaking	Spanish Speaking	Engaged in vaginal/anal intercourse with a man in the past 12 months	HIV-negative or not having being diagnosed as HIV+
Alabama	√	√	√		√		√	√
North Carolina	√	√	√		√		√	√
Florida	√	√		√	√	√	√	√

Based on prior studies, of the total number of women who are screened and determined to be eligible, we anticipate that approximately 80% will agree to participate in the study [Shain, et al. 2007; Crosby et al. 2002; Anton, et al. 2000, Ruiz et al. 2000; Smith et al. 1997]. To maximize the diversity of the sample in terms of age, marital status, sexual risk behaviors, drug use, and psychosocial variables, each site will use three recruitment methods concurrently: (1) venue-based recruiting, (2) respondent-driven sampling (RDS), and (3) general advertisements (Appendix Number 9).

Venue-Based Recruitment

Each research site will conduct field enumerations to identify potential venues that have ample numbers of women eligible to enroll. Potential venues include STD testing sites, family planning clinics, nail and hair salons, laundromats, cafeterias, and CBOs that cater to women.

After compiling a preliminary list of such venues, research teams will enumerate each recruitment site to determine 1) the total number of women who enter, exit, or pass by a specific venue and 2) the number of potentially eligible women as a percentage of the total. To make these enumerations, a trained observer will use a electronic tally counter to make unduplicated counts of the total number of women and number of African-American or Hispanic women (based on physical appearance) during 30- to 60-minute observation periods on different days of the week and at different times during the day (morning, afternoon, evening). This information will be hand-written into a tracking log.

A second phase of enumerations will include a brief venue intercept interview (Appendix Number 5) of African-American and Hispanic women randomly sampled as they enter or exit a venue. Trained study stuff will conduct these intercept interviews during different day/time hours to determine the number of women at a venue who meet the eligibility criteria and would be willing to enroll. The data will help guide decisions about whether a venue should be included as a recruitment location.

Venues purposively selected as recruitment locations will be placed in a weekly sampling frame. Optimal recruitment days and times will be established for each venue. Each week a manageable number of venue day/time periods will be randomly selected as settings for recruitment. Only one or two venues will be visited per day.

Respondent Driven Sampling (RDS)

RDS provides an opportunity to access potentially hidden populations that may be missed with venue-based sampling. RDS begins with an initial set of group members (seeds). Seeds are individuals who meet study eligibility criteria, complete the study protocol, and are then asked to recruit other eligible individuals from their social networks. The initial seeds will be women who were recruited at the venues and agreed to be trained as recruiters. Respondents recruited by seeds, in turn, are asked to recruit the next wave of respondents, with the process continuing until a target sample size is achieved (Appendix Number 10).

RDS uses a coupon system with unique serial numbers that link recruiters and recruits (Appendix Number 10). To limit the number of recruits by a given recruiter, a maximum of three coupons will be issued to each woman interested in recruiting other women in their social networks.

Study Advertising

Fliers (Appendix Number 10) describing the study will be posted in (and around) the venues used to recruit women.

B.2. Procedures for the Collection of Information

Based on prior studies, we anticipate that the prevalence of unprotected vaginal or anal intercourse (UVA) will range from 30% to 40% (displayed in Appendix Number 14.3 as the power to reliably rule out, or not mistakenly claim, an alternative proportion below and above the true proportion). The power calculations are based on a two-sided exact binomial test of a single proportion with significance level (alpha) = .05. We have substantial power to rule out alternative proportions in pooled and site-specific analyses. The power to reliably detect true group differences in the prevalence of UVA by ethnic group (African Americans vs. Hispanics), by site (e.g., the two African American sites),

and by stratification variables (e.g., a median split on an important risk factor) is given in Tables 2 and 3. These power calculations are based on a two-sided Fisher's exact test of two independent groups with significance level (alpha) = .05. Under a range of potential true differences, we have substantial power to detect differences in UVA between African-American and Hispanic women, and between African-American women from North Carolina versus Alabama. Power for the stratification analyses is also acceptable. Each site will use an account with CDC's Secure Data Network (SDN) to assure the safe transfer of data. The SDN encrypts and prohibits any modification of data in transit between the local project site and CDC. The SDN assures that project sites can only deliver and retrieve authorized information from CDC servers.

Mobile vans used for data collection will be equipped with a Sentry fire-safe/waterproof security file lock box. Signed consent forms and locator information will be placed in a lock box immediately after being collected. Documents will be transported to a home office location at each study site on a daily-basis where transfer of consent and locator forms to separate locked file cabinets in a permanent secured space will occur. Only the principal investigators and the study coordinator will have access to locked information.

Settings for Collecting the Data

All three sites will use a research mobile van as well as private space in health department clinics, primary care clinics, and medical schools if respondents find these locations preferable.

Eligibility Screening

The HAPI eligibility screening will take approximately 10 minutes to complete. Eligible women interested in participating will consent to complete a 45-minute survey and be tested for HIV infection. Eligible women who decline participation will be asked

if they are willing to complete a 10-minute HAPI refusal questionnaire (Appendix Number 6.1).

It will be necessary for candidates recruited through RDS or advertisements to call to schedule a screening appointment. Candidates recruited face-to-face at a venue will have the option of screening for eligibility immediately or setting up an appointment for a future date. In all cases, we will attempt to arrange a time and location that is convenient for the respondent.

ACASI Survey

The ACASI survey (prepared in English and Spanish) will take approximately 45 minutes to complete. The survey will be identified only by a unique code number (Participant ID); no personally identifying information will be included.

Rapid HIV Testing and Counseling

Respondents will undergo approximately 45-minutes of HIV testing and counseling. To reduce the total amount of time a participant spends in the counseling session, some of the pre-test counseling activities will take place prior to specimen collection and other counseling activities will take place while the specimen is being processed.

Certified HIV counseling and testing (C&T) staff will perform all testing and counseling procedures in accordance with local, state, and CDC recommendations. We will follow all upcoming CDC guidance on personalized assessment of risk behavior and delivery of risk reduction counseling for rapid HIV test results. With the exception of state-mandated HIV reporting forms for reactive/preliminary positive test results, the counseling session will not involve data collection. Rapid HIV test results will be entered into an electronic data entry system that is password protected.

Pre-Test Explanation of Rapid HIV Test, Personalized Risk Assessment, and Risk-Reduction Counseling

Before the oral specimen is collected, C&T staff will explain the testing procedure, its level of accuracy and processing time, and the need for a confirmatory test if the rapid test is reactive/preliminary positive. After the oral specimen has been collected and is being processed, the counselor will then assist the participant in assessing her risk for HIV infection, identifying ways to reduce risk, and the importance of developing a plan of action.

Post-Test Results and Counseling

If the rapid result is non-reactive/negative, confirmatory testing is not needed. If the rapid result is reactive/preliminary positive, a second oral specimen for a Western blot confirmatory test will be collected. A blood test to determine CD4 cell count will be offered to all women with a reactive preliminary rapid result. Counseling will focus on the meaning of the results and strategies for remaining uninfected or for avoiding transmission if possibly infected.

Qualitative Interview

Every fifth woman who completes the ACASI survey will be approached for participation in a one-hour qualitative interview until a sample size of 60 is reached. Hispanic respondents will have the option of completing the interview in English or Spanish. Women recruited for a qualitative interview will be given options (e.g., day, time, and location) for completing the interview. To maintain the rights and privacy of all respondents, only the respondent code-number already assigned for the ACASI survey will be used. Interview respondents will be instructed not to use personal names during the interview.

CDC will train all qualitative interviewers and coordinate data management and analysis of the qualitative data. To familiarize interviewers with the interview guide (see Appendix Number 8), role-playing and debriefing evaluation techniques will be conducted. Interviewers will also receive training on use of digital equipment and secure transfer of audio files.

B.3. Methods to Maximize Response Rates and Deal with Non-response

The computer-administered survey will increase response rates and decrease non-response to survey items. First, the respondent will hear each question being asked through headphones and will also see the printed question and response categories on the computer screen. Second, each respondent will receive a tutorial on using the ACASI, including the types of response scales in the survey and how to make a response. They will be given several practice items. Third, the ACASI will include programmed skip patterns to smoothly transition the respondent to applicable questions. Fourth, the program will also include validity checks to assure the logical consistency of responses, thus maximizing the number of items on which valid data will be collected. Fifth, questions do not include a "don't know" response category unless a "don't know" response is a meaningful answer. Although each question does have a "refuse to answer" option, which is mandated for all federally sponsored surveys, prior studies that have used ACASI have had few cases of refusals even on questions asking about sexual behavior {Gardner 2006}.

B.4. Test of Procedures or Methods to be Undertaken

All instruments will undergo a translation/back translation process to ensure consistency between English and Spanish versions. All procedures and instruments, including consent

forms will be piloted and field tested. Separate pilot and field test activities will be undertaken for the ACASI survey and the qualitative interview. Each pilot activity will involve 10 women at each site for a total of 30 ACASI survey pilots; 2 qualitative interview pilots will be conducted per site for a total of 6 qualitative pilots.

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

Individuals consulted on statistical aspects of the study design
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UNC's contractor, Rocky Mount Opportunities Industrialization Center, HSC, and the University of Miami will be responsible for data collecting and HIV counseling and testing. CDC, UNC, HSC, and the University of Miami will be involved in the analysis of the information (Appendix Number 13).

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