INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Home-based leg heat therapy for patients with symptomatic peripheral artery disease

You are invited to participate in a research study on the effects of leg heat therapy on the circulation. You were selected as a possible subject because you have obstruction of the arteries in your legs due to peripheral artery disease. One common symptom of peripheral artery disease is intermittent claudication, defined as cramping pain in the leg muscle during exercise. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by:

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About this research

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this study is voluntary

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with your Vascular caregiver.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. **Why is this study being done?**
   The purpose of this study is to investigate whether daily treatment with heat therapy for 8 weeks improves the circulation to your leg and improves the distance you can walk before you feel pain in your legs.

2. **What will happen to me during the study?**
   You will be given a pair of water-circulating trousers and a portable pump and will be asked to wear the pants and apply the water-circulating therapy every day for 90 minutes for 8 consecutive weeks. You will also have a series of MRIs (magnetic resonance imaging), blood draws, treadmill testing and walking tests.

3. **How long will I participate?**
   The treatment will last 8 weeks. You will be asked to return for a final visit 4 weeks after the treatment phase is over, therefore, the total length of your participation will be 12 weeks.

4. **Will I benefit from the study?**
   It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you.

5. **Will taking part expose me to risks?**
   There will be risks related to treadmill testing, the MRI scanning, having blood drawn and the leg heating treatment. For a detailed explanation of risks, please see the *Risks of Taking Part in the Study* section below.

6. **Do I have other options besides taking part in this study?**
   There may be other options for treatment of your vascular condition including creating a treatment plan with your doctor. For more details, please see the *Alternatives to Taking Part in the Study* section below.

7. **Will I be paid to participate?**
   Payment for your time or travel is available if you decide to take part in this study. For more information, please see the *Payment* section below.

8. **Will it cost me anything to participate?**
   There is no cost to you for taking part in this study.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this study.

STUDY PURPOSE

The purpose of this study is to investigate whether daily treatment with heat therapy for 8 weeks improves the circulation to your leg and enhances the distance you can walk before you feel pain in your legs. Heat therapy will be applied to your legs, thigh and buttocks using water-circulating pants connected to a water pump. You will be randomly assigned to one of two groups: a low-heat group or a high-heat group. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in.

You will be given a pair of water-circulating trousers and a portable pump and will be asked to apply the therapy every day for 90 min for 8 consecutive weeks. Before the treatment, half-way through the treatment (4 weeks ± 7 days), at the end of the of treatment (8 weeks ± 7 days), and one month after the end of the treatment (12 weeks ± 7 days) you will have a series of exams, including: measurement of volume and blood flow to your calf using magnetic resonance imaging (MRI), a blood draw, measurement of blood pressure in your ankles and arms, measurement of blood flow to the skin in your leg, a treadmill exercise test and a corridor-based walking test.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of 32 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will initially be asked to come to the laboratory on three different occasions to complete baseline testing. You will need to fast (do not eat anything – do not drink beverages with calories) overnight prior to the experiment but will be asked to take your medication normally. You will also be required to abstain from alcohol and exercise for 24 hours and from smoking for at least 4 hours before this visit.

PHASE I (BASELINE TESTING)

Visit 1 - (Duration 3 hours)
Methodist Professional Center Suite D3100 - Vascular Lab
Methodist Hospital Heart Station – A1076

1) The investigator will ask you questions about your medical history, such as when the pain in your legs first started, any treatments that you received and the medications you are currently taking.
2) Your body weight and height will be measured and recorded.
3) Your ability to detect increases in temperature (thermal sensation) in multiple locations on your thighs, calves and feet will be tested. To do this, a pair of room temperature water-circulating pants and a pair of heated water-circulating pants (110° F) will be used. A portion of the room temperature pant and a portion of the heated pant will be placed in each location and you will be asked whether you feel heat or not. You will be required to detect differences between room temperature and 110°F in all locations on both legs in order to continue with the study.
4) You will be escorted to an examination room and will be asked to lie down on a bed for the measurement of blood pressure in your arms and ankles. Cuffs will be wrapped around your arms and ankles and you will be asked to rest quietly for 15 minutes. Next, ultrasound gel will be applied to the areas where the measurements will be made on your arms and ankles. A device will be used to measure the blood pressure in the artery of your arms and ankles. This is called an ABI measurement.
5) After the blood pressure measurements are completed, you will be familiarized with the cardiopulmonary treadmill test and the measurement of oxygen in your calf muscles. First, the skin in calf where you feel most pain will be shaved and firmly rubbed with ethanol wipes. A device about the size of a cell phone will be taped to your calf to measure the amount of oxygen in your calf muscles. The area where the device is placed will be marked with a pen. The skin in your chest will be shaved and firmly rubbed with ethanol wipes. Ten stickers will be placed on your chest with monitoring wires attached. This is used to monitor your heart rate and rhythm. A blood pressure cuff will be firmly wrapped around your arm to allow for the

measurement of your blood pressure multiple times during the test. You will be asked to put on a facemask that is connected to a computerized gas exchange analysis system. This monitors the oxygen used, carbon dioxide produced, and the breathing pattern. The mask is placed over the mouth and nose (similar to an airplane pilot's mask). It does not restrict breathing and you will only be breathing-in air from the environment.

6) Next, you will be escorted to the treadmill. Before exercise begins, you will be asked to rest for 3 min standing on the treadmill. At the end of the rest period, you will be asked to begin walking at 2 miles per hour. The slope of the treadmill will be increased by 2% every 2 min until you are giving your maximum effort and can no longer continue. You will be asked to report when the pain in your leg first appears. To get the most accurate results, it is important that you give your best effort for as long as you possibly can. After the test is over, you will be asked to continue walking slowly and gently for 3 min to cool down while your vital signs are being monitored. If you experience chest pain, dizziness, shortness of breath or any other abnormal symptom that you do not typically experience when you walk, please report it to the investigators.
7) After completing the treadmill test, you will be allowed to rest for 15 minutes. Next, you will be familiarized with the 6-min walk test, which consists of walking back and forth along a 100-ft corridor around plastic cones for 6 minutes. The goal of this test is to walk as far as possible. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting and resume walking as soon as you are able. If you experience chest pain, dizziness, shortness of breath or any other abnormal symptom that you do not typically experience when you walk, please report it to the investigators.
8) Next, a movement sensor about the size of a cell phone will be strapped around the ankle in the leg where you felt most pain. This device measures steps walked throughout the day. You will be asked to wear this device during waking hours and to remove it before sleeping and while showering.

Visit 2 - Methodist Hospital Heart Station – A1076 (Duration 1.5 hours)

At least three days after visit 1, you will be asked to return for a second visit (**visit 2**). You will be asked to fast (do not eat anything – do not drink beverages with calories) overnight prior to the visit. You will undergo the following procedures:

1) You will be asked to complete a cardiopulmonary treadmill test similar to the one you completed on visit 1.
2) Next, the movement sensor that is mounted on your ankle will be temporarily removed to allow for the information collected to be transferred to the computer. The device will then be strapped on your ankle and you will be asked to wear it during waking hours and to remove it before sleeping and while showering.

Visit 3 - Goodman Hall Research Imaging (Basement Level) + CTSI CRC - 5th Floor (Duration 5 hours)

At least two days after visit 2, you will be asked to return for a third visit (**visit 3**). You will be asked to fast (not eat or drink beverages with calories) overnight prior to the visit. You will undergo the following procedures:

1) The first test will be the measurement of volume and blood flow to your leg using magnetic resonance imaging (MRI). This exam is expected to last approximately 45 min. You will need to stay still with your legs inside the MRI scanner for approximately 25 min. You are allowed to stop the MRI procedure at any time.
2) Prior to entering the imaging room, you will be asked to empty your bladder since emptying the bladder will be more difficult once the scan is under way. You will then be asked lie down on a bed and rest for 15 minutes in silence, after which your blood pressure will be measured.
3) You will be asked to lie down on the scanner and a coil will be placed around the leg in which you feel the most pain. A coil is a device used to send and receive radio waves.
3) A blood pressure cuff will be firmly wrapped around your thigh in the leg where you feel most pain.
4) During this period, pictures of your calf will be obtained for the measurement of muscle volume and blood flow

5) Next, the cuff placed around your thigh will be inflated to occlude (cut off) the circulation to your leg for 5 minutes. Occluding the circulation for 5 minutes will likely cause pain and numbness in your thigh and leg muscles. The cuff will then be deflated and we will measure the changes in blood flow to your leg for 10 minutes.
6) After MRI testing is complete, you will be escorted to the Clinical Research Center to undergo the rest of the exams.
7) First, you will be asked to swallow an ingestible temperature sensor pill that has the size of a vitamin. The pill will pass normally through your gastro-intestinal system and will allow us to record the internal temperature of your body during the experiment. This is the only study visit where you will swallow the temperature sensor pill.
8) You will be asked to lie down on an examination table and a person trained to draw blood will collect a blood sample (20 mL or approximately 4 teaspoons) from in your arm.
9) Next, the skin on your chest will be shaved and firmly rubbed with ethanol wipes. Adhesive electrocardiogram electrodes will then be placed on your chest to allow for heart rate measurements.
10) Equipment about the size of a quarter that measures blood flow to the skin will be taped on your legs. The area where the device is placed will be marked with a pen.
11) Next, the test to measure the blood flow to the skin in your legs will start. The area where the device is placed will be warmed up using a computer system and the changes in blood flow will be measured. This test takes approximately one hour to complete. The blood pressure in your arm will be measured every 5 minutes and your heart rate will be measured continuously for the entire duration of the test.
12) Next, you will be asked to complete the 6-min walk test. You will walk to the hallway outside the examination room to perform the walking test as you did on visit one. You will walk back and forth in the hallway for 6 minutes around the cones.
13) After this test is complete, you will be escorted back to the examination room. You will be given a nutrition shake and will be allowed to rest in the seated position for 15 min.
14) You will then be familiarized with the heat treatment and will receive detailed instructions about how to operate the equipment and apply the therapy at home.
15) First, the skin in your thigh and legs will be gently shaved and cleaned with ethanol wipes. Skin temperature sensors that have the size of a dime will be taped to the skin on your thighs and legs to measure temperature during this familiarization with the treatment. Also, a conventional blood pressure cuff will be placed around your arm for blood pressure measurements via an automated device.
16) You will be asked to dress custom-made, water-circulating 'pants' that will be used to apply heat to your lower body. These water-perfused pants have silicone tubes sewn into it, which allow for water to be pumped through it via an external water pump. You will not get wet during the protocol.
17) The garment will be connected to a small pump that will circulate warm water through the pants for 90 min.
18) Blood pressure, skin temperature and core body temperature will be measured throughout the entire protocol.
19) During the treatment, you will be asked to fill out two questionnaires about your quality of life and problems you have with walking. This is the only study visit where you will undergo the leg heating treatment since you will be doing the leg heating treatment at home daily.
20) After the treatment is completed, the coordinator will teach you how to inspect the skin in your legs, thighs and buttocks to look for adverse reactions to the treatment, how to wash and care for the water-circulating trousers and how to fill the pump with water after each treatment session.
21) Next, the movement sensor will be strapped on your ankle and you will be asked to wear it during waking hours and to remove it before sleeping and while showering.

After initial testing is complete, you be assigned to one of the treatment groups by randomization. You will receive a pair of water-circulating trousers and a portable heat pump and will be instructed to apply the therapy daily for 90 min. You will be able to choose what time each day that you will apply the therapy. You will need to warm up the pump and pants for 40 min prior to use. You should be sitting with the legs extended or lying in bed while applying the therapy. It is very important that you remain in position with your legs extended and keep the pants on for the full 90 minutes. You will not be able to move around for 90 minutes. The pump is equipped with an auto shut-off device that will automatically turn off the pump. If you feel a burning sensation or experience any other adverse effects, please stop the treatment immediately and call the study coordinator. You will receive a logbook and will be asked to write down the exact times you underwent the therapy daily. If for some reason your 90-min session is

interrupted, please make note of that in your logbook. Try to resume the therapy as soon as possible so that the full 90 min of treatment are completed. The study coordinator will call you twice each week to ask you the days and times you applied the therapy and to answer any questions that you might have. You will be asked to fill the pump with water after each session and to wash the water-circulating trousers at least once every week.

PHASE II (MID-TREATMENT EXPERIMENTAL VISITS)

After approximately 4 weeks of daily treatment, you will be asked to return to the laboratory for the mid-treatment assessment.

Visit 4 – Methodist Hospital Heart Station – A1076 (Duration 1.5 hours)

Visit 4 will be conducted 4 weeks ± 7 days after visit 3.
You will stop Home Heat Therapy Treatment for at least 48 hours prior to Visit 4
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergo a Cardiopulmonary Treadmill Test and an ABI measurement.

Visit 5 – Goodman Hall Research Imaging (Basement Level) + CTSI CRC - 5th Floor (Duration 5 hours)

Visit 5 will take place at least 48 hours after Visit 4
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergo the same procedures as Visit 3 (except randomization)

PHASE III (END OF TREATMENT EXPERIMENTAL VISITS)

After 8 weeks of daily treatment, you will be asked to return to the laboratory for the end-treatment assessment.

Visit 6 – Methodist Hospital Heart Station – A1076 (Duration 1.5 hours)

Visit 6 will be conducted 4 weeks ± 7 days after visit 5.
You will stop Home Heat Therapy Treatment for at least 48 hours prior to Visit 5
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergo a Cardiopulmonary Treadmill Test and an ABI measurement.

Visit 7 – Goodman Hall Research Imaging (Basement Level) + CTSI CRC-5th Floor - Duration 5 hours
Visit 7 will take place at least 48 hours after Visit 6
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergo the same procedures as Visit 3 (except randomization)

PHASE IV (FOLLOW-UP EXPERIMENTAL VISITS)

Approximately four weeks after the end of treatment, you will be asked to return to the laboratory for the follow-up assessment.

Visit 8 – Methodist Professional Center Suite D3100 - Vascular Lab (Duration 1.5 hours)
Visit 8 will be conducted 4 weeks ± 7 days after visit 7.
You will stop Home Heat Therapy Treatment for at least 48 hours prior to Visit 8
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergoa Cardiopulmonary Treadmill Test and an ABI measurement.

Visit 9 – Goodman Hall Research Imaging (Basement Level) + CTSI CRC - 5th Floor (Duration 5 hours)
Visit 9 will take place at least 48 hours after Visit 8
You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit – you may take morning medications
You will undergo the same procedures as Visit 3 (except randomization)

RISKS OF TAKING PART IN THE STUDY

The procedures involved in this research protocol involve some risks and side effects as described below. You should discuss these with the investigators before agreeing to participate in this study.

Risks and side effects related to the procedures we are studying include:

Treadmill test: A stress test is generally safe, and complications are rare. But, as with any medical procedure, there is a risk of complications, including:

- Moderate to severe chest pain
- Severe shortness of breath
- Abnormally high or low blood pressure
- Dizziness
- Fatigue
- Abnormal heart rhythms (arrhythmias). Arrhythmias brought on by an exercise stress test usually go away soon after you stop exercising.
- Heart attack (myocardial infarction). Although exceedingly rare, it's possible that an exercise stress test could cause a heart attack.

Gas Exchange Analysis Mask: During the walking test you will wear a mask that may give you a sense of discomfort or feeling of being "closed in".

Blood pressure monitoring: During the walking test you will have a blood pressure cuff wrapped around your arm. You may feel discomfort when the blood pressure cuff is inflated.

6-min walk test: Adverse responses to this exercise test are rare, but there is a minor chance that you may experience: chest pain, difficulty breathing, dizziness, leg cramps, staggering, sweating, and shortness of breath. If you feel any of these symptoms, please stop walking and report it immediately to the investigators.

MRI scan: There are some individuals who should not have an MRI scan. These include persons with some type of metallic implants, such as aneurysm clips or stents, or person with electronic implants, such as cardiac pacemakers. The magnetic field in the scanner can cause displacement or malfunction of these devices. If you have any these devices, you will not be able participate in the MRI exam. Other potential risks include:

- Claustrophobia: the confining conditions of the MR scanner can cause claustrophobia (the feeling of being 'closed in'). If you experience claustrophobia, the scan will be stopped.
- Nerve stimulation: Some subjects undergoing the rapid scanning procedures, which will be used in this scan, have experienced minor nerve stimulation effects, such as tingling sensations. These sensations are temporary and will disappear after the exam is completed.
- Hearing: The MR scanner produces loud tapping sounds during operation. To minimize any discomfort, you will be provided with disposable earplugs or headphones.
- Collision hazard: The magnetic field near the MR Scanner is strong enough to attract objects containing iron with great force. Near the magnet this force can be strong enough to pull objects in and cause them to fly down into the magnet. Such objects can become projectiles that can cause injury or death. We have established a security zone to prevent objects containing iron from coming near the magnet.
- Radio-wave effects: If metal wires or electrodes, such as electrocardiograph (ECG) leads are attached to a person being imaged, the radio-wave energy radiated by the imaging coils of the MR scanner may induce

sufficient electrical currents in the wires to cause burns where the electrodes or wires contact the skin. The scanner operator is well aware of this risk and knows the proper methods to use to avoid this problem.

Circulatory occlusion: The inflation of the cuff around your thigh to cut off circulation for 5 minutes can cause pain, numbness and tingling in your leg. These sensations will disappear as soon as the cuff is deflated.

Blood sampling: Inserting the catheter in a vein in your arm might cause temporary pain. This feels like a quick pinch and is over in seconds. There is a risk of bruising in the area where the catheter was placed, which is common after blood draws. This should disappear in a couple of days. If the bruising continues to spread, becomes excessively painful or swells, please contact the investigators.

Measurement of skin blood flow: You may experience skin irritation from the adhesive tape. There is a minimal risk that the heat may cause discomfort.

Leg Shave: There is a risk of itching or skin irritation from shaving.

Measurement of oxygen level in the calf: There are no risks associated with this measurement, however, you may have itching or skin irritation from having the leg shaved or from the adhesive tape.

Measurement of physical activity levels: There are no risks associated with the measurement of daily walking using a step monitor around the ankle.

Quality of life questionnaires: A risk of completing the quality of life survey is being uncomfortable answering the questions. While completing the survey, you can tell the researcher that you feel uncomfortable or do not want to answer a particular question.

Heart rate test: The skin in your chest will be shaved and rubbed with ethanol wipes and ECG electrodes will be placed for heart rate monitoring. The skin in these areas might get irritated and itchy because of shaving and because of the adhesive electrodes.

Skin temperature measurements: Skin temperature probes will be taped to the skin in your thigh and calf. The skin in these areas might get irritated and itchy because of shaving and because of the adhesive electrodes.

Measurement of core body temperature: There are no risks associated with this measurement. You will be asked to swallow a temperature sensor pill that has the size of a vitamin before visit 3. The pill will pass normally through your gastro-intestinal system. There are no risks associated with this measurement.

Leg Heating treatment: During the treatment with heat therapy, heated water will be pumped through the water-circulating pants to heat your lower-body. You should apply the therapy while sitting with the legs extend or while lying in a bed. You should only apply the therapy for 90 min daily. The skin in contact with the silicone tubing in the garment pants will get red after the therapy and you may experience discomfort during the treatment due to a sensation of warmth/heat. If you feel a burning sensation, please stop the treatment and call the study coordinator. Adverse reactions to heat treatment are rare but it is possible that the therapy might cause skin blistering, burns, pain and swelling of the area. You will be trained to examine the skin after each treatment session for potential signs of injury or adverse reactions to the treatment. Stop the treatment immediately if any adverse signs are observed.

There is a risk of loss of confidentiality.

BENEFITS OF TAKING PART IN THE STUDY

If you agree to take part in this study, you may benefit from the heat therapy treatments and experience a reduction in pain in your legs that occur while walking; however, there is no guarantee that you will experience these benefits.

You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge.

ALTERNATIVES TO TAKING PART IN THE STUDY

You may choose not to participate in the study. You may choose to take the medication cilostazol, which is used to treat leg pain while walking.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. A copy of the report with the results of your first cardiopulmonary exercise test will be given to you. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

WHAT WILL YOU DO WITH MY GENETIC INFORMATION?

Your blood will be destroyed following the testing for this study and therefore no whole genome testing will be performed. Your blood samples will not be used to develop products which could be sold in the future.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the Indiana Clinical Research Center (ICRC), and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), who may need to access your medical and/or research records.

A description of this clinical trial will be available on **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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects
(4) for the purpose of auditing or program evaluation by the government or funding agency
(5) if required by the federal Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information or specimens collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS

You will not be responsible for the costs associated with this study.

PAYMENT

You will receive a total of $500 for taking part in this study. You will be compensated $100 after the completion of the baseline testing, $100 at the end of week 4, $100 at the end of week 8 and $200 after the completion of the study (week 12).

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact researchers Bruno Roseguini at **765-490-6284** or Raghu L Motaganahalli at 317-962-2300. If you cannot reach the researcher, please call the IU Human Subjects Office at (317) 278-3458.

In the event of an emergency, you may contact Bruno Roseguini at 765-496-2612 or Raghu L. Motaganahalli at 317-962-2300.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 .

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University or IU Health Hospitals.

The Investigator may remove you from the study if you have difficulty walking on the treadmill or if any of the following occur while on the treadmill: you feel that your heart is racing, you feel short of breath, you become pale, you feel nauseated or you begin to sweat or feel faint.

WILL I BE CONTACTED TO PARTICIPATE IN RESEARCH IN THE FUTURE?
If you agree, we may contact you after your participation is over to ask if you'd like to participate in future research using this device. Please initial one of the following options:

_____ Yes, I agree to be contacted for the purpose of being invited to participate in future research using this device.

_____ I do NOT agree to be contacted for the purpose of being invited to participate in future research using this device.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____**Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____