



Title of Investigation: The Jackson Heart Study  
Principal Investigator: Herman A. Taylor, MD, MPH

**Introduction:** As one of more than 5,000 persons who were recruited and took part in Exam 1 and 2 of the Jackson Heart Study (JHS), you are being invited to continue your participation in this study by taking part in Exam 3. Please feel free to ask us about any information in this document or about anything we tell you that you do not understand.

**Purpose:** The Jackson Heart Study is a medical research study designed to identify the risk factors and causes of high blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, and/or lung disease in African Americans. It is conducted by Jackson State University, Tougaloo College, and the University of Mississippi Medical Center, and sponsored by the National Heart, Lung, and Blood Institute (NHLBI), the National Center on Minority Health and Health Disparities (NCMHD), and the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

**Procedures:** If you agree to take part in Exam 3 you will come to the clinic for the exam. If you are unable to come to the clinic we will make a home visit or meet you at another location that is convenient for you. This exam will take no more than 3 ½ hours of your time. During the exam the following will be done.

- An **interview** with questions about your physical and mental health, health care, lifestyle and family medical history. To assure all the questions are asked in the same way of everyone, some interviews may be tape-recorded.
- You will fill out a **questionnaire** about how you think.
- An **examination** to measure your blood pressure, height, weight, waist and hip size, and body composition using a special scale.
- **Laboratory tests** will include urine and blood tests to see how well your kidneys are working and blood tests to check your cholesterol (lipids and blood fats) and sugar levels. About seven tablespoons of blood will be drawn from your arm for these blood tests.
- **EKG** (electrocardiogram) will measure the electrical activity of your heart by attaching electrodes (band-aid like stick-ons) to your chest.

- **ABI** (ankle brachial index) monitors, which are small electrical devices that use sound waves, will be placed on your ankles against the skin to measure the pressure in your legs.

### **MRI (Magnetic Resonance Imaging)**

Participants who agree will also come back to have an MRI done, which will take about 45 minutes. The MRI will be done at the University of Mississippi Medical Center Pavilion, which is located near the main hospital; and will be sent to Wake Forest University for review. To see if you qualify to have the MRI we will ask you some questions about your medical history. If you have metal clips or fragments in your body, have a pace maker, artificial heart valve, ear implant or spinal cord stimulator or if you are pregnant or might be pregnant you will not be able to have the MRI.

Before the MRI begins EKG wires will be placed on your chest with a cool gel to help the pads stick; a rubber pad that looks like a large vest will be put over your chest and abdomen with a couple of straps; a clip will be placed on your finger to monitor the oxygen level in your blood; and we will give you head phones to cover your ears and help drown out the noise that the machine makes. You will lie flat on the MRI table, which glides into the chamber. The MRI will take many pictures of the heart from different angles, which will give us information about how your heart looks and works.

### **Results Reporting**

With your permission, any abnormal test results will be sent to your health care provider. If you do not have one, or are unable to afford such care, we will help you locate affordable health care by providing a list of people we can refer you to for such care. Results of your MRI will be sent to us from Wake Forest University and someone from the Jackson Heart Study Clinic will send you a letter describing any abnormal findings. A copy of the MRI may also be given to your primary care doctor if requested.

### **Annual Follow-Up and Records Review**

- After the examination we will contact you once each year to ask about your health during that year. If you were hospitalized for heart disease or related diseases we will also ask you to sign a medical records release, which will allow us to get copies of the hospital and doctor's medical records. In the event of your death, information will be sought from your relatives or other informants including coroner's reports and information from the state health department. In all these instances, your social security number may be used to confirm your identity and assure that the correct records are reviewed.

**Risks:**

All of the procedures included in this study are a part of standard health care and are considered safe. A skilled technician will draw your blood. No materials will be injected into your body. The risks of the MRI scan to an unborn child are unknown, pregnant women may not take part in this part of the research study. Pregnancy tests will be done on all women of child-bearing potential before beginning this phase of the study

- The risk of the MRI exam includes feeling uncomfortable in tight places.
- The risk of drawing blood includes pain, bruising, bleeding, infection, or feeling faint.
- The risk of taking blood pressure measurements includes some discomfort from the temporary tightness of the cuff when it is inflated or annoyance due to repeated blood pressure measurements.
- Some of the interview questions may cause you to be embarrassed or become anxious.

**Benefits:** You may or may not receive a direct benefit from being in this study. You will be given a summary report of all of your results from this examination, including your blood pressure, blood cholesterol, blood sugar, kidney function, Body Mass Index, and body composition, urine protein level. We encourage you to share your summary results report with your health care provider and, with your permission, abnormal results will be sent to her/him. If you do not have regular health care, or are unable to afford such care, the JHS will assist you in locating affordable health care. All study participants will also receive a regular newsletter updating them on the overall findings of the JHS. We hope to learn information that will help others in the future.

**Alternatives:** You may decide not to take part in the clinical examination. Even if you decide not to take part in the examination, you may continue as a JHS participant by responding to annual follow up calls, and by participating in any future JHS clinical examinations.

**Costs:** There will be no costs to you for participating in this study. The JHS will be responsible for the cost of all study procedures including the urine test for pregnancy. If you need care for some problem identified with the MRI Scan, you will be responsible for the costs of that care.

**Research-related injury:** In case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

**Compensation:** You will receive your choice of a \$25.00 check or gifts with an approximate value of \$25.00 (coffee mugs or other similar items) in appreciation for completing Exam 3. If you have the MRI done you will receive an additional \$25.00 check for the extra time involved.

If you need transportation to or from the clinic the JHS will provide a taxi service. If you use your own transportation to get to the clinic JHS will reimburse you for the mileage from your home address to the JHS, up to \$20.00. You will have to provide documentation of the mileage. Child care, if needed, will be provided at the JHS clinic.

**Participation is voluntary:** Your participation in the JHS is completely voluntary and you are free to withdraw your consent and to stop taking part at any time, without affecting any future relationship for you or your relatives with the JHS, Jackson State University, Tougaloo College, the University of Mississippi Medical Center, or the Jackson Medical Mall. You may decide not to answer any question or complete any examination.

**Withdrawal:** You may choose to stop your participation in this study and withdraw at any time. If you decide to withdraw, the information already collected about you may still be used in this study unless you request that your records, and test results obtained from this exam or prior exams be removed from study files. You may also request that your DNA and blood samples and cell lines be destroyed or that all identifiers be removed (including code numbers) from such samples. Your decision to stop your participation will have no effect on the quality of your medical care.

**New Information:** You will be told of any information we learn during your participation in this study that may affect your willingness to participate.

**Confidentiality:** The confidentiality of your information is a top priority for the JHS. Every effort will be made to keep the information we learn about you private. All information collected during this research--including interviews, laboratory data, or examination findings--will be kept confidential and results will not be disclosed to anyone without your permission except as described below. Information may be released to other researchers for scientific purposes, but only after removing your name and all other personal identifiers. Research may be done for conditions not directly related to the heart and blood vessels. Researchers from private companies, under conditions of data confidentiality specified by the JHS and the Institutional Review Boards reviewing the

JHS, may have access to your information or samples, in a way that cannot identify you. Please note that neither the JHS investigators, nor you, nor your family would benefit financially from this.

Study records may be reviewed by the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Institutional Review Boards (IRB) of the University of Mississippi Medical Center, Jackson State University, and Tougaloo College and Office of Integrity and Compliance of the University of Mississippi Medical Center. Study data may be submitted to regulatory agencies in other countries but you will not be identified. If the National Heart, Lung, and Blood Institute or the National Center on Minority Health and Health Disparities shares this information with others, the information is no longer covered by the federal privacy regulations. To help insure your privacy, a Certificate of Confidentiality has been obtained from the National Heart, Lung, and Blood Institute for this study. This Certificate is intended to help protect against the involuntary release of information collected during this study. The researchers can make disclosures of information only in very special cases (for example, if they think that a participant or someone else is in serious danger of harm).

**Protected Health Information:** Protected Health Information is any personal health information through which you can be identified. The protected health information collected in this study includes your name, date of birth, and social security number. A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept indefinitely. While this study is ongoing, you may not have access to the research information beyond the summary report of your clinic examination results. This summary report may be released to your health care provider only upon your special request to do so.

Your information will be grouped with that of all other persons taking part in the JHS and will be used only for statistical analysis to further medical knowledge without disclosing your personal identity. When results of this study are published, presented at medical or research meetings, or to the Jackson community, only group findings will be presented.

**Additional Studies:** You may be invited to take part in other studies conducted by JHS or other investigators outside the regularly scheduled JHS exam cycle.

**Questions:** Any questions about the study, the specific interviews, examinations, laboratory tests, or record reviews, or any questions about the findings of the study can be answered by the Director of the Jackson Heart Study, Dr. Herman A. Taylor. He can be reached at the

Jackson Medical Mall offices of the Jackson Heart Study, 350 W. Woodrow Wilson Drive, Suite 701, Jackson, MS 39213, (601) 815-5050. A pager number is provided through the voice mail for after hours and on weekends.

This research study has been reviewed by the Institutional Review Boards (IRBs) of Jackson State University, Tougaloo College, and The University of Mississippi Medical Center. Any questions about your rights as a research participant can be addressed to one of the following persons:

Richard Ogletree Pharm.D.  
Chair, IRB  
Univ. of MS Medical Ctr  
2500 North State Street  
Jackson, MS 39216-4505  
(601) 984-2815

Sophia Leggett, Ph.D  
Chair, IRB  
Jackson State University  
1400 J.R. Lynch Street  
Jackson, MS 39217  
(601) 979-2931

Madhu Singh, Ph.D.  
Chair, IRB  
Tougaloo College  
500 West County Line Rd  
Jackson, MS 39174  
(601) 977-7737



## STATEMENT OF PARTICIPATION

I have been told about this study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form I am not giving up any legal rights I may have.

For Exam 3, I VOLUNTARILY agree to any of the following conditions marked with an X or √ in the “Yes” column.

**Yes**    **No**

- |   |   |
|---|---|
| <input type="checkbox"/> <input type="checkbox"/> | <p>I give my permission for JHS investigators to review a copy of my medical records. This includes any clinic records that might be requested if, during one of my annual follow-up calls, I indicate that I have been seen by a provider for possible congestive heart failure.</p>   |
| <input type="checkbox"/> <input type="checkbox"/> | <p>I would like to receive JHS results from the clinic examinations.</p>  |
| <input type="checkbox"/> <input type="checkbox"/> | <p>I give permission for JHS to provide my health care provider with my examination results, if they are outside the normal range.</p>  |
| <input type="checkbox"/> <input type="checkbox"/> | <p>I agree to have my study data or samples released to researchers from for-profit organizations who wish to develop diagnostic laboratory tests, medications or other therapies that could benefit many people. (Note: Neither you nor your heirs will benefit financially from this, and your blood samples, blood cells, or DNA will not be sold to anyone for profit.)</p> |
| <input type="checkbox"/> <input type="checkbox"/> | <p>I agree to participate in the MRI Scan portion of the Jackson Heart Study to look at the shape of my heart and how it works.</p>   |
| <input type="checkbox"/> <input type="checkbox"/> | <p>I agree to the use of my study data, including imaging scans, interview data and examination results by scientists for future research studies related to blood pressure, heart or blood vessel disease, obesity, diabetes, kidney disease and risk factors for these diseases.</p>  |

- I agree to the use of my study data, including imaging scans, interview data and examination results for future other research by scientists studying diseases not directly related to heart disease risk factors and related disease.
  
- You may store and use left-over samples of my **blood and urine** for future research studies related to blood pressure, heart or blood vessel disease, obesity, diabetes, kidney disease, or lung disease, and risk factors for these diseases.

By signing this form I am not giving up any legal rights I may have.

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Name of Participant Date

\_\_\_\_\_  
Signature of Participant Date

\_\_\_\_\_  
Participant's legally authorized representative (when applicable) Date

\_\_\_\_\_  
Relationship to Participant Date

\_\_\_\_\_  
Name of Person Obtaining Informed Consent (please print name) Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent. I pledge that I will maintain the highest standards of scientific conduct in carrying out this research to protect this participant from harm. I promise to assure that all participant information is used ONLY for the purposes expressly granted in this consent. Further, I will maintain confidentiality of all participant research information in keeping with the law and federal regulations.

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Signature of Principal Investigator, Herman A. Taylor, Jr. MD, MPH Date