Information Collection Request (New)

Supporting Statement A and B

"Micro-Finance Project for HIV Prevention"

Alternate Title: "An Economic Empowerment Intervention to Reduce Risk of HIV among Impoverished High-Risk African American Women in the Southeastern US: Exploratory Research and Feasibility Assessment"

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STATEMENT A: JUSTIFICATION

A.1. Circumstances making the collection of information necessary

A. 1.a. Background and Need

The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention, National Center for HIV, STD, & TB Prevention (NCHSTP) is requesting a one-year approval from the Office of Management and Budget to conduct focus groups with women who are at risk for HIV infection and community leaders in four communities in the southeastern United States, and to administer one-on-one qualitative interviews with a subset of the women in the focus groups.

The purpose of this project is to conduct formative, feasibility research to determine the most realistic and efficacious approach for developing a micro-finance project to reduce HIV/STD-related risk behavior among unemployed or underemployed high-risk African- American women in the southeastern United States, who are among those most at risk in the country for HIV infection and sexually transmitted disease. This information will be useful to inform future research and programs for the purpose of initiating structural or systemic changes to improve HIV prevention among women who are at risk primarily due to economic stressors that influence behavior.

HIV in the South. Women at risk for acquiring or transmitting HIV or other STDs are disproportionately young, African American, and living in poverty (1 Fitzpatrick 2004, 2 Krieger *et al*. 2003, 3 Ellerbrock *et al*. 2004, 4 Klein *et al*. 2002, 5 Nagy-Agren 2001). Poverty is associated with sexual risk behavior in many ways, but particularly because sex can be exchanged for money, drugs, protection, a place to stay, and countless other commodities and services needed by impoverished women. Given that sexual-economic exchange is often part of a personal economic strategy for at-risk women, interventions focused on reducing or removing the need for such exchange may reduce or eliminate sexual risk taking.

In 2003, women comprised 28% of US HIV/AIDS cases, 68% of which were among non-Hispanic black women; and 29% of US women resided in the South, but 76% of new reported infections among women occurred in the South (6 Fitzpatrick 2005). Local surveillance data indicate that

women of color comprise a growing proportion of new HIV infections in the South (7 Southern State AIDS Directors Workgroup, Southern States AIDS Manifesto 2003). For example, in 2003, the HIV infection rate for black women in North Carolina was 14 times higher than that for white women (8 North Carolina Department of Health and Human Services 2005). And in Palm Beach County, Florida (a high HIV/AIDS prevalence county in a high HIV/AIDS prevalence state), as of March 2005, women account for 39% of HIV cases regardless of AIDS status, and Black women comprised 70% of HIV cases among women (9 State of Florida Department of Health 2004). It is clear that there exists an increased risk for HIV among African American women in the southern states that is worthy of attention. Finally, not only HIV/AIDS, but also rates for other sexually transmitted diseases (Chlamydia and Gonorrhea) are higher among women in the South than in other areas of the country (6 Fitzpatrick 2005).

It is widely acknowledged that addressing structural factors including poverty represent the "next level" in intervention research (e.g., 10 O'Leary 2001 and 11 Sumartojo 2000). Micro-finance projects, which provide small-scale capital for starting local businesses, have been shown to be effective in developing countries for improving women's economic independence and producing favorable health-related outcomes, particularly reproductive health outcomes (12 Schuler and Hashemi 1994). In Africa and Asia, the Grameen Bank and other micro-finance models have been shown to increase women's economic well-being, household health, enhance contraceptive use, and strengthen women's position in families (13 Waters *et al*. 2001, 14 Hashemi *et al*. 1996, 15 Schuler *et al*. 1997). However, given the context of the US economic, social, and legal systems, it is important to understand how to make such an intervention work in the United States, and in particular, for women at risk for HIV/STD transmission in the American South. While most micro-finance programs that track health outcomes have taken place in other countries (e.g., 15 Schuler *et al*. 1997), some preliminary evidence is emerging to show that economic empowerment interventions can reduce sexual risk behavior in the US (16 Sherman *et al*. 2006).

In addition to a consultation meeting with individuals who have experience in micro-finance projects (March 8-9 2006), information from the qualitative interviews with at-risk women and community leaders in the southeast will assist CDC in determining the feasibility of microenterprise

as an HIV prevention intervention that can be evaluated to determine effectiveness in reducing risk for HIV and STD infections.

How this project fits into CDC's research agenda. The project addresses goals of the *CDC HIV Prevention Strategic Plan through 2005* (reference 17), specifically the goal of decreasing the number of persons at high risk of acquiring or transmitting HIV infection.

Specific aims. The aims of this study are:

1) To generate hypotheses regarding the feasibility, utility, and effectiveness of microenterprise as an HIV prevention intervention.
2) To identify socioeconomic and other factors that may impede or facilitate HIV-related risk in the southern US.

A.1.b. Laws and regulations authorizing the study

This activity is authorized under Section 301 of the Public Health Service Act (42 U.S.C 242 [b]) (see Appendix A *Legal Authorizations*).

A.2. Purpose and use of information collection

The information collected for the proposed project will address the connection between risk for HIV/STD infection among poor African American women and the economic stressors that increase risk. Collecting the information indicated below would be necessary for any attempt at addressing HIV prevention through structural approaches using economic parameters; attempting to develop structural-economic approaches using microfinance without the information indicated would be unrealistic.

The proposed data collection will be a one-time, two-hour focus group with six to eight at-risk women in each of four communities in NC and FL and one-time individual qualitative interviews with up to eight of the women from each focus group. That is, we will invite each focus group participant to also participate in a qualitative interview; the number of individual interviews will be determined by the number of women who accept the invitations for individual interviews. We will

also conduct focus groups with six to eight community leaders in each of the four communities. For this study, we have identified southern states with relatively high prevalences of HIV among women. At-risk women research participants will be recruited by persons identified by local health departments and community-based organizations in the respective states as individuals who are experienced and trained in conducting outreach among poor African American women. Participants who are community leaders will be identified and recruited with the help of local health departments through the HIV community planning boards.

In general, the interviews will elicit information about

- What kinds of jobs or businesses would be feasible (can be done with small capitalization and by these women with some training and other preparation), attractive (women will do this work), and useful (likely to produce income to address a reasonable proportion of economic need; the community will use the service or purchase the product of the activity) to the women and the communities in which they live?
- How have other economic empowerment programs functioned in the local communities (for communities that have such programs), and which models would be useful for HIV prevention?
- Would HIV prevention be included as part of the job training or employment activity?
- How should the project be managed?
- What are appropriate measures of and incentives for performance?
- Who are appropriate stakeholders (partners), and how should they be involved in micro-finance projects?

These data will be informative to CDC staff in developing future projects to evaluate the effectiveness of microenterprise as an HIV prevention intervention, and to other federal, state and local officials to help plan and direct future research and program planning in HIV prevention and other health topics where economic pressures are considered critical factors.

Without the information that we propose to collect, we will not have sufficient data to determine the feasibility of implementing a microenterprise-based prevention intervention with the proposed

target population and within the context of their lives (for example, poverty, lower educational levels, decreased access to health care and employment).

A.3. Use of improved information technology and burden reduction

Each focus group and individual interview will take up to two hours to complete, and the interviews will be audio tape recorded with permission of the interviewees. Audio tapes will be transcribed into computer files for data analysis. Audio taping the interviews rather than taking notes during the interviews will reduce the time needed to collect qualitative information and provide more accurate recording of information.

Additionally, because we anticipate that the women in the target population, who will be from poor families and communities, will have no or restricted access to computers, we will not be requesting utilization of on-line or other electronic data reporting for this project.

A.4. Efforts to identify duplication and use of similar information

Several steps have been taken to prevent duplication of efforts. Over the years, CDC personnel on this project have reviewed literature about HIV/AIDS in the South and in rural areas, performed research and reported on HIV in the non-urban South, and communicated with relevant federal (e.g. HRSA) and non-federal colleagues (e.g. at Southern universities and health departments). To our knowledge, the information that will be collected is unique and has not been collected before by federal or non-federal agencies.

A.5. Impact on small businesses or other small entities

No small business will be involved in this study.

A.6. Consequences of collecting the information less frequently

This study involves completion of a one-time interview by community members, including women who may be at risk for HIV transmission.

A.7. Special circumstances relating to the guidelines of 5 CFR 1320.5

There are no special circumstances relating to the guidelines of 5 CFR 1320.5.

A.8. Comments in response to the Federal Register Notice and efforts to consult outside the agency

A.8.a. Federal Register Notice

The initial 60-day Federal Register Notice for this project was published on July 21, 2005 and no public comments were received. The 60-day notice was republished on July 27, 2006 (Vol. 71, No. 144, see Appendix B), and again, no public comments were received in response to the Federal Register notice.

A.8.b. Consultations outside the agency

In Florida, we have consulted with Mr. Glenn Krabec (Executive Director of the HIV/AIDS Education, Prevention, Intervention and Care Coalition [EPICC]) and Dr. Karen Dodge of the Palm Beach County Health Department, and in North Carolina, with Dr. Peter Leone and Evelyn Foust, of the HIV program in the North Carolina Department of Health, with regard to the need for and appropriateness of this project for their HIV prevention efforts. Each of these partners has considerable experience in HIV/AIDS programs and in working with the target population and has expressed interest in assisting with this project. They will be assisting with the field research in addition to having attended the consultation meeting on microfinance as a prevention intervention in March 2006. Their field assistance will consist of helping to identify appropriate communities and local venues in which to identify and recruit research participants and conduct data collection and assisting with logistics of the study (e.g., location of appropriate and secure sites for focus groups and individual interviews). Local subcontractors will identify experienced staff to assist with recruitment of research participants.

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A.9. Explanation of any payment or gift to respondents

Respondents will be compensated $25.00 each for their time and effort. We have been assured by Mr. Krabec and Dr. Leone (above), our principal contacts in the local communities, that this level of compensation 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 indicates that compensation to research participants, either in the form of money or other material compensation (travel tokens, grocery store vouchers, for example), as a symbol or token of appreciation for the time and energy expended, encourages participation in the data collection process .

A.10. Assurance of confidentiality provided to respondents

The CDC Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable to this project. During focus groups, community leader respondents will be speaking from their roles and will provide information about the economic environment in which the focus groups and interviews will be conducted and possibilities for development of microfinance-based HIV prevention interventions in their community. Community leaders will provide limited personal demographic information about themselves; however, this information will not be personally identifiable. Respondents who participate in focus groups and interviews for at-risk women will provide personal information, including information about sensitive topics. Contact information for all respondents is required in order to schedule participation in a focus group or interview, however, as described below, a number of procedures have been designed to ensure that response data are anonymous and never associated with any of the personal identifiers.

CDC staff will conduct data collection in focus groups and individual interviews. Responses to focus group and individual interview questions will be anonymous; no names, addresses, social security numbers, birthdates, driver's license numbers, telephone numbers, or e-mail addresses will be collected by CDC on any permanent record or on any record that can be linked to information collected. Participants will be assigned an ID number, from a list of five-digit ID numbers provided by the CDC project officer, during screening. Once an ID number has been assigned, it will be crossed off the list of available numbers. ID numbers will not be included on contact information forms so that identifiers cannot be linked to response data, and only ID numbers, not names or other identifying information, will be utilized to label audio tapes and transcripts of individual interviews. Use of ID numbers will be useful during the analytical stage for distinguishing respondents from each other; however, no ID numbers will be used to track focus group participant responses, therefore we will not affix ID numbers to focus group audio tapes or transcripts.

To safeguard the privacy of focus group participants, the moderator will instruct them to avoid using names during the discussion, or to use a pseudonym. Any names used during the focus

group discussion (real or made-up) will be deleted from the transcripts. Some respondents who participate in a focus group will also participate in a personal interview which includes questions of a more sensitive nature. Respondent names will not be associated with the personal interviews.

Logistical support for the research will be provided by a contractor, Manila Consulting, and their sub-contractor, the HIV/AIDS Education, Prevention, Intervention and Care Coalition (EPICC) in West Palm Beach, Florida. They will identify and secure locations for the focus groups and interviews, recruit for and screen research participants, provide transportation for participants, if needed, to and from the focus groups and interviews, and provide participants stipends immediately following the focus groups and interviews. During the screening process, EPICC will collect contact information, which will be maintained in a secure file until focus groups and individual interviews have been conducted, up to six months after the project ends. Only the director of EPICC and the EPICC staff person conducting recruitment and screening will have access to the file containing participant contact information. The contact information will be kept separately from information collected in interviews and from screening forms containing ID numbers; interview information only (not contact information), which will have no personal identifiers, will be kept and analyzed at CDC. None of the research data will be identifiable. Local partners will be invited to review and comment upon draft manuscripts that report data collected in their state. Otherwise, EPICC will not have access to data files or the capacity to link individual contact information to information provided by research participants. Another subcontractor, as yet unidentified, will perform the same functions for the NC research site.

We submitted the research protocol to the Institutional Review Board (IRB) at the Centers for Disease Control and Prevention and have received approval (Appendix C *CDC IRB Approval Email and Supporting Documents*). The appropriate local IRB approvals are also being secured. The consent forms (Appendices D, E, F, N, O, and P) will indicate to respondents that the information they provide will be treated with respect and in a secure manner. We have received approval for this research from the Florida Department of Health, and will do so to the North Carolina Department of Health.

A.11. Justification for sensitive questions

Sexual behavior is a primary mode of transmitting HIV, and it is therefore necessary to ask questions about sexual activities that might be influenced or mitigated by economic stressors. In addition, a full understanding of the dynamic linking of sexual risk behavior and poverty necessitates asking questions about individual experience with poverty. These data on sex risk behavior and poverty will increase our understanding of the HIV epidemic among African American women in the south and the possibility for prevention in this population using microfinance programs, and are central to the purposes of the proposed data collection. Participants will be informed at the beginning of the focus group or interview of their right to skip questions that they do not wish to answer. The screening process for this data collection also collects information on Race and Ethnicity, which may be considered sensitive by a portion of respondents. Race and Ethnicity information is required in order to reach the target audience.

A.12. Estimates of annualized burden hours and costs

A.12.a. Annualized burden hours

The following table reflects the total burden hours for the completion of the study.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
African American Women Ages 18-29 Years	Screening Form	55	1	8/60	7
	Contact Form	55	1	3/60	3
	Demographic Information Form	32	1	5/60	3
	Focus Group Guide	32	1	115/60	61
	Individual Interview	32	1	2	64

Community Leaders	**Focus Group Guide (CL)**	**32**	**1**	**115/60**	**61**
	Demographic Information Form (CL)	**32**	**1**	**5/60**	**3**
				Total	**202**

A.12.b. Annualized cost to respondents

While many if not all of the women in our study will not be working full-time and most will not be employed, we have utilized estimates of hourly wages to approximate the value of the time they would contribute to this study. The figures below were drawn from the Bureau of Labor Statistics website (http://www.bls.gov/ncs/ocs/sp/ncbl0843.pdf) figures on the Miami-Ft. Lauderdale National Compensation Survey – December 2005. This part of Florida is located near the proposed research site. We utilized mean compensation figures (rounded) for Educational Administrators to represent estimated wage rates for Community Leader Participants in our target population and mean compensation figures (rounded) for Community and Social Service Occupations to represent estimated wage rates for Women Participants in our target population.

Type of Respondents	**Form Name**	**No. Respon-dents**	**No. responses per respondent**	**Average burden per response (in hours)**	**Average Hourly Wage Rate**	**Total Respondent Costs**
African American Women Ages 18-29 Years	**Screening Form**	55	1	8/60	$20	$147
	Contact Form	55	1	3/60	$20	$55
	Demographic Information Form	32	1	5/60	$20	$53
	Focus Group Guide	32	1	115/60	$20	$1,227
	Individual Interview	32	1	2	$20	$1,280
Community Leaders	**Focus Group Guide (CL)**	32	1	115/60	$45	$2,760
	Demographic Information Form (CL)	32	1	5/60	$45	$120
					Total	**$5,642**

A.13. Estimates of other total annual cost burden to respondents or record keepers

There are no capital, start-up, operation, maintenance, or service costs for respondents.

A.14. Annualized cost to the federal government

Most individuals involved in conducting the study are currently working at CDC as a federal employee (GS position) or as contractors who provide data management and informatics support to CDC. CDC staff or contractors will conduct data collection. Individuals from local health departments and community based organizations will be facilitating recruitment of respondents and locating secure and private interviewing sites. Contractors will assist CDC staff with logistics of the research. The total contract price is $148,833 for the one year project period. The annualized cost, including percentage of salaried personnel devoted to the study, is $169,633 as shown below.

The HIV/AIDS Education, Prevention, Intervention and Care Coalition (EPICC) in West Palm Beach, Florida will work with the local Department of Health to assist CDC to identify potential research participants, locate private space for focus groups and individual interviews, provide stipends of $25 to each research participant, and provide refreshments for focus groups. Additionally, EPICC will maintain a secure file of contact information on potential participants until focus groups and individual interviews have been conducted, up to six months after the project ends. EPICC will also provide (1) field research assistant(s) who will assist in recruitment of participants and with managing audio tape recorders during the focus groups and (2) a professional transcriptionist who will provide verbatim transcriptions of focus group and individual interviews to CDC within 1 month after data collection and following a protocol provided by CDC. EPICC will not have access to data files or the capacity to link individual contact information to information provided by research participants. Another agency, as yet unidentified, will perform the same functions for the NC research site.

Annualized Cost to the Federal Government

Title	Federal Salary Grade	Salary or contract	% Effort	Annualized Cost

		costs		
CDC Project Officer	GS 14	$104,000	20%	$20,800
Contract costs: Data Managers/research assistants/research costs (travel to four research sites, equipment for interviews, incentives to participants, data management costs such as software, transcriptions, etc.)	N/A Contractors (3), including Manila Consulting and their subcontractors in Florida (EPICC) and North Carolina (as yet unidentified)	$148,833	100%	$148,833
Total:				**$169,633**

A.15. Explanation for program changes or adjustments

This project involves new data collection.

A.16. Plans for tabulation and publication and project timeline schedule

A.16.a. Project Time Schedule

Activity	Time Schedule
➢ Review publicly available information on microfinance and microenterprise	During OMB packet review
➢ Microfinance consultation (March 8-9 2006)	During OMB packet review [not part of this packet but related to this project]
➢ Development of study contacts	During OMB packet review
➢ Enrollment and data collection	2-4 months after OMB approval
➢ Data management	2-4 months after OMB approval
➢ Data analysis	4-7 months after OMB approval
➢ Report writing	8-12 months after OMB approval

A.16.b. Data analyses

Data analyses will commence once data have been collected (tape recorded and then transcribed) and checked for accuracy. Accuracy checks will be conducted by comparing audio tapes to written

transcripts. As indicated under Section A.1.a., the aims of this study are entirely descriptive. As appropriate, simple percentages will describe the demographic (e.g., age, education, income categories) characteristics of the interviewees (see Appendices J and K *Brief Demographic Information* forms,). Content analysis of qualitative data from the transcripts will be conducted using NVivo7 software for management and analysis of qualitative data. This will provide information to meet this study's aims as stated above. The CDC project officer for this project is proficient at qualitative data analyses and presentation.

From the focus groups with at-risk women, we will report on the number of women in the groups and their demographic make-up. We will code the information from the transcripts using both pre-determined codes derived from the question frames, unanticipated topics introduced during the interviews by interviewees, and responses to questions. We will assess relevant patterns in these data and provide a description of respondents views on: 1) What kinds of jobs or businesses would be feasible (can be done by these women with some training and other preparation), 2) what kinds of jobs would be attractive (women will do this work), 3) what kinds of jobs would be useful (likely to produce income to address a reasonable proportion of economic need to the women)? We will also identify patterns in the data regarding specific employment and poverty issues within the community.

From the individual interviews with a subset of women from the focus groups, we will report on 1) personal economic histories, 2) personal risk behavior experience, and 3) economic support relationships, for example financial assistance from sex partners.

From the focus groups with community leaders, we will report on the number of individuals in the groups and the demographic make-up of the group. We will code the information from the transcripts using both pre-determined codes derived from the question frames, unanticipated topics introduced during the groups by interviewees, and responses to questions. We will assess relevant patterns in these data and provide a resulting description of respondents views on: 1) What kinds of jobs or businesses would be feasible (can be done with small capitalization and by the target population of poor, African American women with some training and other preparation);

2) what kinds of jobs would be attractive (women will do this work and communities would support the additional economic activity/the activity would fill a gap in community economic activities); 3) what kinds of economic activity would be useful (likely to produce income to address a reasonable proportion of economic need; the community will use the service or purchase the product of the activity) to the women and the communities in which they live; and 4) who would be the appropriate stakeholders in the community, what would their relationship be to a microfinance activity conducted as an HIV/STD prevention intervention, and how should relationships with these stakeholders be organized.

A.16.c. Publications

Publications describing the specific results of this research on the feasibility of microfinance as an HIV/STD prevention intervention in the south will be useful for intervention planning and evaluation. We anticipate that our findings will be published in peer-reviewed academic journals.

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

There are no exceptions to certification for Paperwork Reduction Act submissions requested.

STATEMENT B: STATISTICAL DESIGN AND DATA COLLECTION PROCEDURES

B.1. Respondent universe and sampling methods

This is a qualitative research study among up to 32 women and 32 community leaders. The respondent universe is a non-representative sample of poor, at-risk African American women in four communities in the southeastern United States (NC and FL) and community leaders in those communities. Given the sampling design, we will not provide generalizable data; we will provide in-depth information on the topic of interest.

B.1.a. Inclusion criteria

For the focus groups with at-risk women, the respondents will be

- Female
- African American
- Ages 18 – 29
- Have had sex partners who contributed to their household income in the past 90 days
- Are currently unemployed or employed only part-time or seasonally during the year
- Reside in the designated catchment areas and speak English.

These criteria for inclusion in the focus groups for women were selected because the CDC is interested in learning about the economically-related risk issues among this particular population and how they would respond to economic alternatives.

For the focus groups with community leaders, the respondents will be persons

- With some leadership capacity in the same communities from which the women's focus groups are drawn
- Who are currently active on the state or local HIV community planning board.

B.1.b. General approach to recruitment

Research participants in the focus group with women will be recruited from neighborhood venues such as beauty shops and nail parlors, bars, and churches in the research areas. Recruiters for focus groups with women will be women, selected by the local community based organizations or health departments, who are familiar with the target populations and have demonstrated effective working relationships with them. Participants in the focus groups with community leaders will be recruited through the local HIV community planning boards or councils. CDC staff or local health department staff will attend planning board meetings to recruit for the community leader focus groups.

A subset of women in the focus groups will be invited by the focus group facilitator to participate in individual interviews in which questions of a more personal nature will be explored. Following the focus group, the facilitator will invite women to participant in individual interviews based on the facilitator's assessment of their interest in the topic and ability to talk openly about the topic.

B.2. Procedures for the collection of information

B.2.a. Sampling frame and sample size selection

A sample of four communities in the Southeast US was selected based on their high prevalences of HIV/AIDS and sexually transmitted diseases among women. Given that the AIDS epidemic, like the epidemics of STDS, is moving into populations affected by poverty, we have purposively selected one rural and one urban community in areas of both NC and FL characterized by high poverty rates.

For this study, we are interested in in-depth information regarding the dynamic between economic need and potential on the one hand, and issues related to risk for HIV/STD on the other. Because this is an exploratory and feasibility project regarding the potential for microfinance as an HIV prevention intervention and how communities would respond to this activity, these focus group interviews are designed to provide in-depth descriptive information, rather than information that can be generalized to a larger population. Also, this study is not designed to assess the extent and distribution of patterns of risk in the target population. Thus, the sample will be one of convenience

and not representative of all persons potentially eligible for the study. However, for the community leaders' focus groups, we will attempt to recruit the widest possible array of experience and perspective in the local communities that may be represented on the respective HIV community planning boards. Additionally, within the parameters established for eligibility, we will attempt to arrive at a sample that is as broad as possible among young women; for example, we will attempt to recruit women in the age range 18-29 whose ages are a spread throughout that range and who live in different neighborhoods within the catchment area.

B.2.b. Data collection procedures

B.2.b.1 Recruitment process for focus groups and individual interviews with at-risk women

Community members who have previous experience recruiting and interviewing women in the target population will aid CDC study staff in identifying and recruiting among potential participants for the project. Recruiters will be trained by the CDC project officer on the purpose and goals of the proposed project and securing contact information of potential participants. During their training, recruiters will demonstrate the processes that will be used to secure participant contact information. Recruiters will approach women at local venues identified by local health departments as productive sites for engaging women; e.g., beauty shops, nail parlors, and churches. The women will be screened face-to-face at the recruitment venue using a screening form (Appendices L and Q). If the women are interested in the project but are not available for screening at the venue, they will be asked to provide their telephone numbers so that they will be screened on the phone. A woman can be approached directly by a screener no more than twice before her name and contact information are deleted from a list of potential participants. Women who meet the eligibility criteria (see Screening protocols, Appendices L and Q), express interest, and provide contact information will be given a date and time to return for participation in the group session. If a woman gives permission, she will be called to remind her of the focus group event. This procedure will continue until up to eight participants have been recruited for each women's focus group. Contact information for study participants will be recorded on the Participant Contact Form (Appendix M). When a person is found to be ineligible her contact form will be destroyed as soon as she is found to be ineligible. Contact information for the focus group study participants, including

those who withdraw, will be destroyed within six months after the end of the study. Contact information will be kept in a locked file cabinet by a research partner organization at the study site.

After each focus group, the facilitator will ask up to eight of the women to participate in semi-structured individual interviews. The facilitator may also speak personally to individual women to determine their interest in the one-on-one interviews. The facilitator will then make date, time, and place arrangements for personal interviews with those eligible.

B.2.b.2 Recruitment process for focus groups with community leaders

With the assistance of the local health departments, up to eight community leaders will be recruited through the HIV community planning board of the target communities for each community leader focus group. The local health departments will assist by identifying meetings at which CDC staff can be introduced, describe the project, and recruit potential focus group members.

B.2.b.3 Data collection processes in focus groups and individual interviews

Prior to data collection in the focus group, the research interviewer will read aloud the consent form to participants, who will sign the form after any questions have been answered. The research interviewer will answer questions about the consent form or any other questions that may arise during the process. Each participant will also receive a copy of the consent form to keep for their records.

The focus group facilitator will be a CDC researcher trained and experienced in conducting qualitative research interviews. The facilitator will conduct the groups using lists of discussion questions developed separately for women and for community leaders (Appendices G and H). The topics to be covered have been listed elsewhere in this OMB application. Each focus group will take about two hours to complete. The focus groups will be tape recorded, and the tapes will be later transcribed verbatim. A second CDC research team member will serve as a non participant observer, taking observational notes during the session and managing the tape recorder. Participants will also be asked to fill out a brief Demographic Information Form at the end of each

focus group (Appendices J and K); however, they will not be asked to provide their names on the form.

After the focus group with women, up to eight of the women will be asked to participate in individual interviews. Criteria for selecting women for these interviews include interest in and willingness to discuss the issues raised in the focus group and willingness to discuss related but more personal matters, such as exchanging sex for money or for some financial support to the woman or her family. An experienced and trained CDC interviewer will conduct the individual interviews, using an interview guide (Appendix I). Prior to these interviews, the facilitator will read the consent form with each interviewee, and interviewees will sign and receive a copy of the consent forms. The individual interviews will explore questions of a more personal nature, such as exchanging sex for drugs, money, housing, personal economic profiles (needs, income levels and sources; aspirations), and employment and public assistance histories. Each individual interview will take about two hours to complete. The interviews will be tape recorded with permission of the interviewee, and the tapes will be transcribed verbatim. Again, no names or other personal identifiers will be attached to the tapes and transcripts.

The focus groups will take place in conference rooms designated by the local health departments. Individual interviews will take place in locations in which the women will feel most comfortable; for example the conference rooms designated by the health departments, or other spaces where interviews may be conducted in private such as church conference rooms, also arranged by contacts through the local health departments.

B.2.c. Data entry and cleaning

Audio tape recordings will be made of each focus group and individual interview, with the prior permission of the participants during the consent process. The audio tapes will be professionally transcribed into computer files and reviewed for accuracy by the CDC project officer, who will compare randomly selected portions of the transcriptions with the audio tapes. A transcription protocol will be used that includes deletion of personal identifiers during the transcription process.

B.2.d. Data analysis

Significant analytical work will be devoted to identifying patterns in the data using qualitative content analysis; additionally we will use percentages to report demographic characteristics of the study population. Our analytical procedures are specified in **Section A.16.b**, above. We will not have the ability, given the non-representative sample, to make statements regarding generalizable significant differences among focus groups or individuals with regard to experiences and perceptions on the topic of interest. We will identify patterns among all groups, and to the extent that these are similar, will be able to say with some degree of confidence that these patterns exist and should be taken into account when developing microfinance-based HIV prevention interventions for African American women in the South.

B.3. Methods to maximize response rates and deal with non-response

The primary method used to maximize participation in qualitative interviews and focus groups will be the work of recruiters who are familiar with the population and the community, who can use appropriate verbal and non-verbal styles in a non-threatening manner to introduce the study to potential participants, and who understand the purpose and goals of the project. Recruiters will be trained on the purposes and goals of the project by the CDC project officer, and the recruitment strategy will be developed with them in order to maximize the number of venues from which effective recruitment might take place. In addition, we anticipate that CDC's experience conducting research with the target population and our having consulted with local experts about the project will contribute to improved response rates and assure that we obtain the information needed. Finally, respondents will be paid a small incentive for their time and effort at a level that encourages participation. Given that we will be recruiting a non-representative sample, non-responsiveness will not be a significant issue. We will recruit until such time as we have the number of respondents required. Also, the interviewer has experience in eliciting responses from participants in focus groups and individual interviews in a manner that is both non-threatening and encouraging.

B.4. Tests of procedures or methods to be undertaken

We will not be piloting the question frames for this project given (1) qualitative interviews give researchers the ability to explicate and explore issues with interviewees rather than relying on specific questions, (2) CDC's experience conducting qualitative research with the target population, and (3) the limited time frame for this project.

B.5. Individuals consulted on statistical aspects and individuals collecting and/ or analyzing data

No consultation outside of CDC will be needed for the qualitative data analysis that will be conducted for this project. Additionally, the CDC project officer will conduct the focus groups and individual interviews described earlier. The data collection will be supported by individuals from the local health departments or CBOs who are our partners on this project, as indicated below. Our partner organizations will assist data collection by identifying potential participants; securing private, comfortable interview space; providing stipends and refreshments to focus group and individual interview participants, and managing tape recording equipment during the focus groups. Representatives of our partner organizations are listed below.

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References

1 Fitzpatrick L (2004). HIV Transmission among Black Women in NC. Unpublished data presented December 1 2004, TRIP (DHAP), CDC, Atlanta.

2 Krieger N, Chen, JR, Waterman PD, Rehkopf DH, Subramanian SV. (2003). Race/ ethnicity, gender, and monitoring socioeconomic gradients in health: a comparison of area-based socioeconomic measures-the public health disparities geocoding project. *American Journal of Public Health* Oct. 93(10):1655-71.

3 Ellerbrock TV, Chamblee S, Bush TJ, *et al*. (2004). Human immunodeficiency virus infection in a rural community in the United States. *Am J Epidemiology* 160(6):582-588.

4 Klein C., Easton D., and Parker R. (2002). Structural barriers and facilitators in HIV prevention: A review of international research. In: O'Leary A, editor. *Beyond Condoms: Alternate Approaches to HIV Prevention*. New York, NY: Kluwer Academic Plenum Publishers.17-46.

5 Nagy-Agren S. (2001). Infectious diseases and women's health: link to social and economic development. *J Am Med Women's Assoc*. 56(3):9293.

6 Fitzpatrick, J.D., Forma, F., Greenberg, A., Leone, P., Adimora, A., & Foust E. (2005). HIV infection among young black women. The evolving HIV epidemic: Risk behavior, incidence, and

prevalence. 12th Conference on Retroviruses and Opportunistic Infections, Boston, MA, February, 2005.

7 Southern State AIDS/STD Directors Work Group. (2003). Southern States Manifesto *HIV/AIDS and STDs in the South: A Call to Action*. Kaiser Family Foundation, March 2 2003, retrieved from http://www.hivdent.org/Manifesto.pdf on January 4, 2006.

8 NCDHHS. (2004). Epidemiologic profile for 2005 HIV/STD prevention and care planning. Raleigh, NC: North Carolina Department of Health and Human Services. http://www.epi.state.nc.us/epi.hiv accessed 6/24/05.

9 State of Florida Department of Health. (2004). *Annual Report/Epidemiologic Profile 2004*, retrieved from http://www.doh.state.fl.us/Disease_ctrl/aids/trends/epiprof/epiprofilesind.html on January 4, 2006.

10 O'Leary A (2001). Substance use and HIV: Disentangling the nexus of risk. Introduction to special issue, *Journal of Substance Abuse* 13:1-3.

11 Sumartojo E. (2000). Structural factors in HIV prevention: concepts, examples, and implications for research. *AIDS 14 Suppl. 1:S3-10.*

12 Schuler SR and Hashemi SM. (1994). Credit programs, women's empowerment, and contraceptive use in rural Bangladesh. Studies in Family Planning 25(2):65-76.

13 Waters W., Rodriguez-Garcia R., and Macinko J. (2001). *Microenterprise development for better health outcomes*. Westport CN: Greenwood Press.

14 Hashemi, S., Schuler S., and Riley A. (1996). Rural credit programs and women's empowerment in Bangladesh. World Development 24(4): 635-663.

15 Schuler S., Hashemi S., and Riley A. (1997). The influence of women's changing roles and status in Bangladesh's fertility transition: Evidence from a study of credit programs and contraceptive use. *World Development 25*(April), 563-575.

16 Sherman S.G., German D., Cheng Y., Marks M., & Bailey-Kloche M. (2006). The evaluation of the JEWEL project: An innovative economic enhancement and HIV prevention intervention study targeting drug using women involved in prostitution. *AIDS Care* 18(1):1-11.

17 *CDC HIV Prevention Strategic Plan through 2005*, downloaded 01/19/2006 from http://www.cdc.gov/hiv/prev_prog/ahp/resources/brochures/AHP_Brochure.htm.