RESEARCH PARTICIPANT CONSENT FORM

Title: Molecular Transducers of Physical Activity Consortium (MoTrPAC) Highly Active Participants

JHM IRB Application No.: JHUSIRB00000008

Consent Version: v1.5

Sponsor: NIH Common Fund

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See "Site-specific Consent Information" (Part 2 of this consent form) for your local study team contacts.

You are being invited to take part in a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

This is a multi-site study, meaning it will take place at several locations around the United States. Because this is a multi-site study, this consent form has two parts: **1)** the first part includes information that applies to all study sites; **2)** the second part includes information specific to your study site.

1. Research Summary - Key Information

It is known that exercise has many benefits on health. This study will help researchers and clinicians understand how exercise affects the cells and tissues in the body to bring about these health benefits. Volunteers will have several study visits to determine if they qualify for the study and to measure their fitness level. Once these visits are completed, participants will perform an exercise test (cycling or weight lifting) that lasts about 45 minutes. Blood samples and small pieces of muscle (from the thigh) and fat tissue (from the waist region) will be collected before and after the exercise. This visit will last 4 to 8 hours and participants will have to return the next day for blood and tissue collection, which takes about 1 hour.

The most common risks of this study include the possibility of muscle and joint discomfort from exercise, and bruising and tenderness from the collection of muscle and fat tissue. Other less common risks are described later in this form.

2. Why is this research being done?

The Molecular Transducers of Physical Activity Consortium (MoTrPAC) is a national research study with the goal of learning more about how exercise improves health. You are being asked to take part in this study because you are generally healthy and you regularly participate in either endurance (running, walking, cycling) or resistance (weight-lifting) exercise. Your participation in this research study will last about 2 to 3 months.

Approximately 300 adults will take part in this research.

3. What happens to me if I agree to take part in this research?

The activities for participation occur across 5 study phases that will be completed in about 2 to 3 months: **1)** Screening, **2)** Testing, **3)** Familiarization to Exercise, **4)** Rest (no exercise, no testing), and **5)** an Exercise Test with blood and tissue collection. A table at the end of this section will help explain how much time each phase of the study will take.

Phase 1 - Screening

The Screening Phase will be completed in two or more visits (depending on your schedule) and will take a total of about 1 to 2 hours. Some of these activities will be completed by phone or video calls. During this phase, you will be asked to do the following:

- Review this consent form and learn about the study.
- Provide your contact information.
- Tell us about your medical history and the medicines, vitamins, and minerals you have taken over the last 3 months.
- Have your height, weight, and waist size measured.
- Have a small amount of blood drawn (about 1 tablespoon) for lab tests, including some basic blood tests, such as levels of sugar and electrolytes in your blood and counts of your red and white blood cells, cholesterol levels, and thyroid status. For these blood tests to be accurate, you cannot eat or drink anything but water for 10-12 hours before the visit. Water is encouraged before your visit. The blood will be drawn from a vein in your arm.
- Have your heart electrical activity and blood pressure measured while you are resting. Heart electrical activity is measured with an electrocardiogram (ECG), which is a painless process that involves putting electrodes on your chest.

Phase 2 - Testing

The Testing Phase involves 2 or more visits over several days and will take a total of about 2 to 4 hours. Some of these activities will be completed by phone or video calls. During this phase, you will be asked to do the following:

- Complete a maximal exercise test on a stationary bike as we measure your heart electrical activity (ECG) and blood pressure. The exercise starts easy and gradually gets harder and harder until you cannot go any longer. We will also measure your breathing during the test, which means you have to breathe through a mouthpiece. A clip will be placed on your nose so that you breathe only through your mouth. Before starting the test, we will explain all of the testing equipment and what you have to do.
- Have your bone density and body composition (amounts of lean, fat, and bone tissue) measured by a machine known as a DXA. You will lie on your back for about 10 minutes while x-rays pass through you. You may be asked to change into a hospital gown and to remove any jewelry or other metal objects for this test. Women of child-bearing age will have to complete a pregnancy test to confirm they are not pregnant before this test.
- Complete two tests of muscle strength. Before each test, you will first learn how to use each device safely and perform the test correctly. One of these tests will be a measurement of your grip strength, which will require you to squeeze a device. The other test will be a measurement of the strength of your leg, which will require you to try to extend your knee as hard as you can.
- Fill out questionnaires about your mood, diet, health, and other behaviors.
- Wear a physical activity monitor on your wrist for about 7 days. You will wear this during the day and at night while you are sleeping.

We will let you know if any of the test results during the Screening and Testing Phases are abnormal. In some cases, we may urge you to see your primary care clinician who will determine if any further evaluation or treatment is needed.

Phase 3 - Familiarization to Exercise
The study visits during this phase are different for endurance exercisers (**EE**) and resistance exercisers (**RE**).

- **EE**: You will have 2 study visits, each lasting about 60 to 90 minutes, with 2 to 4 days between visits. These visits will prepare you for the Exercise Test in Phase 5. You will exercise on a stationary bike for up to 30 minutes at an intensity that will feel moderate to hard. We will also measure your breathing during this test, just like in the exercise test in Phase 2.
- **RE**: You will have 3 study visits, each lasting 60 to 90 minutes, with 2 to 4 days between visits. These visits will prepare you for the Exercise Test in Phase 5. You will learn how to perform the weight-lifting exercises with proper form, starting with weights that are easy to lift and increasing to heavier weights. For 3 of the exercises (chest press, leg press, leg extension), we will measure your maximal strength, which is the most weight you can lift one time.

Phase 4 - Rest
You will have 2 or 3 days of no exercise and no testing after your last exercise visit. You will be instructed to:

- Not exercise during the Rest Phase.
- Not take Tylenol, acetaminophen, aspirin, or non-steroidal anti-inflammatory medicines (examples: ibuprofen, Advil, Motrin, naproxen, Aleve) during the Rest Phase,

On the **last day of the Rest Phase**, you will be instructed to:

- Avoid caffeine and alcohol.
- Keep a log of everything you eat and drink.
- Drink a nutrition shake, which will be provided, in the evening, and then remain fasted (no food or drink other than water) until the end of the study visit the next day. Water is encouraged before your visit.

Phase 5 - Exercise Test with Sample Collection
This test will occur the day after the Rest Phase. There will be 2 study visits on consecutive days (**Day 1** and **Day 2**).

Day 1
You will come to the lab early in the morning after an overnight fast and then complete the following:

- Rest for about 30 minutes.
- Have blood, muscle, and fat collections. This is described in more detail below.
- Complete a bout of exercise, which is different for EE and RE:
  - **EE**: You will exercise on a stationary bike for about 45 minutes. This includes about 5 minutes of warm-up and cool-down at an easy intensity and 40 minutes at an intensity that may feel hard. We will measure your heart rate, blood pressure, and breathing a few times during exercise, using the same methods described above, and will collect blood samples at the mid-point and near the end of exercise.

  - **RE**: You will complete the same exercises that you practiced during the Familiarization Phase, lifting weights that will cause your muscles to fatigue. The full exercise session will last about 45 minutes.
- Once the exercise/rest period ends, additional blood, muscle, and fat samples will be collected as follows:
  - Blood – approximately 10 minutes, 30 minutes, and 4 hours after the exercise ends.
  - Muscle – approximately 30 minutes and 3.5 hours after the exercise ends.
  - Fat – approximately 4 hours after the exercise ends.
- You will be given a snack or light meal after the final sample is collected.
- For the rest of Day 1, you must:
  - Avoid caffeine and alcohol the rest of the Exercise Test day.
  - Keep a log of everything you eat and drink.
  - Drink a nutrition shake, which will be provided, in the evening, and then remain fasted (no food or drink other than water) until after the blood, muscle, and fat collections are completed the next day. Water is encouraged before your visit.

Day 2
You will come to the lab early in the morning after an overnight fast and then complete the following:

- Rest for about 30 minutes.
- Have blood and muscle collections, as described below.

The **Sample Collections** involve the following:

- **Blood**: Blood samples will be collected using a needle or a small catheter (a small plastic tube) that is placed in your arm. About 2 tablespoons of blood will be collected for each sample. There will be a total of 7 samples for EE and 5 samples for RE.
- **Muscle**: There will be 4 separate muscle biopsies taken during this visit. For each biopsy, a small needle will be used to inject some numbing medication (similar to what a dentist uses) in your thigh. A small incision (about 1/4 inch) will be made and a special needle will be used to collect 1 or 2 muscle samples (about the size of a pea). The incision will be closed with a bandage and covered for protection. We will give you instructions for how to take care of the wound. This will be done before exercise, and approximately 30 minutes, 3.5 hours, and 24 hours after exercise.
- **Fat**: There will be 2 separate fat biopsies taken during this visit. For each biopsy, a small needle will be used to inject some numbing medication (similar to what a dentist uses) near your navel. A small incision (about 1/4 inch) will be made and a special needle will be used to collect 2 or 3 fat samples (about the size of a grape). The incision will be closed with a bandage and covered for protection. We will give you instructions for how to take care of the wound. This will be done before exercise and approximately 4 hours after exercise.

Because the muscle and fat collections are expected to cause some bruising and tenderness, you can use ice to ease the discomfort. You can also take Tylenol or acetaminophen after the last collection.

The table below provides a summary of all the study activities

When the study is completed, some of your study results that may be important for your clinical care will be provided to you. At this time, there are no plans to return the results of any genetic tests.

Summary of study activities

Phase	Activities	Group Activities	
		Endurance Exercisers	Resistance Exercisers
Screening 1 visit 1-2 total hours	Orientation and consent Medical, medicine history Blood draw Resting blood pressure, ECG		
Testing 2-4 visits* 2-4 total hours	Maximal exercise test Bone density and body composition Muscle strength – hand grip and knee extension Questionnaires Wear physical activity monitor for about 7 days		
Familiarization 0-3 visits 0-4.5 total hours	Learn how to perform exercises	2 visits, 60-90 min each	3 visits, 60-90 min each Measure maximal strength
Rest	No testing and no exercise No use of Tylenol, aspirin, ibuprofen or similar drugs **On the last Rest day:** Keep diet log Avoid caffeine and alcohol Drink a nutrition shake	2 to 3 days	2 to 3 days
Exercise test 2 visits About 8 total hours	Overnight fast, 2 nights Exercise Blood samples Muscle samples Fat samples Keep diet log	Up to 18 hr 45 min - cycling 7 4 2	Up to 18 hr 45 min - weight-lifting 5 4 2

* The number of screening and testing visits can vary to accommodate a person's schedule

4. What happens to data and samples collected in the study?

The blood, muscle, and fat samples we collect will be used to advance science and public health. They will be sent to several labs around the United States that are part of the MoTrPAC study. The labs will conduct state-of-the-art tests to measure thousands of factors in cells that may respond to exercise. The samples contain your DNA, which is your genetic code. These assays will include gene sequencing, which identifies all the genes in your DNA.

Some of your blood, muscle, and fat samples will be saved for future research, which may include cell line development, gene sequencing, and genetic testing. Cell lines are living tissue samples that are grown in a laboratory. A cell line can provide cells in the future without requiring more samples from you. Each cell contains your complete DNA.

Future research may be unrelated to the current study and may include outside research partners. If you are not comfortable with the use of your data or blood/tissue samples in future research, you may not want to participate in this study.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Genomic data sharing (information about your genetic make-up)
Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) data repository that includes genomic and other data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:

- Increase the likelihood that exercise can be used to prevent or treat certain diseases, such as cancer or diabetes, or a condition, such as high blood pressure or obesity.
- Help us understand if exercise can be a treatment for certain diseases in some people, but not in others.

We and our research partners will remove direct identifiers (such as your name and date of birth) and instead code your information before sending it to the repository. The NIH will never receive this code or the identifiers we have removed.

Your data will be stored in a controlled-access repository. This means that your individual de-identified data will be available only to researchers who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure the data will be used for the approved purpose. We will not always know what types of health-related research will be done with the data that are sent to the repository. Information from MoTrPAC participants that is sent to the repository will be shared only with qualified researchers who agree to follow a data use agreement.

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled-access. GSR data does not include information about you as an individual, but consists of statistical information calculated using your data combined with data from other people. Also, as described below in Section 17 (Optional Study Components), you have the option of making some or all of your individual data available without controlled access. The risks and benefits of doing this are described in that section.

What are the risks to your privacy?
There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in employment and health insurance; however, this does not apply to life, disability, or long-term care coverage.

Are there benefits to sharing your genetic information?
There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

5. What are my responsibilities if I take part in this research?

If you take part in this research:

- You will be responsible for following the instructions of the study team.
- It will be very important that you maintain your usual eating habits during the study.
- It will be very important that you maintain your usual physical activity or exercise during the study.
- Women who can become pregnant must use birth control during the study, such as birth control pills or patches, intra-uterine device (IUD), condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant. If you become pregnant, you should notify your study team immediately.

6. What are my rights as a research study participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. You may also discuss the study with your family and friends before agreeing to join. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, you may choose not to answer any questions for any reason. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about why you chose to do so.

7. What are the possible risks and discomforts of the study?

The following possible risks and discomforts apply to all participants:

General. There are no expected psychological, social, financial, or legal risks associated with the planned research. The study team will make every effort to maintain your privacy during and after your participation. Please see the "**Site-Specific Consent Information**" (Part 2 of this consent) and the section on **HIPAA Authorization for Disclosure of Protected Health Information** for more details on how your privacy will be protected.

While appropriate safety measures are in place to mitigate risk of exposure to infectious disease, including from the virus that causes COVID-19, no measure is failsafe and there is a slight chance of infection from your participation in this study.

Exercise Testing. Risks of exercise testing include: dizziness, fainting, abnormal blood pressure, muscle soreness, muscle strain. In rare cases, exercise testing can cause irregular heart function, chest pain, or heart attack. There may also be risks that are unknown at this time. To decrease your risk, exercise testing will be supervised by trained staff. You will also practice the exercises before doing maximal tests.

Body Composition. This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage cells, but at low doses, the body is usually able to repair these cells.

The radiation exposure that you will get in this research study is less than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food, and soil. The risk from the radiation exposure in this research study is very small. If your site is required to provide you with more details regarding total radiation amount(s), this information can be found in the site-specific information section of this form.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other medical tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

Women who are pregnant are not eligible to participate because pregnant women should not undergo a DXA scan. Women who can become pregnant must take a pregnancy test before having DXA scans.

Physical Activity Monitoring. There are no known risks of wearing a physical activity monitor.

Questionnaires. There are no foreseeable risks associated with completing the questionnaires for this study, other than a risk of loss of privacy. We will make every effort to maintain the confidentiality of your responses. You can choose not to answer specific questions.

Needles and catheters for taking blood samples. Taking blood may cause discomfort, bleeding, or bruising where the needle is inserted, and some minor discomfort of having the plastic tube taped to your arm. In rare cases, it may result in fainting. There is a small risk of infection. Blood sampling will be performed by qualified personnel.

Muscle and Fat Sampling. You may experience feeling faint, moderate pain at the site where the sample was collected, some bleeding and bruising, a scar (about ¼ inch for each incision), skin irritation at the site of the bandage, numbness in the area, reaction to the medication used to numb the area, a raised scar (keloid), or infection at the site where the sample was collected. Tenderness and bruising at the tissue sampling site is common and this can sometimes last several days. Sample collections will be performed by qualified personnel.

Genetic Information. Genetic information is unique to you and your family; therefore it uniquely identifies you even without your name or other information. The MoTrPAC Study follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may, in the future, make it easier to re-identify genetic information and the person to which it belongs, so it is possible that your genetic information may be linked to you.

Other potential study risks
In addition to these risks, taking part in this research may harm you in unknown ways. We will tell you about any new information we may learn that could affect your health, welfare, or choice to stay in this research.

8. Are there benefits to being in the study?

There is no direct benefit to you from being in this study, but your study information may help others in the future. You may also find out some medical information helpful for your health.

9. What are your options if you do not want to be in the study?

You do not have to join this study. Other options include:

- Obtaining health screening tests with your personal clinician.

10. Will it cost you anything to be in this study?

No. However, if a health condition is identified as part of the tests conducted for this study, you may be responsible for the cost of any medical care needed to address that problem.

11. Will you be paid if you join this study?

You may be paid for taking part in this research. If you complete all testing, you will be paid $800.

12. Can you leave the study early?

You can agree to be in the study now and change your mind later. If you leave the study early, your data and samples that have already been collected may be used for this study or future research.

13. Why might we take you out of the study early?

You may be taken out of the study if:

- You fail to follow instructions.
- Staying in the study would be harmful to you or others.
- You become pregnant.
- The study is cancelled.

There may be other reasons to take you out of the study that we do not know at this time.

14. Will the study require any of your health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your health care providers.

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

16. What else should you know about this research study?

A description of this study will be 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. If you would like to review the information for this study, or a summary of the results, ask the study team for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB and provide oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator for your study site, which is listed in the **"Site-specific Consent Information"** (Part 2 of this consent). If you wish, you may contact the principal investigator by letter. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call the study site physician at the number listed in the **"Site-specific Consent Information"** (Part 2 of this consent).

17. Optional Study Components

In addition to the types of data sharing that are described above (in section 4), you can decide if you would like for your individual-level information to be more broadly available. Because people have different comfort levels about the degree of data sharing and about how they approach privacy in general, we give you a choice to decide how you want your individual-level data to be shared.

There are two different options you can choose from below. You can decide to share one or both types of data broadly. You can also decide that you do not want to share your individual data more broadly; this will not impact your ability to participate in the MoTrPAC study.

1) You may want to openly share your individual-level data considered to be at "low risk" of identification. Examples include: your sex, your age within a 5-year window (rather than exact age), and some of your health-related measures (such as your total cholesterol level, the amount of a protein in your blood, or a genetic marker that is released from your muscle).
2) You may want to openly share <u>all</u> your de-identified data with anyone who wants to use it. This will include your genomic data, which does carry a chance that you could be re-identified.

Allowing your data to be a part of the open data sharing means that you agree to:

- Allow your de-identified information from this study to be placed in open-access databases, and
- Allow anyone to use the data collected from your samples for any purpose in the future. As one example, information may be used to develop commercial products the profits of which will not benefit you personally.

What risks and benefits are associated with Open Data Sharing?
Your personally identifiable information (name, birthdate, etc.) will be removed for open data sharing, and your sample will include a code to minimize the chance that you could be re-identified. However, because anybody in the world would have access to the information in an open access database, there may be a risk of you being identified. If you tell other people that you participated in the MoTrPAC study, you may increase the chance that someone will be able to link your data to you.

If you decide to withdraw from the study after consenting to open data sharing, we will not have any way to know who has already used your data before being contacted and will not be able to prevent continued use of your data.

There is no direct benefit to you from placing your data in an open-access database, but the potential benefit of open data sharing is in helping a wider range of researchers make discoveries. MoTrPAC is a study of the molecular changes in response to exercise. The hope of the NIH and MoTrPAC researchers is that this database will support studies of human health and disease in the future.

OPTION 1: Open sharing of "low-risk" individual study data
Some individual-level data is considered "low risk" of identification. This includes: your sex, your age within a 5-year window (rather than exact age), and some of your health-related measures (such as your total cholesterol level, the amount of a protein in your blood, or a genetic marker that is released from your muscle).

❒ I agree to open sharing of individual level data considered at "low risk" of identification.
❒ I DO NOT agree to open sharing of individual level data considered at "low risk" of identification.

OPTION 2: Open sharing of <u>all</u> individual study data
Some participants in MoTrPAC may want to allow <u>all</u> their de-identified data to be made widely available to anyone who wants to use it. This will include your genomic data specifically, which does carry a chance that you could be re-identified.

❒ I agree to open data sharing of <u>all</u> de-identified data to anyone who wants to it.
❒ I DO NOT agree to open data sharing of <u>all</u> de-identified data to anyone who wants to it.

There are two additional options that would allow us to contact you in the future:

OPTION 3: Re-contact for MoTrPAC study results
❒ I agree to being re-contacted if results from the MoTrPAC study become available in the future.
❒ I DO NOT agree to being re-contacted if results from the MoTrPAC study become available in the future.

OPTION 4: Re-contact for future studies
Some participants in MoTrPAC may want to be re-contacted to consider participating in future studies that might be done utilizing MoTrPAC data and might require either a specific form of consent or additional participation (either through questionnaires or other data/specimen collection).

❒ I agree to be re-contacted to consider participating in future studies.
❒ I DO NOT agree to be re-contacted to consider participating in future studies.

SITE-SPECIFIC CONSENT INFORMATION

Site Name: Duke University Medical Center

Study Title: Molecular Transducers of Physical Activity Consortium (MoTrPAC) Highly Active Participants

JHM IRB Application Number: JHUSIRB00000008

Consent Version: v1.3

Site Principal Investigator: William E. Kraus, MD

Site Principal Investigator Contact Information:
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Email: William.kraus@duke.edu
Phone: (919) 681-6733

Emergency Contact: William E. Kraus, MD, (919) 660-6613 (during business hours) or (919) 970-7682 (pager) after business hours

Other Study Contact(s): Leslie Willis (919) 660-6782

Introduction

This is a multi-site study, meaning it will take place at several locations around the United States. Because this is a multi-site study, the consent form has two parts: 1) the first part includes information that applies to all study sites; 2) the second part includes information specific to your study site.

This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Site-Specific Study Procedures & Associated Risks:

Risks of Radiation

If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a lean body mass measurement. The radiation exposure from this research is about 30 microsievert. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 4 extra days' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

A possible health problem seen with radiation exposure is the development of cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from this research is negligible. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.

The exact radiation exposure that you will get in this research study is .003 rem (a rem is a unit of absorbed radiation).

Payment for Study Participation:

Payment will be loaded onto the Duke ClinCard assigned to each participant. Payment will occur in upon completion of all study visits.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Compensation for Research-Related Injury:

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. William E. Kraus at (919) 660-6613 during regular business hours and at (919) 970-7682 (pager) after hours and on weekends and holidays.

HIPAA Authorization for Disclosure of Protected Health Information:

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people in the MoTrPAC study, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join may be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of the MoTrPAC study. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

Documentation of Consent/Signatures
WE WILL GIVE YOU A COPY OF THIS CONSENT FORM
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time