Critical Thinking and Cultural Affirmation (CTCA): Evaluation of a Locally Developed HIV Prevention Intervention

New OMB Application

OMB No. 0920-New

SUPPORTING STATEMENT A:

Contact information

Technical Monitor: Jerris Raiford, PhD
Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention
Prevention Research Branch
1600 Clifton Rd, NE, Mailstop E-37
Atlanta, GA 30333

Telephone: 404-639-6104
Fax: 404-639-1950
E-mail: bge5@cdc.gov

July 20, 2012

TABLE OF CONTENTS

EXHIBITS

Attachments

Attachment Number	Document Description
1	Public Health Service Act
2	60-day Federal Register Notice
3	Pre- Screening Form
4	Full Screening Form
5	Brief Locator Information Form
6	Baseline Assessment
7	Record Locator Form
8	Participant Evaluation Forms
9	3-month Follow-up Assessment
10	6-month Follow-up Assessment
11	Exit Survey
12	Exit Interview
13	Informed Consent for RCT
14	Informed Consent for Exit Interview
15	Local IRB Approval
16	CDC Project Determination
17	Recruitment Flyer
18	Certificate of Confidentiality
19	Example health messages

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC) requests approval for a term of 3 years for a new data collection called "Critical Thinking and Cultural Affirmation: Evaluation of a Locally Developed HIV Prevention Intervention." The primary purpose of this project is to implement and rigorously evaluate the efficacy of Critical Thinking and Cultural Affirmation (CTCA)-- a behavioral HIV prevention intervention for African American men who have sex with men (AAMSM). Since 1989, Cleo Manago and the staff of AmASSI, the Los Angeles-based cultural and health services organization he founded, have experimented with a wide range of strategies and models in a search for an appropriate HIV prevention intervention for the diverse AAMSM populations AmASSI serves. The most appropriate model is one Cleo Manago created with his staff – the Critical Thinking and Cultural Affirmation (CTCA) model. The grantee, Loyola University, Chicago, IL, will conduct the evaluation study in collaboration with Black Men's Xchange (BMX). BMX is an affiliate of AmASSI, the California based community organization, where the CTCA intervention was developed.

Critical Thinking & Cultural Affirmation (CTCA) is an approach to HIV prevention and risk reduction for diverse Black/African-Americans. The CTCA strategy combines cultural affirmation with critical thinking and empowerment, to increase reasoning skill, problem solving capacity, self-protective behavior change, and well-being. The CTCA method facilitates the capacity of Blacks/African Americans to reduce or prevent HIV-risky sexual practices, behavior and impulses by building the capacity of participants to think critically, reason and recognize race and sexuality-based self-concept conflicts, self-defeating myths, un-constructive peer pressures and negative societal influences, value their community, themselves and peer group, and commit themselves to constructive and risk-reducing behavior as a way of life.

In 2005, the Centers for Disease Control and Prevention (CDC) reported that African-Americans accounted for 80,187 (51%) of persons diagnosed with HIV/AIDS and African-American men with HIV/AIDS represented 44% of all cases among males (Centers for Disease Control and Prevention [CDC], 2005). These statistics have been consistently bleak since the late 1990s, with African Americans bearing the greatest burden of new HIV cases in most regions of the United States (The Centers for Disease Control and Prevention estimates that at the end of 2006, Blacks are disproportionately affected by HIV. They represent only 36% of Chicago's population yet account for 55% of recently diagnosed HIV infections. Of the 22,650 people living with HIV/ AIDS, 54% are Black, 27% are White, 16% are Hispanic and 3% are of another race. The 2006 HIV infection rate in Blacks is nearly twice the rate of Whites (92 out of every 100,000 Blacks compared to 48 per 100,000 Whites and 31 per 100,000 Hispanics). Among males, Black males accounted for the largest number of diagnosed HIV infections and have the highest HIV infection rate of any race/ ethnicity group (144 per 100,000, compared to 94 per 100,000 for White males and 50 for per 100,000 Hispanic males).

While many HIV prevention and intervention studies include samples of African-American men and AAMSM, beyond demonstrating disparities in seroprevalence between and among racial

groups, few have been specifically designed and evaluated for efficacy among African American men. (Peterson, & Carballo-Diéguez, 2000; Beatty, Wheeler & Gaither, 2004; Mays, Cochran, & Zamudio, 2004; Clarke-Tasker,Wutoh & Mohammed, 2005). Current HIV prevention encompasses a variety of approaches, including Diffusion of Effective Behavioral Interventions (DEBIs), which bring "pre-packaged" science-based, community- and group and individual - level HIV prevention interventions to community-based service providers, and to state and local health departments. There are currently 20 interventions in the CDC's DEBI portfolio; of these, only 4 either were designed for, or rigorously tested with significant samples of, African-American or African American male populations. In addition, of these 4, only 2 were specifically modified for an AAMSM target population (www.effectiveinterventions.org).

A further limitation among HIV risk interventions for AAMSM (and indeed African Americans in general) is that extraordinarily few attempt to address the inter-face (Payne, 2005) between internal, social, and cultural arrangements as a means of HIV reduction. Instead, most address individual-level behavior change or, if addressed to the couple, group or community level, seek to affect changes in norms that will support individual behavior change (e.g., Community Promise). In other words, these interventions typically focus on the circumstances the men face (e.g. risky sexual encounters, use of substances etc) rather than on the underlying factors that frame how men perceive, understand and respond to these circumstances.

Epidemiological data indicate an urgent need for interventions targeted to African American MSM. Such interventions need to incorporate key specific prevention issues for this community, including internalized homophobia, social isolation, identity integration, self-esteem, social support, and disclosure of sexual orientation. Because few HIV prevention interventions targeting AAMSM have been developed and rigorously evaluated, while their HIV infection rates remain disproportionately high and continue to rise, identifying effective interventions for AAMSM is a public health imperative.

Although the CTCA intervention is theory-based and has been implemented for several years, this intervention has never been rigorously evaluated to test the efficacy for reducing HIV-risk behaviors among AAMSM. The efficacy of CTCA will be evaluated using a randomized-controlled trial design to compare receiving the CTCA intervention to receiving basic men's health and wellness messaging only (standard of care). CTCA will be delivered to participants who are randomly assigned to the intervention condition during a 3-day retreat (Friday evening-Sunday afternoon). The Specific Aims of this study are 1) to further explicate and develop the homegrown CTCA intervention, 2) to evaluate its efficacy and cost-effectiveness in reducing AAMSM's HIV risk behaviors and 3) to expand the limited body of research on HIV prevention/risk reduction practices for AAMSM. We hypothesize that participants who complete the CTCA intervention will report greater reductions in sexual risk behaviors than the standard of care comparison group.
The study will utilize a pre-test/post-test design with participants randomized to intervention and comparison groups; have a strategy to retain at least 80% of participants through study completion; collect data at baseline, at 3 months post-intervention, and at 6 months post-intervention; rigorously measure outcomes that directly impact AAMSM's HIV risk. Data will be collected at each assessment point to assess CTCA's ability to improve behavioral outcomes compared with the control that directly impact AAMSM's HIV risk. We hypothesize that CTCA

will: (1) decrease the number of reported unprotected anal and vaginal sex events among participants; (2) decrease the number of reported sex events with persons of unknown HIV status; (3) increase the percentage of HIV negative men who report getting tested and (4) Increase the percentage of men reporting that they asked their sexual partners about their HIV status and /or discussed their sexual partners HIV risk reduction strategies.

The data to be collected for this study will be used to establish the preliminary efficacy of a homegrown intervention and will provide important information about sexual risk behaviors and the context in which they occur. These data are essential for identifying effective homegrown HIV/AIDS prevention interventions for AAMSM. The findings from this study will be shared with Division of HIV/AIDS Prevention leadership and the scientific community through publication in peer-review journals and presentations at national conferences. In addition, this funding opportunity can potentially increase the number of evidence-based interventions (EBIs) for AAMSM at high risk for acquiring or transmitting HIV. Ultimately, the beneficiary of this data collection will be young AAMSM who are at risk for HIV.

The project is in alignment with several goals outlined in the National HIV/AIDS strategy:

- Goal 1- 1.2.1 Prevent HIV among gay and bisexual men and transgender individuals
- Goal 1- 1.2.2 Prevent HIV among Black men and women
- Goal 1- 2.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV in high risk communities
- Goal 1 – 2.4 Expand prevention with HIV-positive individuals
- Goal 1 – 3.2 Promote age-appropriate HIV and STI prevention education for all Americans
- Goal 3 – 2.1 Establish pilot programs that utilize community models

The study also supports the general goals of the Strategic Plan, 2010–2015 of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention's (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2010) and those of the Strategic Plan, 2011-2015 for the Division of HIV/AIDS Prevention (Division of HIV/AIDS Prevention, 2011), all of which are in alignment with and supportive of the goals and sub-goals of the National HIV/AIDS Strategy listed above.

The specific goals and objectives of the Division of HIV/AIDS Prevention Strategic Plan that are supported by the study include:

Goal A: HIV Incidence – Prevent new infections

- Objective 1 - Reduce the annual number of new HIV infections by 25%
- Objective 2 - Increase the percentage of people living with HIV who know their serostatus to 90%
- Objective 3 - Increase the percentage of people diagnosed with HIV infection at earlier stages of disease (not stage 3: AIDS), by 25%
- Objective 5 - Reduce the proportion of MSM who reported unprotected anal intercourse during their last sexual encounter with a partner of discordant or unknown HIV status by 25%

Goal C: Health Disparities – Reduce HIV-related Disparities

Objective 4 - Reduce the annual number of new HIV infections among MSM, Blacks, Hispanics and IDU by at least 25% in each group

The following section of the U.S. Federal Code (**Attachment 1**) is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."

Privacy Impact Assessment

Overview of the Data Collection System

This study will use a randomized controlled trial (RCT) study design to test whether delivery of a, group intervention implemented over three days —CTCA—reduces HIV sexual-risk behaviors among 18- to 55-year-old African American men who have sex with men. All data will be collected and maintained by the Grantees. The data collection system involves eligibility screenings, participant contact information, baseline assessment, 3-month and 6-month follow-up assessments, exit survey, exit interview, and participant evaluation forms. Men will be screened for eligibility during active recruitment using the Pre-Screening Form (**Attachment 3**); this process is estimated to take 5 minutes per respondent. Data collection for pre- screening will occur through a brief interview conducted face-to-face. If a potential participant meets pre-screening eligibility during active recruitment, he will be asked if he is willing to complete the Full-screening Form (**Attachment 4**) now or at a later time. Potential participants will also complete full-screening by either calling the project office or coming to the office. Full screening is estimated to take 10 minutes per respondent.

For men meeting eligibility criteria, project staff will use the brief locator information form (**Attachment 5**) to collect contact information (e.g., name, email, telephone number). The brief locator information will be used to contact men to set up appointments to complete the informed consent process and Baseline Assessment (**Attachment 6**) via ACASI. Enrolled participants will provide more extensive locator information on the Record Locator Form (**Attachment 7**). After participants complete the baseline questionnaire, they will receive their random assignment to the experimental or control condition. Participants in the intervention group will be scheduled for their retreat, and participants in the control group will schedule their 3-month follow-up ACASI appointment. After each intervention session, participants will be asked to complete a Participant Evaluation Form (**Attachment 8**). Participants will be scheduled to complete two follow-up assessments one at 3 months after the completion of their participation in either the CTCA sessions (intervention group) or their baseline assessment (control group) **(Attachment 9)**, and one 6 months after the completion of their participation in either the CTCA sessions (intervention group) or their baseline assessment (control group) **(Attachment 10)**. The Exit Survey (**Attachment 11**) will be offered to all men at the conclusion of their 6-month assessment. The Exit Survey asks if men are willing to be contacted for future follow-up purposes, which will be the Exit Interview (**Attachment 12**).

The sample size will be 438 for the RCT, with 219 men to be randomly assigned to the CTCA treatment group and 219 into a waitlist-control group, which will not receive the intervention, only the basic men's health and wellness messaging. The men in the treatment group will be exposed to the CTCA intervention, while men in the treatment and control group will both receive men's health and wellness promotion messages twice monthly by the participants' preferred method of contact (text, voicemail, and/or Facebook, etc.). Following the 6-month follow-up assessment, men randomly assigned to the control group will be offered CTCA through the Black Men's Xchange agency.

The site will collect information in identifiable form for all participants so that they may track individuals longitudinally. Each study participant will be given a unique identifier, which will appear with the study data. Participant names or other personal identifiers will not be stored with any electronic questionnaire files (e.g., baseline, follow-up measurements) that are associated with the project. Identifying information will not be included with study data and will not be transmitted to CDC or any other agency. CDC staff will not have access to any identifying information. De-identified data (including the baseline, follow-up questionnaires, exit survey, exit interview, arm assignment (i.e., assignment to the experimental or control arm), Participant Evaluation Forms, and session attendance (i.e., number of intervention sessions attended) will be transmitted to CDC via a secure data network. The linking file and the locating information will be destroyed once follow-up is complete. Deidentified study data will be maintained at the site and CDC indefinitely.

Items of Information to be Collected

Participant Screening Data

To participate in the trial, persons must:

a) Be 18 to 55 years old
b) Self identify as African American (Black national)
c) Self identify as a male (because this is a study of an intervention to impact change among Black MSM, only self identified males will be included, therefore no females or transgendered identified persons will be included).
d) Report being sexually active in the past 30 days (ie., one or more instances of vaginal or anal sex with a male or female)
e) Report at least one instance of unprotected anal or oral sex with a male identified partner in the past year
f) Have not previously participated in the CTCA intervention.
g) Have not received an evidence-based HIV prevention intervention in the past 180 days

Men are ineligible to participate in the trial if they:

a) Identify as a transgender woman; OR
b) Plan to move before the end of the study; OR
c) Have participated in any HIV or substance use prevention studies in the last 180 days.

Men do not need to know their HIV status in order to participate in this study. Men will be categorized as HIV positive, negative or unknown based on their self-reporting of HIV status

Prescreening for eligibility will be conducted during active recruitment. The Pre-Screener asks 7 items (in italics below). The questions are: *Are you between the ages of 18 and 55?What do you consider to be your primary race/ethnicity? What is your gender?* **Do you smoke?** *Are you a resident of the Chicago area? If yes, do you have a specific plan to move away from the area within the next 6 months? Have you had anal or vaginal sex with a man or a woman in the past 30 days? Have you had anal sex with a man in the past year?*

Men who meet prescreening eligibility during active recruitment will complete Full-screening at that time if they are willing. Otherwise, they will be instructed to call or come into the study office to complete Full-screening. Men who call the study office or come to the office will complete the Full-screener. The Full-Screener asks 10 items (in italics below). The questions are: *Are you between the ages of 18 and 55? What do you consider to be your primary race/ethnicity? What is your gender? Are you a resident of the Chicago area? If yes, do you have a specific plan to move away from the area within the next 6 months? How many times have you had unprotected anal or vaginal sex with a man or a woman in the past 30 days? How many times have you had anal sex with a man in the past year? Of those times you had anal sex with a man, how many times did you use a condom (Never, Sometimes, Often, All of the time)? Have you ever participated in CTCA? Have you participated in any HIV prevention intervention in the past 6 months?* **When was the last time you saw your doctor?**

The prescreener is a way of quickly assessing initial eligibility when potential participants or recruiters have time constraints. Also, participants may not want to discuss their sensitive sexual activities in recruitment venues where there are other people who can over hear the conversation. According the PI who has extensive experience working with MSM, asking questions about vaginal or anal sex with a man or women are not consider to be sensitive by this population but asking about condom use with a man in public venues could lead to dishonest responding in certain venues if asked at prescreen. Thus, the sex questions about condom use with a man is not asked on the prescreener because of its sensitive nature and the remaining sex question will be asked at subsequent full screening and the two tier process is included to account for men who are recruited in venues (such as bars, clubs or other public places) where asking sensitive questions of sexual practices may be inappropriate. . The use of the brief screening tool is intended only for these instances. In all other recruitment engagements only the full screen will be used. The Pre-Screener and Full-Screener each include 1 red herring question **(in bold font above)**. The red herring items are included to minimize the potential that the screening criteria become known in the community. This is to prevent men from deceiving recruiters to gain entry into the study. The Pre-screening and Full-screening questions can be found in **Attachment 3 and 4**.

Screening Procedures

Prescreening for eligibility will be conducted during face-to-face encounters during active recruitment. During active recruitment, prescreening begins by asking the man if he is willing to speak with the staff member briefly about the project, and asked if he is comfortable answering a

few questions in that location, given the level of privacy available. (For example, if recruitment is taking place at a park, the staff member will make every effort to interview the potential participant in a location that is out of earshot of anyone in the surrounding area.) If he agrees the staff member will give a brief description of the project and ask if the study is something the man might be interested in. If interested study staff will ask the prescreening questions following the verbal script outlined in the Prescreening Form **(Attachment 3)**

If participant meets pre-screening eligibility, the man will be asked if he is willing to participate in a full screening now or at a later time. If he agrees to a full screening at that time, the staff member will continue with full screening. If he agrees to participate in a full screening at a later time, he will be given a project information card and asked to call for the full screening. Note that recruiters will use their best judgment to avoid obtaining verbal consent to screen from a person that is intoxicated, especially in the case of recruitment at a location that serves alcohol. (See below for information on consenting to the pre-screening and full screening).

If at any point the man expresses that he does not want to continue the pre-screening conversation any further, the staff member will give him an information card that contains contact information for the project, and will tell him that he may call the project office for further information about the study. Potential participants will either call the project office or come to the office for the full screening. Each potential participant will be screened for eligibility using the full screening instrument. (See **Attachment 4**, Full Screening Form).

If the man is determined to be eligible, he will be asked if he would like to participate in the study. If he is in the study office, and he agrees to participate, he can move directly into the intake stage of participation (informed consent, record locator information, baseline ACASI, and randomization). If he agrees, but has been screened over the phone, or there is not enough time to do the intake procedures, he will be scheduled to come to the project office to complete the intake procedures.

Participant Limited Locating Information

For men meeting eligibility criteria, project staff will use the brief locator information form (**Attachment 5**) to collect contact information (e.g., name, email, telephone number). The brief locator information will be used to contact men to set up appointments to complete the informed consent process and Baseline Assessment via ACASI.

Baseline, Immediate Follow-up and Three Month Follow-up Data

After giving informed consent **(Attachment 13)**, participants will be asked to complete the Baseline Assessment. The data elements collected in the Baseline Assessment (**Attachment 6**), 3-month Follow-up Assessment, and 6-month Follow-up Assessment include the following: Socio-demographics: age, gender, sexual identity, race/ethnicity, education level, employment status, income level, number of dependents and children, financial status, incarceration history, housing status, socioeconomic status, relationship status, type of area lived in as a child, Behavioral and other characteristics: Negative Experiences with Homosexuality, Sexual Orientation Discrimination, Racial Discrimination, Adverse Childhood Event Scale, Collective

Self-Esteem, Contemplation Ladder for Condoms During Anal Sex, Decisional Balance for Condom Use, HIV Stigma for HIV-positive men, HIV Stigma for HIV-negative men, Internalized Homophobia, Identification and Involvement with the Gay Community Scale, Multidimensional Inventory or Black Identity, Partner Violence, Self-Efficacy, Sexual Behavior Assessment, Religion and Spirituality, Sexual Communication, Condom Use, Cross-site Items
Clinical variables: General Health, STD history, HIV testing history, Knowledge of HIV Treatment, PrEP/PEP use

The data elements collected on the Baseline Assessment are included in the 3-month Assessment **(Attachment 9)** and 6-month Assessment **(Attachment 10)** except certain items:

Modules	Measures	Baseline	3-month	6-month
A	Demographics - ALL	X		
A	Demographics – items (1,7, 10, 13, 14, 15, 16, ,18, ,,24, 25, 26, 27)		X	X
B	General Health	X		X
C	Sexually Transmitted Diseases	X	X	X
D	HIV Testing	X	X	
E	Sexual Assessment	X	X	X
F	Sexual Behavior Disclosure	X	X	X
G	Knowledge of HIV Treatment Scale	X	X	X
H	PrEP/PEP	X		X
I	Condom Use Self-Efficacy	X	X	X
J	Contemplation Ladder – Condoms During Anal Sex (M/F versions)	X	X	X
K	Decisional Balance for Condom Use	X	X	X
L	Self-efficacy/Refusal	X	X	X
M	**HIV Stigma for Positive Men** - Negative Self Esteem Subscale	X	X	X
N	**HIV Stigma for Negative Men** – Disclosure Concerns Subscale	X	X	X
O	Sexual Communication Self-Efficacy	X	X	X
P	Collective Self-Esteem Scale	X	X	X
Q	Negative Experiences	X		X
R	Adverse Childhood Events	X		X
S	Partner Violence	X	X	X
T	Everyday Discrimination-Sexual Orientation	X		X
U	Everyday Discrimination-Race	X	X	X
V	Black Identity (items from the Multidimensional Inventory of	X	X	X

	Black Identity/MIBI)			
W	Identification and Involvement with the Gay Community Scale	X	X	X
X	Internalized Homophobia	X		X
Y	Religion & Spirituality	X		X
Z	Cross-site	X		X

Participant Evaluation Forms

Participants will be asked to complete 6 brief, pen-and-paper participant evaluation forms at the end of each session (**Attachment 8**). These data will assess participant satisfaction with specific sessions and other aspects of the groups. These surveys will be anonymous.

Exit Survey

The Exit Survey (**Attachment 11**) will be offered to all men [in the intervention arm] at the conclusion of their 6-month ACASI. The survey obtains feedback from the participants on their experience as a CTCA study participant. It asks about participant's post-intervention HIV testing behavior and their thoughts on the usefulness of the CTCA intervention. The Exit Survey also asks if men are willing to be contacted for future follow-up purposes, which will be the Exit Interview. The Exit Survey can either be programmed to be administered electronically (but separate from the ACASI and not linked to that data) or completed on a hard-copy (non-electronic) version of the Exit Survey.

Exit Interviews

Of the men who agree to be contacted for future follow-up, 15 who indicated they were more "favorable" (agreeing and strongly agreeing with positive comments about the intervention) and 15 men who were "less favorable" (disagreeing and strongly disagreeing with positive comments about the intervention) will be selected for the Exit Interview. We anticipate that we need to invite 65 men to participate in the Exit Interviews in order to reach this number. After giving informed consent **(Attachment 14)**, the interview will be conducted at the project office by the Exit Interview Social Worker, who will not be involved in the execution of the intervention in order to avoid bias. Questions will be asked, using a qualitative interview guide (**Attachment 12**), to help us understand participant's experiences with the CTCA intervention and their thoughts about the content of the intervention and ways in which it could be improved. The same interview guide will be used for both men who are more favorable and those who are less favorable.

<u>Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age</u>

BMX has established an Internet presence to appeal its members via Facebook (http://www.facebook.com/BMXchangeCHICAGO). Passive recruitment will be conducted by purchasing advertising space on websites identified as appropriate by suggestions of the Core Consulting Group and the research team's assessment of appropriate virtual spaces; this may include Facebook or other social networking websites. Children under the age of 13 are not

eligible to participate and all content on these social networking websites are directed at persons 18 years or older.

2. Purpose and Use of Information Collection

The information that will be collected for this study will be used to assess the efficacy of the CTCA behavioral HIV prevention intervention for AAMSM. The study will use a randomized controlled trial designed to determine if men who are assigned to receive the CTCA intervention report less frequent HIV risk behaviors and increased HIV protective behaviors three- and six-months after intervention delivery, compared to men in the comparison condition.

The behavioral outcomes that are of primary interest to the study and that will be measured in participants are (1) decrease the number of reported unprotected anal and vaginal sex events among participants; (2) decrease the number of reported sex events with persons of unknown HIV status; (3) increase the percentage of HIV negative men who report getting tested and (4) Increase the percentage of men reporting that they asked their sexual partners about their HIV status and /or discussed their sexual partners HIV risk reduction strategies.

Outcomes of additional interest include levels of correct HIV knowledge; understanding of self in relation experiences of racial and HIV stigma; the relationship between risk perception and actual risk; intentions to use condoms; trigger identification self-efficacy; assessing sexual situations self-efficacy; risk reduction decision-making self-efficacy; attitudes toward condoms; condom use/safer sex self-efficacy; sexual communication self-efficacy; knowledge about personal risk; increased ethnic pride; gender pride; sexual identity pride; internalized homophobia; and internalized racial oppression.

While a number of individual- and group-level HIV interventions have been created by and for a variety of AAMSM organizations across the U.S., evaluation data to document the efficacy of these programs is limited. Without the proposed data collection, we will continue to lack effective and appropriate interventions for this at risk population and current HIV incidence trends could continue. Additionally, if effective, published findings from the study can be reviewed by the DHAP Prevention Research Synthesis Project as an intervention to be featured in future Compendium of Evidence Based Prevention Interventions, which community-based HIV prevention programs can use to select appropriate evidence-based interventions to implement in the field. If effective, the intervention could also be replicated via a Replicating Effective Programs project or disseminated through a Diffusion of Effective Behavioral Interventions project (both DHAP activities that aim to translate scientific evidence into program practice). A secondary use of the information collected in this study will be to improve our current understanding of HIV risk behavior and its correlates among young African-American MSM. Understanding the correlates of sexual risk behavior is important as it informs the appropriate development of risk reduction interventions.

Privacy Impact Assessment Information

All data will be collected by the Grantees and will be maintained at the local site. Following data processing and cleaning procedures, de-identified data (quantitative baseline and follow-up questionnaires, and exit survey and interview data) will be transmitted to CDC via a secure data network (SDN) for analyses. Study data files will never include any personally identifying data and data observations will be indexed using only the unique Study ID numbers. The project officers will establish a Memorandum of Understanding between CDC and the study site which prohibits them, under any circumstances, from providing the CDC team the linkage between study ID numbers and participants' names. Results from the study will be shared with the research community via peer-reviewed journals and presentations at national conferences. In order to reach the maximum benefit to existing HIV prevention, CDC will share the study results with the scientific community in the form of publications and presentations.

This study involves the collection of sensitive information. There would likely be an effect on the respondent's privacy if there were a breach of privacy. Therefore, stringent safeguards will be implemented to protect against a breach of security and illegal access to individually identifiable information. The researchers and project staff will keep personal information secure, including HIV status. Confidentiality and scientific ethics will be covered during staff training to emphasize the importance of the issue. All staff will complete NIH human subject protection training. Office procedures are also put in place to maintain sensitive information (e.g., consent forms, contact information, HIV status) under lock and key. Study participant's information, including name, locator information and all data will be stored on secured and password-protected computers. Staff with access to these computers will have to log into and identify themselves to gain data entry or retrieval access.

Quantitative (e.g., ACASI survey and participant satisfaction surveys) and qualitative data (e.g., participant satisfaction surveys, , and post-intervention interview data) will be stored at the study site with an ID only and not with a direct personal identifier such as name or phone number; personal identifying information will be kept locked in project files and a limited number of project staff will have access to keys to the files. The unique IDs will be pre-populated for the 438 potential participants and assigned to blank records/files that will be then available for participant assignment as men come into the study. A linkage file matching name and ID number will be created and maintained under lock and key in a separate file cabinet from the quantitative data. Again, there are no personal identifiers directly associated with any data other than the contact information files.

Contact information and audio recordings from the exit interviews will be destroyed by shredding by a staff member three years after completion of the study unless participants indicate that project staff may keep them on file for future studies or programs, or they request a copy of the primary results of this study. However, six months after the study is completed, study ID numbers for all participants will be de-linked from contact information in the participant database. In addition, CDC collaborators will not obtain individually identifiable private information. Study data files will never include any personally identifying data and data

observations will be indexed using only the unique Study ID numbers.

3. Use of Improved Technology and Burden Reduction

The full-screening instrument may be conducted over the phone by a study recruiter and will be limited to items that directly assess study eligibility, plus one additional question to prevent eligibility criteria from becoming known in the community. Three study questionnaires will be administered (baseline, 3-month follow-up, and 6-month follow-up) using ACASI. The use of ACASI has been found to reduce respondent burden and enhance respondent privacy during data collection. ACASI has also been found to reduce interviewer bias in the collection of sensitive sexual behavior data (Ghanem et al, 2005). In addition to enhancing the validity of self-report data, computerized assessments can be programmed to customize question wording for individual respondent and prevent respondents from having to answer questions that are not applicable to them. We have designed the survey to be given on site, rather than online. Given the length of the ACASI, it must appear on a large screen. We do not know if participants have access to a computer or a large screen in the privacy of their homes to read the assessment. The sensitive nature of the questions and the need to assure timely response we want to have the men conduct the survey on site. Also by doing it in ACASI, on site staff are physically and immediately available to assist if the participant has an adverse reaction to any of the items. All data collection instruments were designed to be as brief as possible. We will only collect the information necessary to evaluate the effect of the intervention, assess potential interactions, and identify specific predictors of sexual risk and protective behavior. Piloting of the assessment indicates this assessment takes between 40-45 minutes to complete

4. Efforts to Identify Duplication and Use of Similar Information

CDC staff conducted several activities to identify duplication and use of similar information. We reviewed currently-funded programs and did not identify potential areas of duplication. No known department or agency develops and evaluates new behavioral HIV risk reduction interventions for African American MSM that are developed and implemented by a local CBO. The purpose of this study is to implement and rigorously evaluate a potentially effective but insufficiently evaluated HIV prevention intervention developed locally for high risk African-American men who have sex with men. This intervention was developed by the community-based organization partner (Cleo Manago, Black Men's Xchange) with substantial input from the served community, and may be referred to as a locally-developed or homegrown intervention. Mr. Manago has collected outcome monitoring data before and after delivering the intervention that demonstrate positive and significant changes in HIV risk behaviors. However, given this intervention has never undergone a rigorous evaluation, this study will measure the effects of the intervention as delivered to one group, in comparison to a group that does not receive the intervention using a randomized controlled trial design. The findings of this study will be used to improve the quality of HIV prevention services delivered in AAMSM community and possibly increase the number of evidence-based interventions (EBIs) for AAMSM at high risk for acquiring or transmitting HIV. There are no known sources for data on the CTCA behavioral

intervention for African American MSM in Chicago (with adequate sample sizes to support analysis) available within the department or agency. Hence, this is a unique study.

One significant effort has been a review of existing HIV prevention interventions for African American MSM. While many HIV prevention and intervention studies include samples of African-American men and AAMSM, beyond demonstrating disparities in seroprevalence between and among racial groups, few have been specifically designed and evaluated for efficacy among African American men. (Peterson, & Carballo-Diéguez, 2000; Beatty, Wheeler & Gaither, 2004; Mays, Cochran, & Zamudio, 2004; Clarke-Tasker,Wutoh & Mohammed, 2005). Current HIV prevention encompasses a variety of approaches, including Diffusion of Effective Behavioral Interventions (DEBIs), which bring "pre-packaged" science-based, community- and group and individual -level HIV prevention interventions to community-based service providers, and to state and local health departments. There are currently 20 interventions in the CDC's DEBI portfolio; of these, only 4 either were designed for, or rigorously tested with significant samples of, African-American or African American male populations. In addition, of these 4, only 2 were specifically modified for an AAMSM target population (www.effectiveinterventions.org).

A further limitation among HIV risk interventions for AAMSM (and indeed African Americans in general) is that extraordinarily few attempt to address the inter-face (Payne, 2005) between internal, social, and cultural arrangements as a means of HIV reduction. Instead, most address individual-level behavior change or, if addressed to the couple, group or community level, seek to affect changes in norms that will support individual behavior change (e.g., Community Promise). In other words, these interventions typically focus on the circumstances the men face (e.g. risky sexual encounters, use of substances etc) rather than on the underlying factors that frame how men perceive, understand and respond to these circumstances. Epidemiological data indicate an urgent need for interventions targeted to African American MSM. Such interventions need to incorporate key specific prevention issues for this community, including internalized homophobia, social isolation, identity integration, self-esteem, social support, and disclosure of sexual orientation.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The data collection activities will occur from August 2012 through April 2015. The study involves multiple, but discrete, data collection points, all of which are needed to conduct the study and evaluate the effect of the intervention. Participants are allowed to participate in the study only once.

If data were not collected, we would not be able to test efficacy of a homegrown intervention and provide important information about sexual risk behaviors and the context in which they occur. It would therefore be impossible to develop, test, and distribute a needed intervention for at-risk

African-American MSM, a population for whom there are currently few effective risk-reduction interventions.

There are no legal obstacles to reduce the burden for Respondents.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

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

A 60-day Federal Register notice to solicit public comments was published in the *Federal Register* on February 28, 2012, Vol. 77, No. 39 page numbers 12057-12059. A copy of this publication is attached (**Attachment 2**). No public comments were received.

Several consultations were conducted with various scientists and public health practitioners outside the agency.

In July 2010, CDC held a principal investigator meeting with external researchers, who were funded under the Cooperative Agreement and have experience conducting behavioral surveys among African-American and MSM populations. The purpose of this meeting was to discuss the study design, eligibility criteria, and behavioral outcomes.

From May 2010 through January 2012, the external Principal Investigator and Sub-Investigators and CDC Project Officers worked as a team to develop the data collection instruments. All team members are experienced in conducting behavioral surveys among AAMSM. During this time, the team met either weekly or bi-weekly to develop the IRB protocol which includes the procedures for sampling, recruitment and retention, screening and randomization, and data collection. External investigators developed the power calculations and analysis plan with substantial input from CDC's biostatistician. The team finalized the IRB protocol and refined the domains to be included in the data collection in January 2012.

In addition to collaboration with external scientists, the study site collaborated with their local Core Consulting Group (CCG). These are composed of representatives from the target population, staff from partner agencies, and members of AIDS service organizations. The CAB was convened in December 2011 to assist with refining the assessment to ensure that the assessment content is relevant and appropriate for the target population.

In accordance with congressional mandate Content of AIDS-Related Written Materials, Pictorial, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992), all intervention materials and research instruments will be reviewed by a local program review panel to ensure that these materials are in accordance with community standards.

9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. This study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV status, and substance use.

To enhance our ability to recruit 438 AAMSM and retain at least 80% of those randomized to each study arm, we will provide participants with tokens of appreciation for their time spent attending group sessions, for completing the three- and six-month follow-up assessments, and for completing the exit survey and interview.

The amount of tokens of appreciation is based on both prior experience and for appropriate consideration of the potential burden in terms of travel and time commitment men will make to participate in the study. The graduated token of appreciation scale is proposed to provide sufficient but not inappropriate amounts to men in recognition of their completion of study visits to complete baseline, three and six month and exit interviews.

Investigators at the site drew upon their experience working with this population and community norms to come up with the following participant token of appreciation plan:

At the end of each data collection visit, participants will be given tokens of appreciation for their time and effort. Individual tokens of appreciation will be:

- $25 gift card and a two-way CTA Transit Pass ($5.00 equivalent) for the baseline appointment,
- $25 gift card and a two-way CTA Transit Pass for the 3-month follow-up visit,
- $50 gift card and a two-way CTA Transit Pass for the 6-month follow-up assessment visit, and
- $50 gift card and a two-way CTA Transit Pass for the exit interview (if selected).

Men who are randomized into CTCA intervention will receive roundtrip CTA Transit Pass ($5.00 equivalent) for each day of the intervention they complete. No tokens of appreciation will be given to men who complete the Exit Survey.

Participants who arrive too late, given the time allotted (based on office hours, staff availability, etc.) to complete the baseline assessment will not receive tokens of appreciation and they will be rescheduled. If an assessment or CTCA retreat is unable to be completed for any reason and participants have arrived or are en route, they will receive two-way Metrocards for their travel and the assessment or intervention will be rescheduled. This procedure will be explained to eligible participants during screening and at the baseline assessment individual session.

Additionally, there will be a raffle with three prizes given away to increase study retention (4 sets of raffle prizes will be given away.) When participants complete the intervention, they will receive an electronic message instructing them to reply with their updated contact information to enter in the drawing for one of the raffle prizes. In addition, prior to the raffle, participants in the control group will receive periodic texts requesting their updated contact information. This way, we can ensure that we have the correct contact information to follow-up with <u>all</u> study participants. Anyone who replies to the message would be entered into a drawing to receive the raffle prize even if they do not complete

all of the follow-up assessments. The grand prize will be worth up to $100, second-place prize will be a $50 gift card, and the third-place prize will be a $25 gift card.

The rationale for the raffle is that we do not want to conflate the impact of consistent incentives with effect of the intervention, thereby creating an artificial outcome that cannot be replicated in a community setting. By informing men of their entry into the lottery it is a way to keep accurate with their provided contact information. Given that local dynamics and emerging technologies may change we will reserve some flexibility in identifying the exact raffle items to assure they are perceived of value by participants, however we will stay in the cost band. We have also included an additional attachment (Attachment 20) which lists several studies and corresponding citations which document using raffles to promote participant enrollment and retention. Our plan builds on the noted successful application of this strategy to engage and retain men in the study.

10. Assurance of Privacy Provided to Respondents

This submission has been reviewed by ICRO, who determined that the Privacy Act applies to this request. The site has a formal certificate of confidentiality **(Attachment 18).**

The researchers and project staff will keep personal information secure, including HIV status. Confidentiality and scientific ethics will be covered during staff training to emphasize the importance of the issue. All staff will complete NIH human subject protection training. Office procedures are also put in place to maintain sensitive information (e.g., contact information, HIV status) under lock and key. Study participant's information, including name, locator information and all data will be stored on secured and password-protected computers. Staff with access to these computers will have to log into and identify themselves to gain data entry or retrieval access. All participants' information will be codified using unique identifiers. All participant documents will be referenced using the unique identifiers. One document that cross references the client to the unique identifier will be maintained in hardcopy by the Principal Investigator. This document will be updated daily and stored in a secured 1,200 lb safe in the PI's Loyola University Chicago office. The PI and Project Coordinator will have access to this information.

Information collected during the study will be kept in locked file cabinets at the PI's Loyola University Chicago office for the duration of the study. There are no personal identifiers directly associated with these materials, and the session participant lists state only a first name and are locked in a cabinet at the PI's Loyola University Chicago office separate from data and contact information. Data collection will be supervised by the project coordinator and the PI.

Local IRB approval was granted for this study **(Attachment 15)** and NCHHSTP project determination was approved (**Attachment 16**).

<u>Informed Consent</u>

All study participants will be given written copies of the IRB approved Human Subject's Informed Consent documents. (**Attachments 13 and 14**)

As part of the study consenting procedures, potential participants will be able to read and/or have read to them the study procedures which will at minimum include, data collection steps, randomization procedures, study goals and purposes, means by which data are being protected, the extent and nature of confidentiality in the study, compensation for study participants, rights and limitations as a study participant and persons to contact for further information about the study and contact information for local and CDC IRB/Human Subjects Officers. Study staff will inform the participant of his right to refuse study participation and/or to refuse to engage in any part of the study at his discretion. The study benefits and risks are detailed in the written consent and will be highlighted orally by the study staff during the consenting process.

Upon reading/having read to him the consent, the potential participant will be asked to actively consent, by signing the consent document. If the participant refuses to sign he will not be enrolled in the study. Participants signing the consent will move into the intake phase of the study following the study protocol for baseline data collection. Those participants refusing to sign will be offered referrals for HIV testing and counseling if desired.

Confidentiality of responses and safeguarding of materials

Quantitative (e.g., ACASI survey and participant satisfaction surveys) and qualitative data (e.g., participant satisfaction surveys, and post-intervention interview data) will be stored at the study site with an ID only and not with a direct personal identifier such as name or phone number; personal identifying information will be kept locked in project files and a limited number of project staff will have access to keys to the files. The unique IDs will be pre-populated for the 438 potential participants and assigned to blank records/files that will be then available for participant assignment as men come into the study. A linkage file matching name and ID number will be created and maintained under lock and key in a separate file cabinet from the quantitative data. Again, there are no personal identifiers directly associated with any data other than the contact information files. Contact information and audio recordings from the exit interviews will be destroyed by shredding by a staff member three years after completion of the study unless participants indicate that project staff may keep them on file for future studies or programs, or they request a copy of the primary results of this study. However, six months after the study is completed, study ID numbers for all participants will be de-linked from contact information in the participant database.

Privacy Impact Assessment

Data from screening and ACASI interviews will be collected on paper and computers designated for data collection, respectively. Each day, the interviews on the data collection computers will be backed-up and moved to the Data Manager's computer by disk. Data will be deleted from the data collection computers as soon as the data is successfully transferred to the Data Manager's computer. All data will be retained for 3 years after the study then hard copies destroyed. Electronic data files will be retained for future data sharing purposes. New data on the Data Manager's computer will be encrypted and uploaded to CDC via a secure data network based at CDC. Personal identifiers will not be sent to CDC.

During data collection, contact information of participants will be collected to facilitate participation. A linkage file matching name and ID number will be created and maintained under lock and key in a separate file cabinet from the quantitative data. These data will be kept in a separate, locked file cabinet to which only staff with a work-related need will have access. We will keep the number of people with access to this information to the minimum necessary. Daily transfer/back-up data disks will also be kept under lock and key. To ensure information security, study ID numbers for all participants will be de-linked from contact information in the participant database six months after the study ends.

11. Justification for Sensitive Questions

Baseline and follow-up assessments used to evaluate the CTCA HIV prevention intervention will include questionnaire items commonly considered of a sensitive nature. These questionnaire items will assess RCT participants' sexual behaviors with partners who are male, female and transgender. Although these questions are considered private, and while some participants may feel uncomfortable answering such questions, the goal of most HIV prevention research is to evaluate hypothesized reductions in potentially "risky" sexual behaviors, including specific sexual practices where condoms are not used. The only currently available method for assessing the efficacy of HIV prevention interventions among study participants is to pose such questions in a private data collection session. To increase our participants' comfort and honesty in answering potentially sensitive questions, we are implementing two specific procedures: 1) we will conduct an informed consent process that indicates the nature of questions to be assessed during the data collection session and the option to refuse to answer any question at any time for any reason; and 2) we are using ACASI data collection methods for sensitive questions to reduce the embarrassment of participants in answering these types of questions. Additional questions that may be considered sensitive by our study population are related to attitudes and beliefs about homosexuality, substance use, incarceration, sexual abuse, experiences with racism, and sexually transmitted infections. To reduce any anxiety about participants' responses to these potentially sensitive items, the informed consent process will assure participants that their responses will not be linked to their names and that their responses are grouped with the responses of other study participants so that there is no possible way to identify a person with their answers.

Without this information the study would not be able to answer the primary research question of whether the proposed risk reduction intervention is effective. These data will increase our understanding of the HIV prevention needs among AAMSM. During the consent process, participants will be informed that this study involves collecting sensitive information. Participants will also be informed at the beginning of each assessment of their right to skip questions that they do not wish to answer. The screening instrument involves several sensitive questions; however, this information is critical to determine eligibility for the study. Participants will be consented before answering the screening questions.

12. Estimates of Annualized Burden Hours and Costs

12A.
Based on our time tests of the study instruments, the estimated time needed to complete the Pre Screening Form for eligibility is 5 minutes per participant. The Full-Screening Form is 10

minutes per participant. The brief locator form will take 5 minutes, the record locator information form 10 minutes, the baseline assessment, 3-month, and 6-month assessments 60 minutes each, the participant evaluation forms that will be completed at the end of each session will take 5 minutes each, the exit survey will take 10 minutes and the Exit interview 30 minutes.

Table 12.A presents participant burden hours for completion of the study. The total participant burden for this data collection is estimated at 588 hours.

Exhibit A12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Respondent	Average Burden Per Respondent (in hours)	Total Annual Burden in Hours
Prospective Study Participant	Pre-Screening Form	333	1	5/60	28
Prospective Study Participant	Full-Screening Form	172	1	10/60	29
Prospective Study Participant	Brief Locator Form	172	1	5/60	14
Enrolled Study Participant	Record Locator Form	146	1	10/60	24
Enrolled Study Participant	Baseline Assessment	146	1	1	146
Enrolled Study Participant	3-month Follow-up Assessment	132	1	1	132
Enrolled Study Participant	6-month Follow-up Assessment	117	1	1	117
Enrolled Study Participant	Participant Evaluation Forms	146	6	5/60	73
Enrolled Study Participant	Exit Survey	117	1	10/60	20
Enrolled Study Participant	Exit Interview	10	1	30/60	5
Total					588

Table A12.B displays the annualized cost to Respondents for burden hours shown in Table 12.A. In order to estimate the cost to the Respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for December 2011 by the US Department of Labor. ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb2.txt; accessed January 25, 2012).

Exhibit A12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Annual Burden in Hours	Average Hourly Wage Rate	Total Annual Respondent Cost
Prospective Study Participant- Pre Screening Form	28	$19.30	$540.40
Prospective Study Participant- Full-Screening Form	29	$19.30	$559.70
Prospective Study Participant – Brief Locator Form	14	$19.30	$270.20
Prospective Study Participant—Record Locator Form	24	$19.30	$463.20
Enrolled Study Participant—Baseline Assessment	146	$19.30	$2,817.80
Enrolled Study Participant—3-month Follow-up Assessment	132	$19.30	$2,547.60
Enrolled Study Participant—6-month Follow-up Assessment	117	$19.30	$2,258.10
Enrolled Study Participant—Participant Evaluation Forms	73	$19.30	$1,408.90
Enrolled Study Participant—Exit Survey	20	$19.30	$386.00
Enrolled Study Participant—Exit Interview	5	$19.30	$96.50
Total	588		$11,348.40

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to Respondents or record keepers associated with this study.

14. Annualized Cost to the Government

The total cost of the five-year study is estimated to be $2,200,000. The annual cost to the government during years 3 through 5 of the study, during which data collection will occur, is $664,983 (Table A.14).

Table A14. Annualized Cost to Government

Expense Type	Government Related Expenses	Annual Costs (dollars)
Direct cost to the Federal Government		
	CDC Project Officer (GS-13, .35 FTE)	$31,000
	CDC Co-Project Officer (USPHS O-3, .35 FTE)	$18,940
	CDC Project Coordinator (GS-11, .12FTE)	$7,198
	CDC Statistician (GS-13 .05 FTE)	$4,845
	Travel	$3000
	Subtotal, direct costs to the government	$64,983
Contractor and other expenses		
	Cooperative Agreement: Loyola University Chicago. This is the average annualized cost for the period of actual information collection, which will occur during years 3 through 5of the 5-year cooperative agreement.	$600,000
	TOTAL COST TO THE GOVERNMENT	**$664,983**

Salary estimates were obtained from OPM salary scale at the following web address: http://www.opm.gov/oca/10tables/html/atl.asp

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Analysis Plan

a) Qualitative data.

Exit Survey data will be assessed to identify potential men for the Exit Interview from men

agreeing to be contacted for future follow-up. Additionally, the Exit Survey data will be assessed to identify men who indicated they were more "favorable" (agreeing and strongly agreeing with positive comments about the intervention) and those who are "less favorable" (disagreeing and strongly disagreeing with positive comments about the intervention). We will invite approximately 15 of the men who are more favorable and 15 of the men who are less favorable to participate in Exit Interviews. Exit Interview data will be used to help us understand participant's experiences with the CTCA intervention and their thoughts about the content of the intervention and ways in which it could be improved.

b) Quantitative data.

Our analyses will focus on the study aims spelled out in the "Protocol Summary" section of this document. We will assess the degree to which our randomization achieved balance by comparing the treatment and control groups on various variables (such as age, income, educational level, use of drugs, etc.) using t-tests for interval or ratio variables and chi square for categorical or dichotomous variables. If we observe differences across the treatment and control groups on certain variables, these variables will be adjusted for in our statistical analyses of the efficacy of CTCA. Since three of our key outcome variables are counts, we will analyze the efficacy of CTCA on those using Poisson Regression models in conjunction with the GEE approach to adjust for within participant correlation. Since we're measuring whether communication has increased with a scale we will treat this outcome as an interval level variable. Thus, the efficacy of CTCA on communication will be assessed with multiple regression modeling in conjunction with GEE. The intention to treat (ITT) approach will also be used to assess the effect of CTCA. We will deal with missing data using multiple imputation. In addition to adjusting for variables for which the treatment and control groups are not balanced and for within participant correlation, we will also adjust for cluster effects by including a given participant's cluster in our models

Exhibit A16. Project Time Schedule

Activities	**Time Schedule**
Begin recruitment	1 month post OMB approval
Complete recruitment, intervention implementation, and data collection	33 months post OMB approval
Data management and validation	34 months post OMB approval
Analysis of key outcomes	35 months post OMB approval
Dissemination of results	36 months post OMB approval

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

CDC is not seeking approval to not display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

References

Beatty L.A., Wheeler D.P., Gaither J. (2004). HIV prevention research for African Americans: Current and future directions. *Journal of Black Psychology*, 30(1): 4-58.

Centers for Disease Control and Prevention. (2005a). Trends in HIV/AIDS diagnoses—33 states, 2001-2004. *MMWR*. 54: 1149-1153.

Centers for Disease Control and Prevention. (2005b). HIV prevalence, unrecognized infection, and HIV testing among men who have with men—five US cities, June 2004—April 2005. *MMWR* 2005 54: 1-5.

Clarke-Tasker V.A., Wutoh A.K., Mohammed T. (2005). HIV risk behaviors in African American males. *The ABNF Journal*, May/June. 16(3), 56-59.

Effective Interventions. (n.d.). Retrieved from Diffusion of Effective Behavioral Interventions: http://effectiveinterventions.org

Ghanem, K.G., et al., Audio computer assisted self interview and face to face interview modes in assessing response bias among STD clinic patients. Sex Transm Infect, 2005. 81(5): p. 421-5.

Mays, V.M., Cochran, S.D., Zamudio A. (2004). HIV prevention research: Are we meeting the needs of African American men who have sex with men? *Journal of Black Psychology*. 30(1): 78-105.

Payne, M. (2005). *Modern Social Work Theory, 3rd Ed. Chicago, IL: Lyceum.*

Peterson, J.L., Carballo-Diéguez A. (2000). HIV prevention among African-American and Latino men who have sex with men. In JL Peterson & RJ DiClemente RJ (Eds). Dordrecht, Netherlands: Kluwer Academic Publishers. pp 217-224.

Wheeler, D.P., Lauby, J.L., Liu, K., Van Sluytman, L.G. & Murrill, C. (2008). A comparative analysis of sexual risk characteristics of black men who have sex with men or with men and women. *Archives of Sexual Behavior*, 37(5), 697-707.

Wilton, L., J. H. Herbst, et al. (2009). "Efficacy of an HIV/STI Prevention Intervention for Black Men Who Have Sex with Men: Findings from the Many Men, Many Voices (3MV) Project." *Aids and Behavior 13*(2): 532-544