

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

IRB Study Number: STU00214038

[Stage 3: Program Evaluation- Control Period]

Investigator: Elisa Gordon, PhD, MPH

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 a culturally sensitive *APOL1* Testing and Counseling Program (study intervention) into transplant nephrology clinical practice.
- Culturally sensitive *APOL1* testing and counseling is expected to improve donor candidates' informed decisions about donating, which is key to protecting their safety.
- The purpose of this part of the study is to recruit participants into the Control Arm of the study.
- In this first year of the research, we are studying the usual care given to potential living kidney donors of African ancestry. No living donor participant is getting the study intervention at this time.

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How long will the research last, and what will I need to do?

We expect that you will be in this control period of the research study for a 1-year time period.

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.

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, Elisa Gordon, PhD, MPH, by phone: 312-503-5563 or by email:

e-gordon@northwestern.edu.

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 transplant nephrologists will be in this research study here out of 12 transplant nephrologists in the entire study nationally.

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What happens if I say “Yes, I want to be in this research”?

You will:

- Deliver usual care to all living kidney donor candidates.
- Permit research staff to audio-record your discussions with living kidney donor candidates (study participants) during their visit to the transplant clinic for evaluation, and during your telephone call to discuss test results. The audio recording is required for study participation.

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.
- 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 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 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 and the National Institutes of Health, which is sponsoring this research.
- 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.

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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.

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.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent