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

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SUBMISSION INFORMATION COLLECTION PLAN

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Center for HIV, STD, and TB Prevention (NCHSTP) of the Centers for Disease Control and Prevention (CDC) is requesting OMB approval to administer a questionnaire, perform rapid oral HIV testing, and conduct a qualitative interview among heterosexual African American and Hispanic women at three sites in the southeastern United States. This proposed data collection will occur over 3 years. This research is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241[b]) (Appendix Number 1).

In the United States, an estimated 1 million people are living with HIV. About 40,000 new HIV infections occur each year. Women account for about 27% of all new HIV/AIDS diagnoses, with women of color in the South being most affected. Women of color represent 80% of all women estimated to be living with HIV/AIDS. In 2005, the rate of HIV/AIDS cases per 100,000 for non-Hispanic African-American adult and adolescent females (61.4) was 21 times higher than that for non-Hispanic white females (3.0). Similarly, the rate of HIV/AIDS cases reported in 2005 for Hispanic women (16.1) was 5 times higher than the rate for non-Hispanic white women [CDC, 2006].

There have been few epidemiologic or behavioral HIV studies conducted among women, especially in the southern U.S., to identify factors for heterosexually transmitted HIV infection. With limited exception, these studies focus on drug using or adolescent females. Further, studies have not examined HIV infection risk from the context of women's experiences [Goggin et al., 2001]. Instead, researchers have largely relied on

studies of men, namely men who have sex with men, to draw inferences about women [Carney, 2003]. By examining the character and dynamics of women's sexual relationships, gender relationships, sex roles, and experiences related to race and ethnicity, it may be possible to better identify and address determinants of sexual and drug behaviors that place women at risk for HIV infection. This information will inform the design of behavioral interventions and community prevention programs for minority women.

The purpose of this study is to recruit African-American and Hispanic women at risk for HIV infection and examine a social-ecological framework for advancing understanding of factors associated with HIV transmission in these women. The framework takes into account the individual, psychological, and behavioral factors that may significantly influence health and risk behaviors, as well as the sociocultural and environmental (contextual) variables that may affect risk behavior.

The study will address four research questions:

1. Among heterosexual African-American and Hispanic women, not previously diagnosed as HIV-positive, what percentage of these groups engages in unprotected vaginal or anal intercourse (UVA) or drug-use behaviors?
2. Are there significant differences in the prevalence of UVA or drug use behaviors between heterosexual African-American and Hispanic women not previously diagnosed as HIV-positive?
3. Is the likelihood of UVA or drug use associated with the following categories of variables: demographic (e.g., age, education, income, employment status, marital status), psychological (e.g., self-esteem, psychological distress, self-efficacy for safer

sex), behavioral (e.g., HIV testing history, alcohol/drug use, concurrent sex partners, incarceration history [self/partner]), sociocultural (e.g., racial discrimination, gender roles and power dynamics of relationship, religious beliefs and practices, acculturation of Hispanics), and contextual/environmental (e.g., residing in high STD/HIV prevalence area, social support networks)?

4. Do the correlates of UVA and drug use (among the variables listed in item #3) differ between African-American and Hispanic women?

Accordingly, the specific aims of the study are to:

- Enroll 850 African-American and 500 Hispanic heterosexually active women between 18 and 59 years of age not previously diagnosed as HIV-positive.
- Conduct rapid oral HIV testing of all women and facilitate linkage to medical care among those identified as HIV-positive.
- Characterize African-American and Hispanic women on demographic, psychological, behavioral, sociocultural, and environmental/contextual dimensions.
- Assess and compare the prevalence of sexual and drug behaviors of African American and Hispanic women.
- Identify demographic, psychological, behavioral, sociocultural, and environmental/contextual characteristics of African-American and Hispanic women associated with sexual and drug behaviors that place them at risk for contracting HIV. Similarly, identify characteristics that protect against becoming infected with HIV.

- Recruit a sub-sample of survey respondents to participate in a qualitative interview to examine in greater depth how relationship dynamics and gender norms may affect a woman's risk for contracting HIV infection.

A.2. Purpose and Use of Information Collection

This study addresses goals of CDC's "HIV Prevention Strategic Plan Through 2005". CDC plans to meet specific goals by (1) decreasing the number of women at high risk of acquiring or transmitting HIV infection; (2) increasing the proportion of HIV-infected women who know they are infected; (3) increasing the number of HIV-infected women who are linked to appropriate prevention, care, and treatment services; and (4) strengthening the capacity nationwide to monitor the HIV epidemic.

The proposed data collection will include:

Activity	**Appendix No.**
375 one-time 3-minute intercept interviews strictly for venue enumeration purposes	5
One-time 10-minute eligibility screening of approximately 2025 women	6.1
One-time 10 minute refusal questionnaire for women who screen eligible but decline participation	6.2
One-time 45-minute survey	7
60 one-time semi-structured qualitative interviews of a subset of women who completed the survey	8

The proposed data collection has important practical utility to the government (specifically the Division of HIV/AIDS Prevention at CDC) as well as public health departments and university-based researchers doing HIV prevention work. The epidemiologic data to be collected will fill important gaps in our knowledge of the demographic and behavioral characteristics of African-American and Hispanic women that place them at risk for HIV infection. This information will help CDC, health departments, and university-based investigators design and target prevention programs to the subgroups of women most at risk for contracting and transmitting HIV.

The domains and variables included in the survey:

Domain	Variables
Demographics	age, ethnicity/race, marital status, income, education, employment
Psychological	self-esteem, psychological distress, self-efficacy for safer sex
Behavioral	HIV testing history, alcohol and drug use, history of sexually transmitted infections, concurrent sexual partnerships, having high risk male partners, transactional sex, incarceration history, experience of domestic violence
Sociocultural	racial discrimination, gender roles and power dynamics in sexual behavior, religious beliefs and practices, and acculturation for Hispanics
Contextual/Environ-mental	residency in geographical areas with high STI and HIV prevalence rates based on postal zip code, social support networks

A.3. Use of Improved Information Technology and Burden Reduction

With the exception of contact information and all initial venue enumeration observations (i.e., counting the number of potentially eligible women in venue catchment area), all data collection will rely on electronic technology. Brief venue intercept, eligibility screening, and refusal interviews will be collected using personal digital assistants (PDAs) through a Handheld-Assisted Personal Interview (HAPI) module. All quantitative survey data will be collected using an audio computer-assisted self-interview (ACASI). Survey questions and response options are simultaneously heard over earphones and read on a computer monitor by the respondent. The respondent enters a response directly into the computer through a touch screen or number keypad. This technology allows women with lower literacy to participate in the study. Use of ACASI will minimize burden and protect privacy.

Before starting the ACASI, each participant will complete a short tutorial that demonstrates the types of questions and responses that they will encounter. The ACASI will also be fully-programmed with logical skip patterns and validity checks and prompts to alert a respondent to an item that was missed. These safeguards will enhance the quality and accuracy of the data. Data will be electronically transferred to a data file

housed on a secure drive at CDC and backed up daily. The data can then be managed and analyzed through an electronic data management and statistical analysis system (e.g., SAS or SPSS).

All 60 qualitative interviews will be audio recorded to ensure that complete and accurate information is documented. Audio recording eliminates the need for the respondent or the interviewer to write out lengthy responses and allows for a more in-depth conversation. Electronic audio files will be transferred to CDC via its secure data network. After audio files are transcribed and transcripts verified for accuracy, all copies of audio files will be destroyed. Transcripts will be electronically managed and analyzed in AnSWR, a qualitative data analysis software program.

A.4. Efforts to Identify Duplication and Use of Similar Information

Several steps have been taken to prevent duplication of effort. CDC personnel have conducted extensive, systematic computerized searches of electronic databases of published articles, abstracts, book chapters, and dissertations. Those databases include MEDLINE, AIDSLINE, PsycInfo, EMBASE, CINAHL, and SOCIOFILE. Hand-searches of relevant journals have also been conducted. We have attended local, national, and international conferences relevant to the topic, communicated frequently with non-federal colleagues at universities, health departments, and community-based organizations (CBOs) as well as with colleagues within the government.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study. Further, the study will not impact small businesses, including health departments, non-profit organizations, dentist or physicians' offices, or CBOs.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time collection. Collection of less information with a smaller sample would reduce (a) the ability to understand HIV infection from a heterosexual context; (b) the opportunity to improve or tailor interventions for African American and Hispanic women; and (c) the opportunity to diagnose infections and provide linkage to care.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances relating to the guidelines of CFR 1320.5.

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

The 60 Day-05-05CH Notice for the proposed project was published in the Federal Register on June 2, 2005, Vol. 70, No. 205, pp. 66333-34 and November 14, 2006, Vol. 71, No. 219, pp. 32340-41 (Appendix Number 2). No public comment was received from these notices.

In 2006, the survey and qualitative interview guide were reviewed for length, clarity, and appropriateness by cooperative agreement grantees and representatives of CBOs with experience in HIV prevention and working with African-American and Hispanic women.

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A.9. Explanation of Any Payment or Gift to Respondents

The respondent is viewed as an integral partner in the research process. Provision of an honorarium can help to increase response rates and avoid biases resulting from the omission of those who decline participation because it would take them away from other tasks, in particular those that generate income [Thompson 1996]. Moreover, an honorarium that takes into account the duration of participation and the procedures involved helps to demonstrate respect and appreciation for the respondent's role in the

research process [Grady 2001; Grady 2005]. Respondents will be given an honorarium valued at $50 to thank them for completing the comprehensive survey and HIV testing, counseling, and referral if needed. Qualitative interview respondents will receive an honorarium valued at $30.

A.10. Assurance of Confidentiality Provided to Respondents

Office of OSRS staff have reviewed this application and determined that the Privacy Act does not apply to this data collection. The Privacy Act does not apply to grantee or cooperative agreement records. While names must be collected at the cooperative agreement sites for testing and scheduling purposes, these data will only be retained for 3 months. Any potentially identifying information collected at the project sites will be stripped from the data before forwarding to CDC.

The research protocol has been granted approval by Institutional Review Board (IRB) A at the Centers for Disease Control and Prevention (Appendix Number 4.1). The Alabama site has signed an agreement to use the CDC IRB (Appendix Number 4.2). The University of North Carolina has received approval from their local IRB (Appendix Number 4.3). The University of Miami has submitted the protocol to their local IRB and review is pending. Because the intercept survey will not include the collection of any personally identifiable information and will consist only of a 3-minute interaction with women at selected venues, a request for waiver of documentation of informed consent under 45 CFR 46.116(d) has been granted. A brief verbal consent script (Appendix Number 3.1) will help minimize the possibility that a signed informed consent could serve as a respondent's sole link to this data collection activity.

HIV testing necessitates collection of name and contact information (Appendix Number 11). Survey respondents will be informed of state-mandated policy requiring that their names be provided to the local health department if they have a confirmed HIV-positive test result. Survey respondents will be further informed that their contact information will be safely secured at the main research sites and destroyed at those sites 3 months after their rapid oral HIV test. Contact information will be used to follow-up with women who: (a) do not return for their confirmatory HIV test results or (b) have been selected to take part in a qualitative interview. The following procedures will be used to protect respondent records:

- Data collection will occur in a private room within the mobile van or clinic setting.
- Staff will complete the computer-based NIH ethics training annually and provide proof of course completion to CDC.
- Data records, including HIV test results, will be labeled with a unique study ID. Personal information will be securely maintained at the sites and will not be provided to CDC. Every three months, contact information will be destroyed.
- At the local site level, state HIV forms for persons confirmed HIV positive will contain names and contact information. This information will not be provided to CDC.
- Access to data will be limited to the study team. No personal identifiers will be associated with completed surveys or qualitative interviews. Electronic data will be placed on password-protected computers, PDAs, and hardcopy information will be placed in locked study files. All hardcopy records, including signed informed consents, will be destroyed five years after study completion.

- Publications and presentations will report only aggregated information from the dataset without any identifying information.

The three sites (collectively) are applying for a Federal Certificate of Confidentiality.

A.11. Justification for Sensitive Questions

To increase our understanding of the HIV epidemic among African-American and Hispanic women, it is necessary to ask sensitive questions about risk behaviors, marital status, reproductive history, mental health, religion, incarceration history, income, and partner risk behaviors to identify determinants of HIV infections. Respondents will be fully informed at the beginning of the survey (Appendix Number 3.2) and qualitative interview (Appendix Number 3.3) of the voluntary nature of the study and their right to skip questions that they do not wish to answer.

A.12. Estimates of Annualized Burden Hours and Costs

The table below reflects the total estimated annualized respondent burden hours for the study. Estimates are based on informal testing and prior experience of conducting similar activities among the target population.

12 A. Estimated Annualized Burden Hours

Type of Respondent	Form/Activity	No. of respondents	No. of responses per Respondent	Average burden per Response (Hours)	Hours
Intercept interviewee	HAPI venue intercept	125	1	3/60	6.25
Eligibility screener	HAPI eligibility screening	675	1	10/60	112.73
Refuser	HAPI refusal questionnaire	90	1	10/60	15
Survey participant	ACASI survey interview	450	1	45/60	337.5
Survey participant	HIV Testing & Counseling **(state reporting form only)**	450	1	45/60	337.5
Survey participant	RDS Training **(activity only)**	450	1	10/60	75.15
Qualitative interviewee	Qualitative interview	20	1	1	20
Total Annualized Burden Hours					904.13

The majority of the respondents will be of lower socioeconomic status (from rural counties in Alabama and North Carolina and from Little Havana and surrounding areas of Miami, Florida). If employed, most will be in service-related jobs with an estimated average hourly wage of $6.50 (based on regional data from the Bureau of Labor Statistics, 2007). Applying this hourly wage to the respondents as a whole, the annualized cost to respondents will be approximately $5,888.

12 B. Estimated Annualized Burden Costs

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Cost per Response	Total Respondent Costs
Intercept interviewee	125	1	.05	6.25	$6.50	$0.33	$41.25
Eligibility screener	675	1	.167	112.73	$6.50	$1.09	$735.75
Refuser	90	1	.167	15	$6.50	$1.09	$98.10
Survey participant	450	1	.75	337.50	$6.50	$4.88	$2196.00
HIV C&T	450	1	.75	337.50	$6.50	$4.88	$2196.00
RDS Referrer	450	1	.167	75.15	$6.50	$1.09	$490.50
Qualitative interviewee	20	1	1	20	$6.50	$6.50	$130.00
Total							$5,887.60

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no direct costs to respondents other than their time to participate in the data and specimen collection.

13 A. Other Total Annual Cost Burden

Annualized start-up costs (1st year only)	Amount	Operational components	Amount	Combined Total
Translation services	$4,000	Local laboratory	$1,000	
9 laptop computers (3 per site)	$10,800	processing fees for		
9 PDAs (3 per site)	$4,500	OraSure specimens		
9 Nova QDS software licenses (3 per site)	$4,455			
1 QDS design studio license	$295			
6 digital audio recorders (2 per site)	$480			
1350 OraQuick oral rapid HIV test kits	$24,300			
30 OraSure oral confirmatory HIV test kits	$480			
TOTAL	$49,310	TOTAL	$1,000	$50,310

A.14. Annualized Cost to the Federal Government

The 3-year study will be conducted under CDC cooperative agreement PS05-107. Awards were made to the Health Services Center, Inc., the University of North Carolina (UNC) at Chapel Hill, and the University of Miami. The total cost of the cooperative agreement awards for the three years is $2,742,519. The annualized cost of these awards as well as the annualized federal cost to support CDC-based project officers and a study coordinator is given in the table below.

14 A. Annualized Costs to the Federal Government

Title	Federal salary grade	Salary	% effort	Annualized cost
3 awardees	-			$914,173
CDC Project Officer	GS 13-6	$90,523	40	$36,209
CDC Co-Project Officer	GS 14-10	$116,401	20	$23,280
CDC Study Coordinator	NA	$69,680	50	$34,840
Total annualized cost				$1,008,502

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Several preliminary analyses will be conducted on the survey data. First, we will compare recruitment methods (venue-based, respondent-driven, advertisements as described in Part B below) by site, demographic, and behavioral variables.

We will operationalize our central constructs (e.g., sexual risk behaviors, demographic, psychological, behavioral, sociocultural and environmental/contextual variables) that were measured in the ACASI survey. For many constructs this will entail combining items to create composite indices (e.g., self-esteem, sexual self-efficacy, and perceived discrimination) or to create other summary measures (e.g., number of male partners with whom a woman engaged in unprotected sexual intercourse in the past 3 months). We will examine the properties of constructed variables (e.g., Cronbach's

alpha, means, standard deviations and distributions on the scales) and compare properties by race/ethnicity, site, and language group (for the Hispanic site).

A descriptive analysis of the central constructs will be performed, including stratified analyses (1) comparing African-American women recruited in North Carolina versus Alabama, and (2) comparing African-American and Hispanic women. We will also determine the number of women with unrecognized HIV infection (i.e., women who report on the survey that they are HIV-negative or do not know their HIV status but are HIV-positive based on confirmatory testing conducted as part of this study). We do not anticipate that this subgroup will be large enough for a reliable analysis, but we will attempt to preliminarily identify the characteristics of women with unrecognized HIV infection (estimate prevalence is 2%).

We will conduct a series of multivariate regression analyses (linear, logistic depending on the type of dependent variable) to identify characteristics independently associated with sexual risk behavior. These analyses will help identify risk-promoting and risk-protective factors.

For the qualitative data, systematic textual data analysis methods will be implemented. A detailed codebook will be developed and an iterative coding approach taken. All text files will be independently coded by two coders using AnSWR. Inter-coder agreement will be assessed using a Kappa statistic. After coding has been completed, code frequency and code co-occurrence reports will be generated to examine coding themes and patterns. Multi-dimensional scaling (MDS) and cluster analysis techniques will be used to display themes. Demographic data (e.g., site, age, education,

income, marital status) from the ACASI survey will be linked to the qualitative database so that descriptive comparisons can be made.

Project Time Schedule	
Activity	**Time Schedule**
Enrollment and data collection (survey and HIV testing)	1-36 months after OMB approval
Recruitment of 60 respondents for a qualitative interview	2-24 months after OMB approval
Data transmittals to CDC and data cleaning	2-36 months after OMB approval
Create final aggregated dataset	36 months after OMB approval
Data analysis	18-36 months after OMB approval
Presentations of findings	24-36 months after OMB approval
Manuscript preparation	36 months after OMB approval

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

We will display the OMB expiration date.

A. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification for Paperwork Reduction Act submissions are being requested.