Cerebral Networks of Locomotor Learning and Retention in Older Adults

NCT03790657

August 23, 2023

Department of Veterans Affairs | VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD **VAMC:** North Florida/South Georgia Veterans Health System

UF Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM

to Participate in Research

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Cerebral networks of locomotor learning and retention in older adults

Short Title: CONTROL Walking Study

3. Who can you call if you have questions, concerns, or complaints about this research study?

Principal Investigator: David J. Clark, ScD
352-376-1611 x105244 (office phone)
352-443-0655 (mobile phone)

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

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4. Who is paying for this research study?

The sponsor of this study is the US Department of Veterans Affairs, Rehabilitation Research and Development Service.

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** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

a) In general, what is the purpose of the research, how long will you be involved?
The purpose of this research is to better understand how the brain controls walking, including if mild electrical stimulation delivered to the brain during practice of a novel walking task can affect learning of the task. Volunteers who qualify for the full study will attend approximately 10 visits spread across approximately 2 months.

b) What is involved with your participation, and what are the procedures to be followed in the research?
We will test your walking and balance abilities, cognitive (e.g., memory) abilities, as well as ask other questions about your health. We will deliver mild electrical stimulation to your brain, which is considered safe and which is comfortable for most people. While this brain stimulation is delivered, you will practice performing a complex obstacle walking task. We will take pictures of your brain using magnetic resonance imaging (MRI) on two visits if you are MRI eligible. We will perform a standard blood draw on two visits.

c) What are the likely risks or discomforts to you?
There is a risk of falling or experiencing other injuries during physical tests of walking and balance. Electrical stimulation can cause mild sensations of itching or tingling. MRI is considered safe unless you have metal implants or devices in your body. We will screen you for these prior to conducting an MRI.

d) What are the likely benefits to you or to others from the research?
There is no direct benefit to participating in this study.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?
The only alternative is not to participate in the study.

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.

A description of this clinical trial will be available 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.

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 medical or other treatment or services that you would receive even if you did not participate in this research study. Nothing in this research study is part of your normal clinical care.

7. What will be done only because you are in this research study?

Screening	Baseline	Locomotor Learning	Post (1 Day)	Post (1 Week)	Post (1 Month)
1 Visit	1-2 Visits	4 Visits	1 Visit	1-2 Visits	1 Visit
• Informed Consent • Cognitive Function • Walking Function	• Obstacle walking with fNIRS • Cognitive Function • MRI: › Structural › Resting state › Task-based (imagined obstacle walking) • Blood Draw	• Active or sham tDCS *during*: • Obstacle task practice 1 - blocked practice 2 - variable practice 3 - combined practice 4 - full task practice	• Obstacle walking with fNIRS	• Obstacle walking with fNIRS • Cognitive Function • MRI: › Structural › Resting state ›Task-based (imagined obstacle walking) • Blood Draw	• Obstacle walking with fNIRS • Cognitive Function

Here we describe the assessments that are planned for each study visit. The exact assessment schedule might differ slightly based on availability of equipment, research personnel, and your availability. If we are not able to complete a particular visit, we will attempt to reschedule any missed assessments.

At the first study visit, all participants will complete several questionnaires and assessment that include demographic information, health/medical information, physical abilities, and cognitive (mental) abilities. These assessments help us to determine if you meet the eligibility criteria for the full study, and include:

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD **VAMC:** North Florida/South Georgia Veterans Health System

Screening assessments:

- walking and balance tests. These may include "complex" tasks like walking while holding a tray, walking fast, stepping over foam blocks, and combinations of multiple tasks.
- cognitive tests that assess memory, attention, and problem solving
- sense of touch, which involves touching your feet with thin wires
- blood pressure and heart rate
- visual exam with a standard eye chart
- measuring your height and weight
- asking you questions about your health and medical history
- ask you questions about your sleep habits
- obtaining a list of medications that you use
- determine if you can safely participate in magnetic resonance imaging

Many of the people who undergo these assessments will not qualify for the full study. After the study screening visit, we will evaluate your assessments and medical records to determine if you meet all eligibility criteria. You will be notified within one week about whether or not you qualify.

For those participants who do qualify for the full study, you will be invited to attend approximately 10 additional visits spread across approximately 2 months. The visit schedule and content will be:

Screening: as described above. This visit lasts about 3 hours.

Baseline Assessments Baseline assessments will take about 4 hours and will be completed during one or two visits. Assessments will include:

Obstacle Walking Task:

We will tape sensors to your body so that we can measure your movement patterns during walking. You will be asked to walk over an obstacle course that includes foam blocks and foam mats. During this test you will wear a gait belt that will help us support you if your balance becomes unsteady.

We will also ask you to perform other "complex" tasks like walking while holding a tray, walking backwards, walking while performing a cognitive task, walking fast, and combinations of multiple tasks.

Subject Name: _____ **Date** _____

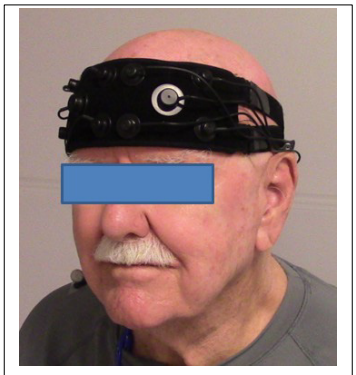
Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD **VAMC:** North Florida/South Georgia Veterans Health System

Walking and Turning Tasks:
We will ask you to walk over a special "floor" that will measure gait (e.g., step length, swing time, etc.) while you perform basic walking tasks such as straight walk, 90 degree turns, 180 degree turns, and 360 degree turns.

Neural recordings:

We will measure your brain activity using an approach called functional near infrared spectroscopy (fNIRS). You will be asked to wear a headband with embedded sensors that measure changes in brain activity.



fNIRS headband

We will measure skin conductance which records "nervous sweating" on the palm of the hand. We will place sticky sensors on two fingers of each hand, which are connected by a wire to a small control unit that clips onto a belt around your waist.

Magnetic resonance imaging (MRI):

If you are eligible for an MRI, we will use MRI to take pictures of your brain. During an MRI scan, you lay flat on an exam table that slides into a tube. The tube is fairly narrow, but open on both ends. To ensure it is safe for you to have an MRI scan, you will first fill out an MRI safety screening form. Next, you will be asked to lie down on a narrow examination table that will move into an enclosed tube. Throughout the scan, we will be able to communicate with you through an intercom.

The MRI scan will take approximately 30 minutes, and you will need to stay awake during this time. You will be asked to lie as still as possible during this entire time.

Blood draw

Using a standard needle and syringe, a trained and experienced staff member will extract a small amount of blood (up to 47.5 ml; about 3 tablespoons) from a blood vessel in your arm. This sample will be used to look at the presence and characteristics of substances in your blood that may be related to health of the nervous system. We will also look at characteristics of particular genes related to how your nervous system may function. We will not use your genetic information for any other purpose, and will dispose of your blood samples at the end of the study.

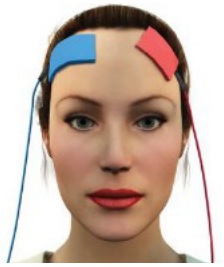
Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD **VAMC:** North Florida/South Georgia Veterans Health System

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

Locomotor Learning Visits: This portion of the study includes 4 visits, each of which lasts about an hour.



Example image of brain stimulation with tDCS.
(Journal of Neuroscience 2013, 33 (47))

Walking practice with brain stimulation:

We will ask you to practice performing the obstacle walking course for 20 minutes. You will be allowed to take rest breaks as needed. You will wear a gait belt that will help us support you if your balance becomes unsteady. During this walking practice, we will deliver a small amount of electricity to your brain using a method called transcranial direct current stimulation (tDCS).

tDCS is a weak form of electrical stimulation that has been widely used in prior research and is considered to be safe. We will randomly determine (like a coin flip) whether you receive a higher or lower amount of brain stimulation. During tDCS, we place two moist pads on your head that are connected to the stimulation device you will wear in a backpack. It is common to feel a slight "tingling" sensation on your skin during tDCS, but it should not hurt. Because of the low level of stimulation that we use, you may hardly feel it or may not feel it at all. tDCS will be delivered for up to 20 minutes per session.

Post Assessment one day after Locomotor Learning

This visit lasts about 2 hours. We will repeat the obstacle walking task with fNIRS discussed above for Visit 2.

Post Assessment one week after Locomotor Learning

These assessments last about 4 hours and will be completed in one or two visits. We will repeat the obstacle walking task with fNIRS and the MRI scan and the blood draw.

Post Assessment one month after Locomotor Learning

This visit lasts about 2 hours. We will repeat the obstacle walking task with fNIRS and other walking tasks discussed above.

Subject Name: _____ Date _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD VAMC: North Florida/South Georgia Veterans Health System

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. How long will you be in this research study?

If you do not meet the eligibility study for the criteria, you will be in the research study for only one visit. If you do meet the eligibility criteria and decide to enroll, you will be in the research study for approximately 10 additional visits spread over the course of 2 months.

9. How many people are expected to take part in this research study?

We expect 100 people to complete the full study. A higher number will complete the screening visit but will not qualify for the full study.

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

10. What are the possible discomforts and risks from taking part in this research study?

There is a risk of falling while we test your walking and balance ability. Falls can lead to injuries ranging from mild (e.g., bruising) to serious (e.g., head injury). There is also a risk of musculoskeletal injury such as an ankle sprain.

It is possible that you may become tired, sore, or uncomfortable due to physical activity either during or after your visit. These symptoms are unlikely to be worse than what you would experience due to physical activity outside of our study. These are normal responses to exercise and generally disappear within 2-3 days.

fNIRS recording is safe. The headband with recording sensors that we ask you to wear may be slightly uncomfortable for some people, but you will only wear it for a short period

Subject Name: _____ Date _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD VAMC: North Florida/South Georgia Veterans Health System

of time. The sensors press against your forehead and may leave slight impressions or redness on your skin that typically disappear within 30 minutes.

Skin conductance recording is safe. The sensors placed on your fingers to record skin conductance are very sticky. Sometimes there may be slight discomfort when removing the sensors.

There is a risk of negative feelings if you are unhappy with how you perform on tests that we conduct, including tests of physical function and mental abilities.

For MRI, there are no known significant risks associated with this procedure. The radio waves and magnetic fields associated with MRI machines are not thought to cause harm. Federal guidelines regulate the permitted amounts of radio wave exposure, and the University of Florida's scanners and this study protocol fall within these guidelines. **You will not be allowed to participate in MRI if you do not pass the MRI safety questionnaire.** An MRI technician will review your answers on that day to ensure that it is safe for you to have an MRI scan.

The risks of MRI are:

- 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.
- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in enclosed spaces ("claustrophobia"). Most people who experience claustrophobia feel anxious immediately after going inside of the scanner. If this happens to you, we can take you out before we start collecting data and the experiment will be cancelled. During the entire scan, you will be able to talk to the MRI technician through an intercom system. If an emergency occurs or if you experience claustrophobia and wish to end the experiment, you can speak aloud. The MRI technician will be able to have you out of the scanner within 1-2 minutes.
- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given hearing protection to reduce this risk.
- You may experience lightheadedness when sitting up after the scan. You will be asked to sit up slowly.

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.

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

Principal Investigator: David J. Clark, ScD **VAMC:** North Florida/South Georgia Veterans Health System

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

This study may include risks that are unknown at this time.

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

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

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

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit for taking part in this study.

11b. How could others possibly benefit from this study?

Others may benefit if we can increase our knowledge of how the brain contributes to successful walking function. This may lead to future studies to assess longer term rehabilitation.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

The other choice is not to participate in the study. If you do not want to be in this study please tell a member of the research team and do not sign this consent form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

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.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator feels that continuation could be harmful to you.
- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information.
- There is a a change in your health and physical functioning making it difficult for you to comply with the protocol.
- You need treatment not allowed in the study.
- Other reasons affecting administration of the research project.

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

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WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There is no fee for participation, but there may be incidental costs related to participation such as gas for commuting to study visits, food, etc.

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

15. Will you be paid for taking part in this study?

Participants enrolled in the full study will be paid up to $275 as follows: All participants will be paid $45 for completing the onsite screening visit; Next, a payment of up to $200 will be processed at the post 1-week visit (this total will be pro-rated (reduced) for missed visits); and, finally, a payment of $30 will be processed at the post 1-month visit.

Additional compensation per visit will be paid to participants traveling from more than 25 miles away (one-way). Round-trip travel compensation is calculated using the current VA travel reimbursement rate times mileage as determined by Bing Maps using the fastest and shortest route from your home to the Brain Rehabilitation Research Center ("door-to-door"). Compensation at the current rate calculates to $20.75 per visit for 50 miles round trip.

Payment process: Subjects enrolled in research studies at the VA receive study related compensation as an electronic transfer of money to a bank account (direct deposit). The compensation for your participation in this research study will be direct deposited from the VA Finance Office to your verified bank account. Account verification requires each subject to complete a "Vendor Form for EFT Payments (direct deposit)" following the VA Finance Office's current verification method which may require completing web-based and/or paper forms.

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

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Information required will include your name, address, social security number, phone number, email address, valid bank account and routing numbers for verification before study payment can be processed. In addition, you may be sent a secure email from the VA Finance Office asking you to confirm the bank account details you provided. Your response to this email will be required for setting up the payments. Payment may instead be issued through a debit card that we provide to you. This option will be at the discretion of study staff, such as for individuals who have no prior financial relationship with the US Dept. of Veterans Affairs. The debit card option requires disclosing your name and contact information to the financial institution that manages the debit card program.

If you are already set up to receive VA direct deposit payments (other than for VA benefits), then there is nothing you need to do.

If you do not complete this step, you may still participate in this study, but you will not be paid.

Note: You may be responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, has to be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses. Please ask your tax advisor if you have any questions about your taxable income.

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

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In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the 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). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Department of Veterans Affairs | VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Cerebral networks of locomotor learning and retention in older adults

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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 alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent 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 privacy will be protected. 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.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

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Consent to be Photographed, Video and/or Audio Recorded

Please indicate whether or not you give permission for us to take photographs, video, and/or audio of you as part of this research study:

Photographs:	Videos:	Audio Recording:
Yes	Yes	Yes
No	No	No

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, Dr. David Clark, or his 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 direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Clark 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