The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Improving Healthcare Outcomes in American Indian and Hispanic Transplant Recipients Using Culturally-Tailored Novel Technology (IMPACT)

You are being invited to take part in a research study about exercise and diet post-transplant in American Indian and Hispanic kidney transplant recipients.

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

By doing this study, we hope to learn more about how exercise and diet can reduce heart problems and weight gain post-transplant. Your participation in this research will last about one year.

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

Reasons you might choose to volunteer for this study may include you may receive a culturally tailored intervention to help you reach exercise and diet goals consistent with post-transplant guidelines and your participation might help researchers come up with new ways to help others 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?

Reasons you might not choose to volunteer for this study may include minimal risks associated with participating in a research study, such as loss of confidentiality, or you do not want to engage in the diet and exercise plan recommended by the study therapist or nutritionist. Whether or not you are randomized to the research intervention, you will still receive usual care post-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.

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, 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 16 September 2019

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

Reasons you may not qualify for this study may include: Not signing this consent form; you are under 18 years of age; you are institutionalized (in jail or in prison); you are pregnant; you 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 research procedures will be conducted at the UNM HSC Transplant Center, and be added to your regularly scheduled post-transplant visit. This process will add about 1 hour to your regularly scheduled visit. No additional appointments will be needed. The total amount of time you will be asked to volunteer for this study is 13 hours over the next year.

WHAT WILL YOU BE ASKED TO DO?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things may happen over the next year. After your transplant, you will be randomly assigned to either the IMPACT Intervention or Usual Care. Normally, you would come to the transplant clinic 13 total times (please see the table below). Depending on the study arm you will be assigned to (IMPACT or Usual Care), your research visits are indicated with an 'X'. Regardless of your research condition, no additional visits will be needed beyond your standard clinical visits.

Patient receives transplant	Day 1 post-transplant	Month 1 1x/week	Month 2&3 2x/month	Month 4&5 1x/month	Month 6 1x/month	Month 12 Follow Up
IMPACT Intervention	X	X	X	X	X	X
Usual Care	X				X	X

If you are randomly selected for Usual Care, you will be interviewed by research staff during three standard post-transplant visits over the next 12 months.

If you are randomly selected for the IMPACT intervention, you will be interviewed by the research staff and have a culturally tailored physical therapy and diet plan throughout the study. This will also be supported through a free phone messaging service, called Twistle, that will link you to the research team.

Twistle can be used with or without a smartphone, even if you live in a rural community. It will be used to create and collect your questionnaire answers, send personalized reminders and check-in with you based on the culturally-tailored exercise and diet plan developed by the IMPACT intervention team. The data collected through Twistle will only be linked directly to a database, called REDCap, and only the study team will have access to it.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Loss of privacy: Participation in a research study may result in some loss of privacy.

Diet and exercise risk: You may feel there is an exercise you cannot do. If so, we will encourage you to discuss your concerns with the physical therapist. If you feel there is a diet that is hard to maintain, please talk to the nutritionist. Both people will work with you to find the right option.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced benefits with exercise and diet post-transplant. If you are randomized to the IMPACT intervention and receive personalized care, you may also experience this benefit. If you take part in this study, information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

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 post-transplant. 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.

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 separate "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 5 years after the study has been closed with the IRB.

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

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 a number of 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 research study. It is important to let the investigator know if you are in another 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 $20.00 for every research related visit in the form of a Visa/MasterCard debit/merchandise card.

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.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 20 people to do so at the University of New Mexico.

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, the 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 notify the investigators in writing, please send a letter notifying them of your withdrawal to:

Larissa Myaskovsky, PhD
MSC04 2785
1 University of New Mexico
Albuquerque New Mexico 87131

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	