SUPPORTING STATEMENT B:

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

New OMB Application

OMB No. 0920-New

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

Respondent Universe

The respondents who will be asked to provide information for the proposed study are Spanish-speaking Latino men who have sex with men (MSM), 18 years of age or older, who are living in eleven counties in central North Carolina (NC). Based on 2010 US Census data, an estimated 1.6 million people, of whom 125,270 are Spanish-speaking Hispanic/Latino adults, live in these counties. Of these, approximately 2,000 are Spanish-speaking adult Latino MSM. This estimate is based on the following calculation: 125,270 Spanish-speaking Latino adults X 1.2 (to conservatively account for undercounting of Latinos in the US Census) X 0.65 (the estimated proportion of males among Spanish-speaking Latino adults in the adult Latino population) X 0.02 (the estimated proportion of MSM among Spanish-speaking Latino adult males) = 1,954 Latino MSM. The total of 300 Spanish-speaking Latino MSM that will be enrolled in the study represents approximately 15% of all potentially eligible Latino MSM who make up respondent universe in the eleven county area of central NC.

Overview of Sampling Method

During the enrollment period, the study will be advertised in tiendas (small grocery stores); laundromats; businesses that employ large numbers of Latinos (such as poultry plants, construction sites, and hotels); sports leagues; English as Second Language classes; common areas in housing communities, apartment complexes, and trailer home communities; Latino restaurants and clubs; gay bars, clubs, and dancehalls; local Community Based Organizations (CBO) and Latino festivals and events throughout the central region of NC. See **Attachments 6a** and **6b** for two versions (described in the Procedures for the Collection of Information section below) of the Spanish-language advertisements that will be used to disseminate information about the study and the English-language translations which are included solely for purposes of review.

Information about the study, using the same text as that contained in the study advertisements, will also be published in the Que Pasa, a free Spanish-language Latino community newspaper with an average circulation of more than 70,000 in Greensboro/Winston-Salem, Charlotte, and Raleigh areas of North Carolina. Radio advertisements may also be used if other efforts to disseminate information about the study do not yield the needed recruitment numbers.

The study staff will also use word of mouth to disseminate information about the study to potential participants. In all cases, a telephone number will be included with study information, and interested individuals will be invited to call the number for additional information and for potential screening for eligibility to participate in the study.

Sample Size Justification

The aim of the study is to determine the efficacy of the HOLA en Grupos HIV behavioral prevention intervention for Latino MSM, and the study design and sample size are based on the steps required to provide evidence of the intervention's efficacy.

Response Rates

Based on their previous research activities with Latino heterosexual males and MSM in North Carolina, the principal investigator at Wake Forest University, and the grantee's research partner, the Chatham Social Health Council, estimate that at least 85% of the men who are screened will be eligible to participate in the study. Given the requirement for a total study enrollment of 300 Latino MSM, an estimated 350 Latino MSM will be screened for eligibility to obtain the required number. 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.

Sample Size Calculations

The behavioral outcomes of primary interest to the intervention study are consistent condom use and HIV testing. The following sample size calculations for consistent condom use are based on a study participant follow-up rate adjusted for baseline (or ANCOVA) model. Calculations were performed using STATA version 10 with the sampsi and sampclus commands. Because the follow-up rates of consistent condom use are expected to be in the range of 20-80%, linearity on the log odds scale corresponds to approximate linearity on the probability scale, so that the logistic model is well-approximated by a linear model. This makes it possible to use the above commands to estimate sample size (Fitzmaurice, Laird et al. 2004).

Table 1 shows the differences between condom use among participants in study intervention (I) and comparison (C) conditions that are detectable at the 6-month follow-up assessment with 80% power, assuming a 5% Type I error rate, a drop-out rate of 20% by the time of the 6- month follow-up assessment, and a total study sample size of 300 (150 participants per study condition) and 400 (200 participants per study condition), respectively, at baseline, and a range of correlations between the baseline and follow-up measures and within-groups.

Table 1. Minimum detectable differences in rates of condom use between intervention and comparison groups at 6-month follow-up with 80% power and a 20% drop-out rate at follow-up, with 150 and 200 participants per study condition at baseline (total sample sizes of 300 and 400)

		Correlation within-groups			
Correlation between baseline & follow-up	# Participants per group at baseline	0.00	0.01	0.03	0.05
0.2	n=150	18%; 50% C, 68% I	18%; 50% C, 68% I	20%; 50% C, 70% I	21%; 50% C, 71% I

	n=200	16%; 50% C, 66% I	16%; 50% C, 66% I	17%; 50% C, 67% I	18%; 50% C, 68% I
0.4	n=150	17%; 50% C, 67% I	17%; 50% C, 67% I	19%; 50% C, 69% I	20%; 50% C, 70% I
	n=200	15%; 50% C, 65% I	15%; 50% C, 65% I	16%; 50% C, 66% I	17%; 50% C, 67% I
0.6	n=150	15%; 50% C, 65% I	15%; 50% C, 65% I	16%; 50% C, 66% I	17%; 50% C, 67% I
	n=200	13%; 50% C, 63% I	13%; 50% C, 63% I	14%; 50% C, 64% I	15%; 50% C, 65% I

- The rate of consistent condom use at follow-up is assumed to be 50% in the control condition based on our Latino MSM study (Rhodes et al., In press) so that detectable differences represent increases in consistent condom use observed in the intervention condition. It is necessary to assume a rate of condom use for one of the two groups to do the sample size calculations.
- The effects of the within-group correlation depend on the number of men in each of the groups that receive the intervention during the study. In this case, we have assumed that each group will contain 10 men, which is small, resulting in a minimal impact or approximately a 9% increase in sample size to detect the same difference.
- A higher-than-expected drop-out rate of 20% is assumed at the 6-month follow-up so that the effective sample size for analysis is 120 per study condition when 150 individuals per study condition are enrolled at baseline and 160 per study condition when 200 individuals per study condition are enrolled at baseline.
- Differences in consistent condom use that are detectable between intervention and comparison participants at the 6-month follow-up range from 15% to 21% when N=150 per study condition, and from 13% to 18% when N=200 per study condition, depending on the assumed correlations.

Based on the calculations shown in Table 1, a total sample size of 300 has been selected (intervention condition =150; comparison condition =150) to evaluate the efficacy of the HOLA en Grupos intervention. The rationale for selecting this sample size is based on the larger detectable differences in condom use that we have found in our other intervention studies with immigrant Latino men (Rhodes, Hergenrather et al., 2009; Rhodes, McCoy et al., In press). The calculations in Table 1 are considered to be conservative because the outcome variance may not be as large as the maximum assumed (i.e. the variance for a binary variable is at its maximum for a rate of 50% as assumed here). The detectable differences in HIV testing for the two study conditions are similar to those described above for condom use.

2. Procedures for the Collection of Information

Training for Study Personnel

The study staff that will be delivering the HOLA en Grupos and comparison interventions will be trained in procedures to follow when insufficient numbers of participants attend an

intervention session or when participants bring a friend to attend. In the former instance, the intervention will be delivered as long as 6 or more participants are present; otherwise, it will be rescheduled for a later date. The group processes that occur during intervention delivery are key to its success. Therefore, if a participant brings a friend to attend, as has often happened in our previous HIV prevention research and practice, study staff members who are delivering the intervention will explain to the friend that because this is a study, he cannot attend. However, the staff member will inform the participant's friend that he can be screened for eligibility to participate in the study by calling the study telephone number, and possibly be included in a future wave of recruitment and intervention delivery.

Those study staff that will be administering the baseline and 6-month follow-up assessment interviews to study participants will be trained by study Principal Investigator (Dr. Scott Rhodes) and the Project Manager (Mr. Jorge Alonzo) on issues particularly salient to research with MSM, and within Latino communities. This training will increase their knowledge concerning these communities and sexuality within the communities, and develop and refine their interviewing skills. Examples of these skills include the proper manner of asking questions, carefully listening rather than talking to respondents, and expressing interest in respondents through verbal and nonverbal cues, such as eye contact (Spradley 1979). Dr. Rhodes and Mr. Alonzo will facilitate role-play activities during the training in which members of the Latino community will play the role of interviewees and present the interviewer-trainees with various challenging scenarios to further develop their interviewing skills. These mock interviews will be videotaped to allow the interviewers to see and hear the interviews, and a debriefing with Dr. Rhodes and Mr. Alonzo will facilitate their learning during the process. These mock interviews will allow the interviewers to identify opportunities for using silence, probing for detail, etc. Piloting the data collection instruments with fewer than ten study staff members will also provide the interviewers with opportunities to practice and develop interviewing skills.

The interviewer training will also ensure that when the interviewers begin their assessments, they have all necessary materials (e.g., consent forms, questionnaires, pencils) and can find an interview location that is safe, private, comfortable, and quiet. The training will provide hints for establishing rapport, maintaining impartiality, reducing bias, providing appropriate replies to respondents' queries, and deciding what to do when a respondent is confused by a question, etc. The Project Manager will review the procedures and steps needed to complete the assessments and how to handle situations in which a participant wants to change an answer.

In addition to receiving the trainings that will be provided by Principal Investigator and the Project Manager, study staff will attend human subjects and client confidentiality trainings that are provided by the Wake Forest School of Medicine. Likewise, the Chatham Social Health Council, the partner in this study, requires all staff and volunteers to complete a thorough training on confidentiality and human subject protection and to sign confidentiality agreements.

Recruitment Procedures

Potential participants will be recruited through the dissemination of advertisements that will be placed in tiendas (small grocery stores); laundromats; businesses that employ large numbers of Latinos (such as poultry plants, construction sites, and hotels); sports leagues; English as Second

Language classes; common areas in housing communities, apartment complexes, and trailer home communities; Latino restaurants and clubs; gay bars, clubs, and dancehalls; local CBOs and Latino festivals and events throughout the central region of NC. See **Attachments 6a** and **6b** for the Spanish-language versions of the advertisement that will be used to disseminate information about the study and the English-language translations which are included solely for purposes of review.

Two versions of the study advertisement will be used to recruit potential participants. One version (see **Attachment 6a)** does not refer to the study inclusion criterion of "having sex with men since age 18 years or older" because of the stigma that is often associated with same-sex behavior. Potential participants who see a flyer that mentions same-sex behavior may be less likely to carefully read the information or look for the study telephone number. Latino MSM, particularly those who are less "out" about their male-to-male sexual activities can be difficult to recruit. These individuals may be worried that they will be seen copying down a telephone number for a study of same-sex behavior or saving the number into their cell phone to call at a later date, and may not be comfortable doing so. Members of our community-based participatory research (CBPR) partnership have recommended using this more neutral approach to advertising the study in order to ensure that MSM who are less "out" will be reached by the HOLA en Grupos intervention. This approach to recruiting MSM populations has been used successfully by other studies (Dodge, Jeffries et al. 2008; Malebranche 2008).

To reach other Latino MSM who are more "out" and who frequent gay venues such as bars and clubs, a second version of the advertisement will be used which describes the study recruitment criterion of "having [had] sex with men since age 18 years or older" (see **Attachment 6b).**

Both of the advertisements describe the study recruitment criteria, explain that participation entails attendance at 4 health education sessions and the completion of two questionnaires, and describes the incentives, totaling up to $250, that are offered as tokens of appreciation (see details in section 3 below). Interested persons are invited to call the study telephone number to find out if they are eligible to participate. Those who call the study number will be screened 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 solely for purposes of review). Most of the screening will occur by telephone; however some may occur during a meeting with study recruitment staff. The instructions on the screening form for study recruiters are provided in English, although the entire screening process will be conducted in Spanish. The English-language instructions are used to remind recruiters that the instructions are for their use only, and not for use with potential participants.

In addition, information about the study will also be published, using the same text as that contained in the study advertisements, in the Que Pasa, a free Spanish-language Latino community newspaper with an average circulation of more than 70,000 in Greensboro/Winston-Salem, Charlotte, and Raleigh areas of NC. Radio advertisements may also be used if other efforts to disseminate information about the study do not yield the needed recruitment numbers.

Finally, the study staff will also use word of mouth to disseminate information about the study to potential participants. In all cases, a telephone number will be included with study information, and interested individuals will be invited to call the number for additional information and for potential screening for eligibility to participate in the study.

Informed consent (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) will be administered to those men who meet eligibility criteria, after which the study staff will administer the baseline assessment questionnaire to them (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). After the completion of the baseline assessment, men will be randomized to receive HOLA en Grupos or the comparison intervention.

Overview of Data Collection Procedures

The intervention will be evaluated using a randomized control group design. Data will be collected from intervention and comparison condition participants at two time-points: baseline and six months post-intervention. The assessments will collect information on risk behaviors, demographics, and psychological and socio-cultural variables.

Once a total of 20 participants have been enrolled and completed baseline assessments, they will be randomly assigned into the intervention and comparison conditions, with 10 participants allocated to each condition using a block-randomization procedure. Given the research partners' experience with the target population, it is anticipated that at least 70% of men recruited will be retained for the six-month follow-up assessment.

Enrollment - After potential participants have been identified and screened, study staff will confirm their willingness to participate and schedule a meeting to complete informed consent procedures and baseline assessment. 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 (**Attachment 7**), and collect a copy of the form signed and dated by those persons who agree to participate. After completion of the consent process, study staff will administer a baseline assessment questionnaire to each participant (**Attachment 4**) during an individual face-to-face interview in a private location. The first page of the baseline questionnaire will contain a pre-assigned unique identification number. This information will enable study staff to link the baseline and the subsequent 6-month follow-up assessments for all study participants.

Baseline and Follow-up Assessments - Demographic, behavioral, cognitive, cultural, social and psychological data will be collected to characterize the sample and evaluate the intervention. The assessments will be administered by interviewers hired and trained by Dr. Rhodes and Mr. Alonzo. At the termination of the baseline assessment, each participant will be asked to provide current contact information, including a cell-phone number (most Latino MSM now have cell-phones), and backup contact information for one or more friend or family member, clergyman, or other service provider, who is likely to know the participant's whereabouts over time. Each

participant also will be given a toll-free number that he can call to provide updated contact information to study staff. The study staff have successfully used this procedure in the past with Latino men who are away from the area, who have used the number to notify staff about the timing of their return to facilitate the collection of follow-up data. If necessary, the 6-month follow-up assessment interview can be completed by telephone with the token of appreciation mailed to the participant.

The community-based participatory research (CBPR) partnership of which the principal investigator and other study staff from Wake Forest University and staff from Chatham Social Health Council are members, has chosen not to use Audio Computer Assisted Self-Interview (ACASI), based on the results of earlier formative research (Rhodes, Eng et al. 2007; Vissman, Eng et al. 2009; Rhodes, Hergenrather et al. 2010; Rhodes, McCoy et al. In press) and feedback from partnership members suggesting that participants are more likely to engage with a well-trained interviewer who can establish rapport and trust. This interview-administered approach was considered to be more culturally congruent given the widely-shared cultural value of personalismo among Latinos that stresses the importance of interpersonal relationships and contacts (Marsiglia and Kulis 2009; Cashman, Eng et al. 2011; Rhodes, McCoy et al. In press). Furthermore, utilizing an interviewer-administered assessment overcomes obstacles that are associated with participants' frequent low literacy levels and poor vision (resulting from lack of access to vision services) (Rhodes, McCoy et al. In press).

To assess potential patterns of social desirability in participants' responses to the interviewer-administered assessment questions, the Marlowe-Crowne Social Desirability-Short, which has been used previously with Latino MSM, will be used in the assessment (Pequegnat, Fishbein et al. 2000). If sufficient levels of social desirability are observed, it will be included as a covariate in the study's data analyses.

Quality Control/Assurance

Data collection - All study assessment data will be collected using interviewer-administered questionnaires. To minimize possible sources of interviewer bias during data collection, the study's interviewers will undergo extensive training. This will include ensuring that all materials (e.g., consent forms, assessment, pencils) needed for the session during which informed consent and the baseline assessment are administered are present; finding a location that is safe, private, comfortable, and quiet; techniques for establishing rapport with participants during information collection, reacting impartially to participants' responses, and maintaining neutral facial expressions during data collection; providing appropriate replies to participant queries; and procedures for what to do when a participant is confused by a question; etc. During the training, Ms. Miller, who is in charge of data entry and data quality assurance, will review with the interviewer-trainees how the assessment questionnaires should be completed and procedures to follow if a participant wants to change an answer.

Data management - Dr. Rhodes and his Wake Forest University School of Medicine co-study staff member, Ms. Cindy Miller, will develop a standardized data collection manual/codebook for use during the study. Ms. Miller will review all completed assessment questionnaires and enter the responses into a password-protected database using TELEform software (Verity, Inc,

Sunnyvale, CA). The Wake Forest University School of Medicine Department of Social Sciences and Health Policy owns the software program and uses a computer dedicated solely to data entry using TELEform. Ms. Miller is experienced in TELEform design, programming, scanning, and configuration; attribute/export option setting; form and data file importation and exportation; and script and command writing. To ensure ongoing quality control and consistency of collected data quality, Ms. Miller will also oversee the use of those features of the study's data entry program that signal all instances of mis-marked, illegible, and impossible values. This will ensure instant and ongoing range checks as questionnaire responses are entered into the database.
In addition, every effort will be made to reduce the likelihood that data will be missed during data collection. These efforts include, in addition to the thorough training of interviewers described above, the use of color-coded skip patterns, and careful review of completed assessments.

To prevent individuals who have already participated in HOLA en Grupos once from trying to enroll in the study, study staff who conduct screening of potential participants will ask all individuals if they have participated in the intervention during the past 12 months, and will disqualify any who report such participation. Because the Chatham Social Health Council has not implemented the HOLA en Grupos intervention since October 2010, study staff do not anticipate encounters with persons who have completed the intervention during the previous 12 month period. To further reduce the likelihood of repeat enrollment during the specified time period, study staff will compare the names given by persons at the time of screening with names and participation dates of persons who completed the intervention previously. 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 solely for purposes of review.

Intervention delivery - Quality assurance procedures will ensure that the HOLA en Grupos and comparison interventions are implemented with fidelity relative to their respective intervention curricula. To assess fidelity of implementation delivery, an observer will attend all sessions of both the HOLA en Grupos intervention and the general health education intervention. The observer will use a guide to document adherence of intervention delivery to the curricula and identify the potential need for modifications. An English-language attendance log will be used to track participants' attendance in all intervention sessions. The observer's guides and the attendance logs will be English-language documents because the observers will be bilingual. In addition, Dr. Rhodes or Mr. Alonzo will observe all intervention sessions. Detected deviations from the intervention curriculum will be brought to the attention of the interventionist and corrected through review and practice supervised by Dr. Rhodes and Ms. Duck.

3. Methods to Maximize Response Rates and Deal with Non-response

Response Rates and Retention

Prior experiences with retention of study participants - Based on previous experience conducting Community-Based Participatory Research (CBPR) studies with Latino populations, and the results of other studies that have been conducted in partnership with community members with whom a strong foundation of trust existed, the principal investigator and research partner expect

attrition in this study to be minimal and the overall response rate to be high (Eng and Blanchard 1991; Eng, Salmon et al. 1992; Eng 1993; Eng, Parker et al. 1997; Thomas, Eng et al. 1998; Cook, Sereika et al. 2001; Angell, Kreshka et al. 2003; Lam, McPhee et al. 2003; Viswanathan, Eng et al. 2004; Rhodes, Hergenrather et al. 2009; Rhodes, Hergenrather et al. 2009). While Latino communities are often described as "unstable," "in transition," or "hard-to-reach," participants from the Latino communities that have been involved in these studies have had low attrition rates. A great deal of this success is due to the community-partnered and CBPR approach that is used. The research partner, Chatham Social Health Council, has observed high retention rates when delivering HOLA en Grupos. During a 3-month photovoice study with Latino men, a multisession formative data collection/intervention approach that is closely aligned with CBPR, there was no participant attrition (Rhodes and Hergenrather 2007; Rhodes, Hergenrather et al. 2009). In the study of the HoMBReS HIV prevention intervention for heterosexual Latino men, more than 80% of the participants were retained for the follow-up assessment after a period of 18 months (Rhodes, Hergenrather et al. In press). The statistical power for the proposed study has been calculated based on a 20% dropout rate at the 6-month post-intervention follow-up assessment, a worst-case scenario which has not been experienced by any of the partnership' studies to date. The research partnership will closely monitor attrition to obtain useful insights for subsequent research efforts.

Procedures to be used to ensure satisfactory retention of study participants - At the time of the study baseline assessment, each participant will be asked to provide (1) current contact information, including a cell-phone number (most Latino MSM use cell-phones); and (2) backup contact information for the US (one or more friend or family member, clergyman, or other service provider, who is likely to know the participant's whereabouts over time). Each participant also will be given a toll-free number that he can call to provide updated contact information. The study staff have successfully used this procedure in the past with Latino men who are away from the area, who have used the number to notify staff about the timing of their return to facilitate the collection of follow-up data. If necessary, the 6-month follow-up assessment interview can be completed by telephone with the incentive mailed to the participant.

A trained study staff member will also make contact with each participant of the HOLA en Grupos and the comparison intervention 3 months after intervention delivery to ensure that he is living at the same address. The study staff member will verify the contact and alternate contact information provided by participants at the end of the baseline assessment and update it as needed (see the contact information questions numbers 143A-146F in **Attachment 4,** the Spanish-language version of the baseline assessment that will be used to collect participants' contact information during the study and the English-language translation which is included for purposes of review only). For those participants who may have moved or have phone numbers that do not work, the study staff will use the contacts provided by participants to locate them for their follow-up assessment. This approach has been successfully used for locating enrolled participants in a recent study of Latino men (see NIH grant no. R24 MD002774, NIMHD, NIH, A Partnership Approach to Reducing HIV Disparities among Latino Men). A participant will be considered lost to follow-up after 3 failed attempts to contact him for his 6-month follow-up assessment.

To further enhance retention, the study staff will: (1) include a meal during each intervention

session; (2) provide Spanish-language appointment cards indicating the next day and time of the next intervention session; (3) provide a graduation dinner upon successful completion of the intervention; (4) provide study-related tokens of appreciation such as t-shirts, caps, and certificate of award for completing the HOLA en Grupos intervention; and (5) provide a laminated wallet-sized stay-in-touch card that will include a toll-free telephone number to stay in touch with the study and report contact changes. In addition, tokens of appreciation will be provided to participants for completing the study follow-up assessments. HOLA en Grupos and comparison intervention participants will be given a token of appreciation of $40.00 after completing the baseline assessment and $50.00 after completing the post-intervention 6-month follow-up assessment. Furthermore, participants in both study conditions will be given a token of appreciation of $40.00 for each of the 4 intervention sessions they attend. To facilitate retention, participants will receive $5.00 for contacting study staff to update their contact information if it changes during the study period. These strategies have been used successfully in previous research.

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.

Differential attrition of participants will be assessed by comparing the characteristics of participants retained in the study for follow-up data collection with those who were lost to follow-up. These characteristics will include demographics as well as behavioral risk. Chi-square and t-tests will be used as appropriate to the measure used.

Assessing Non-Response Bias

Analysis of missing data from participant's assessment responses – In any longitudinal study, some data concerning outcome measures may be missing due to non-random reasons (Little and Rubin 1987). The PI and other study staff have considerable experience dealing with these challenges and with the analysis of data containing partially missing information (TenHave, Miller et al. 2000; Miller, TenHave et al. 2001; Reboussin, Miller et al. 2002; TenHave, Reboussin et al. 2002; Paskett, Naughton et al. 2007). The consequences of these losses may include reduced statistical power, bias, and limitations on generalizability. To address possible power-related issues, the sample size has been calculated assuming a higher-than-expected dropout rate of 20% at the 6-month follow-up assessment (see below). To address issues related to bias and generalizability, exploratory analyses will be conducted to see whether dropout over

time is related to study or participant characteristics (e.g., assigned intervention condition, age, country of origin, etc.) or baseline outcome measures, and logistic regression will be used in which the outcome is drop-out at follow-up. Sensitivity analyses will be conducted to examine different assumptions regarding missing data and its impact on study results and conclusions about intervention effects. Mixed-effects logistic regression models will be used because all available data are analyzed without completely excluding subjects who do have some missing data (e.g., have provided baseline but not 6-month follow-up data). Every effort will be made to minimize missing data during the course of the study's follow-up assessments. If data are missing for reasons that are unrelated to study outcomes (e.g., a participant has a serious work-related accident and cannot complete a follow-up assessment), the mixed-effects models that are planned for the analysis will produce valid results. If however, data are missing for reasons that are potentially related to study outcomes (e.g., a participant does not complete a follow-up assessment because he is worried about HIV risk behaviors), this cannot be ignored and the pattern mixture model (Hedeker and Gibbons 1997) or the propensity score adjustment model (Rosenbaum and Rubin 1983) will be used to address possible bias.

Accuracy and Reliability of Information Collected

To improve accuracy and reliability of information collected, our CBPR partnership has chosen not to use Audio Computer Assisted Self-Interview (ACASI), based on the results of our earlier formative research (Rhodes, Eng et al. 2007; Vissman, Eng et al. 2009; Rhodes, Hergenrather et al. 2010; Rhodes, McCoy et al. In press), and feedback from partnership members that suggested that participants are more likely to engage with a well-trained interviewer who can establish rapport and trust. This interview-administered approach was thought to be culturally congruent because many Latinos value *personalismo*, a cultural value that stresses the importance of interpersonal contacts and relationships (Marsiglia and Kulis 2009; Cashman, Eng et al. 2011; Rhodes, McCoy et al. In press). Furthermore, utilizing an interviewer-administered assessment overcomes obstacles that are associated with participants' frequent low literacy levels and poor vision (resulting from lack of access to vision services) (Rhodes, McCoy et al. In press).

Studies have found that in general, study participants will provide truthful responses if they are assured that their responses will be anonymous or kept private and their names will not be ultimately associated with their responses, and they are provided motivating instructions that stress the importance of honest responses. This underscores the importance for honest responses for the scientific integrity of the research study and emphasizes the scientific importance of the project in general (Pequegnat, Fishbein et al. 2000). An introductory text at the beginning of our assessment questionnaires that addresses these issues has been developed by our CBPR partnership, which includes Latino men. We have had a great deal of success collecting sensitive information from Latino populations, using both quantitative and qualitative methods. Key to our success has been carefully training data collection staff and their effectively establishing trust and rapport with participants. Our dedication to collecting data using this highly culturally congruent approach has led to more informed understanding of public health phenomena and our partnership's overall success (Rhodes In press; Rhodes, McCoy et al. In press).

Additionally, the study assessments include questions that have been previously tested with this or similar populations and have acceptable reliability as determined through statistical analysis (see Table B4 below).

Generalizability

The aim of this study is to collect and analyze data, using a randomized controlled study design, to establish the efficacy of the HOLA en Grupos behavioral HIV/STD prevention intervention for Latino MSM, an example of a homegrown intervention for minority MSM. The collection and analysis of data in this manner is essential for efforts to identify effective interventions for this group of Latino men who carry a disproportionate burden of HIV. Currently, no rigorously evaluated, evidence-based HIV/STD prevention intervention is available for Latino MSM. Although the results of the study, if the HOLA en Grupos intervention is determined to be efficacious, may not be generalizable to all Latino MSM, the results will be generalizable to recent immigrant Latino MSM in conditions similar to those of the individuals who will be recruited to this study. Since the early 1990s, many recent immigrant Latino men, including MSM, have settled in rural areas of the U.S. that share characteristics of the men that will be included in this study. Furthermore, we believe that, given the absence of any efficacious HIV/STD prevention interventions for Latino MSM, the HOLA en Grupos intervention, if determined to be efficacious, will provide the basis for adaptation for Latino MSM in different geographic settings in the U.S. Within the limits that the study has established for eligibility for Latino men to participate in the study, the study will attempt to recruit a diverse sample of Latino MSM within the study area. To accomplish this, the study will be advertised in a variety of community venues throughout the central region of North Carolina.

4. Test of Procedures or Methods to be Undertaken

The measures that will be used in the study assessment questionnaires have been selected or developed based on (a) their successful use in prior studies by the principal investigator and the Community-Based Participatory Research (CBPR) partnership of which the principal investigator, study staff members at the Wake Forest University School of Medicine, and staff members of the research partner, the Chatham Social Health Council, are members, (b) their successful use in other studies of Latinos and Latino MSM, (c) input from the CBPR partnership members and the Community Advisory Board/Materials Review Committee for the HOLA en Grupos intervention study project, and (d) input from the CDC project staff. The measures and the assessment questionnaires have also been pilot tested with fewer than ten members of the Wake Forest University study staff. The measures that will be used to assess the primary behavioral outcomes that the HOLA en Grupos intervention has been designed to affect among the Latino MSM participants are listed in Table B4.

Table B4. Table of Measures

Instrument Name	**Population Previously Used With**	**Publication**	**OMB Approved?**
Condom use during vaginal and anal with female partners and	Heterosexually active Latino men and Latino MSM.	Rhodes SD, Hergenrather KC, Bloom FR, Leichliter JS, Montaño J. Outcomes from a community-based, participatory lay health	No

insertive and receptive anal sex with male partners during the past 30 days and 3 months		advisor HIV/STD prevention intervention for recently arrived immigrant Latino men in rural North Carolina, USA. *AIDS Educ Prev* 2009;21(Supplement 1):104-09. Rhodes SD, McCoy TP, Hergenrather KC, Vissman AT, Wolfson M, Alonzo J, et al. Prevalence estimates of health risk behaviors of immigrant Latino men who have sex with men. *Journal of Rural Health* In press. Rhodes SD, McCoy TP, Vissman AT, DiClemente RJ, Duck S, Hergenrather KC, et al. 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* In press. Rhodes SD, Yee LJ, Hergenrather KC. 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.	
Unprotected anal and vaginal sex with partners of unknown HIV serostatus or with HIV during the past 30 days and 3 months.	Heterosexually active Latino men and Latino MSM.	Rhodes, S. D., K. C. Hergenrather, et al. (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 Ed Prev 21(Supplement 1): 104-109. Rhodes SD, McCoy TP, Hergenrather KC, Vissman AT, Wolfson M, Alonzo J, et al. Prevalence estimates of health risk behaviors of immigrant Latino men who have sex with men. *Journal of Rural Health* In press. Rhodes SD, McCoy TP, Vissman AT, DiClemente RJ, Duck S, Hergenrather KC, et al. A randomized controlled trial of a culturally congruent intervention to increase condom use and HIV testing	No

		among heterosexually active immigrant Latino men. *AIDS and Behavior* In press.	
Numbers of sexual partners during the past 6 months.	NA	Instrument developed specifically for this study	No
Talking with sexual partner about risk reduction	National sample of 18-49 year olds, including 53% males and 14% Hispanic.	van der Straten A, Catania JA, Pollack L. Psychosocial correlates of health-protective sexual communication with new sexual partners: the National AIDS Behavioral Survey. *AIDS and Behavior* 1998;2:213-27.	No
HIV testing and receipt of test results ever and during the past 6 and 12 months	Heterosexually active Latino men and Latino MSM.	Rhodes, S. D., K. C. Hergenrather, et al. (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 Ed Prev 21(Supplement 1): 104-109. Rhodes SD, McCoy TP, Hergenrather KC, Vissman AT, Wolfson M, Alonzo J, et al. Prevalence estimates of health risk behaviors of immigrant Latino men who have sex with men. *Journal of Rural Health* In press. Rhodes SD, McCoy TP, Vissman AT, DiClemente RJ, Duck S, Hergenrather KC, et al. 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* In press.	No

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

The primary persons involved with statistical aspects of this project and data analysis for this study are Dr. Scott D. Rhodes and Dr. Beth Reboussin of Wake Forest University School of Medicine. The study was designed and the study assessment questionnaires were developed through a collaborative effort by the principal investigator and study staff at Wake Forest

University, staff members of the study partner, the Chatham Social Health Council, and CDC project staff.
The principal investigator and study staff at Wake Forest University and staff members of the study partner, the Chatham Social Health Council, will collect and analyze the study data. The federal staff members who have participated in various aspects of designing the study and who are currently with the CDC are listed below.

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References

Angell, K. L., M. A. Kreshka, et al. (2003). "Psychosocial intervention for rural women with breast cancer: The Sierra-Stanford Partnership." *J Gen Intern Med* **18**(7): 499-507.

Cashman, R., E. Eng, et al. (2011). "Exploring the sexual health priorities and needs of immigrant Latinas in the southeastern US: A community-based research approach." *AIDS Education and Prevention* **23**(3): 236-248.

Cook, R. L., S. M. Sereika, et al. (2001). "Problem drinking and medication adherence among persons with HIV infection." *J Gen Intern Med* **16**(2): 83-88.

Dodge, B., W. L. t. Jeffries, et al. (2008). "Beyond the Down Low: sexual risk, protection, and disclosure among at-risk Black men who have sex with both men and women (MSMW)." *Arch Sex Behav* **37**(5): 683-696.

Eng, E. (1993). "The Save our Sisters Project. A social network strategy for reaching rural black women." *Cancer* **72**(3 Suppl): 1071-1077.

Eng, E. and L. Blanchard (1991). "Action-oriented community diagnosis: A health education tool." *International J Community Health Educ* **11**(2): 93-110.

Eng, E., E. Parker, et al. (1997). "Lay health advisor intervention strategies: a continuum from natural helping to paraprofessional helping." *Health Educ Behav* **24**(4): 413-417.

Eng, E., M. Salmon, et al. (1992). "Community empowerment: The critical base for primary care." *Journal of Family and Community Health* **15**(1): 1-12.

Fitzmaurice, G. M., N. M. Laird, et al. (2004). Applied Longitudinal Analysis. Hoboken, NJ, Wiley.

Hedeker, D. and R. D. Gibbons (1997). "Application of random-effects pattern-mixture models for missing data in longitudinal studies." *Psychological Methods*(2): 64-78.

Lam, T. K., S. J. McPhee, et al. (2003). "Encouraging Vietnamese-American Women to Obtain Pap Tests Through Lay Health Worker Outreach and Media Education." *J Gen Intern Med* **18**(7): 516-524.

Little, R. J. A. and D. B. Rubin (1987). *Statistical analysis with missing data*. New York, NY, John Wiley.

Malebranche, D. J. (2008). "Bisexually active Black men in the United States and HIV: acknowledging more than the "Down Low"." *Arch Sex Behav* **37**(5): 810-816.

Marsiglia, F. F. and S. Kulis (2009). *Diversity, Oppression, and Change*. Chicago, IL, Lyceum.

Miller, M. E., T. R. TenHave, et al. (2001). "A marginal model for analyzing discrete outcomes from longitudinal surveys with outcomes subject to multiple cause non-response." *Journal of the American Statistical Association* **96**(455): 844-857.

Paskett, E. D., M. J. Naughton, et al. (2007). "The epidemiology of arm and hand swelling in premenopausal breast cancer survivors." *Cancer Epidemiol Biomarkers Prev* **16**(4): 775-782.

Pequegnat, W., M. Fishbein, et al. (2000). "NIMH/APPC workgroup on behavioral and biological outcomes in HIV/STD prevention studies: a position statement." *Sex Transm Dis* **27**(3): 127-132.

Reboussin, B. A., M. A. Miller, et al. (2002). "Latent class regression models of disability in the elderly with data missing at random." *Applied Statistics* **51**(1): 69-90.

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

Rhodes, S. D., E. Eng, et al. (2007). "Exploring Latino men's HIV risk using community-based participatory research." *Am J Health Behav* **31**(2): 146-158.

Rhodes, S. D. and K. C. Hergenrather (2007). "Recently arrived immigrant Latino men identify community approaches to promote HIV prevention." *Am J Public Health* **97**(6): 984-985.

Rhodes, S. D., K. C. Hergenrather, 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:* 1.

Rhodes, S. D., K. C. Hergenrather, et al. (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 Ed Prev* **21**(Supplement 1): 104-109.

Rhodes, S. D., K. C. Hergenrather, et al. (In press). "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 Ed Prev*.

Rhodes, S. D., K. C. Hergenrather, et al. (2009). "Sexual and alcohol use behaviours of Latino men in the south-eastern USA." *Culture, Health & Sexuality* **11**(1): 17-34.

Rhodes, S. D., T. P. McCoy, 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.*

Spradley, J. P. (1979*). The ethnographic interview*. New York, NY, Holt, Rinehart, & Winston.

TenHave, T. R., M. E. Miller, et al. (2000). "Mixed effects logistic regression models for longitudinal ordinal functional response data with multiple-cause drop-out from the longitudinal study of aging." *Biometrics* **56**(1): 279-287.

TenHave, T. R., B. A. Reboussin, et al. (2002). "Mixed effects logistic regression models for multiple longitudinal binary functional limitation responses with informative drop-out and confounding by baseline outcomes." *Biometrics* **58**(1): 137-144.

Thomas, J. C., E. Eng, et al. (1998). "Lay health advisors: sexually transmitted disease prevention through community *involvement." Am J Public Health* **88**(8): 1252-1253.

Vissman, A. T., E. Eng, et al. (2009). "What do men who serve as lay health advisors really do?: Immigrant Latino men share their experiences as *Navegantes* to prevent HIV." *AIDS Education and Prevention* **21**(3): 220-232.

Viswanathan, M., E. Eng, et al. (2004). *Community-based participatory research: Assessing the evidence*. Rockville, MD, Agency for Healthcare Research and Quality.