SUPPORTING STATEMENT A:

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

Extension

OMB No. 0920-0942

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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 one-year extension of OMB Information Collection Request (ICR) # 0920-0942, which expires June 30, 2015. This extension will enable the completion of the ongoing data collection entitled, "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 delivered 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, is conducting the study to rigorously evaluate the efficacy of the HOLA en Grupos intervention.

Since obtaining OMB approval on June 28, 2012 for the study's first Information Collection Request, the study has accomplished the following (as of August 25, 2014):

(1) 303 individuals have been screened and determined to be eligible for the study.
(2) 245 (82%) of the total sample size of 300 men required for the study have been randomized to receive the HOLA en Grupos intervention or the Comparison intervention.
(3) 13 of 17 intervention delivery waves planned for the study have been completed (a wave includes the complete delivery of the 4-session HOLA en Grupos intervention and the 4-session comparison intervention to men randomly assigned to receive the respective interventions at different locations over two consecutive weekends).
(4) Six-month follow-up assessments have been completed for intervention delivery waves #1-7.
(5) Six-month follow-up assessment data collection for intervention delivery wave #8 is in progress.
(6) Retention for completed 6-month follow-up assessments is 100%.

Completion of enrollment/delivery of HOLA en Grupos intervention and the comparison intervention is expected by mid-February 2015.

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 is being 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 while 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 uses 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 is being 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) is being 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 are testing 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. To date, the study has not produced any presentations or publications. 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 are being 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. All collected data will be maintained by the grantee. For the requested one-year ICR extension period, the 6-month follow-up assessment questionnaire will be administered to 50 study participants. No additional participants will be enrolled to the study will occur during the extension period.

Six-month follow-up assessment – Six months after HOLA en Grupos and comparison participants complete their respective interventions, study staff administer a follow-up assessment questionnaire to them during a face-to-face interview (see **Attachments 3** and **4** for the Spanish-language questionnaire used in the study and the English-language translation, which is included for purposes of review only). The first page of the follow-up assessment questionnaire contains only the unique identification number that was initially pre-assigned to the participant at the time of study recruitment, and does not contain the participant's name or any other personal-identifying information. Completion of the 6-month follow-up assessment requires about 60 minutes per respondent.
During the requested one-year ICR extension period, the 6-month follow-up assessment questionnaire will be administered to 50 study participants.

A master participant file that links participants' names with their study identification numbers is stored in a password-protected database at Wake Forest University. All copies of the 6-month follow-up assessment questionnaires are stored in a locked file cabinet in 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. All electronic information and datasets that are created by entering participants' responses to the 6-month assessment questionnaire are kept in password-protected electronic files.

No data collected from individual participants during the assessments 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 have not had any contact with or collected data from the study participants, and they have not had 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

Six-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 need to be collected from intervention and comparison participants 6 months after intervention delivery (see **Attachments 3** and **4** for the Spanish-language questionnaire used in the study and the English-language translation, which is included for purposes of review only).

The types of data that are being collected during the 6-month follow-up 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.

This study uses only one follow-up assessment, which is conducted 6-months after participants complete the HOLA en Grupos intervention or the comparison intervention. The first page of the 6-month follow-up assessment questionnaire contains only the identification number that was initially pre-assigned to the participant at the time of enrollment and baseline assessment, and does not contain the participants' name. This identification number enables the study staff to link responses to the 6-month follow-up assessments with responses provided during assessments at the beginning of the study.
For the requested one-year ICR extension period, the 6-month follow-up assessment questionnaire will be administered to 50 study participants.

Study staff securely store the completed 6-month follow-up assessment questionnaires 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. University data entry staff enter the questionnaires as electronic records 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 use 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 is being 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 uses 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 and disseminated for use by CBOs and health departments. 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. To date, the study has not produced any presentations or publications.

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 that are being collected for this study will be used to establish the efficacy of the HOLA en Grupos HIV behavioral prevention intervention for Latino MSM.

This study involves the collection of sensitive information, therefore stringent safeguards are implemented to protect against a breach of security or illegal access to individually identifiable information. Before any data are collected, all study staff are 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. The study takes several steps to address possible risks to participants. First, an agreement is established with participants that all information revealed during the study assessments will be kept private. Second, all information collected is stored securely and responses and identifying information are kept in separate locations. Paper copies of datasets or lists of names and identification codes for participants are 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 are provided as needed to address participants' informational or psychological needs. These 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 are collected by the grantee and are maintained at the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest University School of

Medicine. Personal-identifying information is not attached to data obtained from study participants. A unique pre-assigned participant identification number, and no personal identifying information, is included in the 6-month follow-up assessment questionnaire. Participants' names that were collected at the time of their enrollment in the study are linked to their unique identification number in a separate password-protected Excel spreadsheet file at the Department of Social Sciences and Health Policy. Paper copies of the assessment questionnaires and lists of participants' names and corresponding identification numbers are kept separately in a locked file cabinet in 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. All electronic information and datasets that are created by the entering of participants' responses to the 6-month assessment are kept in password-protected electronic files.

The CDC Project Officer and Project Coordinator do 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. To date, the study has not produced any presentations or publications.

3. Use of Improved Technology and Burden Reduction

No technological collection techniques or other forms of information technology are used to collect information during this study, therefore no study responses are collected in this manner. The 6-month follow-up assessment questionnaire (see **Attachments 3** and **4** for the Spanish-language questionnaire used in the study and the English-language translation, which is included for purposes of review only) are printed on paper and are 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 are 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 by the study's principal investigator 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-acculturated, 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-Dieguez 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 is being delivered and assessed by this study, the Carballo-Dieguez 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 this study's current data collection or address the specific needs that will be served by the current 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 data that is currently being collected by this study or address the needs that will be served by the current 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 are involved in this study.

6. Consequences of Collecting the Information Less Frequently

The one-time collection of follow-up assessment data six months after intervention delivery will enable the Principal Investigator to determine the efficacy of the HOLA en Grupos intervention and conduct the other analyses described above.

By collecting assessment data from HOLA en Grupos and comparison intervention participants only at the time of their enrollment in the study and 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.
Participants are 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 08/25/2014; Vol. 79, No. 164, page numbers 50652 - 50653. A copy of this publication is attached (**Attachment 2**). Public comments were received and are provided in **Attachment 2a**.

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.

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 and the CDC Project Officer and Project Coordinator collaborated during frequent conference calls, e-mail communications, and meetings to develop and refine all data collection forms, including the 6-month follow-up assessment questionnaire (see **Attachments 3** and **4**) . 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 5**).

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 his staff 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. 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 his staff have collaborated closely with members (and are members themselves) of a long-standing Community-Based Participatory Research (CBPR) partnership in central NC. 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 of communities in the area. 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 are being used to collect 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 to complete 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 provide participants with tokens of appreciation for attending the HOLA en Grupos and comparison intervention sessions and when completing the 6-month follow-up assessment interviews.

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 provides participants with two types of tokens of appreciation at various points. All participants who complete the 6-month follow-up assessment questionnaire during the requested extension period will receive $50.00. To facilitate retention and completion of the 6-month follow-up assessment, all study participants receive $5.00 in cash for contacting study staff to update their contact information if changes occur during the study period. These cash tokens of appreciation are 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 is provided to participants at each intervention session, and they 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 is held after each wave of participants completes the 4th and last session of HOLA en Grupos or the comparison interventions. 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 5**).

We have selected the forms and the amounts that we 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 entails their participation in the baseline assessment, 4 separate intervention sessions, and the 6-month follow-up assessment. Participants' 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 also reduces the likelihood that participants will rush through the study's assessment interviews, and 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 NCHHSTP, who determined that the Privacy Act does apply to this request. The site will not apply for formal confidentiality protections.

The 6-month follow-up assessment data will collected during the extension period by specially-trained study staff, using an Wake Forest University IRB-approved 6-month follow-up assessment questionnaire (see **Attachments 3** and **4**).

Study staff do not and 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 have access to study files. The CDC Project Officer and Project Coordinator do 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 Wake Forest University School of Medicine during the study (see **Attachment 5**). 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.

<u>Confidentiality of responses and safeguarding of materials</u>

This site has not applied for formal confidentiality protections. Study staff take the following steps to safeguard the privacy of all study participants. First, they establish an agreement with all participants that all information revealed during the assessment will be kept private. Second, they 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 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 do not enter any personal identifying information on the 6-month follow-up assessment questionnaire; they will enter only the participants' unique identification number that is assigned during the enrollment process. Paper copies of all the study assessment questionnaires and lists of participants' names and identification numbers are 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. Fifth, study staff 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).

No study enrollment will occur during the requested extension of the ICR approval beyond its expiration date of June 30, 2015. The 6-month follow-up assessment questionnaire will be administered to 50 study participants during the extension period.

Privacy Impact Assessment

All data collection forms are stored in a locked file cabinet at the Wake Forest University School of Medicine. All electronic information and datasets that are created by the entering of participants' responses to the two study assessments or other information collection forms are kept in password-protected electronic files. Paper copies of all completed information collection forms and lists of participants' names and corresponding identification numbers are 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 6-month follow-up assessment questionnaires (see **Attachments 3** and **4)** that are used during the study include questions about topics that participants may consider to be sensitive in nature. The 6-month follow-up assessments 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.

Although questions in the 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 MSMs' 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 explain to potential participants during the informed consent process that participating in the study involves answering questions about sensitive topics. Study staff 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.
This study has only one follow-up assessment, which is 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 are 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 are also required in the unlikely event that it is necessary to administer the 6-month follow-up questionnaire to study participants by telephone. The 6-month assessment questionnaire contains 379 questions. See **Attachments 3** and **4** for the Spanish-language questionnaire used in the study and the English-language translation, which is included for purposes of review only. Furthermore, not all participants may answer all questions because of skip patterns in the questionnaire. The total participant burden for data collection during the requested extension period is estimated to be 50 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 June 2014 by the US Department of Labor http://www.bls.gov/news.release/empsit.t19.htm: accessed July 10, 2014: accessed July 10, 2014.

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 average annualized cost for data collection during the requested extension period, which will occur after termination of the current Cooperative Agreement on April 30, 2015, is $100,000.00. A no-cost extension of the project will permit continuation of data collection after the end of project year 5 (April 30, 2015).

The annual cost to the government during years the requested extension period is $155,174 (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)	$39,291
	CDC Project Coordinator (GS-11, .12FTE)	$7,270
	CDC Statistician (GS-13 .05 FTE)	$5.613
	Travel	$3000
	Subtotal, direct costs to the government	$55,174
Contractor and other expenses		
	Cooperative Agreement: Wake Forest University School of Medicine. This is the average annualized cost for data collection during the requested extension period, which will occur after the termination of the current Cooperative Agreement on April 30, 2015. A no-cost extension of the project will permit continuation of data collection after the end of project year 5 (April 30, 2015).	$100,000
	TOTAL COST TO THE GOVERNMENT	**$155,174**

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 request for approval of an extension of an ongoing 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:

$$\text{Logit}(p_{ij1}) = \beta 0 + \beta 1 \; Y_{ijo} + \beta 2 \; INTVN + \upsilon_i$$

[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, INTVN =1 for the intervention group and 0 for the comparison group. The random effect υ_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, $\beta 2$ 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. To date, the study has not produced any presentations or publications.

Timeline

Exhibit A16. Project Time Schedule

Activities	**Time Schedule**
Begin recruitment	Completed prior to requested extension period.
Complete recruitment and intervention implementation	Recruitment and intervention delivery will be completed prior to requested extension period.
Complete data collection	2-3 months after OMB approval and beginning of extension period.
Data management and validation	5 months after OMB approval and beginning of extension period.
Analysis of key outcomes	7 months after OMB approval and beginning of extension period.
Dissemination of results	10 months after OMB approval and beginning of extension period.

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.

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