HIV/AIDS Risk Reduction Interventions for African-American Heterosexual Men

Supporting Statement
Part B

0920-XXXX

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

Respondent Universe

The respondents providing the information for the proposed project are African American heterosexual men who live, work, or obtain services in one of the study areas (Brooklyn, NY; South Bronx & Harlem, NY; and Greensboro, NC). The project will be conducted by three sites: a) State University of New York, Downstate-**"SUNY"**(Brooklyn, NY); b) New York Blood Center-"**NYBC**" (Bronx & Harlem, NY); c) University of North Carolina-Greensboro-"**UNCG**" (Greensboro, NC). In each study location, 50-80 African American heterosexual men will be recruited. The following entities comprise the sampling universe:

> SUNY: African American heterosexual men who are clients of barbershops located in Central Brooklyn, NY.
>
> NYBC: African American heterosexual men who are recruited via street intercepts in Harlem & South Bronx, NY.
>
> UNCG: African American heterosexual men who attend college in Greensboro, NC.

The catchment area for the SUNY site includes Central Brooklyn and Flatbush in New York City. The neighborhoods included in these two areas are Bedford-Stuyvesant, Crown Heights, Prospect Heights, Brownsville, Flatbush, East Flatbush, Midwood, and Prospect Lefferts Gardens. Approximately 77-80% of over 634,000 residents in Central Brooklyn and Flatbush combined identify as African American.

For NYBC, the catchment area includes South Bronx, East Harlem, and Central Harlem in New York City. South Bronx is a neighborhood in the borough of the Bronx where 24% of residents are African American. Central and East Harlem residents make up 3% of the New York City population and 67% and 33% of residents are African American, respectively.

For UNCG, the catchment area includes the undergraduate student body at the University of North Carolina Greensboro and North Carolina Agricultural and Technical University. Of the 17,157 students attending UNCG, 476 (16%) are African American. NCAT has a student body of 10,000 undergraduate students, of whom 86% are African American.

An estimated 620 persons (total for all sites) will be screened using Screener Forms (Attachments 3a-3c) to determine eligibility for study participation. The Screener Forms (Attachments 3a-3c) will collect information to ascertain if the potential participant meets the following eligibility criteria: a) self-identify as male; b) self-identify as African American; c) understand/read English; d) report unprotected vaginal or anal intercourse with 2 or more female partners in the last 3 months; e) HIV negative and/or unknown status; and f) willing and able to provide informed consent.

In addition to the overall criteria, the site-specific inclusion criteria included the following:

a) Age 18-45 years old (SUNY & NYBC)

b) Age 18-24 years old (UNCG)

c) Resident of the South Bronx or Harlem communities (NYBC)

d) Currently enrolled as undergraduates at University of North Caroling Greensboro or North Carolina Agricultural and Technical University (UNCG)

The pilot intervention trial will be conducted with 150-240 (total for all sites) African American heterosexual men with a projected sample size of 50-80 participants per site. The intervention trial will be a pretest-posttest design with a baseline and 3-month follow-up assessment (Attachments 3g-3i).

Sampling Procedures: Convenience samples will be used at all three sites. The objective of the project will be to assess feasibility and acceptability of the intervention programs to heterosexual African American males. The analysis will not involve comparing efficacies of interventions across the three programs.

Response Rates:
Due to differences in recruitment strategies and sampling frame, the proportion of eligible persons is expected to vary between the three project sites. SUNY and UNCG estimate that 80% of men found eligible during screening will enroll in the study. NYBC estimates that 75% of men found eligible during screening will enroll in the study. For follow-up rates from baseline to 3-month assessment, SUNY reports an 80% follow-up rate. NYBC and UNCG estimate that 100% of persons will be retained from baseline to follow-up.

2. Procedures for the Collection of Information

Project staff at SUNY, NYBC and UNCG each include: Principal Investigators, a Project Manager, Data Collectors, and a Data Manager. The Principal Investigators will be responsible for study implementation, supervision of all research activities and providing oversight to all staff on the study team. Project Managers will coordinate all aspects of the project, including screening, enrollment, baseline and follow-up assessments. The Project Managers will also be responsible for coordinating all tracking and contact activities including using contact information to locate participants and schedule follow-up visits and will interact as necessary with other staff assisting with maintaining contact with participants.

Prior to beginning data collection, study staff at each project site (SUNY, NYBC, UNCG) will receive training on confidentiality and scientific ethics, recruitment and facilitation skills, referral resources, and managing adverse events, among other important issues. Data Collectors at SUNY and NYBC will be trained to administer the Screener Forms (Attachments 3a-3b), Locator Forms (4a-4b) and the Baseline and Follow-up Assessments (Attachments 3g-3h). Data Collectors at these sites will also receive training on administration of the Baseline and Follow-up Assessments using ACASI. Data Collectors will remain accessible to the participant in case

he needs help or has any questions while he is using ACASI. Trained study staff at UNCG will accessible (by contacting the project office) to provide participants with assistance in completing the Screener Form (Attachment 3c), Locator Form (Attachment 3f) and the Baseline and Follow –up Assessments (Attachment 3i) on-line. Strict ethical guidelines regarding professional conduct will be enforced with all research team members at each site.

An estimated 620 men (total across three sites) will be screened for eligibility using the Screener Forms (Attachments 3a-3c). This process is estimated to take 5-10 minutes depending upon the site. The procedures for screening will involve the following:

> SUNY: a) Data Collector will briefly introduce the study at the barbershop (Attachment 5a1); b) if the potential participant is interested, the Data Collector will provide the potential participant with a blank appointment card (Attachment 5a2) that includes the address and phone number of the project office; c) Data Collector will ask the potential participant to call the project office to complete screening to determine eligibility.
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> NYBC: a) Potential participants will either call the project phone number indicated on flyers/posters (Attachment 5b1) or if the potential participant provided contact information to study staff, potential participants will be called by project staff (Attachment 5b2) to conduct screening; b) screening will then be conducted over the telephone or in-person at the project office.
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> UNCG: a) Invitations to participate in the study will be sent to the email addresses [information in identifiable form (IIF)] of potential participants in the UNCG student database; b) potential participants will also be recruited via posters/announcements in class, student organization meetings, information tables in well-trafficked areas, and radio spots on the campus radio stations (Attachments 5c1-5c2); c) potential participants who agree to participate will then complete an on-line screening to determine eligibility.

The study design is a pilot evaluation (pretest/posttest) with a Baseline and three-month Follow-up Assessment (Attachments 3g-3i). Eligible participants will provide Consent (Attachments 4a-4c). For SUNY & NYBC, the Data Collector will collect basic contact information from the participant using the Locator Form (Attachments 3d-3e). Participants will then complete a Baseline Assessment (Attachments 3g-3i) via ACASI (SUNY & NYBC) or online survey (UNCG). The Baseline Assessment will take approximately 20 minutes (SUNY & UNCG) or 45 minutes (NYBC).

Following the Baseline Assessment (Attachements 3g-3i), participants will be scheduled to complete an HIV risk reduction intervention. The intervention for each site consists of the following: a) SUNY- brief, single session HIV risk reduction group session; b) NYBC- a 4-session, HIV risk reduction group intervention; and c) UNCG - a 5-session HIV risk reduction group intervention.

Three months after completing the intervention, participants will complete the Follow-up Assessment (Attachments 3g-3i). The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with the exception of a few questions regarding acceptability and feasibility of the intervention. The estimated time required to complete Follow-up Assessments will be the same as the Baseline Assessment for each site.

Participants will also be reminded that they will receive a reminder phone call between the intervention activity and Follow-up Assessment. Participants will be given a specific "target date" for the follow-up visit. Participants who miss an appointment for Baseline Assessment or 3-month Follow-up Assessment, within the target window or cannot complete the assessment at that time will be scheduled for an appointment outside of the target window, but within the acceptable window period.

The Baseline and Follow-up Assessment (Attachments 3g-3i) will be administered in private offices (SUNY & NYBC) or via a secured online website (UNCG). The assessment instruments contains questions about participants' socio-demographic information, health and health care, sexual activity, drug use, and other psychosocial issues. Sensitive questions on the assessments (e.g., sexual activity, drug use) will be asked using ACASI. The ACASI/online survey system displays each assessment question on a computer monitor. For the ACASI, the questions are simultaneously playing an audio recording of the question through headphones (SUNY & NYBC). Participants enter their responses to the assessment questions directly on the computer. Use of this method and on-line surveys allow not only for direct entry of data into the computer, but these method has also been shown to result in participants reporting higher rates of sensitive behavior than from other survey methods (Turner, Forsyth. O'Reilly et al, 1998).

For SUNY and NYBC, Data Collectors will demonstrate the ACASI system to each participant and answer any questions about its use. During administration of the assessment, the Data Collector will remain on-site to answer any additional questions or address any problems. For UNCG, online data collections (i.e., Screener, Locator Form, Baseline and Follow-up Assessments) will be displayed on a personal computer screen with access to the project's secured website.

Data quality is ensured by use of computer-assisted interviewing/online survey, data collector training and monitoring, site visits, and data editing. Computer-assisted interviewing improves data quality in several ways. Data Collector errors are reduced because interviewers do not have to follow complex routing instructions; the computer does it for them. Respondent errors are also reduced. Consistency checks are programmed into the assessments so that inconsistent answers or out of range values can be corrected or explained while the interview is in progress. Use of ACASI/online surveys also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and more accurately. A training of local field staff will occur prior to implementation of data collection. This training will cover general interviewing skills, the sampling and recruitment protocol, and a question-by-question review of data collections forms to ensure data collectors understand the purpose of each question and how data collected should be entered on forms and in the computer.

For SUNY & NYBC, data collectors will have opportunities to practice administering the eligibility screener (Attachment 3a-3c), as well as going through the ACASI Baseline and Follow-up Assessments (Attachments 3g-3i). The training will also address data collector integrity, underscoring the importance of collecting quality data and the consequences of inappropriate behaviors, including falsification of data (SUNY/NYBC). The training will cover how to provide technical assistance to respondents who have problems with the ACASI Baseline and Follow-up Assessments. During the data collection period, field staff will be monitored by their Principal Investigator or other management staff.

For all sites, feedback will be provided for areas of improvement or incorrect implementation of the protocol. Supervisors will provide feedback on ways to help improve response rates. CDC will conduct at least one site visit per year. The purpose of the site visit is to monitor adherence to the study protocol and to obtain feedback on study procedures. In addition to the checks provided through the computer-assisted interview program, editing of the data may be performed by CDC, including performing extensive checks of the quality of the files and identification of errors in programs or procedures.

The purpose of this pilot intervention trial is to collect preliminary evidence of efficacy for three HIV behavioral prevention interventions developed specifically for African American heterosexual males. Feasibility and acceptability are common indicators used to assess the potential efficaciousness of pilot interventions. No assumption about the data distribution can be made due to the formative nature of the pilot interventions.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Participant retention during the pilot intervention trial will be enhanced in several ways. This is particularly important in a pilot intervention to provide scientifically-sound evidence regarding feasibility, acceptability and preliminary evidence of intervention efficacy in reducing HIV risk behaviors.

In order to reach the number of men needed to participate in the study, we will monitor recruitment and retention throughout the course of the study. If we are not reaching the number of men needed (e.g., experience greater levels of attrition than anticipated), we will expand recruitment efforts. Expansion of recruitment efforts would differ by site. These efforts include the following:

SUNY

1) During recruitment, study staff will provide potential participants with a study Contact Card (Attachment 5a2) that includes the name, address and telephone number of the project office. This Contact Card will also be used to schedule upcoming appointments (for completion of the intervention and assessments). Study staff will fill out the card and give the card to a participant as a reminder.

2) Staff persons will contact participants between scheduled appointments providing reminders (Attachment 5a3) for follow-up appointments and to encourage continued participation in the study.

NYBC

1) Street intercept recruitment will be supplemented with participant referrals and flyer/posters (Attachments 5b1-5b2) distributed throughout locations within the catchment area. Advertisements in local newspapers and magazines will be used if necessary

2) A locator information database will be used to generate reminder letters (Attachments 5b4-5b5) and a list of participants who need to be contacted via telephone (Attachments 5b3, 5b5) to increase retention for completion of intervention group sessions and assessments.

UNCG

1) Supplemental to on-line recruitment, additional recruitment strategies include various campus marketing efforts (e.g. flyers and poster announcements in classes, student organization meetings, information tables in well-trafficked areas, and radio spots on the campus radio stations (Attachments 5c1-5c4).

2) Participants will be contacted to remind them of upcoming appointments for completing the intervention and assessments (Attachments 5c5-5c6).

Another important method for retention is the use of tokens of appreciation for participation. As discussed previously (Section A.9), the use of monetary incentives has previously been shown to improve retention of participants in projects similar to this (Kamb et al., 1998; Greenberg et al., 1998). Participants will also be provided with transportation assistance, namely money to reimburse transportation costs to the project site (SUNY), bus passes (NYBC), or project-provided van (UNCG).

To maximize reporting of sensitive behaviors in the Baseline and Follow-up Assessments (Attachments 3g-3i), we will use ACASI (SUNY & NYBC) and online surveys (UNCG) for all questions, including sensitive portions of the assessments (i.e., participants' sexual and drug using behaviors). Research suggests that the ACASI technology improves reporting of sensitive behaviors (Des Jarlais et al., 1999; Turner et al.). Data Collectors at UNCG and NYBC will receive extensive training on how to administer ACASI assessments. For UNCG, online surveys will be programmed by TechTriad - a web hosting and design company with experience administrating secure on-line surveys (www.techtriad.com).

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

Due to differences in recruitment strategies and sampling frame, the proportion of eligible persons is expected to vary between the three project sites. SUNY and UNCG estimate that 80% of men found eligible during screening will enroll in the study. NYBC estimates that 75% of

men found eligible during screening will enroll in the study. For follow-up rates from baseline to 3-month assessment, SUNY reports an 80% follow-up rate. NYBC and UNCG estimate that 100% of persons will be retained from baseline to follow-up.

Non-response bias is certainly an issue of concern for any research study, ranging from cross-sectional surveys to observational cohorts to experimental trials. Non-response bias can play a significant role in the accuracy of the intervention effect estimate; however, if the non-response is non-differential, this results in a conservative bias. Despite having a history of successful retention in previous studies, we will assess whether non-response bias, and more importantly differential non-response bias, exists in our data and is affecting our findings. We will go about that using the following strategies:

- Assess potential causes for overall non-response and differential non-response by testing whether any background factors, demographics, or other individual characteristics are associated with non-response, and particularly whether these factors are significantly differentially associated with non-response.

- If differential non-response exists, and particularly if differential underlying factors appear to be related to non-response, then we will employ statistical analyses to attempt to address this bias. First, we will conduct a sensitivity analysis in order to determine the extent to which the missing data affect the outcome. Second, we will consider employing regression modeling techniques for predicting missingness and imputing missing data. Finally, we will consider Bootstrap methods to account for the missingness and improve upon the estimated standard error and confidence interval of the intervention effect estimate for this study.

4. Test of Procedures or Methods to be Undertaken

No new biologic or diagnostic tests will be used in this study.

SUNY

The analytic approach for the SUNY pilot study is designed to: (1) characterize the sample at baseline and 3-month follow-up and (2) assess evidence of intervention efficacy to reduce risk behaviors among study participants. Descriptive statistics (means and standard deviations for continuous variables, percentages for categorical variables) will be used to characterize the study sample on sociodemographics, health, and sexual risk behaviors at baseline and follow-up. To explore inter-relationships among baseline and follow-up variables, chi-square analyses (for discrete variables) and t-tests (for continuous or ordinal variables) will be utilized to describe the individual level and contextual factors associated with heterosexual risk behaviors, and to convey information derived from the process evaluation.

Descriptive statistics will be used to describe intervention acceptability and feasibility. In addition, participant's self-efficacy, attitudes, perceived norms, and behavioral intentions will be described in relation to unprotected anal and or vaginal intercourse (UAVI) with female partners. There will also be an evaluation of the percentage of men who engaged in unprotected anal and/or vaginal sex (UAVI) with a female partner 3 months post-intervention. The analytic

approach will be as follows, using the example of UAVI as one outcome. Repeated measures logistic regression models will be constructed to estimate the effects of program exposure on engaging in UAVI at 3-month evaluation (or linear regression for continuous variables). Factors associated with UAVI at 3-month follow-up will be identified using crude and adjusted odds ratios with corresponding 95% confidence intervals that will be computed using generalized estimating equations (GEE).

It is hypothesized that study participants within each barbershop will be more similar in characteristics than between sites, and will therefore use GEE models which will allow us to adjust standard errors to account for clustering within sites. Backward model-building procedures will be used to produce the most parsimonious subset of explanatory factors predicting the odds of engaging in risky sexual behavior. Factors that contribute significantly to the models ($p < 0.05$ by Wald test) will be retained, and likelihood ratio tests will be conducted to assess differences between models. Other important outcomes (e.g., multiple sexual partners or concurrent sexual partners) will be assessed using a similar approach. In a final analysis, frequency distributions of the variable "attitudes toward condom use" will be compared at baseline and at 3 months. To assess the extent to which program exposure translates to increased awareness and prevention of high risk behaviors (e.g., favorable attitudes toward condom use) at 3 month follow-up, repeated measures, multiple analysis of variance (MANOVA) will be conducted. To examine between-site differences over time, an interaction term (time*site) will be included in all MANOVA models, with a significant interaction meaning that attitudes toward condom use over time between men of the different sites are significantly different. All analyses will be performed with statistical significance set at a two-sided alpha level of 0.05. Data will be collected for the client assessments through ACASI and analyzed using SPSS v 16.0.

NYBC

A single-arm intervention design with baseline and three month follow-up assessments will test the hypothesis that compared to baseline, participants will report a statistically significant reduction in the occurrence of unprotected sex and concurrent partnering at the follow-up visit. Since some of the sexual risk behaviors analyzed in this study (i.e., number of unprotected acts in past 3 months) are very skew, data will be either transformed (i.e. logarithms) or dichotomized as 0 vs. > 0 or as (-1 = decreased, 0 = unchanged, 1 = increased). To consider potential biases resulting from those who discontinue participation, dropouts will be compared to completers with respect to baseline behavior and other characteristics. Primary outcomes include HIV knowledge, attitudes and intention to reduce risk behavior. Other outcomes include occurrence of unprotected vaginal intercourse and/or unprotected anal intercourse with female partners in the past three months; concurrent partnering with female and/or male partners in the past three months. Concurrency will be defined as: vaginal or anal sex with two or more people during a three month period, with at least one instance where sex with partner A occurred both before and after sex with partner B. Our secondary outcomes are occurrence of HIV testing and number of new and total female and male sex partners. Furthermore, intermediate condom-related outcomes (including attitudes and outcome expectancies, self-efficacy, peer and partner norms and perceived responsibilities), as well as acceptability and feasibility of the intervention will be assessed.

As a first step in the analysis, process measures on the proportion of those approached, screened and enrolled in the intervention, as well as, session attendance will be calculated. Exploratory data analysis will be conducted for continuous predictor variables at the baseline and the 3 month visits. Appropriate transformations (logarithms or categorizations) will be made for subsequent analyses. Binary predictor/outcome variables will be examined by 2x2 tables for sufficient variability to be used in comparative analyses. McNemar's discordant pairs tests or sign tests will be used to examine within person change for binary outcomes such as unprotected vaginal sex. For continuous outcomes (e.g., number of partners), paired t-tests will be used. As allowed by the sample size, exploratory analysis will be conducted to adjust for other covariates using conditional logistic regression or linear regression of changes. Intraclass correlations will be examined to see if there was evidence of any cluster effects among individuals in the same intervention group.

UNCG

Data analysis will involve two parts: general descriptions of the study group, and analysis for effects of significant correlates. Analyses on the key dependent variables (i.e. acceptability, feasibility, knowledge, attitudes, and intentions to reduce HIV risk behavior) measured at the two time points (baseline pre-test and a 3 months' post-intervention follow-up test) will be conducted through examination of 2x2 contingency tables and appropriate chi-square tests, to examine differences at the 3-month post-intervention data compared to the baseline.

Simple analytical techniques will be used to describe participants, including descriptive statistics (mean, median, percent). Scatter plots and histograms will be used to evaluate the distribution of the participants according to the variables measured. Simple correlation analyses will be conducted to evaluate the associations between pairs of variables. Nonparametric statistics (e.g., Spearman's rank correlation coefficient, Wilcoxon's rank sum test) will be used when appropriate to evaluate the significance of the associations.

Scale reliability: (internal consistency) will be examined by determining Cronbach's alphas. The closer Cronbach's alpha is to 1.0, the greater the internal consistency of the items in the scale. The following "rule of thumb" guide in evaluating the alpha of each scale: $\alpha>.9$=excellent; $\alpha>.8$=good; $\alpha>.7$=acceptable; $\alpha>.6$=questionable; $\alpha>.5$=poor and $\alpha<.5$=unacceptable. Collected data will be recorded directly into a computerized database. SPSS 11.5 (SPSS, Chicago, IL) and SAS v8.2 (SAS Institute, Cary, NC) will be used for analysis.

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

The study design and data collection instruments were a collaborative effort between CDC, State University of New York, Downstate (SUNY), New York Blood Center (NYBC) and University of North Carolina-Greensboro (UNCG). SUNY, NYBC, and UNCG will be responsible for data collection activities. The primary persons consulted on statistical aspects of this project and who will be responsible for analyzing the data at each site are as follows:

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