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: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Image Parkinson's Disease Progression Study

3. Who do you call if you have questions about this research study?

Principal Investigator: David Vaillancourt, Ph.D. Phone: 773-307-8352

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health.

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?

The purpose of this research study is to investigate how the brain and motor behavior changes Parkinson's disease over time in response to rasagiline and to investigate new methods of evaluating non-invasive MRI-based biomarkers of PD progression in the brain. The drug rasagiline will be tested in this study. Rasagiline has been prescribed by doctors for many years to treat symptomatic Parkinson's disease. It is FDA approved for the treatment of Parkinson's disease but has not been shown to slow disease progression. You are being asked to be in this research study because you meet our criteria for individuals with PD. Clinical assessments will also be performed to help determine whether you are eligible for the study. The study staff will discuss these requirements with you. 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 Website at any time.

You will be asked to come to the researcher's lab at the University of Florida for 2 testing days within a period of about 12 months. You will be tested at your initial visit, and once following one year. We will contact you after 3, 6, and 9 months to assess any changes in your medical status, provide study medication reminders, and mail you medication or placebo pills. You will not be asked to answer any questionnaires or perform any additional assessments during these follow-up calls. We may ask to extend your study medication or delay your one year follow up visit, due to scheduling conflicts or unforeseeable circumstances.

At both visits you will be tested in an "off" medication condition. You will be asked to refrain from taking any of the medications used to control your movement disorder after 6:00 p.m. on the night before the study visit. This includes the medication or placebo pill given to you through this study as well as any additional medications taken to control your movement disorder. At the conclusion of the study, you may request to find out which treatment you received: either the placebo or the study medication, rasagiline. If you do not request to obtain this information, you will not receive this information.

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

During the experiment, you will be asked to complete the following: (1) questionnaires about quality of life, depression, anxiety, and apathy; (2) tests to measure your strength and motor function; (3) tests to measure your cognition; (4) orientation session to learn a precision gripping task; (5) functional MRI scan of your brain; (6) structural MRI scan of your brain; (7) pregnancy test (if applicable); (8) tests to measure sleeping behaviors (9) at the follow up visit – questionnaires about any adverse or serious adverse events.

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

Rasagiline is FDA approved to treat Parkinson's disease symptoms, and is a widely used medication, but it has not been proven to slow the progression of Parkinson's disease. You should not take rasagiline if you have certain medical conditions or are taking certain medications. If you could be pregnant, you should not participate in this study

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

The benefit to you from being in this study may be a slowing of the progression of Parkinson's disease during the study. The study drug will not be provided to you once your participation in the study has ended.

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

This study involves using a drug (rasagiline) to see if it slows progression of Parkinson's disease. You are free to seek clinical care in the same way whether or not you 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.

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)?

This study involves using a drug (rasagiline) to see if it slows progression of Parkinson's disease. You are free to seek clinical care in the same way whether or not you participate in the study. Your normal clinical care will be followed.

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

Half of the participants in this study will be in a group that will receive the study drug (rasagiline), and half will be in a group that will receive a placebo. A placebo is a pill that is made to look like the study drug, but it does not contain any active ingredients. A computer algorithm will randomly decide your group assignment (like the flip of a coin). You will not be told which group you are in. If you are not willing to be in the placebo group, you should not participate in this study. The study staff will not know which group you are in until the study is over. If you develop a medical problem during the study and a doctor needs to know whether you are taking the study drug or the placebo, that information will be made available to the doctor. The study staff will provide you with instructions so that your doctor can request this information, if necessary.

Either rasagiline or placebo will be given to you at the completion of the first visit. You will take the drug or placebo every day for duration of the study, which is one year. The study staff will review with you how often to take the drug each day, which is one pill per day.

You will be asked to come to the researcher's lab at the University of Florida for 2 testing days within a period of about 12 months. You will be tested at your initial visit, and once following one year. We will contact you after 3, 6, and 9 months to assess any changes in your medical status, provide study medication reminders, and mail you medication or placebo pills. You will not be asked to answer any questionnaires or perform any additional assessments during these follow-up calls. We may ask to extend your study medication or delay your one year follow up visit, due to scheduling conflicts or unforeseeable circumstances.

At both visits you will be tested in an "off" medication condition. You will be asked to refrain from taking any of the medications used to control your movement disorder after 6:00 p.m. on the night before the study visit. This includes the medication or placebo pill given to you through this study as well as any additional medications taken to control your movement disorder.

At the conclusion of the study, you may request to find out which treatment you received: either the placebo or the study medication, rasagiline. If you do not request to obtain this information, you will not receive this information.

Orbitofrontal X-ray

If you have a history of metal in your eye or eyes, the researchers will require additional screening to ensure that it is safe for you to enter the magnetic resonance environment. The researchers may refer you to Radiology at Shands UF for an orbitofrontal x-ray. Shands at UF will provide a written report stating whether you are safe for imaging in this study. All expenses related to this procedure will be covered by the National Institutes of Health.

Orientation session

We will explain the study to you, review the informed consent document and answer questions you may have about the study. If you agree to participate in this research, we will begin gathering data. At the one-year follow-up visit, the study and the informed consent document will be reviewed with you once more, and you will again have the opportunity to ask questions about the study.

Clinical Measures

We will gather data about your age, gender, height, weight and medical conditions. You will be asked to complete forms that test your neurological status like the Unified Parkinson's disease rating scale where we will rate your performance on tasks like tapping your fingers and tapping your heels. With your permission, this rating scale will be video recorded to ensure rating reliability. You will be asked to take tests that assess your cognitive abilities, emotional status and quality of life. The cognitive tests will measure aspects like comprehension, memory and attention span. The emotional status tests will assess your current level of depression, anxiety, and apathy. The quality of life tests will assess how your movement disorder affects your daily life. Assessments regarding sleep behaviors will measure sleepiness and rapid eye movement behaviors. If you do not wish to complete all of the questions in the tests mentioned above, you are able to skip questions with no penalty. At your follow-up visit, we will also gather information about any adverse events that might have occurred throughout the duration of your participation in the study.

Measurement of brain structure and brain function

This experiment will require you to lie down on a platform that will move into an enclosed functional Magnetic Resonance Imaging scanner (fMRI). fMRI is a technique used to non-invasively measure changes in brain activity in relation to performance of a specific task. In brain structure measures, you will lie still in the MRI without performing a task. In brain function measures, you will perform a task. You will be asked to practice the experimental tasks described below until you feel comfortable performing them. During this task you will use a small pinch grip device that you will hold between the thumb and index finger. Once inside the scanner, you will be asked to lie still while we perform a scan, which will provide us with an anatomical picture of your brain. You will be asked to complete a series of tasks during which we will obtain pictures of the functional changes in brain activity. During this task you will move your hand under different conditions. In one condition you will be asked to perform the task with no sensory information about the task. We will refer to this as a "self-initiated" task. No stimulus will be presented in this condition. In another condition you will be asked to respond to a stimulus, which will give you information regarding the timing of your movement or the extent to which you should contract your muscles. We will refer to this as an "auditory cued task" or a "visually cued task". Your goal during all movement conditions will be to move as quickly as possible. If you would like a copy of the images collected during this scan, a disc containing the images will be provided for you at your request. You will not receive any clinical feedback regarding your scan.

Physical performance measures

You will be asked to perform different physical tests that will measure your ability to perform daily activities. You may be asked to perform a test that will measure your ability to perform everyday tasks like picking up a penny off the floor, a test that will measure how well you can tolerate walking at various speeds and climbing stairs, a test that will measure your ability to work with your hands and a test that will measure your balance and risk for falling. In addition, you will be asked to do a test of handgrip strength.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form. By agreeing to participate in this study, you are agreeing to complete all checked items in one 24 hour period. If you choose to complete the study over several days, you will be re-consented at each visit with a check only on the items to be completed that day.

Medical history (~10 minutes)
Orientation session to learn a precision gripping task (~30 minutes)
Questionnaires about depression (~5 minutes)
Tests to measure your quality of life and health status (~40 minutes)
Tests to measure your strength and motor function (~20 minutes)
Tests to measure your cognition (mental capabilities) (~40 minutes)
Functional MRI scan of your brain (~30 minutes)
Structural MRI scan of your brain (~30 minutes)

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future.

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 the 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?

You will be asked to come to the researcher's lab at the University of Florida for 2 testing sessions within a period of about 12 months. You will be tested at your initial visit and following one year. Each session may last up to eight hours. Between each of the 2 visits, you will take either a placebo pill or the study medication, rasagiline, once per day and receive follow-up calls after 3, 6, and 9 months to assess any

changes in your medical status, provide study medication reminders, and mail you medication or placebo pills.

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

We expect that up to 200 people will take part in this research 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?

This study might involve the following risks and discomforts to you:

- Rasagiline. Rasagiline is FDA approved to treat Parkinson's disease symptoms, and is a widely used medication, but it has not been proven to slow the progression of Parkinson's disease. You should not take rasagiline if you have certain medical conditions or are taking certain medications. The study staff will discuss these with you. Most side effects of rasagiline are mild and short lived. Reported side effects of rasagiline include joint pain, mild headache, depressed mood, dizziness, drowsiness, hair loss, mild skin rash, numbness or tingling, dry mouth, decreased appetite, constipation, diarrhea, upset stomach or abdominal pain, heartburn, nausea/vomiting, and weight loss.
- Placebo. There is no anticipated risk from placebo, as it contains no active ingredient.
- If you could be pregnant, you should not participate in this study. The use of fMRI scanning on the developing fetus is not known. Therefore, women must be taking an approved form of birth control, be surgically sterile, or postmenopausal. In order to participate in this study, you should have avoided becoming pregnant from the first day of your most recent menses. A negative pregnancy test does not absolutely prove that you are not pregnant. You should not participate if you think there is a possibility that you might be pregnant. If prior to your participation in this study you think you have become pregnant, you must immediately notify the study investigator, David Vaillancourt. Nursing mothers are not eligible for participation in this project. The possibility exists that complications and undesirable side effects, which are unknown at this time, could occur. You will be informed of any significant new findings that may affect your willingness to continue participation in this study.
- If you have some type of implanted electrical device (such as a cardiac pacemaker or a neurostimulator), or a certain type of metallic clip in your body

(i.e., an aneurysm clip in your brain), you are not eligible for participation in the MRI portion of the study. The magnet is very likely to cause malfunction of electrical devices, and metal objects will get hot with exposure to the magnetic fields.

- If you have any metal in your eye or eyes, the researchers will require additional screening to ensure that it is safe for you to enter the magnetic resonance environment. It is very important to report any history of metalworking, especially metalworking involving cutting processes such as grinding, filing, shaving, and threading. In addition, please report any previous injuries or surgeries involving your eyes. For your safety, the researchers may refer you to Radiology at Shands UF for an orbitofrontal xray. Shands at UF will provide a written report stating whether you are safe for imaging in this study. All expenses related to this procedure will be covered by the National Institutes of Health.
- Please take note that some subjects have experienced claustrophobia while inside the scanner. If you begin to feel claustrophobic, you may discontinue the scan at any time. Many people who do experience claustrophobia feel the anxiety immediately after being put inside the scanner. If that is the case, we can take you out before the data collection has begun and the experiment will be cancelled. If you experience a delayed reaction after the experiment has begun, there is a speaker in the scanning room through which we can hear you speak. Speak out and we will come in and have you out of the scanner within 1-2 minutes.
- This research study may involve exposure to radiation from either a skull or orbital x-ray. The radiation exposure from one of these x-rays is approximately 42 millirems, which is comparable to about 7 extra weeks of natural background radiation to which people in the United States are exposed to during their lives. The risk from this radiation exposure is considered to be extremely low when compared to other every day risks. The study doctor will provide you with a contact person if you would like more information about radiation exposure.

If the anxiety and depression questionnaires reveal that you have feelings of harming yourself related to depression, we will refer you to mental health services available at Shands at the University of Florida.

Aside from the above-mentioned limitations of subject participation, there are no known significant risks with this procedure. The radio waves and magnetic fields used by the MRI machine are thought to be without harm. There are conservative Federal Guidelines for radio wave exposure and our examinations fall within those guidelines. We feel these are safe levels.

Again, the exception is if you have a cardiac pacemaker, neurostimulator, or a certain type of metallic clip in your body (i.e., an aneurysm clip in your brain).

It is important that all metallic objects be removed from your person prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. In addition, such objects as watches and credit cards should also be removed as these could be damaged. (These items will be locked up for you.)

When you go “off” your regular PD medications during the study, you may experience increased tremor (shaky hands), increased slowness and trouble walking. In the “off” state, there is also an increased risk of falling. In order to reduce the risk of injury, you will never drive, but be driven to the study by a spouse, by a family member or by a friend who can assist you if you need help. In the case that a friend or family member is unavailable, taxi transportation will be arranged to and from the UF or FSU laboratory. Furthermore, if you have difficulty walking off medication, you will be transported around the laboratory using a wheel chair. Finally, if you have any problems while “off” you regular medications, laboratory staff will contact your physician. At home, we suggest that you are always accompanied by a spouse, family member or friend in the “off” state.

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 affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

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 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 new information that may become available and might affect your decision to remain in the study.

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.

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

The benefit to you from being in this study may be a slowing of the progression of Parkinson’s disease during the study. The study drug will not be provided to you once your participation in the study has ended.

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

Others may benefit from our increased understanding of how the body works. Future therapies and diagnoses may be improved upon by this knowledge.

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 3 of this form may 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 option to taking part in this study is doing nothing. If you do not want to take part, tell the Principal Investigator or his/her assistant and do not sign this Informed 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, the Principal Investigator would like to use any information about you that has already been collected. No further data will be collected.

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

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

- because you have had an unexpected reaction
- or have failed to follow instructions
- or because you are found not to meet eligibility criteria
- or because the study has been stopped.
- Also, if the investigator feels that continuing in the study could be too risky for you or could cause problems for the study, you could be withdrawn from the study.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

Study Drugs

Rasagiline or placebo will be provided at no cost to you while you are participating in this study.

Study Services

The Sponsor will pay for or provide all medical services and activities required as part of your participation in this study as described above in the question "What Will Be Done Only Because You Are In This Research Study". If you receive a bill related to this study, please contact David Vaillancourt, Ph.D. at 773-307-8352.

Items/Services Not Paid for by the Sponsor

Any other medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

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

You will receive $100.00 for each visit to the laboratory. If you are traveling to the Gainesville (University of Florida) area from more than 50 miles away, your transportation costs to and from the testing site and additional meal costs will be reimbursed. Finally, during long testing sessions, food and beverages for you and any family members and/or caregivers that accompany you to the visit will be provided at no expense to you.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

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.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

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

If you are injured as a direct result of your participation in this study, only 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 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 study.

17. How will your health information be collected, used and shared?

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, used, and shared 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, used, and shared with others:

- General medical history including age, gender, height, weight, medications and other medical conditions
- Your name, your medical record number, your contact information, and dates associated with treatments and tests that are relevant to this research study
- Your social security number for compensation purposes
- Anatomical and functional scans of your brain
- Measures of cognitive and motor function as well as quality of life as it relates to PD
- Pregnancy tests

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or 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.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To gain a better understanding of the effects of Rasagiline on the brain and motor behavior
- To help develop ways to improve neurological rehabilitation programs and medications

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

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) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- 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).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United State and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- North Florida/South Georgia VHS
- Your insurance company for purposes of obtaining payment

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study. Some information will be used and disclosed for an indefinite period of time since it will be stored in a coded format in a secure database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use

and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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 in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	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, Dr. David Vaillancourt, 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. David Vaillancourt 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