ICF for Study Title:

Impact and interplay of corticosteroid regimen and exercise training on DMD muscle function

NCT04322357

Date Approved: 11/20/2024

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are a child reading this form, the word "you" refers to you.

GENERAL INFORMATION ABOUT THIS STUDY

1. **Name of Participant ("Study Subject")**

   _____

2. **What is the Title of this research study (this "Research Study")?**
   Impact and interplay of corticosteroid regimen and exercise training on DMD muscle function

3. **Whom do you call if you have questions about this Research Study (the "Study Team")?**

   Principal Investigator: Tanja Taivassalo, PhD: 352-339-6666 or ttaivassalo@ufl.edu
   Study physician: Dr. John Sladky, MD: 404-307-4849 or jsladky@ufl.edu

4. **Who is paying for this Research Study?**

   The sponsor of this study is the Department of Defense, Congressionally directed medical research program focus on Duchenne Muscular Dystrophy.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

Duchenne muscular dystrophy (DMD) is a genetic muscle condition that causes weakness of the body's muscles that decreases the ability to walk and perform various daily tasks. The question of exercise for patients with DMD is increasingly being considered, with current care guidelines recommending swimming and cycling. In addition to these exercises, we recently showed strength training of the legs to benefit boys with DMD. We now want to know whether a combination of cycle and strength exercise might be a more effective approach to improving muscle function in DMD. As a first step in a two-part study, we have assembled a therapeutic exercise chair that will allow patients to perform these two exercise modes on one device and would like to make sure the exercise chair is comfortable and easy to use.

The purpose of this first part of the research study therefore is to get your feedback on the exercise chair. You are being asked to be in this research study because you have a gene associated with DMD. We will ask you to come to the University of Florida for up to 3 visits over a period of 1 month. Two of the visits will take up to 1 hour of your time and one visit may take up to 3 hours.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by the 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.

b) What is involved with your participation, and what are the procedures to be followed in the research?

As part of this research study, you will be asked to cycle on the exercise chair for no more than 30 minutes (total exercise time) and provide your opinion about its use (for example, how comfortable it is, how easy it is to use and follow use instructions). You may be asked to come back for a second or third visit to cycle again or do strength exercise on the chair.

On one study visit, you will be asked to undergo the study procedures listed in Question 7, which include tests intended to monitor how your muscle responds to the exercise. These tests may include a small blood sample and a urine sample), your ability to perform timed functional tests (such as walking, sitting and standing, climbing four steps), muscle strength, and Magnetic Resonance Imaging (MRI), and Magnetic Resonance Spectroscopy (MRS) measurements on your leg muscles.

c) What are the likely risks or discomforts to you?

Discomforts and risks associated with the proposed exercises are minimal. Recent studies in boys with DMD have shown moderate intensity exercise is safe. We have used the study procedures listed in Question 7 in boys with DMD safely and without any risks for the past ten years. Details regarding risks and discomforts of the study procedures are explained in Question 12.

d) What are the likely benefits to you or to others from the research?

You may or may not benefit from participating in this study. Boys with DMD and their families may benefit from learning and interacting with the investigators who are highly interested in muscular dystrophy. You will receive information regarding your strength and ability to exercise.

The information you provide on the use and comfort of the exercise chair will help in part 2 of this study where the investigators will ask boys with DMD to exercise train on this chair at home.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Your participation in this study is completely voluntary and you may stop participating at any time. There are no specific guidelines for exercise in DMD other than avoiding high-intensity muscle contractions. As an alternative to participating in this study, you may not enroll or choose to withdraw from the study at any time. If you do not want to take part in this study, tell the Principal Investigator or other study staff, and do not sign this Informed Consent Form.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Normal clinical care is considered medical or other treatment or services that you would receive even if you did not participate in this research study.

Participation in this study is not part of your normal clinical care. All procedures are being performed only for the purposes of this study. Any clinical care that you are receiving will not change or be impacted by your assessment or enrollment in this study.

7. What will be done only because you are in this Research Study?

Visit 1:

Clinical exam and health history:

- The study physician or study staff will ask you questions about all diseases, illnesses, allergies and operations in the past, including questions about DMD,

age, race, and ethnic origin, and a list of any medications you are currently taking. We will measure your weight and height.

Exercise chair familiarization and practice:

- On visit 1, you will practice doing one of the exercise modalities (leg cycling or strengthening exercise) on the exercise chair. We will measure your height, weight and leg length.
- For the cycling, we will first adjust the seat to make sure your legs reach the pedals comfortably and then ask you to move the pedals forward. Once you are warmed up, we will ask you to cycle as fast as possible for up to 10 minutes and determine the distance you have pedaled. You will be asked to rate your perceived exertion (how hard was it to cycle exercise at the end) on a scale from 1 to 10. We will monitor your heart rate at rest and as it increases during exercise using standard non-invasive techniques (ECG electrodes, chest strap or wrist watch). We may ask you to wear a mask that covers your nose and mouth that allows us to measure the air you are breathing in and out during rest and exercise to give us information about your heart, lung and muscle function. You will also be asked what level of pain on a scale of 0-10 you experienced at the end.
- For the strengthening, we will ask you to bend and straighten your knee while sitting in the chair with a cuff that will not allow your leg to move during the exercise so that it is a safe and low impact type of strengthening exercise. Once you are comfortable with the set-up and your muscles are warmed up after performing these simple exercises, we will ask you to push/kick out or pull back your leg as hard as you can for 3 seconds to measure your maximal voluntary contraction (MVC). This MVC is how hard you can push and pull your leg. Depending on the results, we may ask you to repeat this procedure as many as three to ten times. If at any time you become tired you will be allowed to rest. The MVC is used to see how “strong” your leg muscles are. Once we know this information, we can calculate 50% of your MVC and use it to determine the level of intensity for the exercise training sessions. You will also be asked what level of pain on a scale of 0-10 you experienced at the end.
- After a brief rest, you will practice the cycle or strength exercises at an intensity equal to approximately 50% of your effort for cycling and 50% MVC for strength exercises. For the cycling, we will ask you to pedal for up to 10 minutes. For the strengthening, you will be asked to perform up to 4 sets of 6 reps of leg exercises by pushing/kicking out and pulling in with your legs as described above.

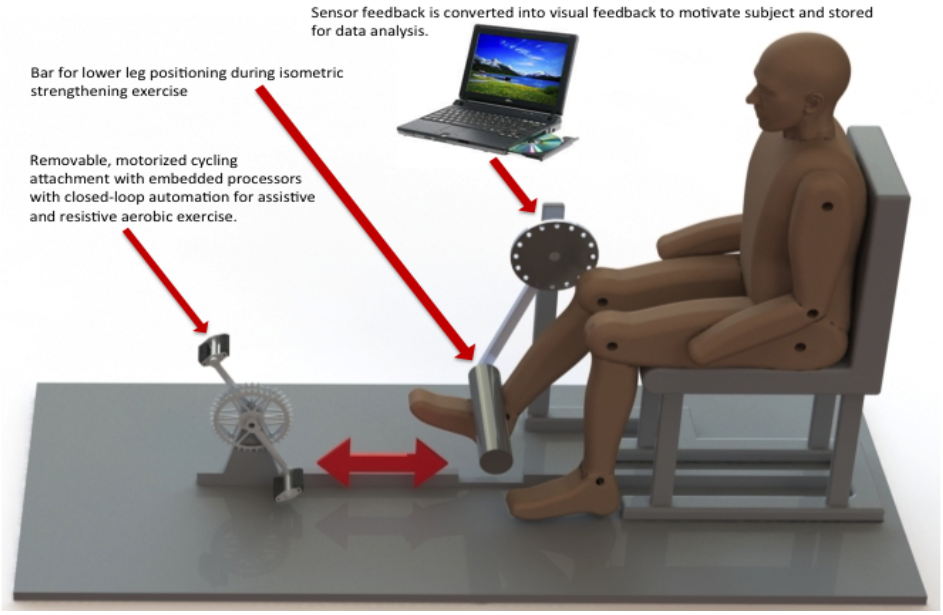

Figure 1. Example of the exercise chair that you will use in this study.

Visit 2:

Based on your experience on the exercise chair during visit 1 and any modifications made to the chair made based on your feedback, we may invite you to a second session of either cycle or strength exercise on a separate day. We will repeat the Clinical Exam and health history, and Exercise chair familiarization and practice as described above for Visit 1.

Visit 3:

We may invite you for a third visit to get your feedback on doing both cycle and strength exercise on the exercise chair. During this visit, we will repeat the Clinical Exam and health history. We will ask you to do the practice exercises only (no maximal effort) for both cycle and strength exercises at an intensity of 50% maximal effort. We may collect blood and perform MRI as described below. This information will help us understand whether combined cycle and strength exercise on the exercise chair can be used as an exercise training strategy.

Magnetic resonance imaging (MRI) and spectroscopy (MRS):

- MRI may be performed for your legs. MRI is a procedure that allows doctors and researchers to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. You will lie on a platform inside the magnet. A series of images will be taken of your legs. The scanning period will take approximately 30 minutes, during which you are required to lie still. Although the measurement is painless, it will be somewhat noisy inside the magnet due to a hammering sound made when a large electrical current is pulsed through the magnet. Disposable earplugs and headphones will be provided to reduce the noise.

- MRS will give us information regarding your muscle chemical composition and uses the same scanner as MRI. If this is performed, the MRS period will take an additional 30 minutes. This technique will help us discriminate between damaged and healthy muscles and fat inside of your muscles, as well as your muscle's capacity to generate energy. The test involves lying in the magnet with your right leg secured and performing muscle contractions for up to 2 minutes.

Blood and urine collection

- A small blood sample (about 2 tablespoonfuls) may be taken by our nurse to monitor your response to the exercise.
- You may be asked to provide a small urine sample (about 2 tablespoonfuls) to determine your response to exercise.

Table of Events: This is an example schedule of visit procedures. Please note start time may vary depending on your schedule and MRI availability

Time of day:	Visit 1	Visit 2	Visit 3
8:00 am	Clinical exam and health history		
8:30 am	Familiarization with exercise chair	Familiarization with exercise chair	Blood and urine collection
9:00 am	Exercise session (cycle or strength)	Exercise session (cycle or strength)	Exercise session (cycle and strength)
9:30 am	Visit finished	Visit finished	
10:00 am			MRI and MRS
11:00 am			
11:30 am			Blood collection and visit finished

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used, and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected and used with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected and used with others:

- Your name, age, phone number, email address, or mailing address.
- Past medical history to determine eligibility for study participation.
- Questionnaires about your physical function health, and medical status.
- Laboratory, x-ray, MRI, and other test results from past medical records as deemed necessary.
- If you provide consent for audio, video, or photography, then this information will be collected and used in a manner with which you have agreed.
- Data generated from the study activities such as data pertaining to MRI/MRS, body composition scans, muscle and functional performance.
- Your social security number (SSN) will be collected for research participation purposes.

All data collected will be stored in secured locations (e.g. locked filing cabinets), on secured, password-protected computer servers, or on encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.
If you choose to enroll in Dr. Taivassalo's 'Vaso Rex Study' (IRB202301491) and have completed the same testing protocols as part of this study within three months prior to

your enrollment in IRB202301491, the previous data collected may be used, shared, and analyzed as part of the 'Vaso Rex Study'.

Sharing your data from this study to the Vaso-Rex study is completely optional, and you may choose whether to give your consent on pages 16 and 17. The goal is to streamline the testing protocols in the Vaso Rex study, which will help reduce the time commitment for participants. By utilizing the available data collected within the specified timeframe, we aim to minimize the testing burden on participants while still gathering valuable data for the study.

The Research Team may collect this information from other healthcare providers, who are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals, or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in Question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in Question 3 of this form), study investigators at the University of Florida associated with this project.
- Other professionals at the University of Florida that provide study-related treatment or procedures.
- Your primary care doctor
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).
- The study sponsor (listed in Question 4 of this form)
- United States governmental agencies that are responsible for overseeing research, such as the Department of Health and Human Services, and the Office of Human Research Protections.

Additionally, representatives of the Under Secretary of Defense (Personnel & Readiness) are authorized to review research records as part of their responsibility to protect human research volunteers.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because the federal privacy law would no longer protect it.

10. How long will you be in this Research Study?

You will be enrolled in this study up to 1 month.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We expect up to 10 patients with DMD will qualify for and enroll in part 1 of this study, with 20 patients being enrolled in part 2 and a total of 95 patients being enrolled in the entire study (which includes patients on daily or an alternate weekend steroid use program).

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

The risks associated with the study interventions are minimal. You may experience some muscle soreness in your legs. As boys with DMD have sensitive muscles, this potential muscle soreness could be more long-lasting or more severe than in people without muscular dystrophy. We have recently completed a study of strength training in boys with DMD using the same type of strength exercise and intensity, and we did not find any evidence of muscle damage. During the exercise training, we will ask you questions about how difficult you find it to do the exercise and whether you are or have experienced muscle pain or increased fatigue since the last time we spoke. We encourage you to let the study staff know if you notice any other changes in your health that we may not have asked you and how you are feeling throughout the intervention to ensure your safety and comfort. An exercise physiologist or licensed physical therapist with experience working with patients with DMD will oversee all participant testing and interventions.

In terms of study procedures, we will work to ensure your safety and comfort throughout all study procedures.

Risks and discomforts that may occur in this study and steps to alleviate them are:

- You may experience some muscle soreness and stiffness as a result of the muscle and functional performance testing. There is a very small risk you may get some other type of muscle damage from doing the exercise testing (called rhabdomyolysis). This is usually because you did not drink enough water before and after you did the exercise testing. You will be offered and encouraged to drink water before and after the exercise testing to minimize this risk.

- Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is routinely used for medical care and is very safe for most people, but you will be monitored during the entire MR scan in case any problems

occur. However, the possibility of unforeseen hazards cannot be ruled out. The risks of MRI are listed as follows:

1. The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.
2. There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan.
3. The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs and headphones to reduce this risk.
4. The MRI scanner that will be used for your scan is approved by the FDA for routine clinical and research studies. This is also true for most of the peripheral components used with the scanner as well as most of the scan types (called sequences) that are performed on the scanner. However, as part of your session we will be using non-FDA-approved components and/or scan types and/or software. In all cases, these components/scans/software comply with all FDA guidelines with respect to MRI safety.

- The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

You may or may not benefit from participating in this study. Boys with DMD and their families may benefit from learning and interacting with the investigators who are highly interested in muscular dystrophy. You will receive information regarding your strength and ability to exercise. The MRI/MRI scans will provide you with comprehensive images and information regarding the presence of fat, detection and monitoring of muscle damage and severity of disease within your leg muscles. This type of information has been previously used in DMD clinical trials involving the leg muscles. If requested, you will be provided with a packet of your information that we gathered during the study and a letter to your doctor. The information given to you will help your doctor learn more about the health of your arm muscles. The letter will describe the details of this study to your doctor and help him/her understand what the results mean.

13b. How could others possibly benefit from this Research Study?

There may be potential benefit to other patients with DMD, their families, neuromuscular disease doctors and scientists through the information found in the study. Currently, very little is known about what exercise parameters may benefit muscle in patients with DMD. This relates in large part to a lack of exercise equipment that is safe and avoids the possibility of doing harmful muscle actions. This study will provide information on the use and efficacy of an exercise chair that safely allows for both cycling and strength exercises. By understanding how muscle in boys with DMD responds to these exercises, this study will provide important evidence supporting the use of exercise training in DMD patient management and clinical care. Lack of physical activity is well known to worsen underlying disease in many other conditions and likely does the same for DMD. This study will help shift the current paradigm and promote exercise for patients with DMD.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

Your other choice is to decline participation in this study. If you do not want to take part in this study, tell the Principal Investigator or the research personnel and do not sign this Informed Consent Form.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study. For example, we may analyze and present the data that we collect. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in Question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- The Principal Investigator or Study Physician decides that continuing the procedures would be harmful to you or the study procedures have a negative effect on you.
- A change in your health and physical functioning making it difficult for you to comply with the protocol or you no longer meet the requirements to qualify for the study
- Other reasons affecting administration of the research project
- Funding for the study stops.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Study Services

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Tanja Taivassalo at (352) 339-6666.

Items/Services Not Pair for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

17. Will you be paid for taking part in this Research Study?

You may receive up to $75 for travel related costs as part of your participation in this study.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands Hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator and Study doctor will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____

Consent & Authorization Signature of Parent/Legal Representative Date

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant:

_____

Print: Name of Subject:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, _____, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date

ICF Addendum #1 – Sharing Data Consent

We have recently updated the protocol for sharing and analyzing data from this study in connection with Dr. Tanja Taivassalo's 'Vaso-Rex Study' (IRB202301491). If you choose to enroll in the Vaso-Rex Study and have completed the same testing protocols within three months prior to your enrollment (from participation in this study), we may use, share, and analyze the previously collected data as part of the Vaso-Rex Study.

Both studies involve similar testing protocols, and we believe that using data from tests completed within this three-month period will allow the research team to streamline the schedule for participants in the Vaso-Rex Study while still utilizing existing data. This approach aims to minimize testing and reduce the burden on participants.

It's entirely optional whether to allow researchers to share your data with the Vaso-Rex Study. If you provide consent, you can change your mind later. If you choose not to give consent, you can still participate fully in this study.

Should you decide later that you no longer want us to store or share your data, please contact Dr. Tanja Taivassalo at ttaivassalo@ufl.edu.

Possible Risks and Discomforts:

- Risk associated with the potential loss of confidentiality related to data collection. Participation includes a risk of loss of confidentiality of personal health information. A number of methods are employed to maintain your confidentiality. First, the collected data are maintained in locked computer files and file cabinets to which only study investigators have access. Second, only study investigators and key research staff have access to the study database. Third, you are assigned a unique study identifier. Your names will ultimately be removed from the study database and only the unique study identifier is used to distinguish you in the database. Collected data will be used only for research purposes. Published data will not contain any individual identifiers. Finally, all research staff members have to retake refresher course certification exams.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Participant Date