CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of the Research Study: Playing, Living, Aging, and You: In-Person Assessments (PLAY-IPA)

Sponsor(s) of the Research Study: Football Players Health Study at Harvard University

Principal Investigator(s) of the Research Study:

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SUMMARY OF THE RESEARCH STUDY:

We found from a survey of over 4,000 retired football players enrolled in the Football Players Health Study (FPHS) that they might face health issues earlier than others. Because you are a former football player who participated in FPHS and completed a survey, we invite you to join the Playing, Living, Aging, and You In-Person Assessments, also known as PLAY-IPA. We also invite you to join the study if you are a brother of a former football player. This form will help you decide if you want to participate.

If you choose to join, you'll need to sign this form and will get a copy for yourself. We plan to include around 150 people from across the country, with about 50 from this area. Please read the entire form carefully and ask us if anything is unclear.

This study aims to measure early aging in former football players through various in-person health tests. We'll also compare these results with those of non-football-playing brothers. If you choose to join, you will be asked to:

- Complete health assessments, including your medical history, current medications, a physical exam, and body composition measurements.
- Undergo tests that check your mood, memory, concentration, attention, and problem-solving skills.
- Have your brain scanned using an MRI.
- Evaluate your physical function, including balance and fall risk, and assess joint health.
- Test your heart function both at rest and during exercise.
- Undergo a sense of smell assessment.
- Complete an overnight sleep assessment

You will spend about 2 days in this study. On the first day at Morehouse School of Medicine, you will have health assessments, cardiovascular tests and imaging, and a smell test. You will

also have a self-administered sleep test the first night. On the second day at Emory University, you will undergo physical function tests, neuropsychological tests, an X-ray, and an MRI scan.

There are some risks involved. These may include minor radiation from imaging, feeling tired, and loss of confidentiality. More details on these risks will be provided later in this document.

This study may not benefit you directly but could help others in the future. We hope the results will help us understand football-related health issues better. You may receive results from the tests, which you can share with your doctor if you wish. This study will also help us learn more about the health problems former football players face. More information will be given later.

You can choose not to participate in this study, and you won't be penalized. If you join but later change your mind, you can leave the study at any time for any reason.

ADDITIONAL INFORMATION ON THE RESEARCH PROJECT:

Study Details:

This study is funded by the National Football League Players Association.

Dr. Albers, one of the researchers, helped develop the smell testing technology used in this study. This technology is owned by Massachusetts General Hospital in Boston, MA. Dr. Albers and the hospital might benefit financially if the technology proves valuable. Dr. Albers is also involved with Aromha, Inc., a company working on scent-based tests for brain diseases and COVID-19. The hospital, Mass General Brigham (MGB), has reviewed and found that these interests do not pose a significant risk to the study or participants. For more information, you can contact the MGB Office for Interactions with Industry at 857-282-2024 or PHSOIIRESEARCH@partners.org.

What You Will Do in the Study:

Before any tests, a study staff member and the study principal investigator will explain the study and answer your questions. If you decide to participate, you will need to sign and date this consent form. You will get a copy of the signed form for yourself.

The study will take place over 2 days. You will receive a schedule before your visit. We will use this schedule to review the consent form with you. Each day, a study staff member will go over the day's assessments with you before starting.

During the study, a study navigator will help ensure you get to each assessment on time. The navigator will also assist with certain tasks and help make sure your experience is positive and comfortable.

Baseline Visit

The baseline visit will be at Morehouse School of Medicine's Clinical Research Center (CRC).

Dual Energy X-ray Absorption Scan (DEXA Scan): You will have a DEXA scan, which measures body fat, muscle, and bone density. The scan will take about 30 minutes.

Fasting Blood Draw: A licensed clinician will draw blood from a vein in your arm. Please do not eat or drink anything except water before this. Afterward, you will get a snack.

Blood Spot Collection: This will take around 20 minutes. You will be asked to prick your finger or a trained study staff member will prick your finger to provide blood spot samples on up to two blood spot cards. One of these blood spot collection cards will provide information on metabolic and heart health, hormone levels, and inflammation and the other will be archived at the Football Players Health Study's Harvard Chan Freezer Core. Please do not eat or drink anything except water before this.

Saliva Collection: This will take around 10 minutes. Before collecting saliva, avoid eating, drinking, smoking, or chewing gum for 30 minutes. You will then spit into a test tube until the saliva reaches the fill line.

General Demographics & Medical History: A CRC nurse or nurse practitioner (NP) will gather your demographic information (like race, ethnicity, education, and employment) and review your medical and surgical history. They will also ask about your medications, family health history, and any use of drugs, alcohol, or supplements.

The NP will do a physical exam, including checking your vital signs (like blood pressure and heart rate) and measuring your height, weight, neck, and waist.

Questionnaires: A study team member will give you some basic questionnaires to fill out.

The study investigator will review the information from these assessments to decide if you can participate in each part of the study. If necessary, the schedule may be adjusted.

After completing all baseline assessments and getting answers to your questions, you will follow the schedule you were given. Your study navigator will help you with this. You can choose to stop participating in the study at any time.

Baseline

The baseline visit will be done at Morehouse School of Medicine's Clinical Research Center (CRC).

- *Dual Energy X-ray Absorptiometry Scan (DEXA)*
  You will be asked to undergo a DEXA scan. This is a whole-body scan that is used to measure body fat, muscle, and bone density. This assessment will take approximately 30 minutes to complete.

- *Fasting Blood Draw*
  You will have your blood drawn by a licensed clinician. A needle will be placed into a vein in your arm to draw blood samples. You will be asked to refrain from eating or drinking fluids other than water before this. You will be provided with a snack after your blood has been drawn.

- *Blood Spot Collection:*
  You will provide up to two blood spot samples, one for analysis and one for archiving. The sample for analysis will show results related to metabolism (blood sugar, insulin), heart health (cholesterol, homocysteine), hormones (testosterone), and inflammation (C-reactive protein). The sample for archiving would go to the Football Player Health Study's Harvard Chan Freezer Core. You will be asked to refrain from eating or drinking fluids other than water before this.

- *Saliva Collection*
  This collection will take about 10 minutes to complete. We will ask you to refrain from eating, drinking, smoking, or chewing gum for 30 minutes prior to the saliva collection. You will then be asked to spit into a test tube until your liquid saliva reaches the fill line.

- *General Demographics & Medical History*
  A CRC nurse or nurse practitioner (NP) will collect general demographic information (e.g. race, ethnicity, education, employment, etc.) from you. They will also review your medical and surgical history, your medications, family history and will review any past or current use of drugs, alcohol, and performance enhancing drugs or supplements.

  The NP will then complete a physical examination which will include collecting your vital signs (blood pressure, heart rate, etc.) and physical measurements (e.g. height, weight, neck and waist circumference).

- *Questionnaires*
  You will be given a few basic questionnaires to complete by a study team member.

The information collected at baseline will be reviewed by a study investigator to consider your ability to participate in each assessment. You may be excluded from certain assessments based on your provided information. If so, the study schedule will be adjusted accordingly.

Once all of the baseline assessments are complete and all of your questions are answered, you will continue with the schedule that you were provided. Your study navigator will assist you with this. Each assessment is described below in the consent. You can decide to stop taking part in this study at any time.

Cardiovascular Testing

Cardiac testing will be done at the Morehouse School of Medicine Clinical Research Center (CRC) and Morehouse Healthcare on Lee Street. Trained technicians will carry out all the tests. You should drink water before and during your visit. The exercise test will take about 45

minutes, the arterial tonometry about 10 minutes, and the coronary artery calcium scan about 15 minutes.

Resting Metabolic Rate: You will lie down and wear a breathing mask and light headgear. We will measure the oxygen and carbon dioxide levels in your breath while you rest comfortably.

Exercise Test: A physician and an exercise physiologist will supervise the exercise test. You will ride a stationary bike while connected to machines that measure how well your heart and lungs work. ECG pads will be placed on your chest to record your heart activity. We will also check your pulse and blood oxygen levels using a device on your finger.

You will first bike without resistance for 3 minutes. Then, the resistance will be increased every minute until you are too tired to continue. While you pedal, you will breathe into a tube that measures the air you inhale and exhale.

Arterial Tonometry (AT): Arterial tonometry is a non-invasive test that measures the thickness and stiffness of your arteries. A small wand and pressure cuff will be placed on your arm to lightly press and measure blood flow in your radial artery. This will take about 10 minutes.

Coronary Artery Calcium (CAC) Scoring: The coronary calcium scan will be done at Morehouse Healthcare on Lee Street. This non-invasive test checks for early signs of coronary artery disease.

You will lie flat on your back with your arms above your head on an exam table. Wires will be placed on your chest for monitoring. The table will slide into the scanner, covering only the upper part of your torso. You will need to hold still and, at times, hold your breath while the scanner takes images.

Olfactory (Sense of Smell) Testing:

This test will take approximately 45 minutes to 1 hour to complete. To smell each odor in the test, you will partially peel the label using the tab, sniff the odor, and replace the label when you are done. Each label contains one odor. Please smell each odor only once. After you smell each odor you will be asked to answer questions about what you smelled. You will move through the test by sampling odors and entering your responses into the app.

- *E-Consent Process:* You will log into the app with your Packet ID#, answer 6 screening questions, then review and sign the consent form.

- *Test 1:* You will smell an odor and be asked to rate the intensity of the odor from 0-10. Then you will be asked to name the odor by choosing the name that best describes the odor. Then you will be asked how confident you are in your odor choice selection. This will happen 9 times.

- *10-Minute Nasal Break:* You will have a 10-minute nasal break to let your nose rest, during which you will answer three questionnaires containing Demographic questions, Nasal Health questions, and COVID-19 and Vaccine specific questions.

- *Test 2:* You will smell an odor and be asked if the odor you smelled appeared in the first test (Test 1). You may answer "Yes" or "No." Then you will be asked to name the odor by choosing the name that best described the odor. Then you will be asked how confident you are in your odor choice selection. This will happen 18 times.

- *Test 3:* You will smell two odors and be asked if these odors are the "Same" or "Different." This will happen 10 times.

Take-home Sleep Assessment

On the night of Day 1 of your study visit, you will be asked to self-administer a take-home sleep assessment using the WatchPAT ™ One device. Study staff will pre-register your sleep device on a study-provided smartphone or iPad. You will be instructed on how to set up and dispose of the device by study staff prior to departing on Day 1. The device will take approximately 5 minutes to set up and should be placed prior to going to sleep and worn for at least 6 hours or the duration you are asleep.

To set up the device, you will be asked to place sensors on your finger, wrist, and chest and proceed to go to bed as you normally would.

Neuropsychological Testing

This assessment checks your mood, memory, and thinking skills, including how you learn and solve problems. It will take place at the Emory Brain Health Center and last about 2.5 hours, with breaks included.

A trained neuropsychologist will guide you through tests using an iPad, computer, questionnaires, and interviews.

iPad Tests: You will complete tests on an iPad to evaluate:

- Language skills
- Imagination
- Problem-solving
- Memory

For example, you might:

- Listen to words and find matching pictures
- Remember and recall the order of pictures
- Identify the direction of objects or match images

Interview Tasks: A trained rater will ask you to:

- Name objects in pictures
- Learn and recall lists of words
- Complete written tasks, like copying a picture

Mood and Behavior Interview: A neuropsychologist will ask about:

- Your mood, emotions, and behavior
- Drug and alcohol use
- Quality of life

You will also fill out some questionnaires on these topics.

A study team member will be with you throughout the testing and provide instructions. If any part of the test is frustrating or upsetting, you can skip questions or take extra breaks if needed.

MRI

You will have an MRI (magnetic resonance imaging) of your brain. This visit will take place at the Emory Brain Health Center. The MRI scanner uses magnetic fields and radio waves to create a picture. This is a test that is routinely used in medical care. We will not inject you with any dyes. Trained MRI staff will conduct the scan. This imaging session will take approximately 30 minutes to 1 hour.

We will ask you some standard questions to make sure that it is safe for you to have the MRI scan. A trained technician will also be able to answer any questions you may have.

- Because MR imaging uses a large magnet, you will be asked to remove all metal items before the scan. If you have certain metal implants you may not be able to have this scan.
- The scanner is shaped like a tunnel. You will be asked to lie on your back on the scanner table and stay still for the duration of the scan. You may have measuring devices placed on you such as ECG (electrocardiogram) sticky pads, which will be placed on your chest to record your heartbeat and a finger monitor which will measure the amount of oxygen in your blood.
- You will need to lie very still during the scan. You will be able to hear and speak to the research staff at all times during the scan. The MR scanner makes loud knocking or beeping sound during your imaging, earplugs will be provided to help reduce this noise.

Physical Function Testing

You will have assessments of your physical function. This consists of a series of tests that will measure your balance, endurance, and cognition. These will be done by a trained research fellow or exercise physiologist and will take place at the Emory Musculoskeletal Institute. This assessment will take approximately 1.5 hours.

You will be able to opt out of any assessment which you may feel unsafe completing or feel that you may have a limitation which will make it difficult to complete. Additionally, before beginning any of the following assessments, the examiner will complete a medical safety check for heart rate and blood pressure and will ask whether you are currently experiencing any dizziness, shortness of breath, chest pain, pressure or tightness.

You will be asked to complete the following activities:

Selective Functional Movement Assessment

- You will be asked to perform 10 fundamental single or multi-joint movements with your neck, trunk, shoulders, hips, knees and ankles.
- You should indicate whether any of the movements are painful or not
- This assessment will be completed by a trained and certified administrator.

Vertical Jump Assessment

- The goal of this assessment is to jump as high as possible from a standing position.
- You will be asked to stand adjacent to a wall and the trained researcher will mark your standing height.
- Your fingers will be marked with chalk and you will be asked to jump as high as possible while marking the wall with chalk.
- You will do this three times.

Modified Balance Error Scoring System (mBESS)

- You will be asked to fit your feet around the provided foot template on a mat and proceed with 3 separate test conditions.
- The assessment conditions will include standing with both of your feet with your eyes closed; standing with one foot with your eyes closed; and standing in a tandem stance with your eyes closed

5x Sit to Stand Test

- You will be asked to sit in a chair and stand up completely before sitting back down again.
- You will repeat this test five times.

Six-Minute Walk

- There will be a long straight course designed with cones in a quiet and low traffic area.
- Prior to participating in the assessment, you will have 5 minutes of rest where you will have a medical safety check. This will include checking your resting heart rate and blood pressure, as well as asking you a few health-related questions.
- You will be instructed to walk as far as possible around the course for 6 minutes, while wearing motion sensors on your foot, wrist, and lower back area. The examiner will demonstrate the test for you.
- You are permitted to slow down or stop and rest as needed.

Dual Task

- For this assessment, there are five different activities. You will be asked to complete each activity three times. A smartphone will be placed in your pocket and various sensors will be places on various parts of your body.
- The assessment includes activities such as standing quietly with your eyes open and then with your eyes closed; standing still while simultaneously performing mathematic subtraction problems; walking as a set speed; and walking at the set speed while also

performing the subtraction problems.

X-rays

The x-ray imaging will take place at the Emory Musculoskeletal Institute by trained technicians.

- Study staff will bring you to the x-ray imaging department and check you in. While you wait, you will be asked to complete a few questionnaires related to your knee, hip, and back function.
- A technologist will bring you into the imaging room and position you as needed for the various images. You will be asked to remain still while images are being taken. We will take images of your knees, pelvis, and spine.

Potential Risks and Discomforts

Blood Draw: You may feel some pain at the needle site and might get a bruise. There is a small risk of infection. Some people feel faint during blood draws. Let the study staff know if this happens to you, even if the effects are mild.

Blood Spot Collection: It is possible that you experience some discomfort in using the spring-loaded lancet to prick your finger. There is also the risk of losing privacy, but your blood spot collection cards only have your study code, not your name. This lowers the risk. Participation is voluntary and you can choose not to participate without penalty. If you join, you can stop at any time and ask us to destroy your sample.

Saliva Sample: There is a risk of losing privacy, but your saliva sample only has your study code, not your name. This lowers the risk. Participation is voluntary, and you can choose not to participate without any penalty. If you join, you can stop at any time and ask us to destroy your sample.

DEXA Scan: There is a small risk of radiation exposure, about 4 µSv. This is about half of what you get from natural background radiation in one day.

Sense of Smell Test: The risk is minimal. You might feel slightly nauseous during the test, but you can stop it at any time, and these feelings should go away.

Cardiac Assessments:

- **Exercise Test:** This test is very safe, with a very low risk of serious heart events. The risks are similar to those of vigorous exercise. You will be monitored closely by a physician and an exercise physiologist, and the test will stop if any concerning symptoms appear.
- **Coronary Artery Calcium Scoring:** This CT scan exposes you to radiation, about 0.08 mSv, which is equal to the natural background radiation you receive in 4 days.

Sleep Study: Possible risks include discomfort and skin irritation from the sensors. These should go away after the sensors are removed. The monitoring might also disrupt your sleep.

Neuropsychological Testing: Completing tests and questionnaires might make you feel tired or, less commonly, distressed. A study investigator will be available to help if needed, and breaks will be provided.

Questionnaires: You will fill out various questionnaires about your health. Some questions may be uncomfortable. You can skip any questions you do not want to answer.

Physical Function Testing: The risks are minimal. Most tests involve low-intensity activities similar to daily tasks. Potential risks include fatigue, muscle soreness, and in rare cases, balance issues or falls. You can stop any activity if you feel uncomfortable or unsafe. The examiner will guide you and ensure your safety.

X-ray Imaging: The radiation from the x-ray sessions will be no more than 3 mSv, similar to the natural radiation you receive in one year.

MRI: MRIs use magnets and do not involve radiation. People with metal implants or who feel claustrophobic might find the MRI uncomfortable. The machine makes loud noises, but earplugs are available. The MRI can be stopped at any time if you feel uncomfortable. There might be slight warming of the skin and tissues, which should be reported immediately.

Some people feel dizzy or occasionally nauseous during an MRI, but these symptoms usually pass quickly and are not permanent.

Risk of Unexpected Findings:

The tests and assessments in this study are for research, not for your personal medical care. Some tests are experimental and might not detect health issues that a standard medical test would find. There may be unforeseen risks with these assessments.

If a physician or specialist thinks you might have a medical problem, we will let you know and refer you to your own doctor for further evaluation. A study doctor can also assist with referrals if needed. You will receive your test results and can ask questions about them. If a health issue is found, it might be added to your medical record. If no issue is found, you might still worry unnecessarily about your health.

If there is a serious health concern during testing, you will be taken to the emergency department for immediate care.

Potential Benefits: What to Expect

You may not gain any direct benefit from taking part in this study. We hope that the results will help us understand football-related health problems better in the future.

You might receive results from the clinical assessments. If you ask, we can share these results with your primary care doctor or a specialist for further advice.

This study will help us learn more about the health issues that former football players face and how these issues develop.

Alternatives to Participation: Other Options

Since this study is for research, not treatment, your only alternative is to choose not to participate.

Financial Obligations: Costs

All procedures, visits, and assessments in this study are free for you. The study will also cover costs for meals, travel, and transportation. Any other approved expenses you have during the study will be reimbursed.

Compensation for Participation: What You Will Receive

You will get $600 for each day you participate in the study, up to a total of $1,200. This payment is for your time, any inconvenience, and expenses like travel and parking. It is not for the study procedures themselves. You will be paid for each visit you make, even if you decide to leave the study before it ends. The payment will be issued to you by check, no later than 60 days following the completion of your study visits.

The study will cover all costs for transportation, meals, and lodging during the 2-day visit. Any other expenses related to your participation will also be reimbursed.

Collection of Personal Information and Samples

In this study, we will collect information about your health and tissue samples. These will be labeled with a study code that connects to your personal details in a secure database. Only the study team will have the key linking your name to this code.

Your information and samples might be used for future research or shared with other researchers. You will not need to give additional consent for this.

Information on the use of your samples: Other information that you should know

Some of your individual research results will not be shared with you. However, some clinical tests will be done in this study. The results of these tests may be important for your health and medical care. These results will be shared with you.

The biospecimens collected from you in this study may be used to develop diagnostic tests. These tests may result in commercial profit. You will not receive any of this profit.

Assurance of Confidentiality: How We Protect Your Information

We cannot promise complete privacy, but we will do our best to keep your information safe. We will not share your details with anyone without your written permission, unless required by law. We respect your privacy and will not reveal that you are in this study.

Here's how we keep your information secure:

- Your personal details are linked to a code, not your name. This code is used for your data and samples from the study.
- The key that connects your name to the code is kept in a secure file, separate from your study data. Only authorized staff at Morehouse School of Medicine, Emory, and the Football Players Health Study can access this key.
- Your personal information is stored safely in a separate database at Harvard, away from your study results.
- If researchers from other places want to use your data or samples, they must send a written request explaining their research. This request will be reviewed and approved by a committee of Football Players Health Study researchers. Usually, we will only share coded information that does not identify you.

Sometimes, researchers may need your personal information, like your name and contact details, for in-person studies. If this happens, we will contact you first to ask if you agree to share your information.

The Institutional Review Board at Morehouse School of Medicine, which approved this study, might also review the research records. We will not identify you in any published papers or reports at scientific meetings.

Certificate of Confidentiality:
A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared

outside of Morehouse School of Medicine, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

During your study visit, you may cross paths with another former player or brother of a former player who is also participating in this study. We ask that all participants respect the confidentiality and privacy of other participants and do not share information about another participant's involvement in this study without the participant's explicit permission.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Emergency Care and Compensation for Injury: What happens if you should be hurt or become ill from being in the study.

We will provide care for you if you are harmed as a direct result of taking part in this study. Morehouse School of Medicine, Grady Health System and/or sponsors of the study will pay for the cost of this care, if your health insurance doesn't cover it. Care for research-related injuries may include reasonable costs for hospitalization and treatment. We will not bill public programs like Medicaid for treating a research injury, unless the law allows it. No funds have been set aside to pay for lost wages, pain or suffering that might result from research injuries. You do not give up any of your legal rights by being in this study. If you feel you have been harmed, contact Dr. Jammie Hopkins at 404-756-8923.

Persons to Contact:

If you have any questions about the research project or in the event of a research related injury or emergency, contact Dr. Jammie Hopkins, Principal Investigator, at 404-756-8923 or email jhopkins@msm.edu.

If you have any questions about your rights as a participant in this research study you may contact the Morehouse School of Medicine's Institutional Review Board. The IRB Office can be reached at IRB@msm.edu. The Chairperson of the Biomedical Institutional Review Board (IRB) is Brenda Klement, PhD. She can be reached at 404-752-1637.

If you have any questions, complaints, or suggestions about the research study, you may contact a representative for research participants. This representative is Carla Holloway and she can be reached at 404-752-8452 or cmholloway@msm.edu.

Other Investigators Working On This Research Study:

- Morehouse School of Medicine Co-PI: Dr. Herman Taylor (htaylor@msm.edu)
- Emory Site-Responsible PI: Dr. Jonathan Kim (jonathan.kim@emory.edu)
- Neuropsychological Co-Investigator: Dr. Jessica Saurman (jessica.l.saurman@emory.edu)
- Physical Function Co-Investigator: Dr. Robert Bowers (rlbower@emory.edu)
- MRI Co-Investigator: Dr. Brent Weinberg (brent.d.weinberg@emory.edu)
- Harvard Medical School PI: Dr. Rachel Grashow (rgrashow@hsph.harvard.edu)

Voluntary Participation and Right to Withdraw from the Research Study:

You are free to join the study or not. You are also free to join the study and later decide to leave for any reason. If you decide not to take part in the research, you still keep all health care services that you would expect to get from the Morehouse School of Medicine. The same is true if you join and then later choose to leave. If you start in the study and later choose to leave, we will tell you about any other places where you can get the services you got through the study. We will also give you any information that may be important to your health. The same is true if the study staff needs to ask you to drop out of the study for any reason. We may ask you to drop out if our sponsor decides to discontinue the study, if we feel that continuing with the study puts your health at risk, or if you have been noncompliant with study requirements. To request to withdraw from the study please notify our Principal Investigator, Dr. Jammie Hopkins, or the study staff.

New Research Findings: Information for You

If we find any new information during the study that might be important for you, we will let you know. This way, you can decide if you want to continue in the study.

Storage of Blood or Tissue for Future Research

We will be storing your blood or tissue samples for future research in collaboration with the Harvard Football Players Health Study. Any samples for future research will be stored at the Harvard School of Public Health Freezer Core. Part of enrolling in this study is to consent to having your samples stored, in other words, consent to participate in this study is also taken as consent for storage. Each stored sample will be labeled with your study code. The key that links your code to your name is only accessible to qualified study staff. We will not label your samples with any demographic data (i.e. your age, sex, or race), however this information will be stored in our secure database and can be linked to your study code only by trained study staff that have access to the key. We intend to store your samples for up to 10 years. Any research results that come from future studies using your stored samples are for research purposes only and will not be shared with you. Your samples may be made available to other researchers at various institutions, however they will be unable to access your identifiable information. All of your samples and data will be stored with a secure code.

Storing Samples for Future Genetic and/or Non-Genetic Research

We would like to ask you for permission to take an additional tube (10mL) or 2 teaspoons of blood to be stored for future genetic and/or non-genetic testing. The storage of blood for future genetic testing is OPTIONAL. If you choose not to have blood stored for future genetic testing you will be permitted to participate in all other aspects of this study.

Genes contain material passed from parent to child that determines the make-up of the body and mind. For example, some genes control the color of your hair or eyes. Genes are contained in your DNA (deoxyribonucleic acid). Most DNA is the same from one human to the next. Genetic testing for the purposes of this study may be done to study genes that are related to areas of health that are part of this study such as cardiovascular health, chronic pain, sleep disorders, or neurocognitive health. These genetic tests would be done for research purposes only and do not have medical importance at this time. We will not give you the results of the genetic tests.

If you elect to allow us to store your samples for future genetic research we will use a code instead of your name on these blood samples. The key linking your name to the code will be kept by the study team and will not be given to anyone else. If later you change your mind and want your samples destroyed, contact the study doctor.

You will be asked below to indicate if you agree or do not agree to have your blood samples stored for future research.**PATIENT/VOLUNTEER CONSENT STATEMENT**

I know that taking part in this research study is my choice. I may choose to leave this study at any time, for any reason, or for no reason. If I decide not to stay in the study, I shall tell the doctor of this decision. I freely consent to take part in this research study conducted under the supervision of Dr. Jammie Hopkins. I know there may be some risks or discomforts to me. I have read about these risks in this form and they have been carefully explained to me. My participation in this research has been clearly explained to me. I have had the opportunity to ask questions about the study and have had time to decide to participate. My questions have been answered to my satisfaction. I know I am free to ask further questions about the study at any time. I have been told about the materials and procedures used in this study. I know what I am supposed to do in this research study. I understand I will receive a copy of this consent form.

I certify that I am at least 18 years of age.

Name of Patient/Volunteer Printed

_____ _____

Signature of Patient/Volunteer Date

Do you agree to have your blood samples stored at Harvard Medical School (HMS) for future genetic research?

YES: _____ ____

NO:_____
Initials: _____

_____ _____
Signature of Witness (if applicable) Date

My signature as witness certifies that the research study has been explained to the patient/volunteer in my presence, that he/she appears to understand the information conveyed and that he/she signed this form by his/her own free will. In my judgment the patient/volunteer, having been fully informed of the research project described herein, has requisite capacity and is knowingly and willingly giving informed consent to participate in this research project.

_____ _____
Signature of Principal Investigator Date
or Authorized Personnel

PLEASE KEEP THIS FORM IN A HANDY PLACE AND REFER TO IT FROM TIME TO TIME WHILE YOU ARE IN THE STUDY.

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT

I have read and understand the above informed consent document concerning this research study. I know that _____ ***(Name of participant)*** who is my _____ *(relationship of the participant to the person authorizing enrollment)* does not have the ability to communicate or make decisions, at this time, regarding medical care and treatment and that I am making an informed substitute judgment in these matters. The experimental procedures and treatment have been explained to me and any questions I have asked have been satisfactorily answered. I understand that I am free to ask any further questions at any time. I understand that my signature acknowledges my good faith and belief that my _____ *(relationship of the participant to the person authorizing enrollment)* would want to participate in this research study and would voluntarily consent to do so if he/she were capable of understanding and communicating. I understand that in the event he/she regains the capability of communicating, that the research doctors will seek informed consent from him/her to continue his/her participation in this research. I am at least 18 years of age and bear the relationship to the patient so indicated on this form.

_____
Printed Name of Person Providing Consent

_____ _____
Signature of Person Providing Consent Date

_____ _____
Signature of Witness (if applicable) Date

My signature as witness certifies that the research study has been explained to the patient/volunteer in my presence, that he/she appears to understand the information conveyed and that he/she signed this form by his/her own free will.

_____ _____
Signature of Principal Investigator Date
Or Authorized Personnel

In my judgment and belief, the legally authorized representative of the patient enrolled in this study, having been fully informed of the research project described herein, has the legal capacity and authority to authorize substitute consent and is knowingly and willingly giving this informed consent on behalf of the patient to be enrolled in this research project.