Research Subject Informed Consent Form

Title of Study:	Evaluation of the Risk of Kidney Failure Among Living Kidney Donors by Presence of Genetic Variants Study ID #: s22-00888
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary, which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to learn about kidney donors’ attitudes toward genetic testing and willingness to complete testing for genetic mutations potentially associated with the risk of kidney disease. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

Scientists have found genetic mutations (also known as variants) in 385 genes associated with increased risk of kidney disease. Among those 385 genes, scientistshavefound two genetic variants on the APOL1 gene in different groups of people but more frequently found in people with African ancestry, including

Black Americans. Because a person inherits one copy of the APOL1 gene from each parent, a person may possess either zero, one, or two APOL1 variants. Recent studies have also found that having one APOL1 variant is associated with a small risk of developing kidney disease and kidney failure, while having two APOL1 variants has been associated with a higher risk of developing chronic kidney disease and kidney failure. However, the science exploring the relationship between APOL1 and kidney disease is new and there is no clear connection between APOL1 and kidney disease.

A positive genetic test result means that a person does have a genetic variant present, but it does not mean that the person will develop kidney disease and kidney failure. A negative test result means that a person does not have the gene variant present, but that does not mean they are less likely to develop kidney disease and kidney failure. There are several other factors that contribute to developing kidney disease, including health-related problems and family history of kidney disease.

You will have the opportunity to talk to a genetic counselor to learn more about genetic testing before deciding to participate in this study.

Another purpose of this study is to measure the prevalence of genetic mutations potentially associated with the risk of kidney disease among Black kidney donors. The information from this study will help us to better understand the impact of genetic testing in order to improve counseling and evaluation for potential living donors.

We are asking you to take part in this research study because you donated a kidney to another person and were identifiedin the Scientific Registry of Transplant Recipients (SRTR) database.

3. How long will I be in the study? How many other people will be in the study?

This study will last about 2 years, overall; however, your participation in this study will last for approximately 3 hours.

About 100 study subjects ages 18 and older are to be entered into this study. Some participants may be selected to participate in qualitative interviews, to which about 20-30 study subjects ages 18 or older will be entered. If you are asked to participate in the qualitative interviews your participation will last an additional 2 hours, one hour for each interview. We will schedule them at a time that is convenient for you.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

In this study, you will be asked to complete an online survey to confirm the information that was collected from you when you registered as a donor, genetic testing and genetic counseling. Once you consent to participate in this study, you will be presented with an online survey. Participants who are selected to participate in the qualitative interviews will be asked to complete one pre-genetic testing interview and one post genetic testing interview. The interviews are to assess your attitude, perception, and

experiences prior to undergoing genetic testing and following testing and genetic counseling. You are free to skip any questions that you prefer not to answer.

A testing kit will be shipped to you via a courier service. The kit will contain a saliva collection tube, instructions for obtaining a saliva sample, and instructions for how to ship your sample collection to Natera, the laboratory that will conduct the genetic testing. If you experience difficulty with providing a saliva sample or prefer to have blood drawn, instead, you will be able to have a blood draw arranged through Natera. If you have blood drawn, 6 ml, about 1 teaspoon will be collected. You will be tested for 385 genes potentially associated with kidney disease. The test used in this study, called Renasight, is commercially available for clinical use; however, it is considered investigational in the context of this research study because it has not been Food and Drug Administration (FDA) approved. The test is obtained in a specially certified laboratory. All results will be returned to you. If you test positive for any genetic mutation, you will have an opportunity to talk to a genetic counselor from Genome Medical about your results. The results of the test cannot be used to diagnose you with kidney disease without further clinical testing by other approved methods.

Regarding the qualitative interviews, we will conduct these interviews via zoom at a time of your choosing. We will audio-video record these interviews and take detailed notes afterward. We will do so only with your permission. You have the right to review and edit the recording to delete any material you do not want recorded. You may also ask us to turn off the recorder at any point in the conversation.

After the interview, the recording will be transcribed and a written copy will be sent to you for review. You may delete anything you do not want included in the interview.

At any time in the study, you may decide to withdraw from the study. If you withdraw, no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

Any identifiable medical information or specimen collected used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Risk of Study

You may experience frustration that is often experienced when completing surveys and interviews, including the risk of distress or anxiety of being recorded. Some questions may be of a sensitive nature, and you may therefore become upset as a result. If, however, you become upset by questions, you may stop at any time or choose not to answer a question.

There is also potential breach of confidentiality is a risk for subjects. Your contact information will be shared using encrypted software to minimize this risk.

There is also a risk that you might find your genetic testing results confusing or upsetting. You will have access to genetic counselors to help you understand your results and discuss any next steps, such as sharing this information with your healthcare provider, that you might wish to take.

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. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease. Health insurance companies and group health plans may not request your genetic information from this research and the Sponsor will not share this information with such companies, plans or employers.

6. What if new information becomes available?

During the course of this study, we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Incidental Findings for Genetic Research:
In this section, we are asking you to indicate whether or not you would like to know about any incidental findings. During the course of this study, we may incidentally find something on a part of your genome that's known to be associated with a certain disease or condition, as reported on your Renasight results. A physician co-investigator will contact Genome Medical to have a qualified genetic counselor evaluate this finding to determine whether or not there is any clinical impact on you or your family. If the finding is determined to have a possible clinical significance, a genetic counselor will speak to you on the telephone regarding the new information within 1 week of the finding. Incidental findings that have uncertain clinical implications or no known treatments or interventions may cause undue concern, anxiety, and worry. Those that identify a major health problem could be of great benefit.

If you would like to know about any incidental findings, it is important for you to know that when the PI or clinician perform tests in a certified laboratory, results will also be included in your medical record, which means that anybody authorized to see your medical record (i.e., your treating doctor) will have access to this information. There is no guarantee that all incidental findings will be identified through this research study.

It is possible that you may have a condition or genetic predisposition that we do not come across as part of this research. If you would like a comprehensive review of your genetic information, we recommend that you undergo further validated genetic testing and seek genetic counseling.

Below we are asking you to indicate whether or not you would like to know about any incidental findings as described above. Please initial one of the options below to confirm whether you would like to be informed of any incidental findings:

____ Yes ____ No

7. What are the possible benefits of the study?

You may not benefit personally from being in this study. However, you might feel that knowing your genetic testing results provides useful information to you or to your family members. We hope that the knowledge gained by doing this study will help others in the future.

8. What other choices do I have if I do not participate?

You may choose to not participate in this research study.

9. Will I be paid for being in this study?

You will be paid to take part in this study. We will pay you with *a* $50 Amazon Gift Card for the completion of the study survey, genetic testing and genetic counseling and an additional $50 for the completion of the interviews.

10. Will I have to pay for anything?

There will be no cost to you for being in this research study.

11. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all the visits, and all information has been collected. This study may also be stopped without your consent because:

- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

12. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

13. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in the section below. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- The study sponsor: Scientific Registry of Transplant Recipients (SRTR)
- Natera affiliated workers
- Genome Medical genetic counselors and affiliated workers

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at 212-263-4110.

When you sign this form, you agree to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

DC 05/08/2020