# Mental Stress and Myocardial Ischemia after MI: Sex Differences, Mechanisms and Prognosis

IRB00113346

Date: March 14, 2024

NCT04123197

# You Are Being Asked to Be in a Research Study

**Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 420 people who are being studied, at Emory.

**Why is this study being done?**
This study is being done to answer the question: does emotional stress increase the risk of heart disease and how this might be different in men and women. You are being asked to be in this research study because you have recently been hospitalized for a heart attack and you are less than 61 years old.

**Do you have to be in the study?**
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

**What do I have to do if I choose to participate in this study?**
If you are eligible and want to be part of the study, you will participate for 1 study visit, 1 week of at home monitoring, and 3 years of follow up phone calls. The researchers will ask you to do the following: blood testing, questionnaires/interview, SPECT scan at rest and after a mental stress task, vascular function testing, ECG/sleep/activity monitoring. All of these procedures will be paid for by the study.

**How is this study going to help you?**
If you are in the study, you will be helping the researchers answer the study question.

**What are the risks or discomforts I should know about before making a decision?**
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

**Alternatives to Joining This Study**
Since this is not a treatment study, the alternative is not to participate.

**Costs**

You WILL NOT have to pay for any of the study procedures. There is more information in the cost section below.

**What Should I Do Next?**

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

**Emory University and Grady Health System**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Mental Stress and Myocardial Ischemia after MI: Sex Differences, Mechanisms and Prognosis
**Principal Investigator:** [redacted], MD, PhD
**Sponsor:** National Institutes of Health

**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.

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.

**What is the purpose of this study?**
The purpose of this study is to look at the link between emotional stress and heart disease in men and women.

**What will I be asked to do?**
Taking part in this study involves one clinic visit, one week of at home monitoring, and follow up phone calls for 3 years. The clinic visit will take around 5-6 hours. The follow up calls will take around 15-20 minutes every 6 months for 3 years.

**Procedures**
The day before your appointment you will be asked not to eat or drink anything except water after midnight. You will also be asked to not take certain medications on the morning of your visit. The study team will go over this with you during scheduling.

On the day of your visit, you will come to the Emory Campus, where a member of our research team will meet with you in a private room and discuss the consent with you to be sure you understand the study procedures before signing. You will then have a health assessment and blood work. We will draw around 3 tablespoons of blood to measure risk factors for heart disease (for example, cholesterol and sugar). We will also do other tests, for example we will check that your kidneys work properly and, for women of childbearing potential, do a urine test to determine that you are not pregnant. You will also fill out some questionnaires about your health and the stress that you may have had or are currently experiencing and we will conduct a psychiatric interview with you.

Before you have the SPECT scan you will have a small needle (intravenous catheter or IV) placed in your arm by a doctor, nurse, or Certified Nuclear Medicine Technician. A radioactive substance will be given through the IV. This will be used to give a picture of the blood flow in the heart. We will continuously monitor your electrocardiogram (ECG), blood pressure and heart rate.

For the SPECT scan you will be asked to lie very still on a narrow table and a flat camera will slide over you and take a picture of your heart. The camera does not come into contact with any part of your body. We will take two pictures of your heart using a SPECT scan. The first scan will be taken at rest. You will then be asked to prepare for and deliver a 3-minute speech in front of a small audience and video camera (mental stress testing). During this test you will receive an injection of a radioactive compound that allows for measurement of blood flow in the heart. You will also be wearing the sensor on your finger for the PAT test during and after your stress. Following this, you will have the second SPECT scan. Again, you will be asked to lie very still on a narrow table and a flat camera will slide over you and take a picture of your heart. We will also collect blood from the IV before, during and after the stress test (a total of around 2 tablespoons), and take measurements of blood pressure and heart rate. The blood will be drawn to measure substances (stress hormones, for example cortisol, inflammatory markers, and markers of cellular aging) that will allow us to examine the body's response to stress. We will also process the blood in a gene sequencing laboratory to measure your genes and investigate the way in which stress affects your heart because of hereditary factors. This information will not be shared with anyone outside of research, and they will be blinded to your identity.

A video recording of your speech may be obtained using the video camera. These recordings will be used for research purposes to look at facial expressions and to obtain information on emotions related to stress. The recordings will be stored with your patient ID and the date. No other private information will be on the recording. The investigators, research team, and trainees working with the investigators will have access to the recordings. These will be kept in locked cabinets inside locked offices until all of the work with study data is completed. After work with the study data is complete the recordings will be destroyed.

We will also run 2 tests that help us determine the health of your blood vessels and their reaction to stress. For the first test, flow mediated dilation, (FMD) is an ultrasound examination of the arteries of your arm. First, we will take readings of blood flow in one of the arteries of your arm. Then a blood pressure cuff will be placed around the widest part of your forearm and will be inflated so as to stop the flow of blood for 5 minutes. After 5 minutes, the blood pressure cuff will be deflated and the readings taken again. For the second test, peripheral arterial tonometry, (PAT), we will attach a thimble-shaped sensor on one fingertip as an additional way to measure your blood vessel health. After the sensor has been placed on your finger, you will sit quietly for about 30 minutes.

We will run the FMD test which measures the health of your blood vessels before and after the stress testing. The PAT test will take place before, during, and after the mental stress testing.

Throughout the heart scans you will wear a device called a "Holter monitor". This is a non-invasive device that monitors the heart continuously. It consists of electrodes (round sticky patches) applied to the chest which are similar to those used for recording a standard ECG (a tracing of your heart beats). The electrodes are attached to a small cassette recorder, similar in size to a cell phone. It is worn on a belt or on a strap around the neck. The Holter data will be used to monitor changes in the heartbeat due to stress. An investigational (or experimental) heart patch that has not been reviewed by the FDA for safety, effectiveness or quality, may also be worn to assess changes in heart motion with stress.

We would like to collect oral samples using a cotton swab (like a Q-tip) and using a saliva collection tube during various time points of the visit. We will take these swabs/tubes to the research laboratory to find out about the types of bacteria that live in the mouth among other things. The bacteria that live on and in the human body (called the microbiome) may tell us more about our health.

After your first visit, you will be given items to take home for an additional 1 week of monitoring. We will send you home with an activity monitor to wear on your wrist of either arm as well as an ECG patch. These are waterproof and can be worn in the shower. These will help us to understand how physical activity and sleep affect your heart. A smartphone may also be sent home with you or we can help you download the survey app on your own phone. We may ask you to rate your stress levels several times per day and/or we may ask that you complete a few surveys about your sleep, activities, and mood. We will collect the monitors from you along with surveys using a prepaid mailer.

Successful return of the activity monitor, patch, smartphone and/or tablet, and surveys will be included as a requirement for your study compensation. The Emory study team is responsible for the payment and/or fees related to the smartphone. If the smartphone is broken, stolen, or lost the Emory study team will pay for a new device; you will not be charged. The smartphone can be remotely wiped of any data if needed. In certain cases, we may ask you to repeat the 1 week of at-home monitoring (wearing the activity monitor, ECG patch, and/or completing surveys about your sleep, activities, and mood using a smartphone or similar device). These would be mailed and a prepaid return mailer would be provided to you.

Every 6 months, for 3 years, we may call you to go over how you have been doing since your last visit/call. The calls will take around 15 minutes to complete. We will ask you about any hospitalizations and tests you have had, medications, and may ask you to repeat some questionnaires that were done at the original visit. Medical records from hospitals and/or doctor's offices will need to be reviewed by the study team.

**Optional Studies**

**Future Contact** - In the future, we would like to contact you. One purpose of this contact would be to update our study records. Another purpose would be to offer you the opportunity to participate in additional studies. This future contact would be made by one of the investigators, coordinators, or recruiters of this study. The contact would initially be made by phone, email, or by sending you a letter in the mail. This contact might include a questionnaire for you to fill out and return. If you do not want to participate or fill out the questionnaire, you will simply be asked to return a card in the mail to us, email, or call us. If we do not hear from you then we may have our study coordinator call you. There is no additional compensation for this future contact.

**Home monitoring** – You may be given or mailed items for an additional 2-7 days of home monitoring. We may send you an activity and/or blood pressure monitors to wear on either arm as well as an ECG patch. These will help us understand how physical activity, blood pressure, and sleep affect your heart. A smartphone may also be sent home with you, or we can help you download the survey app on your own phone to measure stress and behaviors. We may collect the monitors from you along with surveys using a prepaid mailer or ask you to drop them off with us afterwards. Successful return of the study devices will be included as a requirement for your compensation. The Emory study team is responsible for the payment and/or fees related to the smartphone (if provided). If the smartphone is broken, stolen, or lost the Emory study team will pay for a new device; you will not be charged. The smartphone can be remotely wiped of any data if needed. In certain cases, we may ask you to repeat the at-home monitoring (wearing the activity/BP monitor, ECG patch, and/or completing surveys about your sleep, activities, and mood using a smartphone or similar device. These would be mailed, and a prepaid return mailer would be provided or we may ask you to drop this off with the study team.

**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.

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

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

1. Intravenous (IV) catheter and blood draw. Placement of an intravenous catheter for the SPECT scan and blood draws can result in infection, bruising of the skin, a blood clot in the vein, and/or occasionally people have episodes of dizziness or fainting. These complications are not common when done by a professional under sterile conditions. However, you may develop a bruise at the site of the puncture, but this will go away in two to three days. You may have some discomfort from the blood drawing.
2. Holter/ECG patches, activity/sleep monitoring, and Biopac. The holter monitoring and patch (worn during study visit) and ECG patch (worn during study visit and at home) requires you to wear a small device and sticker(s) on your chest, which may represent an inconvenience to you. The adhesive may also cause mild skin irritation or itching. The activity/sleep monitor requires you to wear a bracelet-type device which may represent an inconvenience to you. We may also ask you to wear a wrist monitoring device in the lab. The Biopac may cause mild skin irritation or itching.
3. Fasting. In order to undergo study testing, you need to be fasting from around midnight the night before your study visit until the SPECT scan is completed. Some people may show discomfort from this prolonged fasting, although true hypoglycemia is rare. A sweetened beverage will be administered if patients complain of lightheadedness or other fasting-related symptoms
4. 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.
5. The ultrasound of your arm blood vessels. While the blood pressure cuff is inflated for 5 minutes, you will likely experience mild discomfort at the cuff site and tingling of your left arm, as if it has gone to sleep. The tingling in your arm will go away quickly as blood flow returns in your arm.
6. Mental stress test. Public speaking with mental stressors may be associated with unpleasant or upsetting feelings. 1 in 20 subjects may experience some increased chest pain and 1 in 10 subjects may show some changes in their electrocardiogram (ECG) patterns. The ECG will be monitored and study staff will be present to administer and monitor this procedure. 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.
7. The SPECT scan with a radioactive substance. Some people experience anxiety from the SPECT scans procedure. Study staff will be with you during the procedure. This research study involves exposure to radiation from the SPECT scans. These procedures are routinely used for medical purposes. This radiation dose may not be necessary for your medical care and will occur only as a result of your participation in this study. The radiation dose that you will receive for all scans is estimated to be equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal. The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks.
8. Reproductive Risks**. Women please note**: Since this research may have bad effects on a fetus and should not be done during pregnancy, it is necessary that a pregnancy test be done first, even if, to the best of your knowledge, you are not pregnant now. If the test is positive you will not be able to participate in the study. This study may be hazardous to a breast-feeding child. Breast feeding mothers may not participate in this study.

   Women who may be pregnant should not be in this study because of possible effects of radiation exposure on their unborn child. Both men who may later father children and women of childbearing potential should be aware that exposure to radiation poses a very slight risk of genetic mutation in the next generation.
9. Video Recording. The video recording may make you feel uncomfortable. Recording will be stopped at the end of the speech task. All recordings will be coded with ID and date and stored in a locked cabinet inside a locked office.

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. This study is designed to learn more about emotional stress and heart disease in women and men. The study results may be used to help others in the future.

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

You will get $250 for the completed study visit and $150 for the 1 week of at home monitoring, to compensate you for your time and effort. If you are asked and decide to participate in the optional 2-7 days of at-home monitoring, we would compensate you an additional $150. Payment will be processed after the return of the study equipment and completion of the surveys. You will get $400 total, if you complete the study visit and monitoring. If you participate in the optional 2-7 days of home monitoring or are asked to repeat the week of home monitoring you would be compensated an additional $150. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. Another method of payment is using "ClinCard", which works like a debit card and is provided by Greenphire. When visits are completed or equipment with sufficient data are returned, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. To issue your card, we need to give Greenphire some of your personal information. If you do not wish to provide this information, you can still take part in the study, but you will not be paid (or paid through a different mechanism if applicable). Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep your social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

**What are my other options?**

If you decide not to enter this study, there is care available to you outside of this research study. This study is not designed to prevent or treat you. The alternative to participating in this study is to not participate.

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

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

**Certificate of Confidentiality**

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in

this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

You will be getting scans for research purposes only. The research does not require the scan to be read for healthcare purposes. However, if the researchers are concerned about something they see on the scan they will tell you, and ask you if you want the scan to be reviewed for healthcare purposes (possibly by other clinicians), and you may then be referred for medical treatment. You or your insurance company may have to pay for the review for healthcare purposes, and for any such treatment.

**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, in some circumstances your genetic information has may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

**Medical Record**

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System 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 and Grady Health System medical record you have now or any time during the study.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System 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 will *not* be placed in your medical record. For this study, those items include:

1. All labs, oral swabs
2. SPECT scans (rest and mental)
3. Ultrasounds, vascular function testing
4. Psychiatric assessments/interviews
5. Holter HRV/ECG monitoring, heart patches
6. Activity and sleep monitoring
7. Blood vessel tests (PWV, FMD, PAT, and BP measurements)
8. Video recordings

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System 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 believe you have become ill or injured from this research, you should contact Dr. [redacted], MD, PhD at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Neither Emory, and Grady Health System, nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, and Grady Health System and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Grady Health System, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Grady Health System employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

**Costs**

*There are no costs, research or standard of care related, associated with the study*.

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

**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.

### Main 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 use and share your PHI to provide you with study related treatment and for payment for such treatment. 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.

**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.

**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.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related procedures and to run normal business operations.
- Greenphire, an independent company specializing in payments for research studies and clinical trials.
- 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 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.
- Outside laboratories hired by the researchers to analyze specimens.
- Other researchers who may conduct future research.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System 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 Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

**Optional Studies: FUTURE RESEARCH CONTACT, 2-7 DAY AT-HOME MONITORING:**

**Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study**:

You do not have to authorize the use and disclosure of your PHI for the optional study. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study, but you can still be in the main research study.

**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:
[redacted], MD, PhD
[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 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 besides this study.

**Contact Information**
Contact [redacted] at [redacted]:

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

Contact the Emory Institutional Review Board at [redacted] or [redacted] or [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.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at [redacted].

**Consent and Authorization**

**Consent and HIPAA Authorization for Optional Study:**
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study previously described:

**Future research contact _____Initials**

**2-7 Day at-home monitoring _____ initials**

---

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

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and the optional study you initialed above. 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**

---

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

_____
**Name of Person Conducting Informed Consent Discussion**

_____ _____
**Signature of Person Conducting Informed Consent Discussion** **Date** **Time**