Wake Forest®
School of Medicine

Division of Public Health Sciences,
Department of Social Sciences and Health Policy

(Fry &Flesch-Kincaid Readability: grade=6)

HIV PREVENTION AMONG LATINA TRANSGENDER WOMEN WHO HAVE SEX WITH MEN: EVALUATION OF A LOCALLY DEVELOPED INTERVENTION

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

SCOTT D. RHODES, PHD, MPH, PRINCIPAL INVESTIGATOR

INTRODUCTION

Thank you for your interest in participating in the ChiCAS Study. ChiCAS stands for Chicas Creando Acceso a la Salud (Girls Creating Access to Health), a small-group program designed to reduce HIV by promoting condom use, use of pre-exposure prophylaxis (or PrEP) and medically supervised hormone therapy. Before we talk about the study, we need to test you for HIV to confirm your HIV status for eligibility to participate the study. We will use the rapid INSTI® test. The test involves a quick finger stick in which your blood will be collected from your finger by trained personnel, and results will be available within 60 seconds. The test detects antibodies to HIV.

If you have been exposed to HIV within the past 3 months, the test may not detect HIV infection. You will be told of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you have HIV, you will not be eligible for the study. We will provide you additional counseling about the significance of your care and possible risks to other people, and we will link you to HIV care. We are required by law to report all positive results to the North Carolina State Board of Health. The test results will be released only as permitted by applicable law.

If you agree to take an HIV test now in order to confirm your status, please sign and date below, and we will test you. If you do not want to be tested for HIV, you can decline participation at this time.

Participant Name: _____ Date: _____

FOR PARTICIPANTS WHO ARE ELIGIBLE FOR STUDY PARTICIPATION:

The INSTI® test result confirms that you are eligible for this research study, and we would like to invite you to participate. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are at least 18 years old, identify either as a Latina transgender woman or a Latina woman whose sex at birth was described as male, and your most recent HIV test result was negative.

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00040441
Meeting Date Approved 4/25/2018
Version Valid Until: 8/2/2018

Your participation is voluntary. Please take your time in making your decision about whether or not to participate. Ask the study staff to explain any information or words in this document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to implement and evaluate the ChiCAS program.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

As many as 140 women who identify as Latina transgender women or Latina women whose sex was described as male at birth will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you are interested in participating, you will be asked questions about your background and health behaviors 2 different times. The first time will be at the start of the study or now. The second time will be 6 months later. Questions will ask about your age, education, country of origin, how long you have lived in the United States and in North Carolina, and your health attitudes and sexual behaviors.

The questions will be read to you in Spanish and will take about 60 minutes to complete.

After you have finished answering questions the first time, you may be randomly invited, that is invited by chance, to participate in the *ChiCAS* program that begins in the next few days or weeks, or to wait and participate in the *ChiCAS* program six months later. Randomization means that you are put into a group by chance. Neither you nor the study staff can choose the group you will be in. You will have an equal chance of being placed in either of the 2 groups.

The *ChiCAS* program has 2 sessions of about 4 hours each. In either group, your total participation time will be about 8 hours. All sessions will be held at locations convenient to participants.

The sessions will be led by 2 people who are trained to deliver the *ChiCAS* program. One other person will observe each session to make sure it is done correctly. This person will take notes about each session.

During the study, information will be collected from your medical records at the health centers or clinics where you seek services for PrEP and medically supervised hormone therapy. You will be asked where you received these services, including the names and addresses of the health centers or clinics, and to sign forms authorizing those health centers or clinics to share information from your medical records with study staff. The information collected will include medications, HIV testing history, treatment history, and appointment information.

You may also be invited to participate in one 90-minute in-depth interview. We will select a random sample of participants at the end of the program to participate in interviews. Questions

will ask about your thoughts about the program, including ways to improve the program. There are no wrong answers. The interview will be digitally recorded. This is being done because what you have to say is important and will enable study staff to accurately transcribe the interview. You may request that the recording be stopped at any time during the course of the interview. **If you ever want the recorder turned off, just let the researchers know and they will do that.** You can also withdraw your consent to use and disclose the recording before it is used. You should also understand that you will not be able to inspect, review, or approve the recording before they are used in this study. The recording will be destroyed after the interview has been transcribed and the transcription has been verified.

This interview is optional and not mandatory for participating in the study. Do you consent to participate in an in-depth interview, if selected to do so (please initial)?

_____ Yes

_____ No

Any new findings that may affect your willingness to continue in this study will be provided to you by Dr. Scott Rhodes, the Principal Investigator.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for six months. You will be asked to complete a questionnaire at the beginning of the study and again 6 months later.

You can stop participating at any time. Tell Dr. Rhodes or the study staff if you are thinking about stopping or decide to stop.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm that may result from taking part in this study is not expected to be more than in what is likely to occur in daily life. However, talking about your history and sexual health behaviors may be uncomfortable.

Taking part in this study may involve sharing information that you may consider confidential or private. Efforts will be made to keep your information safe, such as using a code or number instead of your name on research records, keeping research records safe with physical locks and electronic security devices, and allowing only authorized persons to have access to research records.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. However, we hope that what we learn from the study will help you and others in the future. The benefits of taking part in this study may be a greater awareness about PrEP and how to prevent HIV infections; the use of other helpful healthcare services; and changes in your attitudes and behaviors that may be good for your health.

WHAT OTHER CHOICES ARE THERE?

You do not have to participate in this study and you can decide to not do so. This is not a treatment study. Your alternative is not to participate.

WHAT ARE THE COSTS?

There are no direct costs to you for taking part in this study other than the giving of your time. The HIV testing will be paid for by the study and will not be your responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless you authorize it, unless it is required by law, or necessary to protect the safety of yourself or others. There is always some risk that even information that has had identifying information removed from it can be identified.

Participant information may be provided to Federal and other regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

As a token of our appreciation for your participation in the study, you will receive $30.00 for completing the first set of questions and $40.00 for completing the second set of questions 6 months later, in person. If you cannot complete the second set of questions in person, you can complete them by phone, and you will receive $30. In addition, you also will receive $40.00 for attending each of the 2 *ChiCAS* program sessions, for a total of up to $150.00. If you are selected for and participate in an in-depth interview as part of this research study, you will receive an additional $40.00 for your participation once you complete the interview.

WHO IS SPONSORING THIS STUDY?

This study is sponsored by the Centers for Disease Control and Prevention (CDC). They are providing money and other support to Wake Forest Health Sciences to conduct this study. The researchers do not hold a direct financial interest in CDC.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information.

Your personal health information and information that identifies you ("your health information") will only be used by study staff for study purposes, including carrying out the study and determining the study results.

We will make every effort to keep your Protected Health Information secure. We will store records of your Protected Health Information in a locked cabinet in a locked office or on a password protected computer. Only the following people or organizations will be allowed to access to your Protected Health Information:

1) Dr. Rhodes, the study investigator, and his staff or others at Wake Forest University Health Sciences who oversee research.

Center for Disease Control and Prevention (CDC) project staff will not receive any data that includes your name or contact information.

Any Protected Health Information collected from you in this study will be kept in Wake Forest University's research records for not more than three years after the study is closed by the Wake Forest IRB. At that time, research information will be made anonymous by removing all identifying details from the research records.

You can tell Dr. Rhodes that you wish to withdraw your permission to use and share your Protected Health Information at any time by sending a letter to him to this address:

Dr. Scott D. Rhodes
Public Health Sciences
Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157-1063

However, if you withdraw you permission to use your Protected Health Information, your participation in the study will have to stop. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

This agreement is valid for three years after the completion of the study.

All answers that you give will be kept private. This is so because the Centers for Disease Control and Prevention (CDC) has given this study a Certificate of Confidentiality (see 42 U.S.C. Section 241(d)). This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay.

However, a Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you without your consent. For example, we will voluntarily disclose information about incidents such as child abuse or intent to hurt yourself or others. In addition, the Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled.

If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest or new information becomes available.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call If I Have Questions or Problems?

For questions about the study, contact the study investigator, Dr. Scott Rhodes, at 336-713-5080.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this consent form.

Signatures

I agree to take part in this study. I have had a chance to ask questions about being in this study and have my questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Participant Name (Printed): _____

Participant Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ am pm