

## You Are Being Asked to Be in a Research Study

### **What Is a Research Study?**

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

### **Do I Have to Do This?**

**No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.**

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

### **What Is This Document?**

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

### **What Should I Do Next?**

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

**Emory University**  
**Consent to be a Research Subject / HIPAA Authorization**

**Title:** Social Stress, Inflammation, and Chronic Kidney Disease among African Americans

**Principal Investigator:** Kimberly Jacob Arriola, PhD, MPH; Department of Behavioral Sciences and Health Education (BSHE)

**Funder:** National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**Introduction**

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of 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 decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

**What is the purpose of this study?**

The purpose of this study is to determine whether stress related to race increases the risk of chronic kidney disease and poor kidney functioning in African Americans. You are being asked to take part of this study because you are a patient at Emory University Hospital Midtown who self-identifies as African American or Black, are between the ages of 25 and 65 and have chronic kidney disease (CKD).

**What will I be asked to do?**

Taking part in this study involves two clinic visits. If you agree to participate in this study, you will first complete a consent form and then will complete a questionnaire in a small private room at the Emory University Healthcare Nephrology clinic. A member of the research team will assist you with completing this survey if needed. At the conclusion of the questionnaire, you will be paid a part of the monetary incentive (\$50) and asked to wear an ambulatory blood pressure monitor (ABPM) for the next 24 hours. The ambulatory blood pressure monitor is designed to take your blood pressure throughout the day and night as you engage in your normal daily activities. This device has a blood pressure cuff attached to a small, 9 oz recorder (about the size of a cell phone) that can fit comfortably in your pocket. To maximize your comfort, you will be fit with a blood pressure cuff based on the size of your arm. The cuff will inflate every 30 minutes during the day and

every 60 minutes throughout the night. You will also be asked to record the time you fall asleep and the time you are awake while wearing the blood pressure monitor. *Because the device cannot get wet, you will be unable to shower or bathe while wearing the ambulatory blood pressure monitor.* Following the 24-hour blood pressure monitoring period, the monitor will need to be returned to the clinic staff when you return to complete the study (preferably between 9:00 AM and 12:00 PM the next day, or the following day). The project coordinator will help schedule your second clinic visit prior to you leaving.

Your second visit will take place at the Georgia Clinical and Translational Science Alliance in Midtown Atlanta. You will be asked to bring a list of current medications with you so that we may make note of them. During the session, you will first be asked to provide a urine sample and undergo blood pressure testing. Next, a research nurse will insert an intravenous catheter, allow for a 30-minute waiting period so that you can comfortably adapt to the catheter.

Next, you will be asked to recall a racial or non-racialized upsetting experience. Which event you will recall will be by random, and you have a 50/50 chance of getting chosen to tell the racial experience or the non-racialized story. As you are recalling your experience, someone from the study staff will assess any physiological changes you may experience while performing the recall task, such as any changes in your blood and blood pressure. There may also be up to 2 other trained study personnel in the room with you during this portion of the study. Study staff will also explain each step of this visit to you in real time. You will receive \$150 at the conclusion of Day 2 (\$50 for return of ABPM and \$100 for completion the recall task). Over the course of the study, you will provide up to 7 teaspoons of blood, and the sampled blood will allow us to examine the body's response to stress. In total, it will take you approximately 4.5 hours to complete this study, aside from you wearing the ABPM for 24-hours.

### **Who owns my study information and samples?**

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. You may request, however, to have your samples destroyed for use in any future research endeavors.

### **What are the possible risks and discomforts?**

Possible risks are related to: (1) the stress of the psychological tests/questionnaires/interview, (2) intravenous catheter and blood draw, (3) public speaking/mental stress test, and (4) blood pressure monitoring.

1. Psychological tests/questionnaires/interview. Being asked questions about the stress in your life may cause you to have unpleasant and/or upsetting feelings. If this happens, then you can take a break from the interviews. You can also slow down and take longer to do the tests. Should you so desire, a counseling session and/or referral for counseling will be made available.

2. Intravenous (IV) catheter and blood draws. The IV can result in infection, bruising of the skin, or a blood clot in the vein. These complications are not common when the catheter is inserted by a professional under clean conditions. You may have some discomfort from the blood drawing. The risk from blood drawing is minimal, but may include bruising and infection. The use of sterile precautions will decrease the risk of infection. However, you may develop a bruise at the site of the puncture, but this will go away in two to three days.

3. Public speaking/mental stress test. Public speaking with mental stressors may be associated with unpleasant or upsetting feelings. We do not feel that the amount of mental stress produced by this procedure is any greater than that which may be experienced during some normal everyday activities.

4. Blood pressure monitoring. Wearing the ABPM throughout the day and night may be inconvenient for participants, and some people may experience sleep disturbance while wearing the device at night. Some individuals might also experience some bruising where the cuff is located.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

#### **Will I benefit directly from the study?**

This study is not designed to benefit you directly, but we may learn new things that will help others in the future.

#### **Will I be compensated for my time and effort?**

You will be compensated financially for your time, inconvenience, and discomfort and to offset any expenses such as parking, gas, etc. You will receive \$200 total, \$50 following the initial clinic visit, and \$150 at the conclusion of the second clinic visit (pending successful return of the ABPM device). All payments will be in cash.

#### **How will you protect my private information that you collect in this study?**

Emory University and Health System 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.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

#### **How is my Genetic Information Protected? What are the Risks?**

The Genetic Information Nondiscrimination Act (GINA) is a federal law that 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:

- 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 GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

#### Privilege

In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

#### Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results may be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and may not be placed in your medical record. For this study, those items include:

1. Laboratory test results
2. Some blood pressure readings

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know

**In Case of Injury**

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Emory and the funder have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Kimberly Arriola at telephone number 404-727-2600 or Melissa Williams at 404-727-2386. You should also let any health care provider who treats you know that you are in a research study.

**Costs**

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Emory and the funder have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Kimberly Arriola at telephone number 404-727-2600 or Melissa Williams at 404-727-2386. You should also let any health care provider who treats you know that you are in a research study.

**Withdrawal from the Study**

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

**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 the main study and for any optional studies in which you may choose to participate.

**PHI that Will be Used/Disclosed:**

The PHI that we will use or share for the main research study includes:

- Demographic information such as your name, date of birth, and other identifiers
- Medical information about you including your medical history, previous study results, events, 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 use and share your PHI to provide you with study related services and for payment for the study services. 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 (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the funder of the study. The funder 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 funder 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 Office for Human Research Protections.

- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.

**Expiration of Your Authorization**

As this is a research study, your authorization will not expire. You may, however, revoke your authorization later.

**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:

Kimberly Arriola, PhD, MPH  
Professor  
1518 Clifton Rd NE, Room 512  
Atlanta, GA 30322

Melissa Williams, MPH  
Clinical Research Coordinator II  
1518 Clifton Rd NE, Room 738  
Atlanta, GA 30322

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 main 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



A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

### **Contact Information**

Contact Dr. Kimberly Arriola at 404-727-2600:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [irb@emory.edu](mailto:irb@emory.edu):

- 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 and Authorization**

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#### ***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject (18 or older and able to consent)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Signature of Legally Authorized Representative with authority for research decisions

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

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#### ***TO BE FILLED OUT BY STUDY TEAM ONLY***

\_\_\_\_\_  
Name of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time