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: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Revitalizing Cognition in Older adults at Risk for Alzheimer's Disease using Near Infrared Photobiomodulation

3. Who is paying for this Research Study?

The sponsor of this study is the National Institute of Aging that is part of the National Institutes of Health and the McKnight Brain Research Foundation.

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

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 your questions. 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. We have a high standard of mutually respectful interactions between research staff and participants. We pledge that research staff will not engage in disrespectful behavior or use racist, sexist, or other inappropriate language and ask the same of you. 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 learn more about the usefulness of a brain health intervention known as **low-level light therapy** or **near-infrared photobiomodulation**. This type of light is invisible and is something you are exposed to every day when you walk around outside. Prior research has found that younger adults, individuals with traumatic brain injury, and older adults including those with Alzheimer's disease experienced positive effects on tasks of thinking and memory after receiving various doses of near-infrared light stimulation.

We now want to learn whether normal older adults with a family history of Alzheimer's disease might benefit from this type of near infrared light intervention. To do so, we are conducting this study.

The intervention takes 12 weeks and there is a 3-month follow-up. The total amount of time from start to finish is 7-8 months.

This study is taking place at the University of Florida and at the University of Arizona.

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

To participate in this study, you must be between 65 and 89 years old, perform normally on tests of thinking (cognitive) and memory, but nevertheless have noticed mild cognitive changes over the past few years. You must be relatively healthy and be able to undergo two brain scans. You must have a family history of Alzheimer's disease to participate.

You will start by undergoing screening with thinking (or cognitive), mood, and other questionnaires.

If you meet study criteria, you will move forward to participate in the intervention, which involves placing light emitting diodes over your head and special lights inside your nose. The intervention lasts 12 weeks and involves near infrared light. This form of light is naturally occurring in your daily life, but you will receive more focused exposure in this study. You will come to the lab for 16 sessions and also do 'at home' stimulation using special devices. Before and after the intervention, you will receive cognitive and mood tests, undergo a brain scan, and provide a blood sample. There is a 3-month follow-up involving a final set of cognitive and mood measures.

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

The infrared light therapy does not pose any serious risks.

- The light used in this study is invisible, painless, and the device used to deliver this therapy is considered safe by the Federal Drug Administration. It

may feel strange having the light clusters placed against your scalp or nose, but this is not painful.

- There may be some discomfort related to having a blood draw, which is similar to what you experience when you give blood as part of your normal clinical care.
- Likewise, there are some additional risks and possible discomfort associated with having a brain scan. The brain scanner produces a loud hammering noise. There is not much room in the scanner and you may feel uncomfortable if you do not like to be in closed spaces. Before undergoing scanning you will be screened to make sure you don't have metal implanted in your body and that you are not claustrophobic.
- Finally, you may become bored or tired taking some of the cognitive and mood tasks during the baseline and follow-up sessions. You will be given frequent breaks to counteract this.
- Another potential risk is the loss of confidentiality. We will take all precautions necessary to prevent this from happening, like giving your information a 'code' so that your personal information cannot be easily identified.

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

There is a possibility that you might experience some improvement on thinking and memory tests, but it is also possible that no changes may take place. If changes do take place, we do not know how long they might last. Importantly, the results of this study will let researchers know whether this type of light intervention might be useful moving forward as a tool for minimizing cognitive changes in older adults

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

There are few validated treatments for improving cognitive changes. The broad clinical recommendations include aerobic exercise, remaining active and involved, good sleep habits, a healthy nutritious diet, improving mood if that is a consideration, and following medical recommendations for any health conditions that a person might have (e.g., hypertension, diabetes, high cholesterol, etc.).

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.

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?

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

Participating in this study will not influence your typical clinical care.

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

This study has several parts.

First, you will undergo an **initial screening**. The screening will help us learn whether you meet guidelines for our research. We will ask you questions about your background including your medical history, the medications you take and your family health history. As part of your medical history, we will ask you questions about alcohol and substance use, whether you have been diagnosed with HIV or AIDS and other medical conditions like brain surgery or stroke that may exclude you from participating in this study. We will also ask you about your psychiatric history including treatment for depression, anxiety and other psychiatric conditions. We will ask about your ability to undergo MRI scans and your ability to carry out daily activities. As part of screening, you will complete questionnaires and receive brief measures of thinking, memory, and reasoning. We will test your vision and your reading,

Completing all these questionnaires and testing measures will take up to 1.5 hours.

We will also ask someone who knows you well, a family member or close friend, to complete a questionnaire and answer some questions about your thinking and memory and ability to perform daily activities. This person can accompany you to the screening evaluation, or we can speak with them over the telephone with your permission.

If you meet the guidelines for our study, you will be asked to continue with the intervention study. If you do not meet guidelines, you will not continue further. We will thank you for your participation. If you are agreeable, we would like to keep information as to why you did not meet guidelines for this study, but will otherwise destroy any information that might identify who you are. If you are not agreeable, then please do not sign this consent form.

The rest of the study has 4 parts.

- **A baseline evaluation**
- **An intense 12-week intervention**
- **A post-intervention evaluation**
- **A 3-month follow-up**

Assignment to the Intervention Group

After you have qualified to join the study and have signed the Informed Consent Form, we will randomly assign you to one of two groups (see below). Random assignment is

like the toss of a coin; a computer program will select which group you are assigned. Once assigned to a group, it cannot be changed during the 12-week program. Participants will be assigned to groups in a 1:1 manner, meaning there is an equal likelihood that you will be assigned to Group A or to Group B. You will not know which group you have been assigned.

Group A	Group B
Real (or Active) NIR Stimulation for 12 weeks (16 lab sessions + at home NIR)	Fake (or Sham) NIR Stimulation for 12 weeks (16 lab sessions + at home NIR

Group A – Active NIR stimulation: If you are assigned to the Active group, you will have "real" near infrared lights applied to your head and inside your nose during each of the 16 sessions. The infrared light is invisible. This means you won't be able to tell if the infrared lights are turned on or turned off. You will receive 3 sessions a week for the first two weeks. After that you will come to the lab weekly for 10 weeks. Each session will last around 2.0 hours. You will be loaned a device to use at home for intranasal stimulation each day.

Group B – Sham NIR stimulation: If you are assigned to the Sham group, you will have lights applied to your head exactly like in Group A. However, the infrared lights will not be turned on. However, you won't be able to tell because infrared light is invisible. This Sham group is really important and will help us figure out whether the infrared stimulation really works, by comparing this group to the real NIR group. You will receive 3 sessions a week for the first two weeks. After that, you will have weekly lab sessions for 10 weeks. You will also be loaned a device to use at home for intranasal stimulation each day.

Baseline Session

Thinking, Memory, and Mood: During the baseline session, you will be given tests of memory, thinking, and mood.

These cognitive and mood measures tests may take up to **5 hours** to complete. Some tests will measure how easily you learn and remember novel information, whereas others will measure how well you can pay attention, solve problems, and multi-task. Other tests will measure how quickly you can respond. Some tests will be given on a computer, and some will not. Some measures are novel whereas others are more traditional and the type you might receive if you had a clinical exam. You will also complete questionnaires and answer questions about mood and emotions, pain, fatigue level, and sleep.

These cognitive and mood measures may take up to 5 hours to complete. You will be given breaks to help you from becoming too tired. Depending on your schedule, they may be given on the same day or broken up across several days. You can stop at any point and withdraw from the study, if you find these too difficult or tiresome.

***Blood Tests*:** We will collect a small sample of blood in order to measure some biomarkers that may be associated with increased risk for developing Alzheimer's disease. A phlebotomist will draw your blood from a vein in your arm or hand using standard techniques. She (or he) will take approximately 2-3 teaspoons of blood. Your blood samples will be coded without personal identifying information. We want to learn whether the presence of certain genes is associated with better response to the light treatment. Similarly, we want to learn whether other ingredients in your blood (called biomarkers) might be sensitive to the light treatment. These genetic and biomarker tests are for research and will not be released to you. This will be done prior to the intervention and again afterwards.

Brain Scan. As part of the baseline session, you will receive a brain scan or magnetic resonance imaging (MRI. This is being done so that we can learn what areas of your brain, if any, are affected by the near infrared light intervention. To be eligible to have an MRI, you cannot have any metal inside your body or be afraid of being in small confined spaces (claustrophobia). You will have to pass a specific MRI screening questionnaire in order to participate in this study.

Inside the brain scanner, you will lie on a padded table inside a large, metal cylinder with your head resting on a padded holder. Foam pads will hold your head still and make you comfortable. Your head will be restrained in a fixed position because sudden body movements can affect the quality of the data acquired. This is also done to prevent damage to the equipment. Because there is not much room inside the scanner, you will not be able to move your body, only your hands.

While in the scanner you will not be asked to do any tasks except stay still, awake, and with your eyes open. After about 30-40 minutes, you will come out of the scanner for a brief period of time while some adjustments are made. You will then continue with the rest of the scan. With this break, we anticipate the brain scan will take between 60-80 minutes.

To be clear, the brain scan you receive is not a clinical diagnostic scan, but a research scan. Even so, there is a remote possibility that we might observe an incidental finding on your MRI scan. If so, we will discuss this with you in more detail and with your permission we will share it with your primary care physician or other appropriate health care professional.

Twelve Week Intervention Phase (16 visits)

The light therapy intervention lasts 12 weeks. The intervention has two parts. One part involves visits to the lab and a second part involves self-delivered stimulation at home.

Part 1: Laboratory Visits: During each lab visit, we will place a cluster of light-emitting diodes (LEDs) on your head and a small LED in your nose. When turned on, these LEDs emit 'near-infrared light' that is safe, painless, and invisible. You will not be able to tell if the LEDs are turned on or turned off. During this time, you will watch nature documentaries on a screen in front of you. The stimulation part will last about 40-50 minutes. After the LEDs are removed, you will complete short questionnaires about your emotions and other experiences. The total time for each visit is 1.5 to 2 hours.

Below is the schedule of visits to the laboratory over the 8 weeks of intervention.

Week 1:	3 visits to the lab
Week 2:	3 visits to the lab
Weeks 3-12:	1 visit each week to the lab

Part 2: At Home Stimulation. We will loan you a device to use at home for daily stimulation. This device has a tip on which a small LED is located. You will place the small LED just inside your nose using a comfortable clip. When turned on, this device will deliver infrared light stimulation. You will use this device for 25 minutes each day for each nostril, except on the days you come to the laboratory. While using this device, we would like you to watch television, a video or DVD, or perhaps listen to music. After using the device, you will be asked to clean the clip and tip using the hygenic packets that we provide you.

You will keep a daily log of the time you do your stimulation and the activities you engaged in while doing so. You will bring your log and the device to each of your lab visits. During your last visit to the lab, you will return the nose device to us.

Post-Intervention Session

Approximately 1-2 weeks after the intervention, you will undergo tests similar to what you did at baseline. You will receive the same cognitive, memory, and mood measures, along with several new questionnaires. This session may take up to 5 hours. You will receive another brain scan and another blood draw. The brain scan will be identical to the one you had before starting the intervention and will take between 60 and 80 minutes. The blood draw will be similar to the one you had before the intervention and will involve 2-3 teaspoons of blood. Together, this may take place on the same day or across several days if necessary or convenient.

3-Month Follow-up Visit

You will have a final visit approximately 3 months following the intervention. You will receive the same or similar questionnaires and measures that you received at baseline. You will NOT undergo another MRI or blood draw.

Sharing Your Information

This study will be conducted at the University of Florida and part will be conducted by researchers at the University of Arizona. We hope to combine information we collect from you and other participants at the University of Florida and the University of Arizona. To do so, we will remove private information that might identify who you are and use a 'code'. Having information from two different sites will help us better learn if this intervention is important.

If you do not want your data shared in this way, do not sign this consent form.

Video Recording

About 10% of participants will be randomly asked to have videos or photos taken of the testing and intervention sessions. These videos or photos will be used for "quality" control. We want to make sure that our research team is conducting the testing and the intervention in a standard manner. These videos or photos will be reviewed by experts at the University of Florida and University of Arizona to provide feedback to our research team. These videos will be used only by our research team and will not be released.

This is optional and is not required to participate in this study. If you agree to the possibility of being videoed or photographed, please sign the "Consent to be Photographed, Video and/or Audio recorded" at the end of this consent form.

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 1 of the addendum.

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

The Research Team will collect

- Your demographic information (as reported by you) such as age, education, gender, work history, marital status, etc.
- Complete current and recent past medical history to determine eligibility criteria, as provided by you
- Reports of neurologic, medical, neuropathologic, and neurosurgical exams, as provide by you, or permission given by you to review records
- Your psychiatric history (as reported by you)
- Records about medications that you have taken, as provided by you
- Information related to diagnosis and treatment of mental health conditions, including use of illicit drugs, as provided by you.
- Reports of previous neuropsychological and psychological testing (as provided by you)
- Questionnaires that you complete
- Assessments of thinking and memory
- Assessment of mood, behavior, and daily functioning
- Blood tests completed as part of this study
- Brain imaging as completed as part of this study
- Social Security number in order to compensate you for participating in this study

The Research Team may collect this information from other healthcare providers, such as laboratories, which 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 1 of the addendum will use or share your health information as described below to carry out this research study.

8. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 3 of this form);
- Investigators at the University of Arizona and University of Florida
- United States governmental agencies which 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 which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

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 it would no longer be protected by the federal privacy law.

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

From start to finish, you will be in this study approximately 7-8 months. This includes 12 weeks of active intervention, with a 3-month follow-up.

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

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

We plan for 168 individuals to complete the study. To reach this number, we may screen up to 300 individuals. Each individual will have an informant who will answer questions about them. This means that up to 600 individuals may potentially participate.

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

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

This infrared light therapy does not involve any serious risk. The FDA considers the LED equipment used in this study to be a non-significant risk device (no risk to safety, welfare, or health). The light used in the stimulation is invisible, painless, and is safe. The LED clusters used in this study are NOT lasers and there is no chance for eye damage

You may experience some mild discomfort from having the LED light clusters placed against your scalp or nose, however this is not painful. If at any time you feel overly uncomfortable, please let us know.

It is possible that during the course of the study, you may develop a cold or runny nose. It is ok to continue with the intranasal stimulation as long as you feel comfortable doing so. If uncomfortable, then you should stop, record this in your log, and let us know.

It is possible that you may become bored or tired taking some of the cognitive and mood tasks during the baseline and follow-up sessions. If so, we will give you frequent breaks and the opportunity to rest.

You are giving a blood sample. 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.

If we should discover, based on our screening or subsequent evaluations, that you appear markedly distressed or are experiencing other significant cognitive or mood difficulties, we will discuss this with you and offer to make an appropriate medical of psychological referral. This might include counseling or other services.

To help us protect your privacy, we have requested a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

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.

Brain Scan Study. There are some additional risks and possible discomforts associated with brain scanning. Magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) are procedures that allows doctors to look inside the body and brain using a scanner that send out a strong magnetic field and radio waves. The procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to do this study if you have any type of metal implanted in your body, for example, any pacing devices (such as a pacemaker), any metal in your eyes, or certain types of heart valves or brain aneurysm clips, metal orthodontics (like braces), or non-removable body jewelry. We will ask you questions about this before you have your MRI.
- There is not much room inside the MRI scanner. You may feel uncomfortable if you do not like to be in closed spaces ("claustrophobia"). If you suspect that you have claustrophobia, then you should not participate in this study. During the study, you will be able to talk with the MRI staff through a speaker system and in the case of an emergency you can tell them to stop the scan.
- The MRI scanner produces a loud "hammering" noise that has been reported to produce hearing loss in a very small number of subjects. You will be given a set of earplugs to reduce this risk. You are also free to bring your own earplugs.

There is a remote possibility that we might observe an incidental finding on your MRI scan. If so, we will discuss this with you in more detail. If appropriate and with your

permission, we may wish to convey this information to your primary care physician and/or make a referral to another health care specialist

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 1 of the Addendum 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 1 of the Local Addendum to this consent form.

12a. What are the potential benefits to you for taking part in this Research Study?

There is a possibility that you may show some improvement on tests of thinking, memory, and mood that you take as part of this study. However, this cannot be guaranteed, as this is the purpose of the study. We do not know whether improved scores, if they occur, will translate into any changes in your day to day life. Nor do we know how long any changes might last beyond the 7-8 months you are in this study.

12b. How could others possibly benefit from this Research Study?

Although this study may not directly benefit you, findings from this research may help us better understand potential treatments for cognitive changes in older adults.

13. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected.

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

Your decision to participate in this study is entirely voluntary. The alternative is not to participate in this study.

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 decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 1 of the addendum. 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 1 of the addendum 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 1 of the addendum.

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:

- 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 about this
- You are unable to keep the time commitments required for the study or you are unable to keep appointments.
- The study is cancelled.
- You engage in inappropriate or disrespectful interactions with study staff.

Since this research study is being conducted at several institutions, there is an Institution Specific "Addendum" to this consent form. Please read this addendum prior to agreeing to participate 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

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 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

We may make a video-audio recording when you are receiving cognitive testing or when you have an intervention session. Your name or personal information will not be identified on these recordings, and confidentiality will be strictly maintained. However, when video- 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 video-audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These video-audio recordings will be shown under *her* direction to students, researchers, doctors, or other professionals and persons. They will be training videos and are used for quality control.

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**. 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 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