

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

[Intervention Arm]

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)

Your kidney transplant doctor, who is also involved in this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first part of this document includes 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?

- People who are Black or African American have high rates of kidney disease.
- Black/African American living donors have a higher chance of getting kidney failure after donating than white living donors.
- Genetic factors, in addition to systemic and environmental factors, may be part of the reason for this disparity. People with African ancestry are more likely to have changes in a gene that evolved to protect people from sleeping sickness in Africa. These same changes in a gene are related to getting kidney disease.
- We are doing a research study about how doctors talk about genetic testing to potential living donors of African ancestry who may have these changes in a gene.
- We are asking you to take part in this research study because you identify as having African ancestry and are starting evaluation to become a living kidney donor.

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.

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Why is this research being done?

- This research aims to learn how doctors talk about genetic testing to people who are thinking about donating.
- Potential living donors sometimes get genetic tests to see if there are health concerns about donating. These tests can give potential donors more knowledge to make informed decisions about donating. This will better protect their safety.
- Doctor's communication is important because it can impact decisions about donation.
- Specifically, we want to see if doctors talking about genetic testing can make potential donors of African ancestry feel more prepared about donating.
- This study is important for helping healthcare institutions provide all people with the care they deserve.
- This study may show transplant programs in the United States how to better inform potential donors of African ancestry about donation.

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

- We expect that you will be in this research study until 1 month after donating, being medically ruled out for donation, or withdrawing from the living donor evaluation process.
- For this study, you will be asked to complete baseline and follow-up surveys, use a smart phone app, provide a saliva sample for a genetic test, receive counselling by your kidney doctor about getting a genetic test and about the genetic test results, and allow research staff to audio-record the counseling sessions.
- If we are unable to reach you for the follow-up surveys, we may continue to contact you up until 12 months following donation, medical rule out, or withdrawal from living donor evaluation. If you donate and we are not able to reach you to complete the follow-up surveys, we may contact you at your 6-month or 12-month post-donation clinic appointment.

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?

- The most important risks are:
 - Psychological distress from learning about genetic test results.
 - Being medically ruled out from donating based on your genetic test results and other clinical information.

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?

We cannot promise any benefits to you or others from your taking part in this research.

However, possible direct benefits to you include helping you to:

- Better understand your risks of donation
- Feel more prepared to donate
- Feel less conflicted about donating
- Feel more satisfied with making an informed decision about donation

Possible benefits to others include improving the safety and informed consent for potential donors of African ancestry in the future.

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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. Your alternative to participating in this research study is to not participate.

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 195 people will be in this research study here out of 390 people in the entire study nationally.

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

You will take part in the following steps:

1. Surveys

- You will complete 4 surveys that will take place:
 1. During your clinic visit for living donor evaluation, right after agreeing to take part in this study
 2. 6-7 days from today
 3. 1-2 days after your kidney doctor calls you about the genetic test results
 4. 1 month after either donating, being medically ruled out from donating, or withdrawing from living donor evaluation
- Surveys will last 10-30 minutes
- The surveys will cover topics including:
 - how certain you feel about donating
 - how well the smart phone app and counseling prepared you to donate
 - how satisfied you feel with making an informed decision about donating
 - demographics (e.g., age, marital status, education)
- The surveys will be done first in person (taking full safety precautions in light of COVID-19) or by phone before your clinic visit, then by phone with the Research Coordinator or as an online survey.

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2. Mobile App Use

- You will use a mobile app right after survey #1 for 5-7 minutes on your smartphone.
- If you do not have a smartphone, the Research Coordinator will give you a tablet to use.
- The app is a chatbot, which is a computer program that gives you information as though you are talking to a real person. It is called a chatbot because it takes the form of an online chat, as if you were texting or messaging someone.
- Chatbots are used in other areas of healthcare.
- This chatbot, called “GIA”, will give you basic genetic information to prepare you to meet with your kidney doctor this afternoon.
- You will review GIA in a private consultation room. The Research Coordinator will stay with you during that time to assist with any questions you may have.
- All the information you look up in GIA will be recorded by the company that makes GIA. In order to use GIA, the Research Coordinator will first create a record in GIA unique to you by entering your name, date of birth, and email address, and your study ID number.

3. Culturally Sensitive Counseling

- Your kidney doctor often counsels potential living donors about getting a genetic test and genetic test results, as part of routine care. Counseling means giving information, guidance, and emotional support.
- Counseling takes place in two separate meetings: one before testing (today), and one after testing (in weeks) and lasts 10-15 minutes each.
- If you agree to be in this study, your kidney doctor will counsel you using a new way of counseling (which is research) to see if we can remove racial bias in medicine and avoid racial stereotyping. Counseling will not take any longer than routine care.

4. Saliva Sample for Genetic Testing (this is optional)

- In routine care, kidney doctors decide on a case-by-case basis whether a potential living donor should get a genetic test done. In this study, all living donor candidates of African ancestry are being asked to get a genetic test done.
- In routine care, genetic testing occurs via blood draw. In this study, genetic testing will occur by giving a saliva sample.
- Your saliva will be tested for only 1 gene, and not for your full genetic profile.
- Giving a saliva sample will take less than 1 minute.
- You will give a sample in a private consultation room by the Research Coordinator.
- The genetic test results will be entered into your medical record and your transplant doctors will see the results.
- You will be asked if you agree to give a saliva sample after you meet with your kidney doctor.

5. Audio-Recording

- Your kidney doctor will likely talk about the option of genetic testing. The discussion will be audio-recorded to see if your doctor covered all the key points in counseling. Audio-recording is a required part of this study.
- Your kidney doctor will call you to share the genetic test results, counsel you for 10-15 minutes, and help make a decision together about donating.
- Your call with your doctor will be audio-recorded by the Research Coordinator to see if your doctor covered all the key points in counseling. Audio-recording is a required part of this study.

6. Medical Chart Review

- We will look at your medical records to track your genetic test results and track your kidney doctor’s counseling steps, starting today until we complete the final survey.

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Participation steps	Today: Before seeing the kidney doctor	Today: Kidney doctor counseling about getting the genetic test	Today: Immediately after kidney doctor counseling	6-7 days from today	In several weeks*: Kidney doctor call about genetic test results	1-2 days after the call with the kidney doctor	1 month** after donating or being ruled out for donation
First Survey	X						
Use GIA	X						
Counseling about getting a genetic test		X					
Saliva Sample			X				
Second Survey				X			
Audio-Recording		X			X		
Third Survey						X	
Fourth Survey							X
<p>* It takes, on average, 12 weeks to finish living donor testing to be cleared to donate, but it can take longer. It will take up to 2 weeks from today to get the genetic test results. The date when your kidney doctor will call you depends on when you finish all your living donor tests.</p> <p>** If we are unable to reach you to complete the follow-up surveys, we may attempt to contact you up until 12 months following donation, medical rule out, or withdrawal from living donor evaluation. Those who donate may be contacted at their 6-month or 12-month post-donation clinic appointment for the surveys.</p>							

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 to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.
- If you withdraw from one part of the study (e.g., surveys), you will be asked for permission to collect data from another part of the study (e.g., medical chart review).
- If you decide to leave the research, contact the investigator by email [\[akansha.agrawal@nm.org\]](mailto:akansha.agrawal@nm.org) so that she will know to not contact you in the future.

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

Many of the risks of being in the research are the same risks as routine donor evaluation. The risks are noted by X's in the table below.

Risks	Risks from Study Participation	Risks from Routine Care
Minimal Risks		
The risk of discomfort is low. Most survey questions should not cause distress, but some people might feel distress learning about genetic factors. You can skip any questions you do not wish to answer, or end the survey at any point.	X	
As with most survey studies, there is a small chance that people who are not members of the research team could get access to your study data (a loss of confidentiality and loss of privacy).	X	
Moderate Risks		
Genetic test results may cause you anxiety and other psychological distress, or could also affect your future relationships with the potential recipient.	X	X
You may be medically ruled out from donating based on your genetic test results and other clinical information.	X	X
There is a very small risk for genetic discrimination. These results will become part of your medical record. If released, the information could lead to life insurance discrimination, job, or social discrimination. However, a federal law, called the Genetic Information Nondiscrimination Act (GINA) , generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: <ul style="list-style-type: none"> • Health insurance companies and group health plans may not request your genetic information that we get from this research. • Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. • Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.	X	X
There may be unknown risks from participating in this research.	X	

How will you protect my confidentiality?

- This study involves the use of your identifiable, personal information. For any research study, it is not possible to guarantee complete confidentiality.
- In this research study, the chance of a loss of confidentiality occurring is very low. The research team will protect your confidentiality in many ways.
- We will protect your identifiable personal information by using number ID codes instead of your name or other identifying information in study records.

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- This consent form and all paper study documents will be kept in locked cabinets inside the research team's locked offices. Electronic data will be stored on secure, password-protected and encrypted servers at Northwestern University. Participants' anonymized data are kept separately from their identifiable information.
- Only the research team will have access to your study data in order to carry out this research study.
- The research team will not share your identifying information with people outside of the research team.
- Information collected from all participants will be analyzed together, and no identifying information will be used in any publication or report.

For more information, see the section below titled: **"What happens to the information collected for the research?"**

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.
- The cost of genetic testing will be paid for by the research study.
- You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others by being in this research.

However, possible direct benefits to you include:

- Receiving genetic test results and counseling may help you to:
 - Better understand your risks of donation
 - Feel more prepared to donate
 - Feel less conflicted about donating
 - Feel more satisfied with making an informed decision about donation
- Making informed decisions may better protect your safety

Possible benefits to others and society include:

- Improving the safety and informed consent for potential living donors of African ancestry in the future.
- Removing racial bias in medicine in order to avoid the dangers of racial stereotyping.

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.

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- The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.
- The company that makes GIA, called Invitae, will store your name, date of birth, and email address in a secure, encrypted, HIPAA-compliant database. Your information will not be used for any other purpose than for the present study. Your information and record will be deleted after 7 years.
- The genetic testing lab, called Knight Diagnostic Labs (KDL), will store your test results, name, date of birth, gender, ethnic identity, and medical record number in a secure, HIPAA-compliant database. Your saliva sample will be destroyed. Your information will not be used for any other purpose than for the present study. No further research will be done on your DNA and test results. Your information and record at KDL will be retained indefinitely as part of KDL's medical record.
- 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 will tell you about any new information that may affect your health, welfare, or choice to stay in the 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.

What else do I need to know?

Today	Baseline survey + chatbot use	\$20
7 days after today	Second survey	\$10
1-2 days after nephrologist counseling	Third survey	\$10
1 month after donating or rule out	Fourth survey	\$25
Total for completing all surveys		\$65

Compensation:

- If you agree to take part in this research study, we will pay you up to a total of \$65 for your time in the study. You will receive payments after completing surveys at the time points described in the table above.
- You will receive payment in the form of a virtual payment card or e-gift card that you will receive via email. After each timepoint described above, funds will be approved and loaded onto your virtual payment card. In order to process payment, we will need to obtain your name, email address, and mailing address at the time of your first interview.

Study Results:

- If you would like to see the results of the study, you may visit the following website, which will post published research and updates from the study: www.Apol1consent.org.

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HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes dates and information about the following:

- Nephrologist discussions about genetic testing, test results, and donation
- Doctor's order for genetic testing, including type of genetic test
- Genetic test taken and results
- Kidney-Pancreas Committee meetings and decisions
- Living donation, or rule out and reason
- Referral to genetic counselor and genetic counselor discussion

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Northwestern Memorial HealthCare. Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Members of the research team at Vanderbilt University Medical Center and Northwestern University who are also working on the study.
- Government agencies and public health authorities, such as the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

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PI's Name: Akansha Agrawal, MD
Institution: Northwestern University Feinberg School of Medicine
Departments: Department of Medicine, Division of Nephrology and Hypertension;
Department of Surgery, Division of Transplant Surgery
Address: 676 North St Clair Street, Suite 1900, Chicago IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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.

Optional Element:

The following research activity is optional, meaning that you do not have to agree to it in order to participate in the research study. Please indicate your willingness to participate in this optional activity by placing your initials next to the activity.

I agree

I disagree

The researcher may take a saliva sample from me in order for me to get the *APOL1* genetic test.

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

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Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent