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)

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

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")?

Sensory Intervention for Boys with Autism

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

Principal Investigator: Stefanie Bodison, OTD, OTR/L
University of Florida
Department of Occupational Therapy
(352) 273-9883
stefaniebodison@phhp.ufl.edu

4. Who is paying for this Research Study?

The sponsor of this study is the United States Department of Defense.

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 study is to learn more about how sensory interventions might improve the way the brains of boys with autism spectrum disorder (ASD) use sensory information. 40 boys, 6-8 years of age, who have been diagnosed with autism spectrum disorder (ASD) by a physician, psychologist, neurologist, or psychiatrist will be recruited to participate in this study. Total involvement in the study is between 18- to 20-weeks.

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

If you decide to participate, you will attend at least two in-person visits with the research team at the University of Florida. The first visit will occur when you enroll in the study, and the second visit will occur approximately 18-20 weeks later. During these visits, you will complete behavioral assessments of sensory and motor functions and participate in one research magnetic resonance imaging (MRI) scan. In between these visits, some children will receive an occupational therapy research intervention at the University of Florida, and some children will be in a control group, where they will not receive any intervention. At the end of the control period, the children who were in the control group will have the opportunity to receive the research occupational therapy intervention if they remain eligible.

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

Each child will participate in an MRI procedure, where they will have to lie still on a table that is inside the MRI tube. Sometimes, being in this small space can be uncomfortable. Also, the MRI makes loud banging noises, and you will wear earplugs to help dampen the sound. You will also be able to watch a movie while in the MRI scanner. Despite these supports, you may still be uncomfortable. You will be able to stop participating in the MRI at any time.

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

The 16-week sensory intervention may improve your communication, reciprocal social interactions, repetitive behaviors, and/or restricted interests.

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

Standard occupational therapy services provided by your healthcare provider might benefit you. You should ask your pediatrician about the appropriateness of a referral for these services.

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)?

Whether or not you participate in this study, your normal clinical care will not be impacted.

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

If you participate in this study, you and your parent/legal representative will be asked to do the following things:

a) During an initial telephone screening with a research team member, parents/legal representatives will be asked a series of questions related to your sex at birth, diagnosis, language abilities, and sound sensitivity. If you are determined to be eligible to participate in this study after this screening procedure, you will be scheduled for your first in-person visit.
b) Approximately one week prior to your first in-person visit you will meet with the lab manager over Zoom to review the consent form and MRI safety screening.

c) At the first in-person visit, we will confirm the diagnosis of autism using the Autistic Diagnostic Observation Schedule-2nd Edition (ADOS-2). Next, you will complete various behavioral assessments of sensorimotor function using the Sensory Integration and Praxis Tests (SIPT), dynamic posturography, and the Sensory Processing Measure (SPM); complete a short Test of Nonverbal Intelligence-4th Edition (TONI-4); and participate in an MRI scan. This first visit will take approximately 5 hours. You will be provided with a 30-minute break during this visit. To ensure fidelity of assessment we will videotape all assessments. If we are unable to complete all measures during this visit, we will schedule a second visit that will occur within a week of the first visit.
d) While you are being assessed, parents/legal representatives will complete three surveys about you: a background information form, the Vineland Adaptive Behavior Scales-3rd Edition, and the Child Behavior Checklist. If the parent does not complete these during the visit, they will be invited to complete these on their own device after the visit.
e) After your first in-person visit, your behavioral assessments and MRI scan will be reviewed for continued eligibility. If still eligible, you will then be randomly assigned to either a 16-week in-person sensory enriched intervention group or a 16-week control group, where you will not have regular in-person contact with the occupational therapist. The lab manager will follow-up with parents/legal representatives approximately two-three weeks after your first visit to notify them if you are still eligible to be included in the study and if so, to which group you have been assigned.
f) If you are assigned to the intervention group, you will participate in an in-person occupational therapy intervention that includes playing on swings, scooter boards, climbing equipment, bolsters, and ball pit You will participate in intervention sessions for 60-minutes, two times per week, over 16-18 weeks for a total of 32 possible sessions. These sessions will be scheduled at a consistent time that is convenient for you. You will also be administered the the Structured Observations of Sensory Integration-Motor (SOSI-M) to help guide the intervention. To ensure fidelity to the intervention, all intervention sessions are videotaped.

g) If you are assigned to the control group, parent/legal representatives will only receive calls every four weeks from the lab manager to check-in. Children in the control group who participate the full 16 weeks and complete the activities described in "g" detailed below, will also be offered the 16-week intervention. This is completely optional.
h) Within two weeks of completing either the intervention or control condition, families will be contacted to schedule post-testing. During post-testing, you will participate in the same MRI procedures and clinical behavioral assessments of sensorimotor function as during the first in-person visit. The ADOS and TONI-4 will NOT be re-administered.
i) Every four weeks during the 16-week period of time, we will call parents /legal representatives to go over a short form where we will document any new services or therapies you receive.
j) All MRI scans will be reviewed by a radiologist on this study who will look for incidental findings. You will only be notified if there are incidental findings so you can follow up with your pediatrician.

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

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

The Research Team will collect: demographic and background information including history of services or therapies your child has received or is currently receiving, Autistic Diagnostic Observation Schedule-2nd Edition (ADOS-2), Sensory Integration and Praxis Tests (SIPT), dynamic posturography, Sensory Processing Measure (SPM),Test of Nonverbal Intelligence-4th Edition (TONI-4), a research MRI, Structured Observations of Sensory Integration-Motor (SOSI-M; intervention condition only).

The Principal Investigator listed in question 3 will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- United States Department of Defense
- 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

We have an ongoing collaboration with Drs. Hartman and Soehner and their team at the University of Pittsburgh. This group is particularly interested in understanding sleep health in children. You will have an opportunity at a later time to consent to participate in their ancillary sleep study if you are interested. If you consent to participate in their ancillary sleep study, we will share the following identifiable data including: demographic and background information, processed neuroimaging data, and your responses on a sensory history.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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.

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

Your participation in this research study will last between 18 to 20-weeks or less, depending on if you withdraw your consent or are withdrawn by the investigator.

After this study is over, any information that could identify you might be removed. After the removal, other information from this study could be used for other research studies or shared with another researcher. This would be done without your additional permission.

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

40 boys with ASD between 6 to 8 years of age are expected to take part in this research study.

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

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

Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is 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 MRI scanner that will be used for your scan is approved by the FDA for routine clinical and research studies.

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, certain types of heart valves or brain aneurysm clips, or dental devices such as braces. 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 close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan.

- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

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 the Principal Investigator listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

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

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

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

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

The 16-week sensory intervention may improve your communication, reciprocal social interactions, repetitive behaviors, and/or restricted interests.

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

By participating in this study, you will help researchers understand and learn more about non-pharmacological interventions for children with ASD and how their brains use sensory information.

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

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

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

The alternative to participation is to choose not to participate in this study.

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 Principal Investigator listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Principal Investigator listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Principal Investigator 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 Principal Investigator. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with the Principal Investigator listed in question #3.

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

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

- If, after enrolling in this study, your child begins receiving direct occupational therapy services in a sensory enriched environment similar to that being provided in this Research Study.

WHAT ARE THE FINANCIAL CONSIDERATIONS IF YOU PARTICIPATE?

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

No. This study is funded by the Department of Defense. Participants and their families are not responsible for any of the research costs involved in this study.

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

Yes. For the consent meeting, initial testing, and post-testing, you will receive $20 per hour of participation. The intervention is provided free of charge, so no additional compensation will be provided to children in the intervention group. Each caregiver will be compensated $15 per 30-minute check-in with which they participate.

If you are paid more than $199 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. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, 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 Research Participant Payments (RPP) 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 (RPP) 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.
If you have any problems regarding your payment, contact the study coordinator.

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

If you are injured as a direct result of your participation in this study, you should access your regular primary care physician, public or community emergency services if required, and as covered by 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 Dr. Stefanie Bodison if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

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

_____ _____

Signature of Person Obtaining Consent & Authorization Date

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

_____ _____

Consent & Authorization Signature of Parent/Legal Representative Date

_____ _____

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

_____ _____

Print: Name of Participant: Participant's Date of Birth:

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

_____ _____

Assent Signature of Participant Date

Consent to be Photographed, Video and/or Audio Recorded

As described in the Informed Consent Form, we will videotape all sessions to ensure fidelity of the intervention.

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. Bodison, or her successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Bodison 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, t**he 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, t**he 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 of Parent/Legal Representative Date