Study title: Echocardiographic assessment of pulmonary transit time following exercise

NCT number: NCT04336995

Document date: date of IRB approval – 4/20/2021

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Echocardiographic assessment of pulmonary transit time following exercise
Version Date:	9 April 2020
PI:	Ken Monahan, M.D.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

This study seeks to measure the amount of time it takes for blood to travel through the lungs at rest and during exercise using ultrasound and a contrast agent delivered to you through an IV placed in your arm. The study may not benefit you directly. However, if successful, the technique being studied could help obtain information about blood flow through the lungs in a less risky way than is currently used.

The main risks of the study are related to placement of the IV and to the contrast agent; complications from these parts of the study are rare.

The study will involve a single visit to the Vanderbilt Clinical Research Center and will take approximately 2 hours. There are no limitations or restrictions on daily activities, food intake, or medications surrounding the study. There is no cost to you for participating in the study and there is no exposure to extra radiation. The contrast agent that you will receive is FDA approved.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Study Title:	Echocardiographic assessment of pulmonary transit time following exercise
Version Date:	9 April 2020
PI:	Ken Monahan, M.D.

You are being asked to take part in this research study because you are a relatively healthy individual who exercises fairly regularly.

The main purpose of this study is to measure the time it takes for blood to travel from the right-side of the heart through the lungs to the left-side of the heart both while resting and after exercising.

As part of the procedure, you will have ultrasound pictures taken of your heart before and after exercise. In addition, you will have an IV (a small plastic tube) inserted by a nurse into a vein in your arm. Contrast material will be given to you through this IV before and after you exercise in order to help measure the time it takes blood to flow through the lungs. The exercise part of the study will consist of either walking on a treadmill following the Standard Bruce Protocol or riding a stationary exercise bicycle. The Standard Bruce Protocol is an exercise program in which you will start walking slowly at a modest incline – every 3 minutes, the treadmill speed will increase and the incline will increase as well. The exercise protocol will stop at any point at your request or when your heart rate has increased to the desired level, whichever comes first. If the treadmill is not available, riding a stationary exercise bicycle will be used for exercise. You will be asked to pedal at a pace that is moderately difficult, but at which you can sustain. The resistance on the bicycle will be increased every 3 minutes until the desired heart rate is achieved or until you request to stop, whichever comes first.

If you decide to take part, your time in this study will be about 2 hours and will include 1 visit to the Clinical Research Center, an area of Vanderbilt Medical Center dedicated to conducting research studies. We are seeking to enroll approximately 15 individuals in this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

There are minimal risks to this study

There are rare (< 1%), but potentially severe/life-threatening complications that can occur with administration of echocardiographic contrast (Definity or Optison).

Study Title: Echocardiographic assessment of pulmonary transit time following exercise
Version Date: 9 April 2020
PI: Ken Monahan, M.D.

Specifically, with Definity, serious cardiopulmonary reactions (including fatalities) have occurred during or following administration; most serious reactions occur within 30 minutes of administration. These include: Cardiovascular: Flushing (1%) Central nervous system: Headache (2%) Gastrointestinal: Nausea (1%) Neuromuscular & skeletal: Back pain (1%) Renal: Renal pain (1%).

Specifically, with Optison, serious cardiopulmonary reactions (some fatal) have occurred uncommonly during or within 30 minutes following administration. Serious anaphylactoid reaction. Cardiovascular: Flushing (4%), chest pain (1%) Central nervous system: Headache (5%), dizziness (3%), chills (≤1%), fatigue (≤1%), malaise (≤1%) Gastrointestinal: Nausea (≤4%), vomiting (≤4%), dysgeusia (2%) Local: Discomfort at injection site (1%) Neuromuscular & skeletal: Weakness (≤1%) Respiratory: Dyspnea (1%), flu-like symptoms (1%) Miscellaneous: Fever (≤1%).

There are also rare (< 1%), but complications that can occur with the placement of an IV, similar to those of a blood draw. These include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. (There are also rare (< 1%)complications that can occur with the type of exercise that you will do as part of this study. These include muscle pain, joint pain, and orthopedic injury. Rare complications of this type of exercise also include injury from loss-of-balance or equipment malfunction and triggering of cardiac events (heart attack or dangerous heart rhythm).

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study are a better understanding of how blood flows through the lungs during exercise.

b) You may experience no benefit from this study at all as care will not be affected in any way and treatment will not be given based on information collected as part of the study.

Payments for your time spent taking part in this study or expenses:

You will not be paid for being in this study.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Study Title:	Echocardiographic assessment of pulmonary transit time following exercise
Version Date:	9 April 2020
PI:	Ken Monahan, M.D.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Sherry Bowman RN or Dr Monahan at 615 322 2318. If you cannot reach the research staff, please call the Vanderbilt Medical Center operator at 615 322 5000 and have the operator page Dr Monahan.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

Your study doctor may choose to withdraw you from this study if it is felt that is in your best interest. If you are withdrawn, you will be given a reason why.

What will happen if you decide to stop being in this study?

You can withdraw your consent at any time from this study. Should you choose to stop being in this study, you must write Dr Ken Monahan at the Vanderbilt Heart and Vascular Institute – 1215 21st Avenue South – Medical Center East 5th Floor – Nashville TN 37232 and request your consent be withdrawn. At that time, no further data will be collected about you. Data collected before your request may still be used for research.

Study Title:	Echocardiographic assessment of pulmonary transit time following exercise
Version Date:	9 April 2020
PI:	Ken Monahan, M.D.

Confidentiality:

The information collected from this study will be maintained on a computer. Members of the research team will be the only people that will have access to your personal information and the study results. The research team will keep track of this information after the study is completed.

The study sponsors and/or Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. The sponsors, Vanderbilt, Dr Monahan and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

Study results will not be shared with you.

Study Title: Echocardiographic assessment of pulmonary transit time following exercise
Version Date: 9 April 2020
PI: Ken Monahan, M.D.

Authorization to Use/Disclose 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 (including both Vanderbilt University Medical Center and others) 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 at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. 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.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent

Study Title: Echocardiographic assessment of pulmonary transit time following exercise
Version Date: 9 April 2020
PI: Ken Monahan, M.D.

form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____