Title: Access to Kidney Transplantation in Minority Populations (AKT-MP)

NCT Number: NCT04615819

Version: December 14, 2020

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Access to Kidney Transplantation in Minority Populations (AKT-MP)

You are being invited to take part in a research study comparing the impact of two approaches to help Hispanic and American Indian patients complete evaluation for kidney transplantation.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn whether a streamlined evaluation process (Fast Track) is more or less effective than peer-assisted transplant evaluation process (Peer Navigator). Your participation will start after you consent to participate in the study and last until you complete the kidney transplant evaluation process.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to volunteer for this study because you will either: (a) have your transplant evaluation workup scheduled for you within a short period of time (Fast Track); or, (b) have a previous kidney transplant recipient walk you through kidney transplant evaluation process (Peer Navigator). Also, your participation will help researchers come up with new ways to help kidney transplant patients in the future. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study because of the minimal risks associated with participating in a research study, such as loss of confidentiality. Regardless of which arm of the study (Fast Track or Peer Navigator) you belong to, you are still entitled to, and will receive, all the usual care other patients receive before and after the kidney transplant. For a complete description of the risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer for the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Larissa Myaskovsky, PhD, of the University of New Mexico Health Sciences Center, Department of Internal Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is (505) 272-0070.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 14 December 2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You may not qualify for this study if you: do not sign this consent form; have had a previous kidney transplant; cancel your evaluation for kidney transplantation; are under 18 years of age; are institutionalized (in jail or in prison); are pregnant; have an active infection; you have had a non-skin malignancy or melanoma in the past 2 years; or you have a known cognitive impairment.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The transplant evaluation procedures will be conducted at UNM Hospital. Once you have consented, you will be randomly assigned to either Fast Track or Peer Navigation. Randomization means you will be assigned to one of the two groups randomly, like the flip of a coin. Both study arms are designed to help you complete the transplant evaluation process. The total amount of time you will be asked to volunteer for the telephone interviews is about an hour and a half, outside of your regular transplant evaluation visits. If you are assigned to the Peer Navigator condition, you are allowed to talk to your Peer Navigator at any time throughout the study.

WHAT WILL YOU BE ASKED TO DO?

You are being asked to participate in this study because your transplant team has determined you are eligible to participate based on your age, transplant status and ethnicity. After you consent to participate in the study, but before you complete your first transplant evaluation clinic appointment, we will call you for a telephone interview to discuss different topics, such as your quality of life, your experience in healthcare, your background, and your health history. This interview will take no more than an hour and a half. Then, depending on the study arm to which you have been assigned, you will either proceed with the Fast Track or Peer Navigator kidney transplant evaluation. After all of your transplant evaluation visits have been completed, we will call you to complete a follow-up interview which will last about 30 minutes.

If you have been assigned to Fast Track and need to stay in Albuquerque, you may stay at Casa Esperanza at a reduced cost.

If you have been assigned to Peer Navigation and need to contact your navigator throughout the study, you may interact with them over the phone or through a secure, private videoconference called Zoom. Zoom meetings will be recorded and transcribed.

A small number of study participants will be asked to complete an in-depth interview, which will be recorded and transcribed. If you are randomly selected, you may be contacted for this additional interview to talk about your experience with the study and your suggestions to make the study better for others.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of the interview and interventions are limited to discussing personal things about yourself and time burden. The interview and survey data responses will NOT affect your eligibility for kidney transplant in any way. Any information you provide is private and confidential and will not be relayed to

the transplant team. Topics discussed during the interview may cause you some temporary emotional distress. Talking about kidney transplant with family members or friends may also cause emotional distress. Participation in a research study may result in some loss of privacy; however, these risks are small and will be lessened by limiting who has access to your study information to only the approved members of the study team. Some risks are unforeseen.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. Some people may experience reduced time to complete the transplant evaluation if they have been assigned to fast track, and others may have the added support from a previous transplant recipient guiding them through the transplant evaluation process. However, if you take part in this study, information learned may help others undergoing transplant evaluation and help researchers and doctors understand the costs and benefits of either approach.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

If you need to stay at Casa Esperanza, you will be charged a refundable $15 deposit and your insurance company will be billed for each night. If you do not have insurance, the nightly rate is $35.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Please refer to the "HIPAA Privacy Authorization" document that explains more specifically how your personal information will be protected.

Every effort will be made to maintain your privacy. You will be given a unique study identification number. This number and your initials will be used to record your study information into a database called REDCap. A log of the participant names, participant ID numbers, and personal information (such as home address, telephone number, and emergency contact information) will be maintained in a locked area with the research team. Only authorized members of the research study will have permission to see this data. The data collected in this study will be stored for 6 years after the study has been closed with the IRB.

A Certificate of Confidentiality from the National Institutes of Health covers this research. The researchers with this Certificate of Confidentiality may not disclose or use the information, documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by the Certificate of Confidentiality cannot be disclosed to anyone who is not connected to the research. Except if, there is a federal, state, or local law that requires disclosure, (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute for Minority Health and Health Disparities (NIMHD) and the National Institute of General Medical Sciences (NIGMS), which is funding this project, 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. If this happens, the study intervention will no longer be provided to you. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the directions, if they find that your participation in the study is more risk than benefit to you, or the agency paying for the study chooses to stop the study early for scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another kidney research study. It is important to let the investigator know if you are in another kidney research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you have a medical emergency during the study, you should go to the nearest emergency room. You may contact the Principal Investigator listed on this form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care, you get for the injury, but you may also be responsible for some of them. If you think you have been injured because of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on the first page of the consent form.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive $40.00 for each of your interviews in the form of a merchandise card. If you are randomly selected for an additional in-depth interview, you will receive another $40 for that interview.

If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 400 people to do so at the University of New Mexico. Study records will be kept for six years after study closure and then destroyed.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION.

Identifiable information such as your name, medical record number, or date of birth will be removed from the information collected in this study. After removal of your identifiable information, the rest of your information may be used for future research or shared with other researchers without your additional informed consent.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATIN (PHI).

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, as described in 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 includes medical history and demographics.

In addition to researchers and staff at UNMHS 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 health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

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. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. 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:

Larissa Myaskovsky, PhD

MSC04 2785
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 the date that your withdrawal is received.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Myaskovsky to inform her of your decision.
- Researchers may use and release your health information already collected for his research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

Printed name of research subject

Signature of person obtaining informed consent/HIPAA Authorization

Date

Printed name of person obtaining informed consent/HIPAA Authorization