Permission to Take Part in a Human Research Study

Title of Research Study: Integrating a Culturally Competent *APOL1* Genetic Testing Program Into Living Donor Evaluation

[Stage 3: Program Evaluation – Intervention Period]

IRB Study Number: STU00214038

Investigator: Akansha Agrawal, MD

Supported By: This research is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate.
Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a transplant nephrologist who performs transplant evaluation of living kidney donor candidates.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
- The overall study aims to integrate the culturally sensitive ***APOL1* Testing and Counseling Program** into transplant nephrology clinical practice.
- The purpose of this part of the study is to:
  - Deliver *APOL1* counseling and genetic testing.
  - Evaluate the implementation of the ***APOL1* Counseling Training Program**.
- Culturally sensitive *APOL1* testing and counseling is expected to improve donor candidates' informed decisions about donating, which is key to protecting their safety.

How long will the research last, and what will I need to do?
We expect that you will be in this research study for a 5-year time period.

You will be asked to:
- Encourage living kidney donor candidates of African ancestry (study participants) to undergo *APOL1* genetic testing.
- Deliver culturally sensitive counseling about *APOL1* before and after *APOL1* genetic testing to living kidney donor candidates of African ancestry (study participants).
- Use clinical decision support in the electronic health record (EHR) to guide and document counseling.
- Permit audio-recording of your discussions with living kidney donor candidates of African ancestry (study participants) before *APOL1* genetic testing.

- Permit audio-recording of phone calls in which you counsel living donor candidates (study participants) about *APOL1* genetic test results.
- Complete 3 interviews (30 minutes each) over 4 years. These interviews will be audio-recorded.
- Complete 4 surveys (~ 5 minutes each) over 4 years.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
There is a low chance of a breach of confidentiality.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include

- Reducing decisional conflict and improving informed consent about donating for potential living kidney donors of African ancestry, and thereby protecting their safety.
- Helping to determine whether the ***APOL1* Counseling Training Program** is feasible and effective for counseling potential living kidney donors of African ancestry.
- If the ***APOL1* Counseling Training Program** is effective, it will be disseminated to other transplant programs to help nephrologists counsel living kidney donor candidates of African ancestry in the future.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:
The rest of this document includes detailed information about this study
(in addition to the information listed above).

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Akansha Agrawal, MD, by phone: 312-695-8900 or by email: akansha.agrawal@nm.org.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 7 people will be in this study here out of 12 people in the study nationally.

What happens if I say "Yes, I want to be in this research"?
You will:

- Encourage living kidney donor candidates of African ancestry (study participants) during in-person evaluation to undergo *APOL1* genetic testing via a saliva swab. The swab will be taken by research staff immediately after your visit with the donor candidate.
- Deliver culturally sensitive counseling about *APOL1* genetic testing during the first evaluation visit, and about *APOL1* genetic test results thereafter to living kidney donor candidates of African ancestry.
- Use clinical decision support in the electronic health record (EHR) to guide and document counseling. When we review participating living donor candidates' EHR, we will collect information about how you use clinical decision support in the EHR in response to the candidates' *APOL1* genetic test results.
- Permit research staff to audio-record your clinic visit with living donor candidates (study participants) in which you counsel them about *APOL1* genetic testing. The audio recording is required for study participation.
- Permit research staff to audio-record the phone calls in which you counsel living donor candidates (study participants) about *APOL1* genetic test results. Audio-recording is required for study participation.
- Take part in 3 interviews (30 minutes each, over 4 years) by telephone or Zoom about your experiences delivering *APOL1* counseling. The interviews will be conducted by Elisa Gordon, PhD, MPH (grant Principal Investigator) at Vanderbilt University Medical Center, or a trained research coordinator at Northwestern University. If Dr. Gordon conducts your interviews, she will have access to your name and contact information for the purpose of scheduling and interviewing you. These interviews will be audio-recorded, which is required for study participation.
- Take part in 4 online or telephone surveys (~5 minutes each, over 4 years) about the *APOL1* Testing and Counseling Program's acceptability, appropriateness, feasibility and sustainability.
- Provide your email address after giving consent, so that research staff may email you the online surveys.

What happens if I say "Yes", but I change my mind later?

- You can leave the research at any time; it will not be held against you.
- Choosing not to be in this study or choosing to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Your choice not to be in this study will not negatively affect your present or future employment.
- Any data collected up to the point of withdrawing from the study may be used by the research team.

Detailed Risks: Is there any way being in this study could be bad for me?

- Risks are believed to be minimal.
- The interview and survey questions are neutral.
- There is a small risk of loss of confidentiality by access to data by people who are not part of the research team.

Will it cost me anything to participate in this research study?

- Taking part in this research study will not lead to any costs to you.

What else do I need to know?

- The results of this study may be used for teaching, publications, and/or presentations at scientific meetings.
- If you would like to be informed of the results of the study, you may visit the following website where publications and reports from the study will be posted: www.Apol1consent.org.

What happens to the information collected for the research?

- Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy.
- Organizations that may inspect and copy your information include the IRB and other representatives of this institution, Vanderbilt University Medical Center, which is coordinating the data for this study with Northwestern University, and the National Institutes of Health, which is sponsoring this research. Vanderbilt University Medical Center will have access to a limited dataset for the study that is deidentified except for dates.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- We may publish the results of this research. However, we will keep your name and other identifying information confidential.
- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). 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. 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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Signature Block for Capable Adult

Your electronic signature documents your permission to take part in this research. You can choose to have a copy of this signed document emailed to you.

_____ _____

Verified Electronic Signature of Participant Date

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Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent