

SUPPORTING STATEMENT A:

HIV Prevention among Latino MSM: Evaluation of a locally developed intervention

New OMB Application

OMB No. 0920-New

Contact information

Technical Monitor: Thomas M. Painter, 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: 404-639-6113

Fax: 404-639-1950

E-mail: tcp2@cdc.gov

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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 “HIV prevention among Latino MSM: Evaluation of a locally developed intervention.” The primary purpose of this project is to implement and rigorously evaluate the efficacy of HOLA en Grupos: Hombres Ofreciendo Liderazgo y Apoyo en Grupos (Hello in Groups: Men Offering Leadership and Support in Groups) -- a Spanish-language behavioral HIV prevention intervention for Latino men who have sex with men (MSM). HOLA en Grupos was originally developed by the Chatham Social Health Council, a community-based organization (CBO) in Siler City, North Carolina (NC), which has been delivering the intervention to Latino MSM in several nearby counties since 2006. The grantee, the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine, Winston Salem, NC, will conduct the evaluation study in collaboration with the Chatham Social Health Council.

HOLA en Grupos is a small-group behavioral intervention that is designed primarily to increase consistent and correct condom use with sex partners and HIV testing among participating Latino MSM, and secondarily to reduce other behavioral and psychosocial factors that can increase the vulnerability of Latino MSM to infection from HIV or other sexually transmitted diseases (STDs). The efficacy of HOLA en Grupos will be evaluated by delivering it to Latino MSM who are randomly assigned to receive the intervention, and comparing the behavioral and associated outcomes among men who receive the intervention with outcomes of Latino MSM who are randomly assigned to the comparison condition and who receive a general health intervention.

Latinos are the largest and fastest growing ethnic minority group in the U.S. and have the second highest rate of HIV/AIDS diagnoses of all racial/ethnic groups in the country. From the beginning of the epidemic through 2007, Latinos accounted for 17% of all AIDS cases reported to the CDC; through 2007, the percentage of AIDS diagnoses represented by Latinos and African Americans increased while decreasing among whites (CDC, 2007b). In 2007, Latino males had an HIV/AIDS case rate (56.2 per 100,000 pop.) that was three times higher than the rate for white males (18.7), while the HIV/AIDS case rate for Latino females (16.0) was nearly five times higher than the rate for white females (3.3) (CDC, 2007b).

Among Latino males, male-to-male sexual contact is the single most important source of HIV infection, accounting for 46% of HIV infections in U.S.-born Latino men from 2001 to 2005, and for more than one-half of HIV infections among South American, Cuban, and Mexican-born Latino men in the U.S. (CDC, 2007a; 2007b). In 2006, male-to-male sex accounted for 72% of new HIV infections among Latino males. Relative to other MSM, the rate of HIV infection among Latino MSM is twice the rate recorded among whites (43.1 vs. 19.6 per 100,000). Among Latino MSM, most new HIV infections occur among men aged 13-29 years, while among whites most infections occur among men in the 30-39 year range (Centers for Disease Control and Prevention, 2008).

North Carolina is one of several southern states that had few if any Latino residents prior to the early 1990s that have since become important destinations for Latino migrants and immigrants. As a result of this rapid influx, the number of Latinos living in North Carolina increased by more than 700% from 1990 to 2007, (U.S. Census 1990; 2007b), giving the state the fastest-growing Latino population in the US (Kasarda & Johnson, 2006; North Carolina Institute of Medicine, 2003; US Census Bureau, 2007a). In 2006, HIV incidence rates in the state were 40% higher than the national rate, and HIV and STD infection rates for Latinos in NC were 3 and 4 times greater, respectively, than for non-Latino whites (North Carolina Department of Health and Human Services, 2007; 2008). Behavioral studies suggest that Spanish-speaking Latinos in the state are disproportionately at risk for HIV compared to English-speaking Latino and non-Latino counterparts. The state's 2003 Behavioral Risk Factor Surveillance Survey found strikingly higher differences in self-reported health risks and healthcare access for Spanish-speaking Latino men compared to other adult men. The ten counties that are served by the Chatham Social Health Council include a population of approximately 1.6 million persons, of which nearly 125,300 are Latino adults. We estimate that Latino MSM in this area number approximately 2000.

Despite the high levels of HIV/STD infection risk that affect Latino MSM, no efficacious interventions to prevent HIV/STD infection are available for this vulnerable population. CDC's Prevention Research Synthesis group, whose role is to identify HIV prevention interventions that have met rigorous criteria for demonstrating evidence of efficacy, has not identified any behavioral interventions for Latino MSM that meet current efficacy criteria, and no such interventions are listed in CDC's 2011 update of its Compendium of Evidence-Based HIV Behavioral Interventions (<http://www.cdc.gov/hiv/topics/research/prs/compendium-evidence-based-interventions.htm>).

There is an urgent need for efficacious, culturally congruent HIV/STD prevention interventions for Latino MSM. The HOLA en Grupos intervention is a Spanish-language, small-group, 4-session intervention that is designed to increase consistent and correct condom use and HIV testing among Latino MSM and to reduce other behavioral and psychosocial factors that can increase their vulnerability of HIV/STD infection.

This study will use a randomized controlled trial design to assess the efficacy of the HOLA en Grupos intervention compared to a general health comparison intervention. HOLA en Grupos will be delivered to participants who are randomly assigned to the intervention condition during four 4-hour sessions on four separate days over a two week period. The general health intervention (comparison condition) will be delivered to participants who are randomly assigned to the comparison condition during four 4-hour sessions on four separate days over a two week period. The general health intervention has been designed to increase participants' knowledge about cancer, diabetes, alcohol abuse, and cardiovascular disease. If HOLA en Grupos is found to be efficacious, the study results will increase the number of known evidence-based interventions that can be potentially used with Latino MSM who are at high risk for acquiring or transmitting HIV and other STDs.

In this study we will test the hypotheses that HOLA en Grupos participants, relative to comparison participants, will demonstrate:

(1) Increased consistent and correct condom use

- (2) Increased HIV testing and receipt of test results
- (3) Decreased unprotected anal and vaginal sex with partners of unknown HIV serostatus or with HIV-positive partners
- (4) Decreased numbers of sexual partners
- (5) Increased discussion with sexual partner about risk reduction

We also expect changes in the following psychosocial mediators; i.e., factors that can contribute to the HIV/STD risk-reducing behaviors listed above. We expect that HOLA en Grupos participants, relative to comparison participants, will demonstrate:

- (1) Increased knowledge of HIV and STDs and prevention strategies
- (2) Increased condom use skills, self-efficacy, and intention
- (3) Increased sexual communication and safer sex negotiation skills and self-efficacy
- (4) Decreased negative and increased positive attitudes toward condoms
- (5) Reduced adherence to traditional notions of masculinity and fatalism
- (6) Decreased homonegativity
- (7) Increased ethnic group pride
- (8) Reduced perceived barriers to HIV testing

The results and products from this study will be disseminated to inform and improve HIV prevention-related practice, research, and policy for Latino men who have sex with men (MSM). These will include: (1) a Spanish-language, culturally congruent intervention to reduce HIV/STD risks and increase HIV testing among Latino MSM that will be ready for packaging and dissemination if found to be efficacious; and (2) a deeper understanding of HIV/STD risk and intervention among Latino MSM. The findings from this study will be shared with the CDC's Division of HIV/AIDS Prevention leadership and the scientific community through publication in peer-review journals and presentations at national conferences. If the HOLA en Grupos intervention is found to be efficacious, the study results will increase the number of known evidence-based interventions in general that can be potentially used with Latino MSM who are at high risk for acquiring or transmitting HIV and other STDs. Currently no efficacious HIV/STD prevention interventions exist for Latino MSM in the U.S.

This study supports the primary goal of the National HIV/AIDS Strategy (The White House Office of National AIDS Policy, 2010) of reducing new HIV infections in the U.S. and the following sub-goals of the strategy:

- Goal 1- 1.2.1 - Prevent HIV among gay and bisexual men and transgender individuals
- Goal 1- 1.2.3 - Prevent HIV among Latino Americans
- 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 2 - 2.3 - Expand access to effective prevention services.

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

All aspects of the study and data collection will be completed by the principal investigator and staff from the grantee organization, the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine, in collaboration with the study’s co-investigator and staff members of the Chatham Social Health Council. All collected data will be maintained by the grantee. The Chatham Social Health Council is located in the area of central North Carolina where individuals will be recruited to the study, will receive the HOLA en Grupos or the comparison intervention, and where the study assessments will be conducted. The study’s data collection system consists of a screening process to determine the eligibility of interested individuals to participate in the study and the collection of preliminary contact information from interested individuals, a baseline assessment of behavioral and associated factors of concern to the study and the collection of additional contact information from participants, and a follow-up assessment 6 months after participants complete HOLA en Grupos or the comparison intervention.

The screening process – During the screening process, study staff will collect information from potential participants to determine their eligibility to participate in the study. Study recruitment staff will need to screen an estimated 350 Latino men for eligibility using the Participant Screening Form (see **Attachment 3** for the Spanish-language version of the screening form that

will be used during the study and the English-language translation which is included for purposes of review only) in order to obtain the total of 300 participants (150 men in the HOLA en Grupos intervention condition and 150 men in the comparison condition) required for the study. Most screening of potential participants' for eligibility will occur by telephone; however some screening may occur in person. The script (**Attachment 3**), will be used by study staff when screening potential participants by telephone. At the end of the screening process, study staff members will collect the name and phone number of each eligible person on page 3 of the 3-page Participant Screening form. Study staff will use this information to set up appointments during which interested and eligible individuals will be given additional information on the study, will review the consent forms with study staff, and if they agree to participate, will sign and receive a copy of the consent form, and complete a baseline assessment (described below). Completion of the screening process for potential participants by telephone or in person will require about 10 minutes per respondent.

The informed consent process – At the time of their pre-determined appointment, potential study participants will meet with study staff who will explain the intervention study, review the consent form with potential participants (see **Attachment 7** for the Spanish-language version that will be used during the study and the English-language translation which is included for purposes of review only), and collect a copy of the form signed and dated by those persons who agree to participate. The study staff member will give one copy of the signed consent form to the participant. The study staff member will then mark the unique pre-assigned identification number that appears on page 1 of the baseline assessment questionnaire that will be administered to the participant (every baseline assessment questionnaire will have a different pre-assigned identification number; see next section) on the first page of the retained copy of the consent form. Study staff will securely store the retained copy of the consent form in a lock-box at the Chatham Social Health Council.

Baseline assessment - After completion of the consent process, study staff will administer a baseline assessment questionnaire to each participant (see **Attachment 4** for the Spanish-language version that will be used during the study and the English-language translation which is included for purposes of review only) during an individual face-to-face interview in a private location. The first page of the baseline questionnaire will contain only the pre-assigned unique identification number and will not contain the participant's name. This identification number will enable study staff to link the baseline and the subsequent 6-month follow-up assessments for all study participants. The baseline assessment will begin by collecting information from each participant to verify his continuing eligibility to participate in the study, followed by the collection of information on behavioral and psychosocial outcome variables that are described in detail below that are key to assessing the efficacy of the HOLA en Grupos HIV prevention intervention and improving current understanding about factors that affect HIV/STD infection risks among Latino MSM.

During the baseline assessment (and only during this step of the study), study staff will also ask each participant to provide his address, telephone number(s), e-mail address, and the names, addresses, telephone numbers, and relationship information for three persons (e.g., friend, family member, clergyman, or other service provider) who know him and who will know how to contact him in the event that study staff experience difficulty contacting the participant to remind

him about the dates and times of intervention sessions and the 6-month follow-up assessment. The study staff member will also enter the participant's name at the top of the form. The questions that will be used to collect this contact information are questions 143A-146F on the last three pages of the baseline assessment questionnaire (see questions 143A-146F in **Attachment 4** and Participant Contact Information section below). Immediately after completion of the baseline assessment and collection of participants' contact information, study staff will remove the three pages at the end of the assessment questionnaire that contain contact information to ensure that the study data do not contain any participant individual identifying information. The last 3 pages containing participant contact information will be stored separately from the rest of the baseline assessment data in a lock-box at the Chatham Social Health Council. Completion of the baseline assessment will require about 1 hour and 45 minutes per respondent.

After completing the baseline assessment, participants will be randomized, using a block randomization scheme generated with nQuery v6.0.21, to receive the Spanish-language HOLA en Grupos intervention or the Spanish-language general health education comparison intervention. Following randomization, participants will be given the specific date and time of the first HOLA en Grupos or comparison intervention session. The process of administering informed consent, enrollment to the study, completion of the baseline assessment, and randomization to one of the two study conditions will occur sequentially on the same day.

Six-month follow-up assessment – Six months after HOLA en Grupos and comparison participants complete their respective interventions, study staff will administer a follow-up assessment questionnaire to them during a face-to-face interview (see **Attachment 5** for the Spanish-language version that will be used during the study and the English-language translation which is included for purposes of review only). The first page of the follow-up assessment questionnaire will contain only the identification number that was initially pre-assigned to the participant at the time of the baseline assessment, but will not contain the participants' name. This identification number will enable the study staff to link the baseline and the 6-month follow-up assessments for all participants. The 6-month follow-up assessment questionnaire is similar to the baseline assessment, but will contain fewer questions than the baseline assessment (see details below). Completion of the 6-month follow-up assessment will require about 60 minutes per respondent.

No personal-identifying information will be attached to any of the study data. Each participant will be assigned a unique study identification number which will appear with study data. A master participant file that links participants' names with their study identification numbers will be stored in a password-protected database. Immediately after completing screening and the baseline assessment, any participant contact information that is collected will be separated from the screening and assessment forms and stored separately. The signed consent forms will also be stored separately. As noted above, a unique identification number that has been pre-assigned to the baseline assessment questionnaire, but not the participant's name, will be entered on the consent form at the completion of the informed consent process.

During the implementation of the study in areas of central North Carolina where Latino MSM will be contacted and enrolled in the study, copies of all completed information forms, as

described above and explained in greater detail below, will be initially stored in separate locked boxes at the Chatham Social Health Council. In all cases, no later than 48 hours after completion of these data collection forms, study staff will transfer the documents to the offices of the principal investigator at the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine where they will be stored separately in a locked file cabinet. All electronic information and datasets that will be created by entering participants' responses to the two study assessments or other information collection forms will be kept in password-protected electronic files.

No data that will be collected from individual participants will be released to the public. Summary data without any personal identifier information may be used in reports, presentations, and manuscripts for publication. The CDC Project Officer and Project Coordinator will not have any contact with or collect data from the study participants and they will not have access to any of the study participants' individually identifiable information. Aggregate data without any personal identifying information from study participants will be submitted to the CDC project officer at the end of the study as required by the cooperative agreement grant. All such data transfers will be made using a secure data network. The CDC Project Officer and Project Coordinator will establish a Memorandum of Understanding between the CDC and the study site to prohibit the transfer of individually identifiable private information to the CDC.

Items of Information to be Collected

Participant Screening Data

Information will be collected during the screening process to determine the eligibility of persons to participate in the study. Eligible individuals include those who (a) are male; (b) self-identify as Latino or Hispanic; (c) are 18 years or older; (d) speak Spanish; (e) have had sex with another man since attaining age 18; (f) have not participated in HOLA, HOLA en Grupos, HoMBReS or other Latino Partnership interventions developed and delivered by the Chatham Social Health Council or Wake Forest University during the past 12 months. Men who have had sex with at least one woman since attaining age 18, but who have not had sex with at least one man since attaining age 18 will not be eligible to participate in the study. The study recruiter will ask an additional question, listed below, to obtain this information. The seven questions that will be asked to determine eligibility are: "Are you Hispanic or Latino?" "How old are you?" "In which language would you consider yourself to be fluent?" "What is your gender?" "Since turning 18 years old, have you had sex with at least one man?" "Since turning 18 years old, have you had sex with at least one woman?" and "In the past 12 months, have you participated in HOLA, HOLA en Grupos, HoMBReS or other Latino Partnership interventions developed and delivered by the Chatham Social Health Council or Wake Forest University?" See **Attachment 3** for the Spanish-language version of the Participant Screening Form that will be used during the study and the English-language translation which is provided solely for purposes of review.

Screening Procedures

Participants will be recruited through the dissemination of advertisements that describe the study that will be posted or distributed at tiendas (local grocery stores), laundromats, businesses that

employ large numbers of Latinos (such as poultry plants, construction sites, and hotels), sports events, English as a Second Language classes, common areas in housing communities, apartment complexes, and trailer home communities, Latino restaurants and clubs, and gay bars and clubs throughout the central region of NC. The advertisements will invite interested men to call a study recruiter to determine their eligibility to participate. As noted above, most screening will be done by telephone; however, some screening may be done in person.

Study outreach/recruitment staff will use the Participant Screening Form (see **Attachment 3** for the Spanish-language version of the Participant Screening Form that will be used during the study and the English-language translation which is provided solely for purposes of review) to determine the eligibility of interested individuals, based on the criteria listed above. The number of men that are screened and are determined to be eligible and ineligible will be maintained by study staff in a master recruitment file, which will be located in a password-protected database. At the end of the screening process, the study recruiter will collect the name and phone number of each eligible person on page 3 of the 3-page Participant Screening form (**Attachment 3**) and separate page 3 from the first 2 pages of the form. Study staff will later use the contact information to set up appointments during which interested and eligible individuals will be given additional information on the study, will review the consent forms with study staff, and if they agree to participate, will sign and receive a copy of the consent form and complete a baseline assessment. Completion of the screening process will require about 10 minutes per respondent.

Study staff will securely store pages 1-2 and pages 3 of the screening forms in separate lock-boxes at the Chatham Social Health Council. No later than 48 hours after completion, study staff will transfer all of these pages to the offices of the principal investigator at the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine. Pages 1-2 from the screening forms will provide a count of all persons screened during the previous 48 hours and will then be destroyed. Page 3 of the screening forms will provide a count of all eligible persons screened during the previous 48 hours and will be stored in a locked file cabinet. Information collected on page 3 of the screening form will be entered by university data entry staff into a password-protected database. Study staff will contact eligible men by telephone from the Department of Social Sciences and Health Policy at Wake Forest University or the offices of the Chatham Social Health Council (CSHC) to make appointments to complete informed consent and the baseline assessment. To make the reminder telephone calls at CSHC, study staff will take a list of names and contact information for all eligible persons that need to be contacted from the Wake Forest offices to CSHC in a locked box. Once study staff at CSHC have completed the appointment for informed consent and the baseline assessment of persons on the list, or have made 3 unsuccessful attempts to contact persons who are then considered lost to follow-up, the lists will be transferred to Wake Forest University in a locked box where they will be destroyed by study staff.

Baseline and 6-month Follow-up Assessment Data

In order to evaluate the efficacy of the HOLA en Grupos intervention, compared to the general health comparison intervention, assessment data will be collected from intervention and comparison participants during the baseline assessment before intervention delivery (see

Attachment 4 for the Spanish-language version of the baseline assessment questionnaire that will be used during the study and the English-language translation which is provided solely for purposes of review) and again 6 months after intervention delivery (see **Attachment 5** for the Spanish-language version of the 6-month follow-up assessment that will be used during the study and the English-language translation which is provided solely for purposes of review).

Baseline Assessment - The first page of the baseline questionnaire will contain only the pre-assigned unique identification number and will not contain the participant's name. This identification number will enable study staff to link the baseline and the subsequent 6-month follow-up assessments for all study participants. The baseline assessment will collect information to verify the participants' ongoing eligibility to participate in the study and on behavioral and psychosocial outcome variables that are described in detail below that are key to assessing the efficacy of the HOLA en Grupos HIV prevention intervention and improving current understanding about factors that affect HIV/STD infection risks among Latino MSM.

The types of data that will be collected during the baseline assessment include the following:

Behavioral outcome variables: Condom use; unprotected anal and vaginal sex with partners of unknown HIV serostatus or who are known to be infected with HIV; numbers of sexual partners; discussing ways to reduce HIV infection risks with a sexual partner; HIV testing and receipt of HIV test results.

Mediating variables: Knowledge about HIV and STDs; condom use skills; condom use self-efficacy; intention to use condoms; attitudes about condoms; masculinity; fatalism; homonegativity; ethnic group pride; perceived barriers to HIV testing.

Socio-demographics: Age; gender; ethnicity/race; sexual identity; relationship status (and gender of dating partner/partner/spouse); educational attainment (and current school status); type of employment; financial status; self-reported sexual identity; time in the U.S. and NC; Spanish-language comprehension and literacy; country of origin; current city of residence; and current zip code.

Other Variables: Self-reported health status; acculturation; religiosity; mental health; perceived discrimination; perceived access to care; social support; community attachment; foregoing unsafe sex/abstinence; use of enemas for cleansing prior to anal sex use; use of electronic technologies such as the internet; overall satisfaction with sex life; HIV/STD history; condom procurement; where participant first met most recent partner; substance use; substance use during sex.

Participant contact information: Contact information will be collected from all participants using the last 3 pages of the baseline assessment (see questions 143A-146F in **Attachment 4** for the Spanish-language version of the baseline assessment questionnaire that will be used during the study and the English-language translation which is provided solely for purposes of review). Study staff will ask each participant to provide his address, telephone number(s), e-mail address, and the names, addresses, telephone numbers, and relationship information for three persons (e.g., friend, family member, clergyman, or other service provider) who know him and who will know how to contact him in the event that study staff experience difficulty contacting the participant. This information will be collected only once and will be used by study staff to contact participants and remind them about intervention sessions and their appointment for the 6-month follow-up assessment visit. Immediately after completion of the baseline assessment,

study staff will remove the three pages at the end of the assessment questionnaire that contain this information and securely store them in a lock-box at the Chatham Social Health Council. As with all other information collection forms, no later than 48 hours after completion of the contact information pages, study staff will transfer them to the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine, where it will be stored in a locked file cabinet and eventually entered by university data entry staff as an electronic record in a password-protected database. Study staff will make reminder telephone calls from the Department of Social Sciences and Health Policy at Wake Forest University or the offices of the Chatham Social Health Council. To make the reminder telephone calls at CSHC, study staff will take a list of names and contact information for all persons that need to be contacted from the Wake Forest offices to CSHC in a locked box. Once study staff at CSHC have completed their reminder calls for intervention sessions or 6-month follow-up assessments for persons on the list, or have made 3 unsuccessful attempts to contact persons to complete their 6-month follow-up, who are then considered lost to follow-up, the lists will be transferred to Wake Forest University in a locked box where they will be destroyed by study staff.

Six-month follow-up assessment – This study has only one follow-up assessment, which will be conducted 6-months after participants complete the HOLA en Grupos intervention or the comparison intervention. The 6-month follow-up assessment questionnaire is similar to the baseline assessment, but will contain fewer questions because there is no need to ask some questions at two different points in time. The topics and the number of questions that are asked for each topic during the baseline assessment that are not included in the 6-month follow-up assessment concern eligibility-related issues (7 questions); acculturation (12); age at first sex with a man (1); use of enemas for cleansing before sex (1); age at first sex with a woman (1); childhood trauma questions (concerning events during the participant’s first 18 years of life) (10); educational attainment and employment (7); religiosity (12); place of birth (1); number of years in the U.S. (1); and contact information (24). Completion of the 6-month follow-up assessment will require about 60 minutes per respondent. The first page of the follow-up assessment questionnaire will contain only the identification number that was initially pre-assigned to the participant at the time of the baseline assessment, and will not contain the participants’ name. This identification number will enable the study staff to link the baseline and the subsequent 6-month follow-up assessments for all participants.

Study staff will securely store the completed baseline and 6-month follow-up assessment questionnaires in a lock-box at the Chatham Social Health Council and, no later than 48 hours after completion, transfer them to the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine, where they will be stored in a locked file cabinet and eventually entered by university data entry staff as an electronic record in a password-protected database.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This information collection activity does not involve the use of any web-based or online data collection methods and does not refer respondents to websites of any kind. Children under 13 years of age are not eligible to participate in the study.

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 HOLA en Grupos behavioral HIV prevention intervention for Latino MSM. The study will use a randomized controlled trial designed to determine if men who are assigned to receive the HOLA en Grupos intervention report less frequent HIV risk behaviors and increased HIV protective behaviors six-months after intervention delivery, compared to men in the general health comparison condition. The behavioral outcomes that are of primary interest to the study and that will be measured in participants are increases in consistent, correct condom use with sex partners, HIV testing, and receipt of test results. Outcomes of additional interest include reductions in unprotected anal and vaginal sex with sex partners who are HIV-positive or of unknown HIV serostatus, reductions in the number of sex partners; and increases in talking with sexual partners about risk reduction.

Currently there are no effective behavioral interventions to prevent HIV/STD infection among Latino MSM despite their high risk of becoming infected. CDC's Prevention Research Synthesis group, whose role is to identify HIV prevention interventions that have met rigorous criteria for demonstrating evidence of efficacy, has not identified any behavioral interventions for Latino MSM that meet current efficacy criteria, and no such interventions are listed in the 2011 update of the Compendium of Evidence-Based HIV Behavioral Interventions (<http://www.cdc.gov/hiv/topics/research/prs/compendium-evidence-based-interventions.htm>). There is, therefore, an urgent need for efficacious, culturally congruent HIV prevention interventions for Latino MSM.

Without the proposed information collection, we will continue to lack culturally appropriate, effective HIV prevention interventions for this at-risk population, and current HIV incidence trends among Latino MSM will continue. Published findings from the study will be reviewed by the CDC's Prevention Research Synthesis group for possible inclusion in the Compendium of Evidence Based HIV Behavioral Interventions, which lists those interventions that service provider organizations can use when selecting evidence-based HIV prevention interventions for their communities. If found to be effective, HOLA en Grupos can be packaged through the CDC's Replicating Effective Programs project and disseminated to CBOs and health departments through the CDC's Diffusion of Effective Behavioral Interventions project. In addition, the information collected by this study will improve current understandings about behaviors and factors that affect the HIV infection risks of Latino MSM, and can inform the further development of appropriate risk reduction interventions for this vulnerable population.

The Spanish-language HOLA en Grupos intervention covers the following topics during its four 4-hour sessions:

Session 1 - General information about the program and an introduction to sexual health

Topics: Purpose of the program; magnitude of HIV and STDs among Latinos and Latino MSM internationally, nationally, and in NC; information about HIV, STDs, and healthcare services; HIV and STD-related vocabulary.

Session 2 - Protecting Yourself and Your Partners

Topics: Demonstration of the correct use of condoms; developing and practicing condom use skills; how to negotiate condom use; deciding what type of condom(s) participants prefer

Session 3 - Cultural Values that Affect Our Health

Topics: What does it mean to be a Latino gay man or an MSM? Latino cultural values and how they influence health; how to overcome socio-cultural barriers to health

Session 4 - Review/Bringing it all together

Topics: Transmission of HIV and STDs; what it is like for someone living with HIV; abstinence; being safe

The Spanish-language general health comparison intervention emphasizes healthy lifestyles and is designed to increase participants' knowledge about the following topics during its four 4-hour sessions: cancer (specifically: prostate, lung, and colorectal cancer), diabetes, alcohol abuse, and cardiovascular disease.

Privacy Impact Assessment Information

The data to be collected for this study will be used to establish the efficacy of the HOLA en Grupos HIV behavioral prevention intervention for Latino MSM. To identify individuals who are appropriate and eligible for the study, study staff will use a screening form (see **Attachment 3** for the Spanish-language version of the form that will be used during the study and the English-language translation which is included for purposes of review only) that asks questions of potentially interested persons based on the study's eligibility criteria described above. Study staff will also collect name and telephone number information from eligible interested persons. Staff will use this information to set up appointments during which these individuals will be given additional information on the study, will review the consent forms with study staff, and if they agree to participate, will sign and receive a copy of the consent form and complete a baseline assessment. Six months after completing the intervention, participants will complete a follow-up assessment.

This study involves the collection of sensitive information, therefore stringent safeguards will be implemented to protect against a breach of security or illegal access to individually identifiable information. Before any data are collected, all study staff will be trained (or retrained) in IRB and informed consent procedures and procedures for collecting sensitive health data. All Wake Forest University School of Medicine employees who conduct human subjects' research are required to complete an online certification every 2 years. This requirement also applies to staff of our study partner, the Chatham Social Health Council, for whom the Wake Forest University IRB is the official IRB of record. Several steps will be taken to address possible risks to participants. First, we will establish an agreement with participants that all information revealed during the assessment will be kept private. Second, all information collected will be stored securely and responses and identifying information will be kept in separate locations. Hard copies of datasets or lists of names and identification codes for participants will be kept in separate locked file cabinets in the Department of Social Sciences and Health Policy, Divisions of Public Health Sciences, Wake Forest University School of Medicine. Third, resources and referrals will be provided as needed to address participants' informational or psychological needs. These will include referrals as needed, to locally available service providers (e.g., health department, mental health agencies, partner violence support services, Latino-serving

organizations), and the provision of low-literacy Spanish-language written materials with information about local resources and HIV and STD prevention (including counseling and testing), and Spanish-language toll-free resources (e.g., HIV/AIDS hotline). Fourth, each participant is free not to answer any of the questions that are asked. Finally, each participant may stop an interview at any time without any adverse consequences.

All data will be collected by the grantee and will be maintained at the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine. Personal-identifying information will not be attached to data obtained from study participants. Immediately after completing the baseline assessment, the participants' personal contact information will be separated from the assessment questionnaire. The signed consent form will also be stored separately. A unique pre-assigned identification number will link the participants' responses for the baseline and 6-month follow-up assessments with their consent forms. Participants' names will be linked to their unique identification number in a separate password-protected Excel spreadsheet file at the Department of Social Sciences and Health Policy. All information collected will be stored securely and all identifying information will be stored separately in secure locations.

During implementation of the study in areas of central North Carolina where Latino MSM will be contacted and enrolled in the study, all completed sections of the screening form with participants' initial contact information, retained signed copies of the signed consent forms, the completed baseline assessment questionnaire, the 3 pages of the baseline assessment with the participants' additional contact information, and the completed 6-month follow-up assessment questionnaire will be stored in separate locked boxes at the Chatham Social Health Council.

As noted above, no later than 48 hours after completion, study staff will transfer all data collection forms to Wake Forest University School of Medicine where they will be stored in a locked file cabinet. All electronic information and datasets that will be created by the entering of participants' responses to the two study assessments or other information collection forms will be kept in password-protected electronic files. Paper copies of all completed information collection forms and lists of participants' names and corresponding identification numbers will be kept separately in a locked file cabinet in the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine.

The CDC Project Officer and Project Coordinator will not interact with or collect data from the study participants. If needed, the study site will transfer study data without any individually identifiable information to CDC via a secure data network during the study. The Project Officer and Project Coordinator will establish a Memorandum of Understanding between CDC and the study site to prohibit the transfer of individually identifiable private information to CDC. Results from the study will be shared with the research community via peer-reviewed journals and presentations at national conferences.

3. Use of Improved Technology and Burden Reduction

No technological collection techniques or other forms of information technology will be used to collect information during this study, therefore no study responses will be collected in this

manner. The screening of individuals to determine their eligibility to participate in the study will be conducted by a study recruiter using a printed script, mainly during telephone contacts and possibly during face-to-face encounters, and will be limited to collecting information needed to assess their eligibility (see **Attachment 3** for the Spanish-language version of the screening form that will be used during the study and the English-language translation which is included for purposes of review only). Completion of the informed consent process will be done by a study staff person who, if necessary, will read the Spanish-language consent form (see **Attachment 7** for the Spanish-language version of the consent form that will be used during the study and the English-language translation which is included for purposes of review only) to each potential participant who will also receive a paper copy to keep. The questionnaires that will be used for collecting baseline and 6-month follow-up assessment data during the study (see **Attachments 4** and **5** for the Spanish-language versions of the assessment questionnaires that will be used during the study and the English-language translations which are included for purposes of review only) will be printed on paper and will be administered by trained interviewers during face-to-face encounters with individual participants. The assessment questions have been designed to be as brief as possible, and will be used to collect only the information that is necessary to evaluate the efficacy of the HOLA en Grupos HIV prevention intervention, assess potential effects of the factors described above on participants' HIV/STD-related risk behaviors, and identify specific predictors of sexual risk and protective behavior. The decision not to use electronic data collection methods is based on experience gained during more than ten years of conducting research among Latino populations in North Carolina, including formative research to identify the most appropriate and effective methods for gathering information from these populations (Rhodes et al, 2007a; 2010; In press; Vissman et al., 2009). The research partnership's earlier work has shown that using an interviewer-administered approach fits well with cultural values that are shared by many Latinos that stress the importance of direct interpersonal interactions and relationships (Cashman et al., 2011; Rhodes et al., In press; In review). More specifically, prior formative research and feedback from long-standing partners in the Latino communities in which studies have been conducted indicate that Latino study participants are more likely to engage with a well-trained interviewer who can establish rapport and instill a sense of trust. The research partnership has also found that using face-to-face, interviewer-administered assessments is useful for overcoming potential barriers to understanding that may occur among study participants that are recruited from populations of recent Latino immigrants whose literacy may be limited and who, in addition, may suffer from vision problems that also make reading difficult (Rhodes et al., In press).

4. Efforts to Identify Duplication and Use of Similar Information

CDC staff have reviewed information from published studies and HIV-prevention interventions that are delivered by various service provider organizations in an effort to identify duplication and use of similar information. We have not identified potential areas of duplication. Furthermore, and as noted above, CDC's Prevention Research Synthesis group, which identifies and reviews hundreds of HIV prevention interventions each year, has not identified any HIV prevention interventions that have been developed for Latino MSM that have shown efficacy in reducing HIV risks actions for this at-risk population. No such interventions are listed in the

2011 update of the Compendium of Evidence-Based HIV Behavioral Interventions (<http://www.cdc.gov/hiv/topics/research/prs/compendium-evidence-based-interventions.htm>).

No known department or agency develops and evaluates new, locally-developed (“homegrown”) behavioral HIV risk reduction interventions such as HOLA en Grupos for Latino MSM; that is, interventions for Latino MSM that have been developed and implemented by local community-based organizations (CBOs) based on considerable input from the served Latino communities. HOLA en Grupos is a locally-developed HIV prevention intervention that has been designed specifically for Latino MSM who are recent immigrants (predominantly Mexican) and who reside in rural areas of North Carolina, one of several states in the U.S. South where the presence of Latino populations is a very recent development. Typically, these Latino MSM are monolingual Spanish-speakers, are less-aculturated, and have less access to and participate less in health care services due to language barriers, social and physical isolation, and fear that their frequently undocumented immigration status will be disclosed. Prior to conducting this study, there have been no sources for data that make it possible to assess the efficacy of the locally-developed HOLA en Grupos intervention or any other intervention designed for a population with these particular characteristics in a rural setting. Therefore, this is a unique study.

While no efficacious HIV prevention interventions are known to exist for Latino MSM having the characteristics in the circumstances that are the focus of the proposed study, some information has been published on Latino MSM having different characteristics in different settings than those of concern to this study. In 2005, Carballo-Diequez et al. described the assessment of an intervention for Latino MSM. However, their study was conducted with Latino MSM who were not recent immigrants and who resided in a major urban setting – New York City – which also has one of the largest and longest-established Latino populations in the U.S. Furthermore, and unlike the HOLA en Grupos intervention, which will be delivered and assessed by this study, the Carballo-Diequez et al. intervention study was not developed through a long-standing community-based participatory research partnership involving researchers and multiple stakeholders, including Latino MSM in the Latino community. Finally, the New York City-based intervention was determined not to be efficacious when compared to observed effects in the study’s comparison condition. While the data from the New York City study are similar to those that will be collected by this study, for the reasons given above, they do not duplicate the proposed data collection or address the specific needs that will be served by the proposed data collection.

Other HIV prevention interventions have been developed for populations that include non-MSM Latinos and have shown evidence of being efficacious at reducing HIV behavioral risks, including, in some cases, drug-related behaviors that can increase the risks of HIV infection. Some of these interventions are being disseminated by service provider organizations with CDC support. However, these interventions have not been designed for Latino MSM, much less for primarily Mexican-born Latino MSM such as those who reside in rural central North Carolina. Instead, they have targeted heterosexual Hispanic men and women (predominantly from Puerto Rico) and African American men and women (O’Donnell et al., 1998) and drug-using heterosexual Latinos (Robles et al., 2004). The risk profiles of these heterosexual, drug-using, non-migrant or recent immigrant Latino populations are very different from those that are of

concern to this study - recent immigrant Latino MSM in rural NC who rarely inject drugs and whose HIV risks are primarily due to their male-to-male sexual contacts (Rhodes et al., 2006).

In summary, the data that have been collected by other studies do not duplicate the proposed data collection or address the needs that will be served by the proposed data collection. No known HIV prevention intervention for Latino MSM exists whose efficacy has been demonstrated by a randomized trial (Herbst et al., 2011) or that have been identified by CDC as meriting inclusion in the Compendium of Evidence-Based HIV Behavioral Interventions (<http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm>).

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 information collection activity will occur from May 2012 through July 2014. Specific steps in the study during this period will include a one-time collection of information to determine the eligibility of potential participants and the collection of initial contact information; a one-time administration of informed consent that will ask those who agree to participate to sign their name; the one-time collection of baseline assessment data before intervention delivery; the one-time collection of more detailed participant contact information to facilitate efforts by study staff to contact participants and ensure that they attend all HOLA en Grupos and comparison intervention sessions and the 6-month follow-up assessment; and the one-time collection of follow-up assessment data six months after intervention delivery. This assessment data will be used to determine the efficacy of HOLA en Grupos and to conduct the other analyses described above. By collecting assessment data from HOLA en Grupos and comparison intervention participants only at baseline and 6-months after delivery of the interventions -- at only two time points -- data collection has been reduced to the minimum required to compare the effects of the two study conditions and rigorously assess the efficacy HOLA en Grupos. In addition, as explained in the Baseline and 6-month Follow-up Assessment Data section above, the 6-month follow-up assessment asks participants fewer questions than the baseline assessment.

If assessment data were not collected at two time points as proposed, it would not be possible to evaluate the efficacy of HOLA en Grupos with the Latino MSM populations for whom it was designed or describe and clarify the nature of behavioral and circumstantial factors that affect the HIV/STD risks of Latino MSM in rural areas of the South. Finally, if the data were not collected as proposed, it would preclude the potentially important contribution of this study, which consists of testing an HIV prevention intervention for Latino MSM developed by and with the Latino community that can be made available for potential use by HIV/STD prevention service provider organizations that work with this extremely vulnerable population.

Participants will be allowed to participate in the study only once.

There are no legal obstacles to reduce the burden for study participants.

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 October 25, 2011; Vol. 76, Issue No. 206 page numbers 66069--66070. A copy of this publication is attached (**Attachment 2**). No public comments were received.

CDC staff have consulted with public scientists and practitioners outside the agency during the development of the study. In July 2010, CDC organized a meeting for all the principal investigators and their study partners who are funded under the Cooperative Agreement (PS09-007 - Evaluating Locally-Developed/Homegrown HIV Prevention Interventions Project) that supports the proposed study, and who have considerable experience conducting behavioral surveys among Latino MSM and other racial minority MSM populations. The purpose of this meeting was to discuss issues related to study design, methodological issues, eligibility criteria, and behavioral outcomes. See **Attachment 10** for a list of names, affiliations, and contact information for the meeting participants.

From May 2010 through June 2011, the study's external Principal Investigator, Dr. Scott Rhodes and his staff from the Wake Forest University School of Medicine, their study partners at the Chatham Social Health Council, and the CDC Project Officer and Project Coordinator collaborated during frequent conference calls, e-mail communications, and meetings to develop and refine all study forms and data collection questionnaires (see **Attachments 3-6a & 6b**) that will be used for collecting information from prospective and actual study participants, and the procedures for screening, enrolling, randomizing, and retaining study participants, and collecting, managing, protecting, analyzing, and reporting data collected from the study participants. Staff from Wake Forest University completed a power analysis to determine the study sample size and develop a plan for analysis of the study data. All forms, questionnaires, plans, and procedures were reviewed and approved by the CDC Project Officer and other reviewers at multiple levels within CDC's Division of HIV/AIDS Prevention, by a CDC biostatistician, and the Wake Forest University IRB (see **Attachment 8**).

In addition, throughout the process of developing procedures for collecting information from study participants and disseminating information about the study in Latino communities, the Principal Investigator, Dr. Rhodes and staff from the Chatham Social Health Council have collaborated closely with a local Community Advisory Board (CAB) for review and approval of the content and form of all questions to be asked of study participants and the manner in which they are asked to collect study information (see **Attachment 11** for a list of the CAB members). These procedures are in accordance with congressional mandate Content of AIDS-Related Written Materials, Pictorial, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992), that requires all intervention materials and research instruments to have been reviewed and approved by a local program review panel (the CAB, described above) to ensure that these materials are in accordance with community standards.

Furthermore, and somewhat unique to this study, the Principal Investigator and staff from the Chatham Social Health Council collaborated closely with members (and are members themselves) of a long-standing Community-Based Participatory Research (CBPR) partnership in the Siler City, NC area. Both the CAB and the CBPR partnership are composed of representatives from the Latino community, including Latino MSM, staff members from other service provider agencies, and other key stakeholders in the communities that are served by the Chatham Social Health Council. It is noteworthy that the CBPR membership has also provided substantial input into the design of the HOLA en Grupos and the general health comparison condition interventions and the development of the instruments that will be used for collecting information from study participants.

9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for persons who participate in studies are widely used in research and are particularly important for conducting research with the Latino MSM that will be included in this study. This study aims to recruit, enroll, and follow up with a hard-to-reach, possibly hidden MSM population, and to ask sensitive questions related to their sexual risk behaviors, known HIV status, and alcohol and drug use. To enhance our ability to recruit the 300 Latino MSM that will be required for this study and retain at least 80% of those randomized to each study arm for purposes of completing the follow-up assessments as required by the cooperative agreement that funds the study, we will provide participants with tokens of appreciation for attending the HOLA en Grupos and comparison intervention sessions and when completing the baseline and six-month follow-up assessment interviews. The tokens of appreciation are described during the informed consent process (see **Attachment 7** for the Spanish-language version of the consent form that will be used during the study and the English-language translation which is included for purposes of review only).

Previous research experience by members of the study team indicates that tokens of appreciation in the form of money or other material goods (e.g., supermarket gift cards, bus passes, and clothing with project logos) are very effective for encouraging and sustaining participation in studies. This study will provide participants with two types of tokens of appreciation at various points. All participants in the HOLA en Grupos intervention and the comparison condition will receive \$40.00 after completing the baseline assessment and \$50.00 after completing the 6-month follow-up assessment. In addition, participants will receive \$40.00 for attending each of the four HOLA en Grupos and comparison intervention sessions. To facilitate retention and completion of the 6-month follow-up assessment, all study participants will receive \$5.00 in cash for contacting study staff to update their contact information if it changes during the study period. These cash tokens of appreciation will be used solely for purposes of engaging and retaining participants in the study and are not used during the routine delivery of the HOLA en Grupos intervention. In addition, a meal will be provided to participants at each intervention session, and they will receive a t-shirt and baseball cap with the HOLA en Grupos intervention logo and a certificate after they complete all steps in the study. Finally, a graduation dinner will be held after each wave of participants completes the 4th and last session of HOLA en Grupos or the comparison interventions. The Chatham Social Health Council uses these in-kind tokens during the routine delivery of the HOLA en Grupos intervention to Latino men. The Principal Investigator and the collaborating partners have considerable experience with the use of these tokens of appreciation and incentive strategies in their previous studies (Rhodes et al., 2009; In press). The use of these tokens of appreciation has been approved by the Wake Forest University

Institutional Review Board during its review and approval of the entire study protocol (see **Attachment 8**).

We have selected the forms and the amounts that we will offer study participants as tokens of appreciation based on (a) a great deal of input from our community advisory board, which includes members of the Latino community and Latino MSM, and (b) our past experience, spanning more than a decade, of conducting research within Latino communities. These amounts have ensured that hard-to-reach participants, such as recent Latino immigrants, remain engaged in all aspects of the research throughout its duration. In the case of the proposed study, this will entail their participation in the baseline assessment, 4 separate intervention sessions, and the 6-month follow-up assessment. Participant's completion of all of these study components is critical to obtaining satisfactory retention levels over time and the overall success of the study. Providing these tokens of appreciation will also reduce the likelihood that participants will rush through the study's assessment interviews, and will increase the likelihood that they will recognize the seriousness of the study and the data collection process, the importance of providing accurate data, and affirm their efforts to take the process seriously.

10. Assurance of Privacy Provided to Respondents

This submission has been reviewed by ICRO, who determined that the Privacy Act does apply to this request. The site will not apply for formal confidentiality protections.

All assessment data will be collected by specially-trained study staff, using the Wake Forest University IRB-approved baseline and 6-month follow-up assessment questionnaires (see **Attachments 4-5**). The study staff (interventionists) who deliver the interventions will not collect assessment data from study participants. In the event that a participant discloses sensitive information, for example that he is HIV-positive, the interventionist will adhere to human subject protection guidelines and not disclose this information to others. In these cases the interventionist will also provide the participant with information and referrals based on training that interventionists will receive before the study begins. In addition, the interventionists will attend human subjects and client confidentiality training that will be provided by Dr. Rhodes, the study's principal investigator. The Wake Forest University's collaborator for this study, the Chatham Social Health Council, also requires its staff and volunteers to complete training on confidentiality and human subject protection and to sign confidentiality agreements.

Study staff will not release any data on individual participants to the public. At the end of the study, an electronic copy of all study assessment data, stripped of participants' personal identifying information, will be submitted to CDC as required by the Cooperative Agreement. Summary data may be used in reports, presentations, and manuscripts for publication. Only authorized study staff will have access to study files. The CDC Project Officer and Project Coordinator will not collect data from or interact with research participants. If needed, the study site will transfer study data to CDC via a secure data network during the conduct of the study. Although individual identifiers will be linked to the data in the local database, no individually identifiable private information will be shared with CDC. The Project Officer and Project Coordinator will establish a Memorandum of Understanding between CDC and the study

site to prohibit the transfer of individually identifiable private information to CDC. De-identified study data will be maintained at the site and CDC indefinitely.

The IRB of the Wake Forest School of Medicine has approved all components of the study and the specific functions of the two partner agencies for this study: the Wake Forest University School of Medicine and the Chatham Social Health Council (see **Attachment 8**). The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention has reviewed the study protocol and has determined that the CDC Project Officer and Project Coordinator are not engaged in this information collection activity (see **Attachment 9**).

Informed Consent

All eligible persons who wish to participate in the study will be asked to provide signed consent after receiving detailed information from study staff about the study. During the informed consent process, a study staff member will review the consent form with potential participants and read it aloud if warranted. The consent form explains the interventions, the randomization process, the baseline and post-intervention 6-month follow-up data collection, and tokens of appreciation that will be offered to all participants. The study staff person will also answer any questions that potential participants may have. If individuals agree to participate in the study, they will sign the form and the staff member will provide them with a signed copy.

Although an 8th grade-reading level is acceptable for informed consent, lower levels are recommended, particularly in a participant group in which literacy levels are not a criteria for exclusion from study participation (Rhodes et al., 2007b). We used the Flesch-Kincaid Readability Test (grade 7.6) to evaluate reading levels in English and the Fry Readability Graph (FRG) to evaluate reading levels in Spanish (grade: 5) (Berland et al., 2001). See **Attachment 7** for the Spanish-language consent form that will be used in the study and the English-language translation of the form which is included for purposes of review only.

At the time of informed consent, study staff will explain to individuals that all the information that will be collected from them will be kept in a secure manner, and that any reports from the study will not include the names of any participants, but will only describe the study results for the group of participants as a whole. Study staff will explain to those who agree to participate in the study that their names will not appear on any of the assessment questionnaires, and that only identification numbers that are assigned uniquely to them will appear on the assessment questionnaires. Study staff will also explain to participants that their personal information will not be disclosed unless otherwise compelled by law. All elements of this project have been approved by the Wake Forest University School of Medicine IRB local IRB (See **Attachment 8**).

During the informed consent process, study staff will explain to all participants that their participation in this study is completely voluntary and that they may refuse to participate in the project without any penalty whatsoever. Study staff will also explain that all participants who begin the baseline or follow-up assessments can refuse to answer any question without any penalty whatsoever. Study staff will endeavor to provide information to participants about the date and time of the different intervention sessions and the follow-up assessments. However, all

participants may decline to be contacted by study staff who attempt to provide this information, and may decline at any time and without any penalty whatsoever to participate in the study; that is, in the intervention sessions or the assessments (see **Attachment 7** for the Spanish-language version of the consent form that will be used during the study and the English-language translation which is included for purposes of review only).

Confidentiality of responses and safeguarding of materials

This site will not apply for formal confidentiality protections. Study staff will take the following steps to safeguard the privacy of all study participants. First, they will establish an agreement with all participants that all information revealed during the assessment will be kept private. Second, they will explain to each participant that he is free not to answer any of the questions that will be asked at any time during the study. Third, they will explain to each participant that he may cease an interview or participation in an intervention session at any time without any adverse consequences. Fourth, study staff will not enter any personal identifying information on the baseline and 6-month follow-up assessment questionnaires; they will enter only the participants' unique identification number that is assigned during the consent process. Fifth, they will separate all participant personal identifying and contact information that is collected during the screening process and at the end of the baseline assessment immediately after these processes are complete, and securely store the information in locations that are separate from the secure locations used for storing the screening forms and the completed assessment questionnaires. Paper copies of all the study assessment questionnaires and lists of participants' names and identification numbers will be kept in separate locked file cabinets in the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine. Sixth, study staff will offer resources and referrals as needed to address participants' informational or emotional needs. Resources include low-literacy, Spanish-language written materials on HIV and STD prevention (including counseling and testing) and access to a toll-free Spanish-language HIV/AIDS hotline. Referrals can also be provided to local service providers, including health departments, mental health agencies, partner violence support services, and other Latino-serving organizations).

At the time of screening persons for eligibility to participate in the study, study staff will ask all eligible persons to provide their name and phone number. This contact information (page 3 of the 3-page screening form; see **Attachment 3** for the Spanish-language version of the form that will be used during the study and the English-language translation which is included for purposes of review only) will be separated from pages 1-2 that contain responses to the screening questions at the end of the screening process. Study staff will destroy pages 1-2 and store page 3 with the participants' contact information in a secure location in the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine study office. Study staff will ask enrolled participants to provide additional contact information at the end of the baseline assessment only (see questions 143A-146F in **Attachment 4**), and will use this information to ensure that they can reach participants to remind them of upcoming intervention sessions and their follow-up assessment. Immediately after completion of the baseline assessment and collection of participant contact information, study staff will remove the pages with contact information from the baseline assessment questionnaire. Study staff will store all participant contact information in locked study project office files at the Department of Social

Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine that are separate from other study materials, which will also be stored in a locked file cabinet in the Department. Study staff will destroy all participant paper forms and electronic files that contain contact information six years after the completion of the study.

Paper copies of signed consent forms and the two study assessment questionnaires will be stored separately in the Department of Social Sciences and Health Policy. No personal-identifying information will be recorded on any of the completed assessment questionnaires. The unique participant identification number that appears on page 1 of the baseline assessment questionnaire will be entered on the consent form when eligible persons agree to participate, will be the same as the number on page 1 of the 6-month follow-up assessment, and will serve as a link for the three documents. As individuals in the counties surrounding Siler City, NC consent to participate in the study and complete consent forms, the baseline assessment and the 6-month follow-up assessment, the signed consent forms, the completed assessment questionnaires, and participants' contact information will be stored in 3 separate lockboxes in the offices of the Chatham Social Health Council. No later than 48 hours after completion, study staff will transfer all assessment questionnaires, contact information, and consent forms to the offices of the principal investigator at the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine, where they will be stored in a locked file cabinet. Following entry of assessment data by university data entry staff into the electronic database, all electronic data records will be kept in password-protected files.

Privacy Impact Assessment

No later than 48 hours after completion, study staff will transfer all data collection forms to Wake Forest University School of Medicine where they will be stored in a locked file cabinet. All electronic information and datasets that will be created by the entering of participants' responses to the two study assessments or other information collection forms will be kept in password-protected electronic files. Paper copies of all completed information collection forms and lists of participants' names and corresponding identification numbers will be kept separately in a locked file cabinet in the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of Medicine.

11. Justification for Sensitive Questions

The screening form (see **Attachment 3**) and the baseline and 6-month follow-up assessments (see **Attachments 4** and **5**) that will be used during the study will include questions about topics that participants may consider to be sensitive in nature. The screening form will ask potential participants their age and if they have had sexual intercourse with a man and with a woman since turning 18 years of age. The baseline and 6-month follow-up assessments will ask enrolled participants about their sociodemographic characteristics; general health and access to health care; acculturation to norms and values in the U.S.; knowledge about HIV and STD transmission and prevention; sexual identity; sexual behaviors with men and women; skills with using condoms; circumstances and frequency of condom use; condom-related self-efficacy and expectations; intentions to use condoms; communication with sex partners that may be protective

against HIV/STD infection; self-reported STD infections; masculinity; perceived and experienced barriers to HIV-testing; mental health; discrimination; alcohol and drug use; perceived and experienced reactions by others to homosexuality; employment and education; religiosity; fatalism; ethnic identity; immigration experience; social support; and community attachment, including participants' perceptions of the possible effects of their documentation status on their social relationships and access to and participation in various services.

The use of sensitive questions during the screening process is necessary to determine the eligibility of potential participants to enroll in the study and to ensure that all study participants are of the kind that is of concern to the study and the HOLA en Grupos intervention.

Although questions in the baseline and 6-month follow-up assessments may be sensitive and it is possible that some participants may feel uncomfortable when answering, the collection of this kind of information is necessary to rigorously assess the efficacy of the HOLA en Grupos intervention compared to the comparison condition in reducing the study participants' HIV/STD risk actions (e.g., having unprotected sex) and increasing their HIV/STD protective actions (e.g., using condoms during sexual intercourse or learning their HIV serostatus through HIV testing in order to potentially reduce their risk behaviors with sex partners). The only currently available method for assessing the efficacy of HIV prevention interventions such as the HOLA en Grupos intervention among study participants is to pose these kinds of questions during a private data collection session. In addition, as explained above, collecting this kind of sensitive information is necessary to better understand the behaviors and circumstances that affect Latino MSM's risks of HIV/STD infection. Although participants are asked several questions about their perceptions concerning the possible effects of their documentation status on their social relationships and access to and participation in various services, they are not asked the more sensitive question of whether or not they are in the country without documentation. Study staff will explain to potential participants during the informed consent process that participating in the study involves answering questions about sensitive topics. Study staff will also inform participants at the beginning of each assessment about their right to skip questions they do not wish to answer or to stop the assessment at any time.

The Principal Investigator and his study partners have had considerable success collecting sensitive information of this kind from Latino populations, using quantitative and qualitative methods. The key to their success has been careful training of data collection staff and efforts by data collection staff to establish rapport and a sense of trust among study participants. The staff members' dedication to collecting data using this culturally congruent approach has led to a more informed understanding of public health phenomena and the overall success of our long-standing community-based participatory research partnership in Latino communities of North Carolina (Rhodes et al., In press; Rhodes, In press).

12. Estimates of Annualized Burden Hours and Costs

12A.

We estimate that it will be necessary to screen 350 men in order to enroll 300 eligible individuals for random assignment to receive the HOLA en Grupos (150 men) intervention or the comparison intervention (150 men), respectively.

Based on our time tests, we estimate that 10 minutes per person will be required to complete the screening form (see **Attachment 3** for the Spanish-language version of the screening form that will be used during the study and the English-language translation which is provided solely for purposes of review) during telephone or face-to-face contacts with potential participants. The screening form asks potential participants 7 questions.

Based on our time tests, we estimate that 1 hour and 45 minutes per person will be required to complete the baseline assessment questionnaire, which includes the collection of participant contact information. Study staff will administer the baseline assessment to participants immediately after completion of informed consent (see **Attachment 4** for the Spanish-language version of the questionnaire that will be used during the study and the English-language translation which is provided solely for purposes of review). The baseline risk behavior questionnaire contains 458 questions, however not all participants may answer all questions because of skip patterns in the questionnaire.

This study has only one follow-up assessment, which will be completed by participants 6-months after they receive the HOLA en Grupos intervention or the comparison intervention. Based on our time tests, we estimate that 60 minutes per person will be required to complete the 6-month follow-up assessment questionnaire during a face-to-face interview with project staff. If the participant is not in the study area at the time his 6-month follow-up assessment is due, study staff are prepared to administer the questionnaire by telephone. We estimate that 60 minutes per person will also be required in the unlikely event that it is necessary to administer the 6-month follow-up questionnaire to study participants by telephone. As explained above, the 6-month follow-up assessment questionnaire will require less time to administer than the baseline assessment because several questions that are asked in the baseline assessment will not be asked during the 6-month follow-up. The 6-month assessment questionnaire contains 379 questions. See **Attachments 4** and **5** for the Spanish-language versions of the baseline and 6-month follow-up questionnaires that will be used during the study and the English-language translations which are provided solely for purposes of review. Furthermore, as was the case for the baseline assessment, not all participants may answer all questions because of skip patterns in the questionnaire. The total participant burden for this data collection is estimated to be 883 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	Participant Screening Form	350	1	10/60	58
Enrolled Study Participant	Baseline Assessment	300	1	1.75	525
Enrolled Study Participant	6-month follow-up assessment	300	1	1	300
Total					883

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 January 2011 by the US Department of Labor (<http://data.bls.gov/pdq/SurveyOutputServlet> [Series Id: CES0500000003]; accessed August 2, 2011).

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- Participant Screening Form	58	\$22.86	\$1325.88
Enrolled Study Participant- Baseline Assessment	525	\$22.86	\$12,001.50
Enrolled Study Participant – 6-month Assessment	300	\$22.86	\$6,858.00
Total	883		\$20,185.38

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 \$1,000,000. The annual cost to the government during years 3 and 4 of the study, during which data collection will occur, is \$653,943 (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)	\$38,900
	CDC Project Coordinator (GS-11, .12FTE)	\$7,198
	CDC Statistician (GS-13 .05 FTE)	\$4,845
	Travel	\$3000
	Subtotal, direct costs to the government	\$53,943
Contractor and other expenses		
	Cooperative Agreement: Wake Forest University School of Medicine. This is the average annualized cost for the period of actual information collection, which will occur during years 3 and 4 of the 5-year cooperative agreement.	\$600,000
	TOTAL COST TO THE GOVERNMENT	\$653,943

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

Analysis of the collected information has been designed to (a) provide a general description of all study participants and comparative descriptions of those participants who receive the HOLA en Grupos intervention and the comparison intervention, respectively, (b) assess the efficacy the HOLA en Grupos intervention relative to the comparison intervention, and (c) assess the effects of factors that are significantly correlated with observed changes in HIV/STD risk behaviors among intervention and comparison participants.

General description of the study group - Frequency tables and percentages for categorical variables and means, medians, standard deviations and ranges for continuous variables will be tabulated and used to describe the overall sample of participants. Comparisons between intervention and comparison groups will be analyzed as well. Scatter plots and histograms will be used to evaluate the distribution of the participants according to the variables measured. 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.

Evaluation of intervention effects - Our primary data analyses to evaluate the effects of the HOLA en Grupos intervention will include comparing rates of past 3-month consistent condom

use and past 6-month HIV testing reported by intervention and comparison group participants at the 6-month follow-up assessment, while adjusting for baseline rates of condom use and HIV testing. This follow-up adjusted baseline approach has the advantage of being unaffected by baseline differences. If baseline rates, by chance, were different in the intervention group, the intervention effect would be overestimated by looking at change scores and underestimated by a follow-up score analysis. This ANCOVA approach gives the same answer whether or not there is baseline imbalance. Additionally, this approach generally has greater statistical power to detect an intervention effect than the other methods (Vickers & Altman, 2001). Statistical analysis will be performed using generalized linear mixed modeling, sometimes referred to as random effects logistic regression, for binary outcomes (Wolfinger & O'Connell M, 1993). These models can assume a logit link for binary data (i.e. presence or absence of behavior) and allow for the modeling of within-group correlation of risk behaviors. The generalized linear mixed model is an extension of general linear models that allows for non-independence of observations.

The hypothesis that intervention and comparison groups differ in their prevalence (p) of self-reported consistent condom use at 6-month follow-up, for example, will be tested with the random-effects logistic model:

$$\text{Logit}(p_{ij1}) = \beta_0 + \beta_1 Y_{ij0} + \beta_2 \text{INTVN} + u_j$$

[Equation 1]

where p_{ij1} is the probability of self-reported consistent condom use at the 6-month follow-up for participant i in group j , Y_{ij0} is 1 if participant i in group j reports consistent condom use at baseline and 0 otherwise, and, $\text{INTVN} = 1$ for the intervention group and 0 for the comparison group. The random effect u_j is the random effect for participants in group j . The variance component for this random effect addresses the within-group correlation. Under the model in Equation 1, β_2 corresponds to the difference in prevalence of consistent condom use at the 6-month follow-up between the intervention and comparison groups on the logit scale. The random effects logistic regression model in Equation 1 will be fit using adaptive Gaussian quadrature implemented in SAS PROC NLMIXED (Pinheiro & Bates, 1995).

This regression approach will allow us to produce estimates of consistent condom use and HIV testing (the outcome variables) adjusting for covariates, which will be compared to unadjusted estimates. Individual-level covariates may include age, country of origin, education level, and length of time in US. To assess the importance of covariates, we will use a backwards elimination model building approach, with primary consideration on assessment of confounding on the intervention-group difference. If confounding is present (defined to be greater than a 10% change in the regression estimate of the intervention-group effect), the confounder will be retained in the multivariable model. Interactions with intervention group will be tested first and retained if significant at the 5% level. All analyses will be two-sided (Fleiss, 1987).

The study's principal investigator, Dr. Rhodes, and members of the HOLA en Grupos intervention study team -- staff of the Wake Forest University School of Medicine and the Chatham Social Health Council -- will lead efforts to disseminate the study findings through publication in peer-reviewed scientific journals and presentations at conferences and other

venues. The CDC project staff also will collaborate as partners in the dissemination of study findings.

Timeline

Exhibit A16. Project Time Schedule

Activities	Time Schedule
Begin recruitment	1 month after OMB approval
Complete recruitment, intervention implementation, and data collection	27 months after OMB approval
Data management and validation	36 months after OMB approval
Analysis of key outcomes	42 months after OMB approval
Dissemination of results	43 months after 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

- Berland GK, Elliott MN, Morales LS, Algazy JI, Kravitz RL, Broder MS, et al. (2001). Health information on the Internet: accessibility, quality, and readability in English and Spanish. *JAMA*;285(20):2612-21.
- Carballo-Diéguez A, Dolezal C, Leu CS, Nieves L, Díaz F, Decena C, Balan I. (2005). [A randomized controlled trial to test an HIV-prevention intervention for Latino gay and bisexual men: lessons learned](#). *AIDS Care*. 2005 Apr;17(3):314-28
- Cashman R, Eng E, Simán F, Rhodes SD. (2011). Exploring the sexual health priorities and needs of immigrant Latinas in the southeastern US: A community-based research approach. *AIDS Educ Prev*;23(3):236-48.
- Centers for Disease Control and Prevention. (2007a). HIV/AIDS among Hispanics – United States, 2001-2005, MMWR. 2007; 56:1052-1057.-
- Centers for Disease Control and Prevention. (2007b). HIV/AIDS Surveillance Report, 2007. Vol 19. Atlanta, GA.:U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009:1-63. Available at: <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>. Accessed July 1, 2011.
- Centers for Disease Control and Prevention. (2008) Subpopulation estimates from the HIV incidence surveillance system--United States, 2006. *MMWR Morb Mortal Wkly Rep*;57(36): 985-9.
- Division of HIV/AIDS Prevention. (2011). *Strategic Plan, 2011-2015 for the Division of HIV/AIDS Prevention*. Atlanta, GA: Division of HIV/AIDS Prevention. August.
- Fleiss JL. (1987). Some thoughts on two-sided tests. *Journal of Controlled Clinical Trials*;8:394.
- Herbst JH, Stallworth JM, Mejia R, Bauermeister J, Villarruel AM. (2011). HIV/AIDS in Hispanic/Latino communities. In: BJ Hall, JC Hall, & CJ Cockerell (Eds.), *HIV/AIDS in the post-HAART era: Manifestations, treatment and epidemiology*. Shelton, CT: PMPH-USA, pp. 679-708.
- Kasarda JD, Johnson JH. (2006). *The economic impact of the Hispanic population on the state of North Carolina*. Chapel Hill, NC: Frank Hawkins Kenan Institute of Private Enterprise, 2006.
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. (2011). Strategic Plan, 2010–2015. Atlanta, GA: National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. February. Available at: http://www.nchhstp.cdc.gov/docs/10_NCHHSTP%20strategic%20plan%20Book_semi%20final508.pdf. Accessed August 11, 2011.

North Carolina Department of Health and Human Services. (2007). 2006 HIV/STD surveillance report. Raleigh, NC: NC Department of Health and Human Services.

North Carolina Department of Health and Human Services. (2008). New estimates profile new HIV infections in North Carolina. *Assessed 8 December 2008*: <http://www.dhhs.state.nc.us/pressrel/2008/2008-9-12-New-estimates-profile-new-HIV.htm> 2008.

North Carolina Institute of Medicine. (2003). *NC Latino health 2003*. Durham, NC: North Carolina Institute of Medicine, 2003.

O'Donnell CR, O'Donnell L, San Doval A, Duran R, Labes K. (1998). Reductions in STD infections subsequent to an STD clinic visit. Using video-based patient education to supplement provider interactions. *Sex Transm Dis*;25(3):161-8.

Pinheiro JC, Bates DM. (1995). Approximations to the log-likelihood function in the nonlinear mixed-effects model. *Journal of Computational and Graphical Statistics*;4(12-35).

Rhodes SD, Yee LJ, Hergenrather KC. (2006). A community-based rapid assessment of HIV behavioural risk disparities within a large sample of gay men in southeastern USA: a comparison of African American, Latino and white men. *AIDS Care* 2006;18(8):1018-24.

Rhodes SD, Eng E, Hergenrather KC, Remnitz IM, Arceo R, Montañó J, et al. (2007a). Exploring Latino men's HIV risk using community-based participatory research. *Am J Health Behav*;31(2):146-58.

Rhodes SD, Hergenrather KC, Yee LJ, Wilkin AM, Clarke TL, Wooldredge R, et al. (2007b). Condom acquisition and preferences within a sample of sexually active gay and bisexual men in the Southern USA. *AIDS Patient Care STDS*;21(11):861-70.

Rhodes SD, Hergenrather KC, Bloom FR, Leichter JS, Montañó J. (2009). Outcomes from a community-based, participatory lay health advisor HIV/STD prevention intervention for recently arrived immigrant Latino men in rural North Carolina, USA. *AIDS Education and Prevention*; 21(5 Suppl):103-108.

Rhodes SD, Hergenrather KC, Aronson RE, Bloom FR, Felizzola J, Wolfson M, et al. (2010). Latino men who have sex with men and HIV in the rural south-eastern USA: findings from ethnographic in-depth interviews. *Cult Health Sex*; 12(7):797-812.

Rhodes SD, McCoy TP, Vissman AT, DiClemente RJ, Duck S, Hergenrather KC, et al. (In press). A randomized controlled trial of a culturally congruent intervention to increase condom use and HIV testing among heterosexually active immigrant Latino men. *AIDS and Behavior*.

Rhodes SD. (In press). Demonstrated effectiveness and potential of CBPR for preventing HIV in Latino populations. In: Organista KC, editor. *HIV Prevention with Latinos: Theory, Research, and Practice*.

Rhodes SD, Vissman AT, Eng E, Alegria-Ortega J, Aronson R, Bloom FR, et al. (In review). Sex, immigrant Latino gay men and MSM, and health disparities in the rural Southern USA: Findings from iterative, in-depth interviews using CBPR. In review.

Robles RR, Reyes JC, Colon HM, Sahai H, Marrero CA, Matos TD, et al. (2004). Effects of combined counseling and case management to reduce HIV risk behaviors among Hispanic drug injectors in Puerto Rico: a randomized controlled study. *J Subst Abuse Treat*;27(2):145-52.

U.S. Census. (1990). Table DP-1, *General Population and Housing Characteristics, 1990 Census of Population and Housing, Summary Tape File 1 (100% Data)*. Washington, D.C.: U.S. Bureau of the Census, 1990. Available at: <http://factfinder.census.gov> (Accessed July 28, 2011).

US Census Bureau. (2007a). *2007 American Community Survey Data Profile Highlights: North Carolina Fact Sheet*. Washington, DC: United States Department of Commerce, 2007.

U.S. Census. (2007b). Table DP-1, *General Demographic Characteristics, 2007 Population Estimates*. Washington, D.C.: U.S. Bureau of the Census, 01 July 2007. Available at: <http://factfinder.census.gov> (Accessed July 21, 2011).

Vickers AJ, Altman DG. (2001). Statistics notes: Analysing controlled trials with baseline and follow up measurements. *British Medical Journal*;323(7321):1123-4.

Vissman AT, Eng E, Aronson RE, Bloom FR, Leichliter JS, Montañó J, Rhodes SD. (2009). What do men who serve as lay health advisors really do?: Immigrant Latino men share their experiences as *Navegantes* to prevent HIV. *AIDS Educ Prev*;21(3):220-32.

The White House Office of National AIDS Policy. (2010). NATIONAL HIV/AIDS STRATEGY FOR THE UNITED STATES. Washington, D.C.: The White House Office of National AIDS Policy. July. Available at: <http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>. Accessed August 11, 2011.

Wolfinger R, O'Connell M. (1993). Generalized linear mixed models: A pseudo-likelihood approach. *Journal of Statistical Computation and Simulation*;48:233-43.