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

Relationship between Health Literacy and Chronic Kidney Disease Outcomes

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Matthew Borrego, who is the Principal Investigator, and his associates. This research is being done to evaluate the relationship between health literacy and kidney health outcomes. You are being asked to participate because you are seeing a kidney specialist. Approximately one hundred and fifty people will take part in this study at the University of New Mexico. This study is being sponsored by Southern Illinois University Edwardsville.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

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 will happen: 1) A research assistant will ask you some questions to determine if you meet specific criteria that are required for the study. If you meet study criteria, you will be interviewed further by the interviewer where he/she will ask you additional questions about how you manage the health of your kidneys and about your understanding of health information. After the interview, your most recent kidney function laboratory test will be obtained from your medical record.

Participation in this study will take a total of 20-25 minutes over a period of a one-time visit.

What are the possible risks or discomforts of being in this study?

Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality. There are small risks of possible stress and inconvenience in answering the research assistant's interview questions. Further there might be inconvenience of time due to having to stay to answer questions

How will my information be kept confidential?

Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by research at the University of New Mexico and Southern Illinois University Edwardsville (SIUE), federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research.

What are the benefits to being in this study?
There may or may not be direct benefit to you from being in this study. However, your participation may help find out the best way to provide information to you and other patients about how to manage their kidney health based on their level of understanding of health.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate.

Will I be paid for taking part in this study?
If you complete the screening criteria statements and the study surveys, you will be compensated with a $20 Wal-Mart merchandise card at the end of the interview. Even if you complete screening criteria, but are not eligible to complete the study, you will receive the $20 Wal-Mart merchandise card as compensation at the end of the screening.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your relationship with your doctor or the care that you receive.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation. The researchers from the University of New Mexico or Southern Illinois University Edwardsville may stop the study at any time.

Authorization for Use of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you. 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: information in the medical chart as well as laboratory kidney function tests such as serum creatinine levels.

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 a HIPAA Research Withdrawal Form or letter notifying them of your withdrawal to:

Dr. Matthew Borrego
MSC 09 5360
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 allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Dr. Matthew Borrego, Ph.D , or his associates will be glad to answer them at 505-272-5945 from Monday through Fridays from 8:00 a.m to 5:00 p.m. . If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects.

What are my rights as a research subject?
If you have questions regarding your rights as a research subject, you may call the HRRC at (505) 272-1129 or visit the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

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 subject.

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 subject 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

Child Assent
You are making a decision whether to participate (or to have your child participate) in this study. Your signature below indicates that you read the information provided (or the information was read to you).

_____	_____/_____
Name of Child Subject	Signature of Child Subject/Date
_____	_____/_____
Name of Parent/Child's Legal Guardian	Signature of Parent/Legal Guardian/Date