

**HIV prevention among Latina transgender women who have sex with men:
Evaluation of a locally developed intervention**

OMB 0920-1266

Section A: Supporting Statement

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- 5a. ChiCAS Consent English
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- **Goals of the study:** To evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a two-session Spanish language intervention that provides HIV prevention services to Hispanic/Latina adult transgender women who have sex with men.
- **Intended use:** Data collected during this study will be used to evaluate the efficacy of the locally developed ChiCAS HIV prevention intervention for Hispanic/Latina transgender women.
- **Methods to be used to collect data:** ChiCAS study participants will complete quantitative assessments at two intervals (baseline and 6-month). One-time qualitative interviews will also be conducted with a subset of intervention participants.
- **The subpopulation to be studied:** 140 HIV-negative adult Latina transgender women who have sex with men and who live in metropolitan areas in and around North Carolina will be invited to participate in the intervention. Potential study participants will be invited to use the OraQuick In-home HIV test to confirm their self-reported HIV-negative serostatus and eligibility for the study, will complete the study’s consent process and baseline assessment, and will then be randomly assigned to receive the ChiCAS intervention (n=70) shortly after the consent process and completion of the baseline assessment, or to receive the intervention 6 months later, after completing 6-month follow-up assessment (n=70). Additionally, 30 of the 70 participants who receive ChiCAS shortly after completing the study consent and baseline assessment will be invited to participate in the semi-structured, qualitative interviews.
- **How data will be analyzed:** The study design will use a randomization process to assign eligible Hispanic/Latina transgender women to the ChiCAS intervention condition or a waitlist (delayed-ChiCAS intervention) condition and will collect baseline data from participants in each condition following randomization. The study analysis will compare pre-intervention (baseline) and post-intervention (6-month follow-up) levels of participation by women assigned to the respective conditions in the primary intervention outcomes of consistent condom use and use of PrEP and medically supervised hormone therapy. The study design satisfies CDC criteria for rigorously evaluating the efficacy of HIV prevention interventions that, if determined to be efficacious, can be included in CDC’s *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention*. Qualitative data from the semi-structure interviews will be analyzed to describe intervention strengths and weaknesses to inform intervention improvements and future dissemination.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention’s (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval to extend data collection for 2 more years for OMB-approved project 0920-1266 entitled “HIV prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention.”

This study will evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a two session Spanish-language small-group combination intervention designed to promote consistent condom use and the use of pre-exposure prophylaxis (PrEP) and

medically supervised hormone therapy by HIV seronegative Hispanic/Latina transgender women who have sex with men.

Currently there are no known efficacious behavioral HIV prevention interventions targeting Spanish-speaking transgender women despite the extreme HIV burden that affects them. An estimated one in four transgender women is infected with HIV,¹⁻³ and infection rates as high as 39% have been reported.⁴ ⁵ The odds of becoming HIV positive are estimated to be 34.2 times higher for transgender women than for other US adults.² Furthermore, many transgender persons are not tested for HIV,^{3,6,7} and less than half of HIV-positive transgender women may know their HIV status.¹ Transgender women of color, including Hispanic/Latina transgender women^{4,7-10} and transgender women who engage in sex work may be particularly affected by HIV.^{11,12}

Hispanic/Latina and other transgender women of color report high rates of condomless sex. A systematic review of 29 US-based studies of transgender women, 75% of whom were women of color, found that the average reported rate of receptive anal sex without a condom was 44.1%; the average rate of insertive anal sex without a condom was 27.4%.¹ In a New York City study of transgender women, nearly half of whom were Hispanic/Latina, 35% reported not using a condom during vaginal or anal sex at last sex.¹³ Nearly half (47%) of transgender women of color in San Francisco with a history of exchanging sex for money or drugs reported condomless receptive sex with a primary partner in the past 30 days.¹⁴

Pre-exposure prophylaxis (PrEP) is a relatively new HIV prevention approach for use by HIV negative individuals who are at high risk of HIV infection. It entails taking daily doses of anti-retroviral medications (tenofovir and emtricitabine). However, studies of PrEP usage by transgender women for HIV prevention are limited. Our own research among Hispanic/Latina transgender women in NC suggest that they have very limited knowledge about and use of PrEP.¹⁵ A recent National Center for Innovation in HIV Care report emphasized the need for more PrEP-related information to be provided to transgender women.¹⁶

Transgender women may also obtain hormone therapy from non-medical sources, a pattern observed among more than one-third of those included in a systematic review. Hispanic/Latina transgender women may access medically supervised hormone therapy less than non-Hispanic/Latina white transgender women. This is illustrated by a San Francisco study: 9.5% of Hispanic/Latina transgender women in the study reported using no transition-related healthcare services, including hormone therapy, while all non-Hispanic/Latina white transgender women reported using some of these services.¹⁷ Hispanic/Latina transgender women in our NC studies report limited use of medically supervised hormone therapy.¹⁸ These use patterns may contribute to potential dangers associated with non-medically approved procedures and sources of hormones. They may also contribute to increased HIV risks. Transgender women, for example, who face financial barriers to obtaining hormone therapy may prioritize gaining access to those services over concerns about HIV prevention, leading to participation in sex work or transactional sex without condoms in order to pay for needed hormones.^{19,20} By contrast, the use of medically supervised hormone therapy is associated with HIV-protective behaviors and lower rates of suicidal ideation and drug/alcohol use.¹⁷

The ChiCAS intervention supports HIV prevention and health promotion efforts by HIV-negative Hispanic/Latina transgender women by promoting consistent condom use and the use of PrEP and medically supervised hormone therapy. It provides tailored, detailed information to participants concerning where to obtain PrEP and medically supervised hormone therapy, the terms of accessing those services (e.g., eligibility requirements and costs), the conditions for accessing the services (e.g.,

availability of interpretation services and hours of operation), how to request services (e.g., making an appointment and what to bring), and what will happen during their medical visit (e.g., HIV testing for PrEP, informed consent process for hormone therapy, and follow-up appointments).

This project will advance the field of HIV prevention research by potentially identifying an efficacious intervention for use with Hispanic/Latina transgender women who have sex with men, who are disproportionately affected by HIV and for whom no known efficacious, behavioral HIV prevention interventions currently exist. Currently, only two risk reduction interventions focused on transgender women are included within Currently, CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention (<http://www.cdc.gov/hiv/topics/research/prs/compendium-evidence-based-interventions.htm>) and both of these interventions were developed, implemented, and evaluated prior to the approval of PrEP as a biomedical strategy to prevent HIV. If our study results determine that the ChiCAS intervention is efficacious, the results and products from this project may be disseminated to support public health practice and inform research and policy. Results and products from the study will include: (1) a Spanish-language combination HIV prevention intervention that is culturally congruent, designed to reduce risk among Hispanic/Latina transgender women, and ready for dissemination for use by service providers; and (2) a deeper understanding of HIV risk and intervention among Hispanic/Latina transgender women.

The project is in alignment with the following national HIV prevention goals:²¹

- 1.A.2 Focus on high-risk populations (including transgender women)
- 1.B.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities, and prioritize and promote research to fill gaps in HIV prevention science among the highest risk populations and communities
- 1.B.2 Support and strengthen integrated and patient-centered HIV and related screening (for sexually transmitted infections [STI], substance use, mental health, intimate partner violence [IPV], viral hepatitis infections) and linkage to basic services (housing, education, employment)
- 1.B.3 Expand access to effective prevention services, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).
- 3.B Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities.

The following section of the U.S. Federal Code 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.” (**Attachment 1**)

2. Purpose and Use of the Information Collection

The purpose of this information collection is to evaluate the efficacy of the ChiCAS intervention by comparing consistent condom use and the use of PrEP and medically supervised hormone therapy by Hispanic/Latina transgender women who receive the ChiCAS intervention shortly after enrolling in the study with these behavioral outcomes among participants (waitlist participants) who receive the intervention six months after enrolling. This information collection is needed in order to fill a gap in existing HIV prevention and health promotion resources for a population that is extremely vulnerable to HIV infection and associated health threats. Currently no known efficacious HIV prevention interventions exist for this vulnerable population. If the ChiCAS intervention is determined to be efficacious, it will provide the government and its health care provider partners with a much-needed HIV prevention tool.

ChiCAS is a small group, two-session Spanish language HIV prevention intervention designed exclusively for Latina transgender women and that will be delivered by experienced interventionists from the community: a self-identified Hispanic/Latina transgender woman and a Hispanic/Latino gay man. ChiCAS is designed to increase knowledge and build the skills necessary to reduce HIV risk in a safe and culturally appropriate environment. Special emphasis is given to knowledge and engagement in PrEP care, consistent condom use and medically supervised hormone therapy. ChiCAS also provides the information needed to find local healthcare services. The ChiCAS intervention is based on social cognitive theory²²⁻²⁵ and the theory of empowerment education.²⁶⁻²⁸ Social cognitive theory emphasizes 4 components critical for promoting behavior change: (a) information, (b) mastery of self-protective skills and development of self-efficacy (e.g., role plays that will provide practice for participants around talking with providers), (c) enhancement of social proficiency, and (d) social support for personal change.²²⁻²⁵

The design of our proposed information collection is consistent with the intended use of the study data described above. One hundred and forty adult HIV negative Spanish-speaking Hispanic/Latina transgender women who have sex with men will be recruited to the study. Our plans for facilitating participant access to the intervention will promote the collection of needed information to assess a potentially effective HIV prevention method with this population. During our study, we will make the ChiCAS intervention available to participants in and around North Carolina- including seven CBOs and clinic provider locations in five metropolitan areas in North Carolina: Asheville (2 providers), Charlotte, Greensboro/Winston-Salem/High Point, Raleigh, and Wilmington (2 providers). Recruitment and screening will be carried out by study staff.

To publicize the study for recruitment purposes, we will post flyers in tiendas (small shops frequented by Hispanics/Latinos), laundromats, businesses that employ large numbers of Hispanics/Latinos (such as construction sites and hotels), English as a Second Language (ESL) classes, housing communities and apartment complexes, at community-based organizations, in Hispanic/Latino-serving restaurants throughout NC, and at festivals and events that attract large numbers of Hispanics/Latinos and transgender persons. We will post flyers and set up recruitment tables at various bars and clubs that are frequented by Hispanic/Latina transgender women. We will also use social media, such as Facebook and GPS-based “apps” that some sexual and gender-identity minorities use for social and sexual networking, to advertise the study. We will ask recruited participants to spread the word about the study to encourage persons in their social networks to call the study telephone number or meet with a member of the research team (**Attachments 3a and 3b**).

Interested participants will complete a brief screening process for eligibility and contact information will be collected (**Attachments 4a and 4b**). Study staff will schedule a follow-up appointment with potential participants to take an OraQuick In-home HIV test to confirm their eligibility and complete informed consent procedures (**Attachments 5a and 5b**). ChiCAS and wait-list group participants will complete an interviewer administered quantitative assessment at baseline (immediately following screening and consent) and again 6 months after the baseline assessment (**Attachments 4c and 4d**). The baseline and 6-month follow-up assessment instruments are identical. The study assessment includes socio-demographic characteristics; knowledge, practices and perceptions about PrEP, condoms and medically supervised transition services (the primary outcomes); psychosocial factors including social support and ethnic group pride; and other variables including acculturation, perceived discrimination and community attachments.

In order to identify and explore the strengths and weaknesses of the intervention based on participants’ self-reported behavior changes or lack thereof during the six months following their participation in

ChiCAS, we will randomly select and interview up to 30 participants from the intervention group after they complete their 6-month follow-up assessments. The 30 participants will include ten women who report an increase in at least one HIV prevention behavioral outcome (PrEP or condom use) and who report an increase in the use of medically supervised hormone therapy; ten who do not report an increase in at least one HIV prevention behavioral outcome (PrEP or condom use) and do not report an increase in the use of medically supervised hormone therapy; and ten women with mixed results. We expect to be able to identify at least 10 individuals who will have experienced one of the outcomes described above from the 70 women in the intervention condition. The interview will include questions about general intervention experiences and recommendations; knowledge, perceptions and use of PrEP, condoms and medically supervised hormone therapy and the role of the intervention in shaping these perceptions; and additional questions about sexual and general health and discrimination (**Attachments 4e and 4f**).

The study protocol and all data collection instruments have been approved by Wake Forest University Health Science IRB (**Attachment 6a**).

Exhibit 2.1: Overview of Key Variables

Baseline and Follow-up Assessments (Attachments 4c, 4d, 4e. and 4f)
<ul style="list-style-type: none"> • Demographics (Baseline Assessment Only) • Perceived discrimination, internalized transphobia and social support (Baseline Assessment Only) • Self-reported health status, history of health care use, and HIV/STD testing history (Baseline Assessment Only) • Acculturation, ethnic group pride and community attachment (Baseline Assessment Only) • PrEP use • Use of medically supervised hormone therapy • Consistent condom use • Knowledge about HIV/STDs, PrEP and hormone therapy • Access/Barriers to HIV/STD testing, PrEP and medically supervised hormone therapy • Skills, intentions and readiness to use condoms, PrEP and medically supervised therapy • Trust and communication with health providers • Perceived discrimination, internalized transphobia and social support • HIV/STD testing (Follow-up Assessment Only)
Qualitative Interview (Attachments 4e and 4f)
<ul style="list-style-type: none"> • General intervention experiences and perceptions • Intervention experiences and perceptions specific to the primary outcomes including <ul style="list-style-type: none"> ○ PrEP knowledge, awareness, interest and use ○ Condom skills and use ○ Hormone therapy knowledge, awareness, interest and use • Sexual health priorities • Discrimination (intervention and health outcomes mediator)

We will use multiple convenience and referral-based sampling methods rather than random sampling methods to identify and recruit study participants because transgender women are a unique and hidden population for which no known sampling frame exists. Because we are not using random sampling methods to recruit participants, the study results will not be generalizable beyond the specific populations and geographic contexts in which they are contacted. The results will be used to demonstrate a relationship between receipt of the ChiCAS intervention and improvements in sexual health and HIV prevention behaviors over time among participants in the study.

Results from this data collection will be used to assess the effects of ChiCAS intervention participation on the primary outcomes (PrEP use, use of medically supervised hormone therapy and consistent condom use). If ChiCAS is determined to be efficacious, it will be the first such intervention designed for and potentially available for use with Hispanic/Latina transgender women. We expect to report the study results in multiple manuscripts that will be published in peer reviewed journals and to present the results at national conferences. Links to these publications and presentations will be available through the CDC website.

3. Use of Improved Information Technology and Burden Reduction

Our information collection will use person-to-person contacts and exchanges rather than the use of information technologies, and aim to minimize the information collection burden on study participants (see below). During study recruitment, we expect that interested participants will be screened for eligibility prior to enrollment during person-to-person contacts, while some may be screened by telephone (**Attachments 4a and 4b**). This will allow participants to complete the screening form at a place and time that is convenient for them. Participant contact information is collected on the screening form. For study enrollment, participants will begin the consent process by agreeing to use the OraQuick In-home HIV test to verify their eligibility based on their self-report during the screening process of being HIV negative. If they are verified to be eligible, they will complete the process of providing informed consent to participate in the study, sign the study consent form, complete the baseline assessment (**Attachments 4c and 4d**), and will be randomly assigned to receive the ChiCAS intervention (intervention participants) shortly after enrollment or after they complete the six-month follow-up assessment (waitlist participants). Study staff will schedule consent and assessment appointments at a time and location that is convenient to the selected participants.

The quantitative baseline (Attachment 4c and 4d) and 6-month follow-up assessments (**Attachments 4e and 4f**) will be administered by a trained interviewer. Question skip patterns in the assessment instrument are designed to minimize the number of questions that participants will need to answer and thus, will reduce the respondent burden. Findings from our earlier formative research indicate that study participants are more likely to engage with a well-trained interviewer who can establish rapport and trust; therefore, we will not use Audio Computer Assisted Self-Interviews (ACASI) for baseline and 6-month study assessments.²⁹⁻³⁴ Latino men and women, including transgender persons, in our formative studies have described our interviewer-administered assessments as being culturally congruent; some Hispanics/Latinos value *personalismo*, a shared cultural value that stresses the importance of interpersonal relationships.^{29-31, 35, 36} Interviewer-administered assessments can also overcome obstacles to using ACASI methods that may be associated with participants' frequent low literacy levels and poor vision (resulting from lack of access to vision services) and limited experience with technology.^{30, 37}

Study staff will conduct individual in-depth qualitative interviews (**Attachments 4g and 4h**) with randomly selected participants at a time and location of their choosing which offers privacy. Study staff will request participant permission to audio-record the interviews and transcribe the recordings after the interviews, and will do so only after participants give their permission.

4. Efforts to Identify Duplication and Use of Similar Information

As noted above, our search of the published intervention research literature did not identify any efficacious behavioral HIV prevention interventions for Hispanic transgender women. Furthermore, the CDC Compendium of Evidence-based Interventions and Best Practices for HIV Prevention does not list any such interventions for them; therefore, we believe that our intervention study will address an

important gap in prevention resources for this population.³⁸ In addition and based on our reviews of research publications cited above, we believe that no other survey data collection effort has been conducted or has been planned to collect similar information for this population. Therefore, our evaluation of the ChiCAS intervention requires the collection of primary data not previously collected, as proposed in this Information Collection Request.

5. Impact on Small Businesses or Other Small Entities

This information collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

The study is designed to provide the quantitative and qualitative data needed to evaluate the efficacy of the ChiCAS HIV prevention intervention for Hispanic/Latina transgender women. We require an additional 2 years to complete data collection.

Quantitative assessment data will be collected twice from each intervention and wait list participant in the study - at baseline and again six months later. Collecting assessment data less frequently than twice over the 6-month period would make it impossible to rigorously assess changes over time in the measures of intervention effectiveness: consistent condom use and the use of PrEP and medically supervised hormone therapy, and to compare these changes among intervention and waitlist participants, respectively. The number of assessment surveys administered is the minimum required to assess any effects of the intervention and post-intervention decay.

Qualitative interview data will be collected once from 30 randomly selected intervention participants following the six-month assessment. This data will help us to better understand the effects of the ChiCAS intervention. If this qualitative data were not collected, it would not be possible to develop an in-depth understanding of intervention participants' perceptions and experiences with the intervention and the effects of the intervention on their sexual health knowledge and awareness and the expected behavioral outcomes. Collecting this qualitative data will make it possible for us to tailor the intervention for purposes of eventual dissemination and increase its potential effectiveness with this vulnerable population.

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

This data collection does not involve any special circumstances and fully complies with the regulation 5 CFR 1320.5.

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

The 60-day FRN notice to solicit public comments was published on 02/25/2021, Volume 86, Number 36, Page 11533 (**Attachment 2a**).

In addition, Wake Forest University, University of North Carolina at Greensboro, and Triad Health Project were consulted for the development of this study. There were no unresolved issues associated with the consultation process.

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9. Explanation of Any Payment or Gift to Respondents

This study aims to recruit, enroll, and follow members of a population that is particularly vulnerable to HIV infection and, in addition, is a small, hard-to-reach, and possibly hidden population. Recent estimates, for example, suggest that transgender adults may make up only 0.3% of the US population.³⁹ In addition, our study will ask participants sensitive questions about issues such as sexual behavior, HIV and sexually transmitted infection status, and substance use. The Hispanic/Latina transgender women in our study may also have limited access to transportation and need to pay for travel to and from the intervention sessions. They may also work very long hours and on weekends and need to take time off from their jobs to attend intervention sessions.

To enhance our ability to recruit and retain the required 140 Hispanic/Latina transgender women and retain at least 80% of those who are recruited to our study sample, we will provide participants with tokens of appreciation to better engage them in the intervention and the data collection processes, which are critical for the success of this evaluation. Study staff have developed a plan for administering tokens of appreciation to study participants based on their considerable experience of working with this population and their in-depth understanding of community values and social norms. We will give each participant in the ChiCAS intervention and the delayed-intervention comparison (waitlist) group cash tokens of appreciation for their participation: \$30 will be provided to each participant after completing the baseline assessment, and \$40 will be provided after completing each of the two intervention sessions. In addition, \$40 will be provided to study participants who complete the 6-month follow-up assessment with a study staff member. Intervention group participants who participate in a qualitative in-depth interview will receive a cash token of appreciation of \$40. Participants will be provided

cosmetic bags with logos and a framed signed certificate of completion after completing the two-session intervention. We have found this certificate to be another important component in our research with Hispanics/Latinos.

The Office of Information and Regulatory Affairs Office of Management and Budget has issued the following guidance for justifying the use of incentives as part of Information Collection Requests (ICRs), “Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions...”⁴⁰

Tokens of appreciation can be particularly useful when recruiting minorities and historically underrepresented groups to research. We know from our previous intervention studies of non-English-speaking populations (see details below) that cash is preferred to gift cards as tokens of appreciation because cash is easier for study participants to use. Cash tokens of appreciation are particularly well-received by immigrant populations who may not trust gift cards, experience barriers when trying to use gift cards (e.g., transportation, language, and misunderstanding the rules for their use), and who may worry about their identification being checked. Based on formative data we have collected among Hispanics/Latinos over the past 15 years, we have learned that cash is an important factor in recruitment and retention.^{29, 41} In each of the following intervention studies that were implemented and evaluated with CDC or NIH funding, cash was successfully used as a token of appreciation: HoMBReS,⁴² which is listed in the CDC *Compendium of Evidence-based Interventions and Best Practices for HIV Prevention* as a best-evidence community-based behavioral intervention;³⁸ HoMBReS Por Un Cambio;^{31, 43} HoMBReS-2;³⁰ HOLA en Grupos (OMB 0920-0942, exp. 3/31/2018),^{44, 45} also listed in CDC’s *Compendium* as a best-evidence behavioral intervention; HOLA;^{46, 47} and CAPRELA.^{41, 48} In each of these intervention studies, enrollment and retention rates were high, ranging from 88% to 99%. Our follow-up retention rates included the following: 95% at 24-month follow-up,⁴⁶ 89% at 18-month follow-up,⁴² 100% at 6-month follow-up,⁴⁴ and 98% at 3-month follow-up.³⁰ Within each of these interventions, cash amounts provided as tokens of appreciation ranged between \$30 and \$50. These amounts were determined based on the amount of each participant’s time involved in completing assessments and attending the sessions.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHHSTP Associate Director for Science Office has reviewed this project and determined the Privacy Act applies to this information collection activity. However, no participant names or contact information collected during the study will be transmitted to the CDC.

The grantee, Wake Forest University and partners, University of North Carolina at Greensboro and Triad Health Project, will be responsible for collecting all data for this study. Study staff will inform study participants that their responses will be kept private to the extent permitted by the law. All study participants interviewed will be informed that the information collected will not be attributable directly to them and will only be discussed among members of the research team. Terms of the CDC Cooperative Agreement authorizing data collection require the grantee to maintain the privacy of all information collected. Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue

Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. This study meets those requirements. The Certificate of Confidentiality further protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced (for example, by court subpoena) to disclose identifying information from study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

As this study will collect several types of sensitive information – including HIV test results, PrEP use and sex behaviors – from transgender women who have sex with men, we are sensitive to the need to protect personal health information (PHI). To ensure that respondents' PHI is protected, we will take several measures to separate personally identifiable information from study-related data.

All participants will be assigned a unique identification number for the study. Data sent to CDC will not contain participant names or contact information, and each person's data will be identified only by a study participant ID. There will be four types of files that contain participant names and contact information: the consent form file, the contact information file, the intervention attendance log file, and the linkage file. Access to these study files will be limited to key study staff. Consent, Contact and Attendance files will be maintained as paper documents, kept in a locked cabinet, separate from other study files in the offices of the principal investigator at Wake Forest University School of Medicine. Attendance data will be de-identified and uploaded as password protected electronic files to a secure server. The linkage file, used to link participant names and identification numbers, will be stored as a password protected file on a secure server and accessible only to the Data Manager (Lilli Mann Jackson).

Screening and assessment data will be collected on paper forms. Immediately after completing screening and assessment, personal contact information will be separated from the paper forms, therefore no personal-identifying information will be attached to the forms. The de-identified assessment data from the paper questionnaires will be scanned using the TELEForm software system and uploaded and saved on a secure and password protected network maintained by Wake Forest School of Medicine. Screening data will be maintained as a de-identified paper document. Hard copies of study data will be kept in separate locked file cabinets in the Department of Social Sciences and Health Policy, Divisions of Public Health Sciences, Wake Forest School of Medicine. All assessment information collected will be stored securely in a de-identified format.

During data collection outside of the Wake Forest university office, completed assessments, participant contact information, and consent forms will be stored in 3 separate locked boxes to ensure that each participant's information cannot be linked to their responses. The locked boxes will never be left in the car of a data collector overnight. Within 48 hours, all assessments, contact information, and consent forms will be transferred to Wake Forest School of Medicine.

In-depth interview data will be collected utilizing only a Participant ID. Because in-depth interviews will be digitally recorded, verbal consent to record the interview also will be secured prior to recording. Participants will be informed of their right to have the digital recorder turned off and/or to stop the interview at any time. The digital recordings will be stored as password protected files on a secure server maintained by the Department of Social Sciences and Health Policy, Division of Public Health Sciences, Wake Forest School of Medicine. Digital audio files will be transcribed into MS Word documents. Names or other identifying information inadvertently disclosed during the interview will be excluded from interview transcripts. Digital recordings will be destroyed by erasing after the recording

transcriptions are verified.

De-identified, summary data may be used in manuscripts, presentations and reports that highlight the activities and successes of this program. Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. Data on individual participants will not be released to the public. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant contact information (**Attachment 7**).

All recordings of qualitative interviews will be destroyed by erasing after the recording transcriptions are verified. All study records containing personally identifiable information (PII) will be destroyed by the Wake Forest University Principal Investigator no later than three years after closure of the study protocol by the Wake Forest IRB.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The study protocol, the data collection instruments, and all accompanying documents have been reviewed and approved by the Wake Forest University Health Sciences IRB (**Attachment 6a**). For purposes of this study and information collection, the study research partners, the Triad Health Project and the University of North Carolina, Greensboro, defer to the IRB of Wake Forest University Health Sciences (**Attachments 6b and 6c**). Amendments to the study protocol, data collection instruments, and all accompanying documents have been reviewed and approved by the Wake Forest University Health Sciences IRB (**Attachments 6d, 6e, 6f, 6g, and 6h**).

Sensitive Questions

This study is designed to evaluate the efficacy of an HIV prevention intervention for Hispanic/Latina transgender women at high risk for HIV infection. As such, our study entails the collection of sensitive HIV risk-related information. All study staff will be trained to provide respondents with referrals to sources of prevention and care, such as mental health organizations, as needed. Sensitive questions will be asked to identify the HIV risk level of participants. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

This study will enroll up to 140 Hispanic/Latina transgender women to participate in the intervention and assessment survey. In addition, 30 of the 70 intervention participants will be selected to participate in a semi-structured qualitative interview.

Transgender women will be recruited either online through web advertisements or in-person through venue-based sampling and outreach, print advertisements, or word of mouth (**Attachments 3a and 3b**). All potential participants will complete a screening process for eligibility (**Attachments 4a and 4b**) prior to consent and data collection. Eligible participants will be consented for participation (**Attachments 5a and 5b**). All recruitment and data collection activities will be carried out by study staff.

Study data collection is requested for 2 more years. We expect to screen 280 Hispanic/Latina transgender women. Of these, we expect 50% to be eligible and to enroll in the ChiCAS intervention. We expect that screening will take 3 minutes and providing contact information will take about one minute (**Attachments 4a and 4b**). Data collection will include a quantitative assessment administered to each participant at baseline and again at 6 months post-intervention. The baseline assessment will take about 60 minutes to complete (**Attachments 4c and 4d**). The 6-month follow-up assessment will take about 45 minutes to complete (**Attachments 4e and 4f**). Data collection will also include a qualitative assessment administered one time to a subsample of 30 intervention participants. We anticipate that it will take 90 minutes to complete each interview (**Attachments 4g and 4h**). The total number of burden hours over the entire data collection period is 310 hours. The estimated annualized burden (for a 12-month period) is 155 hours. Per OMB recommendations for total burden hours, all fractions have been rounded up to the nearest whole hour. Exhibits 12.1 and 12.2 provide further details about how the estimates of annualized burden hours and costs were calculated.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Eligibility Screener (Attachments 4a and 4b)	140	1	3/60	7
General Public-Adults	Contact Information (Attachments 4a and 4b)	70	1	1/60	2
General Public-Adults	Baseline Questionnaire (Attachments 4c and 4d)	70	1	1.0	70
General Public-Adults	Follow Up Questionnaire (Attachments 4e and 4f)	70	1	45/60	53
General Public-Adults	Interview (Attachments 4e and 4f)	15	1	1.5	23
Total					155

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2019 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this request. The estimated annualized burden cost is \$4423.84. This cost

represents the total burden hours of general respondents multiplied by the average hourly wage rate (\$25.72).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Respondent Costs
General Public-Adults	Eligibility Screener (Attachments 4a and 4b)	7	\$25.72	\$180.04
General Public-Adults	Contact Information (Attachments 4a and 4b)	2	\$25.72	\$51.44
General Public-Adults	Baseline Questionnaire (Attachments 4c and 4d)	70	\$25.72	\$1800.40
General Public-Adults	Follow Up Questionnaire (Attachments 4e and 4f)	53	25.72	1363.16
General Public-Adults	Interview (Attachments 4g and 4h)	23	\$25.72	\$591.56
				Total \$3986.60

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

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The annual cost to the government for the data collection is estimated to be \$695,535 (Exhibit 14.1).

Exhibit 14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Project Officer (GS-13 0.40 FTE)	\$40,810
	CDC Scientist (GS-13, 0.20 FTE)	\$20,405
	CDC Project Coordinator (GS-12, 0.40 FTE)	\$34,320
	Subtotal, Direct Costs	\$95,535
Cooperative Agreement Costs	Annual Cooperative Agreement #PS15-002 Costs	\$600,000
	ANNUALIZED COST TO THE GOVERNMENT	\$695,535

15. Explanation for Program Changes or Adjustments

This is a request to extend the project expiration date for 2 additional years for OMB-approved project 0920-1266, HIV prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention. The current OMB expiration date for the project is June 30, 2021 and this request would extend the project to 06/30/2023. Due to COVID-19 restrictions including shelter-in-place, stay-at-home orders, and continuing social distancing recommendations, the study had to suspend recruitment, enrollment and data collection activities in March 2020. In addition, the development and incorporation of new study procedures to ensure participant and staff safety during the ongoing pandemic will likely cause delays in restarting the study. We are requesting the extension to ensure that the study has adequate time to meet all study goals and objectives. CDC is also requesting approval for 310 burden hours, a reduction in 34 burden hours from our originally approved 344 burden hours. The reduction was achieved by the removal of redundant questions from the second follow-up assessment. In addition, CDC is also requesting an expansion of the recruitment area to metropolitan areas adjacent to North Carolina. This increased catchment area will ensure that highly mobile populations with close economic and community ties to metropolitan areas in and around North Carolina will have the opportunity to participate in this evaluation.

16. Plans for Tabulation and Publication and Project Time Schedule

Our analysis will focus on questions related to the study objectives. Our analysis plans for assessing the efficacy of the intervention include a tabular analysis to compare the pre- (baseline) and post-intervention (6 month) distribution of study variables among participants who have received the intervention and participants who have not yet received the intervention (delayed-intervention or waitlist group). Specifically, we will measure the number of behaviors critical to HIV prevention (PrEP engagement, condom use and medically supervised hormone therapy) at baseline and 6 months.

Data collection is requested for an additional 2 years. The project timeline is detailed in exhibit 16.1.

Exhibit 16.2: Project Time Schedule

Activity	Time Schedule
OMB Approval Date	June 2021
Develop data collection tools, sampling and data plans, study protocol	September 2016 – June 2019
Recruitment	9 months
Data Collection	15 months
Data analysis finalized and report drafted	24 months
Final de-identified data set submitted to CDC	24 months

In compliance with the CDC policy on data management and access, we will develop final, de-identified (names, other personally identifiable information, and locations will be removed) quantitative and qualitative datasets for this study along with the corresponding data documentation, which will be made

publicly available within 30 months of the end of data collection. It is anticipated that the data collected through this study will be shared as summary data tables and restricted use dataset(s). A data use plan for information collected during this study has been developed. The plan describes in detail how data access will be provided and the provisions for protection of privacy, security, intellectual property, or other rights (**Attachment 7**).

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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