The University of New Mexico Health Sciences Center
Consent to Participate in Research

Tribal Home-Based Kidney Care Study

Purpose and General Information
You are being asked to participate in a research study that is being led by Drs. Kevin English at the Albuquerque Area Indian Health Board, Inc. (AAIHB) and Vallabh Shah and Mark Unruh at the University of New Mexico (UNMHSC) along with their community health workers. Funding for this study is provided by the Patient Centered Outcomes Research Institute. This study is being done to find out if home-based kidney care can help reduce the risk of chronic kidney disease (CKD) among members of your community. If you agree to be in this study, you will be asked to read and sign this consent form.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?
Screening procedures: The first step is screening to determine if you are eligible to participate in the study. We will ask you questions about your age, gender, and medical history. We will also measure your height, weight, blood pressure and waist and hip areas. Blood will be taken from a finger stick to measure glucose control. A sample of your urine will also be collected to measure protein, which can be an early sign of kidney disease.

Randomization: After screening, we will determine if you qualify for the study based on the lab values and measurements. If you agree to participate, you will be randomized to the Home-Based Kidney Care (HBKC) intervention group or the "delayed intervention" group. Randomization is like the flipping of a coin to determine what group you are assigned to. A total of 240 individuals are expected to participate in this study. All participants in both groups (120 participants in each group) will receive HBKC. Some will receive it **right-away** and **some will receive it after a delay of 12 months**.

Home-Based Kidney Care (HBKC) Intervention: If you are randomized to the first HBKC intervention group, you will receive educational home visits or telephone calls from a community health worker (CHWs) at a time of your choice every 2 weeks for 12 months. The first session will last about 1 hour and all others will be approximately 30-45 minutes. The community health worker will talk about topics like nutrition, exercise, diabetes, kidneys, blood pressure, and medication. You are encouraged to participate in all visits. CHWs will give you updates on your progress and will also help you create a healthier home to support your nutrition and physical activity. You will be also asked to attend a 30 to 60 minute educational group session with other participants (intervention and delayed group) every 90 days about 4 times during the year. During the group session, we will talk about diabetes, lifestyle changes, goal setting and other related topics. These sessions may be conducted via videoconference. Participants will also have the option to call in if videoconferencing technology is not available or internet connections are unstable.

Blood and urine tests will take place at the beginning, middle (6 months) and end of the intervention (12 months), as well as four months after the intervention (16 months). Blood will be taken from a vein in your arm to measure, glucose levels and glucose control, kidney function, cholesterol levels, electrolytes (salts in your body) and measures of inflammation. Approximately, two tablespoons of blood will be taken. At home glucose and urine checks will also take place at months 3 and 9. We will share these test results with you and to your doctors/nurses at your local tribal/Indian Health Service (IHS) health facility. No additional tests will be performed on your samples. We will not store your blood and urine samples.

At the beginning, middle (6 months) and end of the intervention (12 months), we will also ask you questions about your overall health, medication use, habits, and knowledge about kidney disease related issues. You may refuse to answer any of these questions at any time. The questionnaire will take about 30 minutes to complete.

We will also provide you with cell phone coverage to receive motivational text messaging for about 4 months, paid by the project.

RISK AND DISCOMFORTS: There are some small risks to your health if you take part in the study, including:

- You may have mild pain when we draw your blood. There is a small risk of bleeding, bruising (less than 10%) and infection (less than 1%) in the area where we put the needle.
- Rarely, we may ask you for an additional blood sample. In the rare event (less than 1%) that a sample is lost, broken or wrongly labeled we may ask you for an additional blood sample.
- If any of your lab values are found to be critically abnormal, you will be immediately referred to the local Tribal/IHS facility for care.
- There is the risk that information about you may become known to people outside this study. We have established procedures to protect the confidentiality of your information. Nevertheless, accidental disclosure of study data may occur.

BENEFITS: Participants in this study may benefit individually from earlier diagnosis of chronic kidney disease (CKD). Home based kidney care may result in better control of blood pressure, diabetes and cholesterol. Improving these items could slow down kidney disease. This study may also help future generations and other tribal communities by identifying new ways to manage diabetes and kidney disease.

CONFIDENTIALITY: Your name or other personal information will not be collected by the study team because this information is confidential. Only the community health worker and providers at your local tribal/IHS health facility will have access to this information. Instead, a unique code will be used to protect your privacy. The information that you provide during this study will be combined with information from other participants and tribes to evaluate the intervention. All data will be kept in a secure, password-protected computer database for analysis at the offices of study personnel. Hard copies of all study results will be kept in locked file cabinets. Your name and your tribe's name will not be used in any published reports about this study.

PAYMENT FOR PARTICIPATION: You will receive a merchandise card of $25 in partial compensation for your time during the screening. If you enroll in the study, you will receive a $50 merchandise card at the beginning, followed by $25 merchandise cards every 3 months when you are asked to provide a blood or urine sample (3 months, 6 months, 9 months, 12 months, and 16 months). You will receive a $25 merchandise card in partial compensation for your participation in each group session.

ALTERNATIVES TO PARTICIPATION: Joining this study is voluntary. You may choose not to join. If you decide not to participate there will be no penalty. You will still receive the health care you are entitled to.

HOW WILL YOUR HEALTH INFORMATION BE COLLECTED, USED AND SHARED?
As part of this study, we will be collecting health information about you and sharing it with your doctors at the local Tribal/IHS health facility. This information is "protected" because it is identifiable or "linked" to you. The protection comes from the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, 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: results of physical exams, medical history, body mass index, and clinical lab values.

In addition to researchers and staff at AAIHB Inc. and UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the 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.

<u>Right to Withdraw Your Authorization</u>
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. You may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Vallabh Shah or Kevin English
MSC 08 4670
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 protected health information (PHI), you will not be allowed to take part in the research study.

WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?
Withdrawal: You have the right to choose not to be a part of this study. You may quit this study at any time. The study investigators can remove you from the study, if being a part of the study is not in your best interest or if the study is stopped.
New findings: You will be told about anything important that is found out during the study, such as changes in the risks or benefits of being part of this study.

WHAT IF I HAVE QUESTIONS OR COMPLAINTS ABOUT THIS STUDY?
If you have any questions, concerns or complaints about this study, please call Drs. Shah (505) 272-9615 and English (505) 764-0036 at any time between 8:00 A.M. and 5:00 P.M Mondays through Fridays. For questions or emergencies that arise after hours or on weekends, call (505) 272-2111 and ask for the kidney doctor (nephrologist) on call.

If you would like to speak with someone about your rights as a research participant, you may call the University of New Mexico Human Research Review Committee (HRRC) at (505) 272-1129 or Rachell Tenorio with the Southwest Tribal Institutional Review Board (SWTIRB) at (505) 764-0036. The HRRC and SWTIRB provide independent oversight of safety and ethical issues related to research involving human participants.

Consent and Authorization
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this consent form. A copy of this consent form will be provided to me.

Name of Adult Participant (print)	Signature of Adult Participant	Date /

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

Name of Research Team Member	Signature of Research Team Member	Date /