Informed Consent Form

Title: Reducing disparities in living donor transplant among African Americans

NCT Number: NCT03819686

IRB Approval Date: 03/23/2023

Emory University
Oral Consent Script
For a Research Study

Study Title: Reducing Disparities in Living Donation among African Americans
IRB #: IRB00098952
Principal Investigator: Rachel E. Patzer, PhD, MPH; Department of Epidemiology; Kimberly Jacob Arriola, PhD, MPH; Department of Behavioral, Social & Health Education Sciences (BSHE).
Funding Source: National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Introduction and Study Overview

Thank you for your interest in our Living ACTS research study. We would like to tell you everything you need to think about before you decide whether or not to join the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.

The purpose of this study is to learn more about what African Americans think and know about the option of living donor kidney transplant. It is expected that what we learn from you will give us specific information about how people can be educated about living donor transplant. You are being asked to participate because we are seeking African American adults aged 18 to 65 years, have a body mass index (BMI) less than 35, are English speaking, and have no cancer infection. Your participation will last until you've completed the post-study questionnaire. A total of up to 850 people will enroll in this phase of the study.

The study is funded by National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

This study will take about 1 hour and 30 minutes to complete.

If you join, you will be asked to take part in a study that involves you visiting a website designed to educate about living donor kidney transplant. First you will verbally complete a pre-study questionnaire. After that, you will view the website. You will then complete a post-study questionnaire, verbally. The study will take place during this Zoom video call. Over the next 12 months, we will get information from the Transplant Center on how many people called the center to learn about the possibility of serving as a living donor for you.

Some of the items on the questionnaires may bring up unpleasant feelings or make you feel uncomfortable. You can skip any question in the questionnaires that you do not feel comfortable answering. You can leave the website at any time and can stop taking part in the study at any time. There may be other risks, discomforts or side effects that are not yet known.

Taking part in this study may not benefit you, but we researchers may learn new things that will help others.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent

we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for this study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:
Medical information about you including your medical history and present/past medications.
Results of exams, procedures and tests you have before and during the study.
Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who Will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.

Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

The following people and groups will use your PHI to make sure the research is done correctly and safely:
Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
Government agencies that regulate the research including: [the National Institutes of Health].
Public health agencies.
Research monitors and reviewer.
Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Dr. Rachel E. Patzer at [redacted], or Dr. Kimberly J. Arriola at [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records

that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Compensation
You will receive $30 for completing this study.

Voluntary Participation and Withdrawal from the Study
You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. Any research information provided prior to your withdrawal will still be used by study staff.

Contact Information
If you have any questions about this study, you may contact Dr. Rachel E. Patzer at [redacted], or Dr. Kimberly J. Arriola at [redacted]

Contact the Emory Institutional Review Board at [redacted]
if you have questions about your rights as a research participant.
if you have questions, concerns or complaints about the research.
You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____

Name of Legally-Authorized Representative (if non-treatment study, must be parent/legal guardian of minor, or have Power of Attorney for Research)

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Relationship of Legally-Authorized Representative to Participant

_____ _____

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Signature of Person Conducting Informed Consent Discussion

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Date Time

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Name of Person Conducting Informed Consent Discussion