Healing Hearts, Mending Minds in Older Persons Living with HIV

Informed consent version date: March 14, 2018

NCT02711878

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

Title: Healing Hearts, Mending Minds in Older Persons Living with HIV

Short Study Title: FiT BRAiN

Principal Investigators: Drenna Waldrop-Valverde, PhD, School of Nursing
Rebecca Gary, RN, PhD, FAHA, FAAN, School of Nursing

Sponsor: National Institute on Nursing Research (NINR), National Institutes of Health (NIH)

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 see if exercise is helpful for improving memory, concentration thinking abilities, physical function and quality of life of 160 adults, 40 to 89 years of age living with HIV. The study will be conducted on Emory University's campus, the Ponce clinic, Emory Midtown Clinic, or Absolute Care Clinic. The exercise intervention will last for 13-15 weeks and you will take part in up to 7 study visits over 14 months after you start the study plus 4 group study visits. The study will test 2 kinds of intervention exercises: one group will walk for exercise and the second group will stretch for exercise. Members of both interventions will be asked to participate in one-on-one interviews/assessments, measures of physical functioning, and some sessions with others who are also enrolled in the study. The table below describes the study visits.

What Will I Be Asked to Do?

Schedule of Study Visits	
Study Visit 1 (BL1 – Week 1)	You will be asked to do a 6 minute walk test, answer some questions about your medical history and do a treadmill test (walking at a steady pace and walking uphill at a steady pace). You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. All of these activities will take about 2-2½ hours of your time. These activities will be done before the intervention starts.
Study Visit 2 (BL2 – Weeks 2-3)	You will be asked to give a blood sample (about 2 tablespoons of blood – 30 mLs) after overnight fasting. That means no eating between 4 am – 11 am, no caffeine (preferably only water) and to refrain from certain medications. In addition, you will have a blood pressure cuff placed on your arm and special recording devices (ultrasound) that will measure the blood flow in your arm. You will also be asked to perform some activities to check your memory and attention. You will also be asked to answer some questions about your mood, exercise, sleep and other survey questions. You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level.

	These activities and questions normally take about 3-3½ hours to complete. You will also be randomized into one of two groups: 1. The Let's Move Group or 2. The Let's Flex Group. Depending on which group you are randomized to you will be provided instructions specifically for that group. This will include paperwork you will be given to fill out during the time you are part of the study, information about equipment you might need to use and different ways that the research staff can contact you while you are part of the study. This part will normally take about 1 hour to complete.
Group Motivation Sessions (Weeks 5-8)	After you have been randomized to one of the 2 groups and receive your instructions, you will be asked to attend 4-group sessions to take place once each week for four weeks. These groups will include other people who are also part of the study. These group sessions will take about 1-1½ hours each week for 4 weeks in a row. These sessions may be audio or video taped for quality control purposes only.
Study Visit 3 (T1a – Week 15-17)	You will complete a 6 minute walk test, answer some questions about your medical history and maybe do a treadmill test. You will also be asked to give a blood sample after overnight fasting. You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. All of these activities will take about 2-2½ hours of your time.
Study Visit 4 (T1b – Week 15-17)	You will complete some activities to check your memory and attention. You will also be asked to answer some questions about your mood, exercise, sleep and other survey questions. You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. These activities and questions normally take about 3-3½ hours to complete.
Study Visit 5 (T2a – Week 28-30)	You will complete a 6 minute walk test and instead of a treadmill test you will have a blood pressure cuff placed on your arm and a special recording device (ultrasound) that will measure the blood flow in your arm (same as in visit 2). You may be asked to provide urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. All of these activities will take about 1½-2 hours of your time.

Study Visit 6 (T2b – Week 28-30)	You will complete some activities to check your memory and attention. You will also be asked to answer some questions about your mood, exercise, sleep and other survey questions. You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. These activities and questions normally take about 2½-3 hours to complete.
Study Visit 7 (T3 – Week 54-58)	You will complete a 6 minute walk test. You will also be asked to give a blood sample after overnight fasting. You will also be asked to perform some activities to check your memory and attention. You will also be asked to answer some questions about your mood, exercise, sleep and other survey questions. You may be asked to provide a urine sample for a drug screen and take a breath analyzer to screen for blood alcohol level. All of these activities will take about 3½-4 hours of your time.

Intervention Group Activities

You will be placed in the walking intervention or the stretching intervention by random assignment – like flipping a coin. If you are placed in the walking intervention, the following activities will take place as part of the intervention.

If you are placed in the walking group, the following activities will take place:

- You will be asked to walk 5 times per week for 12 weeks for a minimum of 30 minutes. As you progress throughout the study period your walking time and how hard you feel your body is working will increase as you become more conditioned.
- During the first 2 weeks of the program, a member of the research team will contact you to talk about your walking and to be sure you feel safe doing your exercise.
- You will be asked to use a Fitbit, a heart rate (HR) monitor and/or a pedometer when you go walking. We will give you instructions on how to use this equipment and set up an account where we can monitor your number of steps, heart rate and exercise duration for up to 12 months.
- After the first 1-2 weeks of walking, you will be asked to attend 4 consecutive group meetings at Emory University's School of Nursing or other selected site to discuss how you are progressing with your walking and ways to keep you interested in your exercise.

- During the group meetings, a member of the research team will look at your walking logs and will download your Fitbit and/or pedometer data to a computer that will be used to help you better focus your walking progress.
- You will also receive telephone calls each week by a member of the research team to monitor your walking progress and to change your walking duration or intensity level based on your progress.
- It is expected that the walking will take about 150 to 300 minutes weekly during the study.
- You will receive educational materials and exercise information that may be discussed during the course of the study as well.

If you are placed in the stretching group, the following activities will take place:

- You will be asked to stretch up to 5 times per week for 12 weeks for a minimum of 30 minutes. As you progress throughout the study period your stretching time and how hard you feel your body is working will increase as you become more conditioned.
- During the first 2 weeks of the program, a member of the research team will contact you to talk about your stretching and to be sure you feel safe and comfortable doing your stretching.
- After the first 1-2 weeks of stretching, you will be asked to attend 4 consecutive group meetings at Emory University's School of Nursing or other selected site to discuss how you are progressing with your stretching and ways to keep you interested in stretching.
- During the group meetings, a member of the research team will look at your stretching logs and that will be used to help you better focus your stretching progress.
- You will also receive telephone calls each week by a member of the research team to monitor your progress and to change your duration or intensity level based on your progress.
- It is expected that the stretching will take about 90 to 180 minutes weekly during the study.
- You will receive educational materials and stretching information that may be discussed during the course of the study as well.

Activities

You will be asked to come to a special part of Emory University Hospital that provides a special space and staff for research studies, called the Clinical Research Network (CRN). Activities will involve overnight fasting (which means no eating/no food) (between 4 am – 11 am) before you begin the study.

You will have about two tablespoons (30 mLs) of blood taken from your arm. The blood will be used to see how the walking/stretching affects your memory and thinking abilities. Your blood will be coded, labeled and stored in a special freezer until it can be analyzed. When the study is completed, the blood sample will be destroyed. Your blood sample will not be used for any other purpose than described here.

The treadmill test will measure your fitness level and takes 30 minutes or less to complete for most people. You will be asked to breathe in a mask while seated for about 2 minutes to measure your resting oxygen use. You will continue to wear the mask during the treadmill test. Before getting on the treadmill, your vital signs will be taken and a machine will measure your heart rate and rhythm. You will be asked to walk on the treadmill for one minute to warm up. Once the treadmill test starts you will have your heart rate recorded and monitored and your blood pressure will be taken every 5 minutes. You will walk at a constant rate of 3.2 mph during the treadmill test and experience a gradual incline every 2 minutes while breathing into a mask. Each time the treadmill incline goes up you will be told ahead of time. You will be asked to continue to walk on the treadmill until you feel that you cannot walk any further.

The forearm test will measure how well your blood is passing in your arm and gives a good idea about how blood is flowing in other parts of your body. You will have a blood pressure cuff placed around one of your arms. The blood pressure cuff will be inflated and a special ultrasound device will measure the blood flow in your arm before and after the measurements.

After completing the activities at Visit 1, including the treadmill, and you have been cleared by the study cardiologist, you will be given an appointment for Visit 2. At Visit 2 you will be asked to come back to Emory University's School of Nursing and/or the Clinical Research Network to complete blood draw, forearm test and several activities to check your memory, attention and thinking. You will also be asked to fill out several surveys. You may request to stop and rest at any time during the procedures. Before you complete Visit 2 you will be randomized to one of the 2 exercise groups and provided with information for that group. You will be asked to do these same activities listed above at study Visits 3 through 7 as listed in the table above.

Prior to each visit you might be asked to provide a urine sample and/or breathe into a breath analyzer. The urine sample will be used to screen for COC (cocaine), THC (marijuana), OPI (opiates), AMP (amphetamine), and mAMP (*meth*-amphetamine). The breath sample will be used to check blood alcohol concentration. The results of these tests will **only** be used to

determine if you can continue and complete the various activities listed above or if your visit needs to be rescheduled. The results of these screenings will NOT be shared with anyone else.

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:

- becoming short winded or tired,

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

- have a rapid or irregular pulse,
- have high or low blood pressure changes,

Rare but possible risks include:

- develop chest pain or feel lightheaded,
- you could fall while on the treadmill test
- bone or muscle pain which is also rare.

The treadmill test will be administered in the Clinical Research Network (CRN) clinic at Emory hospital by an exercise specialist. In addition, if an adverse event should occur, nurses, doctors and emergency equipment are available nearby to help you, which rarely occurs. A continuous EKG will be taken. If there are any abnormal EKG changes during the treadmill test, it will be stopped right away. If there are any negative vital sign changes such as lower or higher BP, irregular heartbeats, chest pain or dizziness the study cardiologist (Dr. Quyyumi) will be notified. If treatment is necessary you will receive emergency treatment in the CRN and transferred to the ER for further watching, which rarely occurs.

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.

Walking-Related Risks

The risks of the walking program are expected to be very small. Any potential heart problem that poses risk to you should be found during the treadmill test. In addition, the walking time will be limited to 30 minutes during the first 2 weeks and at an intensity level that is not likely to result in any heart or other health problems; if necessary you can rest as much needed until the 30 minute duration of walking is completed.

You will be asked to wear a Fitbit or a special Heart Rate (HR) monitor so that how hard you feel you are working can be closely watched. A research team member will review some safety information prior to walking at home without someone; the risk associated when you are walking alone therefore, is anticipated to be very minimal. You will be provided with detailed directions on how to self-monitor your heart rate, blood pressure and symptoms associated before, during and after walking.

Also, you will be given a target heart rate range to stay within during the study period. You will be asked to wear the Fitbit or Polar HR monitor during each walking session. You will be asked to take your heart rate prior to and after each walking session and record it in your walking calendar. You will be asked to call the research staff if your heart rate or blood pressure is outside your normal range. You will be asked to take your medicines as usual prior to walking.

You will be shown how to wear the Fitbit or heart rate monitor by a research staff. When your heart rate approaches 5-10 beats of the target heart rate range you will be asked to slow the walking pace down. In addition, you will be instructed to monitor your rate of perceived exertion (RPE), or how hard you feel you are working during the walking session. You will be given instructions on how to monitor your rate of perceived exertion (RPE) using the Borg 6 to 20 scale, and to keep your RPE at 12-13 during the initial weeks and to gradually progress with instructions to 15 as directed.

For safety reasons, you will be asked to carry a cell phone when you walk at home in the event of an emergency or sudden event.

Stretching Related Risks

Minimal risks are associated with stretching. Care should be taken to stretch at a comfortable level and to move slowly from one position to another.

Blood Draw-Related Risks

The blood sample will be collected by research staff or a laboratory assistant trained in blood drawing techniques at Visit 2, Visit 3, Visit 5 and Visit 7. Slight bruising at the site of the needle stick is possible. You may also feel dizzy or faint when your blood is drawn. If you are on blood thinner medications, there will be additional pressure to the site until it stops bleeding.

Other Study-Related Risks

Measuring the blood flow in your arm may be painful. The blood pressure cuff is pumped up to very high levels that may be briefly painful. After the procedure the pain goes away very fast. You will have sticky pads placed on your chest for the EKG to be taken. This may cause some discomfort when the pads are removed especially if you have hair on your chest.

For some people answering questions or filling out surveys can be stressful. One of our surveys will ask you about depressive symptoms and suicidal thoughts. If you report that you are having suicidal thoughts, the study psychiatrist (Andrew Miller, MD) and/or the Principal Investigators(s) will be contacted so that he/they can talk with you. You may be referred for mental health care by the study psychiatrist. We can also help you find a counselor if you are feeling depressed.

Disclosure and awareness of drug and alcohol screenings can also be stressful. The results of these tests will **only** be used to determine if you can continue and complete the various activities listed above or if your visit needs to be rescheduled. The results of these screenings will NOT be shared with anyone else.

Will I Benefit Directly From the Study?

The benefits to you for taking part in this study may be that you have better memory and thinking abilities, be better able to perform your day-to-day activities and better quality of life. What is learned from this study may be useful to other people who are living with HIV and who have memory issues. Doctors and nurses may also benefit from the information in this study by learning how to manage HIV patients with similar memory concerns and reduced physical function. While the study is designed to benefit you it is possible there will be no benefit from being in this study.

Will I Be Compensated For My Time and Effort?

You will be paid $50 for Visit 1, $65 for Visit 2, $20 for Visit 3, $20 for Visit 4, $30 for Visit 5, $30 for Visit 6 and $100 for Visit 7 for your participation. In addition, you will be paid $20 for attending each of the group sessions for a total of $80 for the 4 group sessions. If you stay and

complete the study you will receive a total of $395 for your participation for attending all the study visits and group sessions (over 54-58 weeks/14 months). You will not be paid for telephone calls. As a token of appreciation, you will receive study related promotional items as you complete visits. Some transportation costs (i.e. study staff created transportation services, parking and/or Marta can be compensated).

What Are My Other Options?

You do not have to take part in the study in order to receive treatment. If you decide not to enter this study, there is care available to you outside of this research study. Other procedures and/or treatments that you have been receiving or are currently receiving from your doctor will continue.

How Will You Protect My Private Information That You Collect in This Study?

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory Health System employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance, the Office for Clinical Research, the Radiation Safety Committee, Grady Research Oversite Committee, etc. Study sponsors may also look at your study records. Emory 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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, [except as explained below].

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a

member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities such as child abuse and neglect, or harm to self or others.

Storing and Sharing Your Information
Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

Medical Record
If you have been an Emory or Grady Health System patient before, then you already have an Emory or Grady Health System medical record. If you have never been an Emory or Grady Health System patient, you do not have one. Please note that an Emory and/or Grady Health System medical record will be made for you if an Emory or Grady Health System provider or facility gives you any services or procedures for this study.

If you agree to be in the study, a copy of the consent form/HIPAA authorization that you sign will be put in any Emory and/or Grady Health System medical record you have now or any time during the study.

Emory and/or 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/or 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. Some 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: results from blood draw, measures of how well your blood is passing in your arm, 6 minute walk test,

treadmill test, any information collected from the computer survey and any results from the memory or attention activities.

Tests and procedures done at non-Emory and non-Grady Health System places may not become part of your Emory and/or Grady Health System medical record. Emory Health System and/or Grady Health System will not send any test or procedure results from the study to these providers. 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 and Grady Health System will help you to get medical treatment. Emory and Grady Health System and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Grady Health System or sponsor 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. Drenna Waldrop-Valverde at telephone number 404-712-9487 or Dr. Rebecca Gary at telephone number 404-712-8993. You should also let any health care provider who treats you know that you are in a research study.

Costs

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.

Withdrawal From the Study

You have the right to leave a study at any time without penalty. Your participation in this study is completely voluntary and you have the right to refuse to be in the study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.

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, you do not follow study instructions or if you were to object to any future changes that may be made in the study plan. You maybe also asked to return any devices provided if you are removed from the study.

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 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:

- 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 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 and Grady Health System 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 Institute on Nursing Research, 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.
- 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 IRBs, the Grady Research Oversight Committee, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration; Veterans Administration].
    - 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.

Expiration of Your Authorization
Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.

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: 404-712-9487.

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.

Contact Information

Contact Dr. Drenna Waldrop-Valverde at 404-712-9487 or Dr. Rebecca Gary at 404-712-8993:

- 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 404-712-0720 or toll-free at 877-503-9797 or 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.

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 research@gmh.edu.

Participating in Future Research Studies

We would like to contact you in the future to see if you would be interested in participating in other research studies conducted by Dr. Waldrop-Valverde. Please indicate below by initialing if you are willing/not willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

Consent and Authorization

TO BE FILLED OUT BY PARTICIPANT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be a volunteer for research 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 this consent form to keep for your records.

_____	_____	_____
Participant's name (printed)	**Date**	**Time**
_____	_____	_____
Participant's name (signature)	**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**