The University of New Mexico Health Sciences Center

CONSENT FORM TO PARTICIPATE IN RESEARCH

5-16-17

STUDY TITLE:

Comparing Program Options for Latinos with Diabetes

Why am I being asked to sign this Consent Form?

This Consent Form explains the study that you are being invited to be part of, including possible risks or benefits to participating. This explanation will help you decide whether or not you want to participate. Please read this Consent Form carefully. Ask the person giving you this form to explain any words or information you do not clearly understand.

What is this study about?

This is a research study about diabetes self-management programs led by Janet Page-Reeves who is a researcher in the Department of Family & Community Medicine at the University of New Mexico (UNM). Diabetes is a big problem in the Latino community and a lot of people have trouble figuring out how to deal with their diabetes in their everyday lives. With this project, we are trying to learn about which diabetes self-management programs work best to help Latino diabetes patients take care of themselves. We want to know what features of programs are good to have and what features are not so good. We are working with two programs for this study: One Hope Clinic and the Center for Diabetes Education Program at the UNM Hospital.

Why am I being invited to be in this study?

You are being invited to be in this study because you fall into one of three categories: 1) you are Latino and are a diabetes or pre-diabetes patient at one of the two programs in the study, 2) you provide social support to one of the diabetes patients who is in our study, or 3) you work with one of the two programs participating in this study.

We are inviting 240 diabetes or pre-diabetes patients to participate in this study. Each of the patients in our study will identify a person who provides them with social support to be in thes study as well. And, we are also inviting some of the people who provide services at One Hope Clinic and the Center for Diabetes Education Program to answer some questions about their program.

What research activities will I be part of if I decide to participate?

All participants will be asked to sign this Consent Form and to fill out a Participant Information Sheet.

- This Consent Form asks for your signature to give us your permission that you agree to be part of the study.
- For people who are patients or social supports in this study, the Participant Information Sheet asks for your contact information so that we can contact you when we need to during the study, and it asks you some questions about yourself.
- For patients, we also ask for your doctor's contact information.
- For people who work for one of the programs, we only ask for your contact information.

If you are a diabetes or pre-diabetes patient, you will be asked to:

- Identify a family member or friend who provides you with social support to also be invited to participate in this study with you.
- Meet for a research appointment with one of our team members at 4 points during the study. Your first appointment will happen now or very soon, then again 3 months from now, then at 6 months, and 12 months.
- At each of the four appointments, we will ask you some questions for a survey, we will draw your blood for A1c testing, we will record your height and weight, and at two of the appointments, we will take a small sample of your hair to test for chronic stress.
- By signing this form, you agree to allow CDE or One Hope to share your most recent A1c results with us for our records..
- We will also invite a few of the patient participants to be part of a group discussion session or to answer some questions in an individual meeting session.
- For women patients, at each research appointment, we will ask you if you are pregnant because if you become pregnant during the study, this might affect our study results related to diabetes. So, if that happens, you will not be able to continue in the study, but it will not affect your ability to participate in your diabetes program. We will also provide you with a referral to the UNM program for pregnant women who have diabetes.

If you provide social support to one of our patient participants with diabetes or pre-diabetes, you will be asked to:

- Meet for a research appointment with one of our team members at 4 points during the study. Your first appointment will happen right now or very soon, then again 3 months from now, then at 6 months, and at 12 months.
- At each of the 4 appointments, we will ask you some questions for a survey.

- We will invite a few of the social support participants to do a group discussion session or to answer some questions in an individual meeting session with a member of our team.

If you work at One Hope Clinic or the UNM Hospital Diabetes Education Program, you will be asked to:

- Answer some questions in an individual meeting with a member of our team.

What will these research activities be like?

Research Appointments

If you are a patient or their support person, Research Appointments with will be held at One Hope clinic, at the Center for Diabetes Education building, or at a place and time that is convenient to you. At each Research Appointment, the study team member will ask you some questions and record your answers. For patients, we will also draw your blood, record your height and weight, and at two of the appointments, we will snip off a tiny sample of your hair. Each Research Appointment may take up to an hour.

Individual meeting sessions

If you are invited to answer some questions in an individual meeting session, you will be asked questions about diabetes and diabetes self-management programs. The individual meeting session will be held at a time and location that you choose and that will provide privacy. An individual meeting session will last approximately 1-2 hours. Your responses to questions you answer during the session will be sound-recorded with a little electronic sound recorder.

Group discussion sessions

If you are invited to be part of a group discussion session, the session will be held at One Hope Clinic at a time that is convenient for the participants in the group and in a space that provides privacy for the group. The group discussion session will include a small group of other participants who will discuss answers to questions as a group. The questions will be about diabetes and diabetes self-management programs. The group discussion session will last approximately 1-2 hours. The group discussion session will be sound-recorded with a little electronic sound recorder.

What will happen next?

After each Research Appointment

After each Research Appointment, the study team member will take the information that you provide (survey answers, blood test results, information about your height and weight, and your hair sample) and assign a code to it so that your name or any identifiable information is not together with your information. This makes it possible for you to be anonymous is our study.

The study team member will:

- Record the answers you provided to the survey questions on our password-protected computer.
- Send your blood to be analyzed for A1c. After the lab finishes the A1c test, they will dispose of your blood in a safe way. When we receive the lab results, your A1c levels will be recorded on our computer and we will let you know what your results say. If your A1c level is high and we feel concerned, we will contact you and your provider with information about your A1c. If you would like, we will connect you with Dr. Mark Burge who is a diabetes specialist and a member of our team, and he will instruct you what to do.
- Record your height and weight.
- Store your hair sample in a plastic bag in a cool place until it can be sent for analysis for the hormone cortisol. This will tell us if you have chronic stress.

After each individual meeting session or group discussion session

We will upload the recordings from the sound recorder onto our computers and save them as sound files (MP3 files). After we do that, we will delete the sound recording off of the little sound recorder. We will store the sound recordings on our password-protected computers and we will assign each one a code so that the recording won't have your name or any information to identify you. We will send each sound recording to a person who will type-up each individual discussion session or group discussion session so that we can read it rather than having to listen to it. Each typed-up individual discussion session and group discussion session will be assigned the code. All typed-up individual discussion sessions and group discussion sessions will be stored as an electronic file on our computers or on paper in a locked file cabinet in the offices of the study team, accessible only by members of the study team.

From our research

To make sure the information you provide stays private and confidential, we will not use anybody's name in presentations, reports or publications that are developed from this work. Once analysis is complete, all sound-recordings will be deleted. When the study is done, we will contact you to invite you to a presentation of our findings at a location in the community. You can choose to attend the presentation or not, depending on your interest. In addition, if we are conducting a similar study, we may contact you in the future to follow-up on this research and to invite you to participate in the new study.

Are there risks of being in this study?

The risks involved in participating in this study are minimal and we do not think that you will experience any negative consequences or effects. However, there are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality that can happen in any research study where you answer questions about yourself, your experiences, and your opinions, or where you provide blood samples, hair samples, or BMI information.

Are there benefits to being in this study?

You may find the experience of being in this study and thinking about your own personal experience with diabetes programs to be interesting. Further, by allowing us to look at your information in relation to those of the other participants, you will contribute to our understanding of what types of diabetes programs work best for Latinos.

Will I be paid for taking part in this study?

You will receive a merchandise card to thank you for taking the time to contribute to this research

- For each of the 4 Research Appointments, you will receive a Walmart card worth $50
- If you are invited to do an individual meeting session or group discussion session, you will receive either a Walmart or an Amazon card worth $50.
- If you work at the UNM CDE program and you do an individual meeting session, you will not receive a card, as this is disallowed by UNM policy.

When we give you a card, we will ask you to sign a receipt and provide some information for our financial record files. Apart from your signature to verify you received the card, you do not have to provide any information that you do not care to share.
While we hope that you will complete each activity you agree to, and it is best for our study results to have complete information from each activity, you will receive the card if you participate in a research activity even if you have to leave early or if you decide to stop in the middle.

How will my information be kept private?

We will only keep a record of your name on the consent form and on the contact sheet that we will use to contact you with your A1c results and to schedule Research Appointments, private discussion s or group discussions. We will store the consent forms and contact sheets in separate locked cabinets. We will do everything we can to protect the privacy of all your personal information, but we cannot absolutely guarantee confidentiality about your participation in this study. All data and biospecimens from this study will be identified numerically and your name will not be used as a label. The UNM Human Research Protections Office (HRPO) that makes sure we are treating people who participate in research at UNM properly sometimes asks to see our records of the information you provide. Although unlikely, we could be required for legal reasons to share study information. However, your name will not be used in any published reports, publications or presentations about this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality for this project 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,

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 agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 of such as child abuse and neglect, or harm to self or others.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it is identifiable or “linked” to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: A1c test results, your height and weight used to calculate your body mass index (BMI), and the levels of cortisol that we find in the sample we take of your hair.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Dr. Janet Page-Reeves, Ph.D.
MSC09-5065
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be able to take part in the research study.

Can I stop being in the study once I begin?
Your participation in this study is completely voluntary.
You have the right to choose not to participate now or to stop participating at any point in this study.

Who can I call if I have questions about this study?
If you have any questions or concerns at any time about the research study, Dr. Janet Page-Reeves will be glad to answer them at 505-306-3041. If you would like to speak with someone other than Dr. Page-Reeves, you may call the UNMHSC HRRC at (505) 272-1129.

Who can I call if I have questions about my rights as a research subject?
If you have questions regarding your rights as a research subject, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who are not involved in this project. They look out for the interests of people who participate in research projects at UNM. For more information, you may also check out the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

CONSENT TO PARTICIPATE IN THE RESEARCH
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided. By signing this consent form, you are not waiving any of your legal rights as a research subject. A copy of this consent form will be provided to you.

I have had a chance to ask questions and all questions have been answered to my satisfaction.
By signing this consent form, I agree to participate in this study.

_____
Print your name.

_____ _____
Sign your name Date

Investigator Signature

I have explained the research to the participant and answered all of his/her questions.
I believe that he/she understands the information described in this consent form and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date