INFORMED CONSENT FORM

Diabetes Prevention Culturally Tailored for Mexican Americans

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Consent for Participation in Research

Title: *Diabetes Prevention Culturally Tailored for Mexican Americans*

Introduction

The purpose of this form is to provide you with information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study about diabetes prevention in Mexican Americans. The purpose of this study is to determine whether a diabetes prevention program, which is designed specifically for Spanish-speaking Mexican Americans and is focused primarily on diet and physical activity, can prevent, or at least delay onset of, diabetes in this high-risk group.

What will you be asked to do?

This study will include 300 participants. If you agree to participate, you will be assigned to:

1) a group of 10-15 participants who will attend weekly educational sessions for 3 months, biweekly support group sessions for 9 months, and then "booster" sessions at 18, 24, and 30 months; ***OR***
2) receive individualized guidance on how to improve your health and decrease the risk of developing diabetes in the future.

Before beginning the study, all individuals will be asked to spend approximately 2 hours to complete questionnaires about your personal health history, current health behaviors in which you engage (diet, physical activity), and how you feel about preventing diabetes in the future. Six teaspoons of blood will be drawn at this time to measure your blood glucose level, as well as to conduct other diabetes-related blood tests (e.g., cholesterol). You also will be scheduled for a 2-hour oral glucose tolerance test during which you will be fasting and asked to drink a liquid sugar drink. This procedure enables us to verify that you have prediabetes. You will be asked to complete the same questionnaires and have additional blood drawn at 3, 6, 12, 24, and 36 months. Oral glucose tolerance tests will be conducted at 12, 24, and 36 months to determine if your diabetes status has changed during the course of the study. We also will be accessing research data that were collected by Dr. Hanis in past studies, including results from the genetic study in which you are currently participating.

If you are assigned to group sessions, you will learn about diabetes prevention, such as how to alter your diet while maintaining your cultural dietary preferences, how to safely increase your physical activity, how to monitor your health status, etc. Areas about which you will be taught will be those that were shown in the National Diabetes Prevention Program as important for diabetes prevention. Sessions will be taught in Spanish and/or English,

depending upon the preferences of each group of participants. A nurse and/or a dietitian, all residents of Starr County, will conduct the sessions.

If you are assigned to the group that receives individualized instruction, at each data collection period (e.g., at the beginning of the study and at 3, 6, 12, 24, and 36 months), a project staff member will review your laboratory results with you and provide you with guidance on actions you can take to decrease your risk for developing diabetes. You will also be given written Spanish-language pamphlets and other handouts relevant to diabetes prevention.

NOTE: This is a research study and, therefore, not intended to provide a medical or therapeutic diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

What is the time commitment involved in this study?

For those people receiving group sessions, the study will involve weekly 2-hour education sessions for 12 weeks, followed by 2-hour support group sessions every other week for about 9 months. For those receiving individualized guidance, we ask you to commit to an additional 15-30 minutes with a project staff member after each of the 6 data collection sessions held during the project (beginning and at 3, 6, 12, 24, and 36 months). Further, all study participants will be asked to attend these 6 data collection sessions, which tend to last about 2 hours plus attend 2-hour appointments for the oral glucose tolerance tests at baseline, 12, 24, and 36 months.

What are the risks involved in this study?

There are no foreseeable risks to participating in this study; it does not involve any dangerous procedures or medications. There is a risk of discomfort and slight bruising associated with drawing blood scheduled several times during the course of the study. If you experience nausea, headache, or other discomfort during blood testing, including during the 2-hour oral glucose tolerance test, you should inform the Research Field Office staff. All laboratory testing procedures will be conducted by a certified phlebotomist and/or a nurse who has training and experience in blood drawing techniques. Aseptic techniques will be used, which include the use of sterile and/or disposable equipment (e.g., blood collection apparatus) and adherence to standard medical precautions. We will keep your physician informed of your health status on a regular basis during the course of the study.

What are the possible benefits of this study?

Possible benefits of participating in this study are that you will receive a thorough examination of your blood glucose levels and other laboratory tests. You will receive a free comprehensive diabetes prevention program or individualized health guidance that, if followed, will potentially help prevent or delay onset of diabetes in the future. There is a need for such relatively low-cost health programs designed for Spanish-speaking Mexican Americans. Without prevention, we can only anticipate even greater rates of diabetes in this rapidly growing ethnic group.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect in any way your relationship with The University of Texas at Austin, the University of Texas Health Science Center at Houston, or any staff members at the Research Field Office.

Will there be any compensation?

You will not receive any type of payment for participating in this study. All participants will receive free laboratory work. You will not be charged for any tests or for the diabetes prevention program or individualized guidance. There is no provision for free medical care or treatment beyond that provided by the diabetes prevention program and tests. Participants in the *experimental groups* will receive free Fitbit activity trackers and $100 credit (called "tool box" in the national DPP study), which can be used for purchasing healthy foods, more individualized time with project dietitian, etc. Participants in the *"enhanced" usual care control group* will receive free personalized advice, based on their laboratory results, held during each data collection at the exit interview. For their time commitment, all participants will receive a $25 gift card upon completion of each glucose tolerance test they participate in.

How will your privacy and confidentiality be protected if you participate in this research study?

While project staff will know you by name, your privacy and the confidentiality of your data will be protected. Individual interviews will be held in private offices in the Research Field Office. All forms will be kept in locked files and/or on computers that are secured with double passwords. At the end of the program any data collected (e.g., questionnaires and blood tests) will be identified by a code number known only by Dr. Sharon Brown and Dr. Craig Hanis. Only Drs. Brown and Hanis, plus the project managers (one in Houston and one in Austin) and data analysts will have access to these files, computers, and relevant passwords. The physician you designate as your health care provider will be informed of your participation and will provide any medical care that is required, but this will be at your own expense. Your name will not be used when results of this study are published or presented at research meetings.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

If you choose to participate in this study, groups in which you may participate may be audio recorded to document that correct intervention procedures have been consistently followed. Any audio recordings will be stored securely and only the research team will have access to these recordings. Recordings will be kept for 3 years from the completion of the study and then erased.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below*.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of NIH-funded projects. You should understand that a Certificate of Confidentiality 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if we become aware of harmful situations, such as child or elder abuse or neglect or intention to harm one's self or others.

NOTE: A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Whom to contact with questions about the study?

Prior, during, or after your participation, you can contact the researcher, Dr. Sharon A. Brown at (512) 232-4704 or send an email to sabrown@mail.utexas.edu for any questions or if you feel that you have been harmed.

This study has been reviewed and approved by The University of Texas at Austin Institutional Review Board and the study number is 2016-12-0040**.**

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, The University of Texas at Austin Institutional Review Board by phone at (512) 471-8871 or email at: orsc@uts.cc.utexas.edu.

Participation

If you agree to participate, return this form signed below to the staff at the Research Field Office in Rio Grande City.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date