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Research Consent Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

407521
Committee#

Name of Study Participant

Title of Research Study: TMS for Improving Response Inhibition in Adolescents with OCD
Principal Investigator: Kristen Benito, PhD

Your child is being asked to take part in a research study because they may have symptoms of Obsessive-Compulsive Disorder (OCD). People with OCD experience recurrent, intrusive thoughts and images called "obsessions" and repetitive behaviors called "compulsions". A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether participating in this study is the best decision for your child. Taking part in this study is completely voluntary. Even if you decide to allow your child to take part in the study, you and your child are free to leave at any time if you change your minds. The researcher will explain the study to you and your child and answer any questions you may have. We encourage you to discuss this study with others (your family, friends or other doctors) before you agree to have your child participate in the research.

If you decide to allow your child to be in the study, you will be asked to sign this consent which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. The "assent" (agreement) of your child will also be obtained by the researcher before your child may participate in this study. Your child must sign the assent form. You will be given a copy of the signed consent form to keep.

Study Information

A. What is the purpose of the research?

The purpose of this study is to test whether brain stimulation can improve connections between specific areas of the brain, and whether it improves the ability to stop unhelpful behaviors. We will be using a form of brain stimulation called transcranial magnetic stimulation (TMS), which uses magnetic fields to stimulate nerve cells in the brain. If TMS does improve these brain connections and the ability to stop unhelpful behaviors, we hope this may eventually lead to a new treatment for teens with OCD.

B. What is experimental/new in this study?

Response Inhibition is a type of brain function that is involved in stopping unwanted or unhelpful behaviors. This brain function is thought to play a role in OCD compulsions, a type of OCD symptom that involves repeating unhelpful behaviors. We will be using TMS to stimulate the brain and to record the effect this stimulation has on your child's response inhibition and brain connections.

Although TMS is approved by the Food and Drug Administration (FDA) as a treatment for OCD in adults, the use of TMS for adolescents is investigational – not approved by the FDA for treatment. The FDA has approved the use of TMS in this study for investigational purposes only (not as a treatment).

C. What do I have to do in this research?

You and your child will attend 3 sessions for this study. The first session will be done remotely (by phone or web) and will be a screening for the study. Sessions 2 and 3 will be at Butler Hospital where the TMS procedures will take place. Your child will complete questionnaires, thinking tasks, electroencephalography (EEG) recording, and TMS procedures during sessions 2 and 3. Your child will complete questionnaires between each study session. You will also be asked to complete questionnaires.

D. What could go wrong?

Your child may experience a sensation of tapping or pain sensations around the placement of the TMS device. Other possible side effects associated with TMS applied to this area of the head are scalp, jaw, face, or neck discomfort or muscle twitching in those areas, or toothache, or headache. A very uncommon side effect (1 in 1,000 participants), but important to mention, is a seizure.

E. What are the benefits?

Your child may or may not receive direct benefits from this study. We do not expect your child to receive any lasting benefits from this study. Your child may experience a temporary improvement in his/her ability to stop unhelpful behaviors.

F. Other things I should know about this research?

This is not a treatment study.

G. If I don't want to take part in this research what are my other choices?

Your child's currently available, clinical psychiatric care. This is not a treatment protocol.

• Please carefully read this form, additional detail about each item just described is found below
• Please listen to the study team explain the study and this form to you
• Please ask questions about anything that is not clear

1. Nature and Purpose of the Study

The purpose of this study is to test what effect a single session of brain stimulation (called repetitive transcranial magnetic stimulation [rTMS]) has on 'response inhibition.' In TMS, an electrical magnet is used to stimulate part of the brain for a short time. TMS can noninvasively (without any part of the device entering the brain directly) stimulate the brain from outside the head to study specific brain areas and how they work. During TMS, a plastic device is held against the outside of the head. The device contains a wire (called a "coil") that is attached to a machine that sends an electric current through the wire to the device. This creates a magnetic field next to your skull that can stimulate a part of your brain.

In this study the use of TMS is investigational. That means TMS is not approved by the Food and Drug Administration (FDA) as a treatment for OCD in adolescents or children. We have specific approval from the Food & Drug Administration (FDA) to conduct this study for investigational purposes only (not as a treatment).

We expect to enroll 25 adolescents (13-18 years) with OCD into this study. Participation in this study consists of one remote session and two visits to Butler Hospital. The first visit (remote) will last approximately 1.5 hours and the 2 visits (Butler Hospital) will last approximately 2 hours each.

Sessions 2 and 3 (Butler Hospital) will include your child wearing an electroencephalogram (EEG) cap, completing tasks on a computer, and TMS sessions, while visit 1 (remote) will involve a clinical assessment, review of medical history and questionnaires. Your child will receive one session of TMS at each of visits 2 and 3—one of these visits will be active TMS and the other will be "sham" (fake) TMS. You will not know which one your child receives at which visit.

In order to decide whether or not you wish your child to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research team will discuss with you and your child. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, risks associated with the procedures, possible benefits of participation, and possible alternatives. Once you understand the study, you will be asked if you wish your child to participate; if so, you will be asked to sign

this form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This research is sponsored by the National Institute of General Medical Sciences (NIGMS).

2. Explanation of Procedures

Study Timeline

A. **Visit 1 Screening (remote visit):** If you decide to have your child join the research study, some screening tests will be done first to see if your child is eligible to participate. This visit will happen remotely (by phone or web as you prefer). This visit will include a clinical assessment, review of your child's medical history, a TMS screening questionnaire, and parent questionnaires regarding background/demographics. During the clinical assessment, an evaluator who is part of the research team will ask you and your child questions about your child's OCD symptoms and other possible mental health concerns. This assessment will be audio or videotaped to ensure that the research team is following the assessment procedures accurately. Videotapes will be destroyed at the end of the study. The evaluator may ask some questions about suicidal or homicidal thoughts and drug or alcohol use. If your child reports suicidal or homicidal thoughts to the evaluator or on the questionnaires, researchers will determine whether this requires treatment beyond that provided by this study and prompt action will be taken to provide appropriate care or referral.

   You will be asked to sign releases to let us obtain a note from your child's doctor (in order to review your child's most recent physical exam). These procedures will help to determine if your child is eligible to receive TMS. Some adolescents will not be eligible to participate based on the results of these screening tests.

   If the screening tests show that your child meets all study requirements, then the researcher will be able to assign your child to the study treatment. If the screening tests show that your child does not meet all the study requirements and cannot be in the research study, the research investigator will discuss other options with you.

B. **Visits 2-3: TMS Procedures (including cognitive testing and EEG):** If your child qualifies to take part in this research study, they will be asked to complete two TMS sessions (which will both occur after visit 1). These TMS sessions will use the Magstim Super Rapid2 Plus 1 stimulator. During the first TMS session (which will be visit 2 of the study), we will use a brief series of TMS pulses to measure your child's motor response in order to determine the optimal level of stimulation for your child's TMS sessions.

   a. EEG: The study is examining whether TMS can improve brain activity, as measured with an EEG cap. The EEG cap will be applied before any other activities. Your child

will be asked to play a cognitive task while wearing the cap before and after TMS. The EEG cap will measure your child's brain activity. This EEG is not a diagnostic EEG that can replace clinically administered EEG; data is only used for research purposes.

b. TMS: During one session, your child will have active TMS and the other session will be a sham (fake) TMS session. You and your child will not be told which session is which. The active TMS session will deliver a total of 600 pulses over approximately 3-5 minutes. Your child will complete the TMS sessions on different days, with at least 5 days in between the sessions. Your child will be monitored during the study for any adverse events that may occur. We will screen for adverse events by asking your child if he/she about any discomfort or other symptoms right after the session.

c. Cognitive tasks: Immediately prior to the TMS session, your child will be asked to complete computer tasks that take about 15-20 minutes. These tasks will evaluate aspects of response inhibition. Your child will be asked to complete these same tasks again following TMS.

C. **Post-visit Assessments.** Over the two days following each visit (visits 1, 2, and 3), your child will be asked to complete a series of very brief surveys (about 2 minutes each) about symptoms. Your child will be asked to do this at different times throughout those two days (during the hours of 9am to 9pm only), up to 20 times total. When it is time to complete a survey, your child will receive a text message with a secure survey link.

Optional: Study forms sent electronically

With your permission, we will send study survey links via text message to you and/or your child. Surveys will use REDCap (Research Electronic Data Capture), a secure web application for building and managing online surveys and databases. The study will not cover the cost of text messaging, normal text messaging and data rates may apply.

You have my permission to send survey links via:

Yes	No	
☐	☐	Text message to my phone Phone number: _____
☐	☐	Text message to my child's phone Phone number: _____

Reimbursement for participating in this study:

Your child will be compensated up to a total of $300 for study participation. You can choose to receive compensation in the form of an electronic gift card, mailed check, or cash.

Study Activity	Compensation	Time of Compensation
Visit 1 (remote)	$50	End of visit
Visit 2 (Butler Hospital)	$100	End of visit
Visit 3 (Butler Hospital)	$100	End of visit
Post-visit Assessments	$2 each + $10 bonus for 80% completion (up to $50 total)	3 days after each visit

Optional: Study compensation sent electronically

With your permission we can send compensation for study activities to your email or your child's email via electronic gift cards.

You have my permission to send electronic gift cards via:

Yes No

☐ ☐ My email address:
Email: _____

☐ ☐ My child's email address:
Phone number: _____

Assessment reminders and Questionnaire links from study staff

Study staff can send you emails and text messages to remind you of upcoming study visits and questionnaires to complete. All forms of communication will not contain personal information other than the date and time of upcoming visits. You can opt out of email communication at any time, but text messaging is required for study participation (so that your child can complete the series of very brief surveys after each study visit). The study will not cover the cost of text messaging, normal text messaging and data rates may apply.

You have my permission to send reminders and questionnaire links via:

Yes No

☐ ☐ Text message to my phone
Phone number: _____

☐ ☐ Text message to my child's phone
Phone number: _____

☐ ☐ My email address:
Email: _____

☐ ☐ My child's email address:
Phone number: _____

_____ _____

Signature of parent/guardian Date

Costs for participating in this study
Your child will be compensated for expenses incurred in participating in this study, such as medical record fees and parking for the study visits (up to $50 total). There will be no costs to you or to your insurance for study activities (including assessments, cognitive testing, EEG, and TMS). In the event that your child experiences a research injury, it is possible that some or all of the cost of treating your child could be billed to you or to your insurer.

Contact Information:
If you have any questions, concerns or complaints about this research or experience any problems, you should contact the principal investigator, Kristen Benito, Ph.D. at (401)-432-1054.

3. Discomforts and Risks

Any medical treatment or procedure may have unforeseen side effects. You should know that the prediction of effects from a treatment or procedure for any individual cannot be done with certainty, and unexpected potentially harmful effects occasionally occur with the administration of any type of treatment. If you have questions about investigational procedures or treatments, or if your child experiences any disturbing side effects during participation in this study, inform study personnel. In the event of any unexpected, potentially harmful effects of any treatment or procedure administered in this study, we will monitor your child's condition closely and institute appropriate treatment. If significant new knowledge is obtained through the course of the research which may impact your willingness to continue participation, you will be informed of this knowledge.

- **Risk of Side Effects from TMS Sessions**

In order to minimize potential risks of TMS, your child may not participate in this study if they have any of the following: metal in the head (except for in the mouth), medical condition that increases pressure in the head, suicidal thoughts, possibility of pregnancy, history of stroke, history of epilepsy in themselves or a family member, taking a medication that lowers seizure threshold, a cardiac pacemaker, an implanted neurostimulator, an implanted medication pump, intercardiac lines (surgically implanted lines for monitoring heart function), significant heart disease, bipolar disorder, or have used alcohol heavily within the last 48 hours. During sessions, your child may experience a sensation of tapping or painful sensations around the place where the application coil is positioned on his or her head. Most patients who have had TMS therapy usually report these sensations to be mild and find they diminish over time as their body adjusts to the stimulation procedure. Other possible side effects associated with TMS applied to this area of the head are scalp, jaw, face, or neck discomfort or muscle twitching or numbness in those areas, or toothache, or headache. Over the counter pain medications such as Tylenol (acetaminophen) may be helpful for reducing discomfort from TMS. Parents are encouraged to bring such pain medication from home, as it will not be provided by the hospital. When TMS has been delivered to parts of the brain near the face, there have been reports of mild

discomfort associated with eye makeup. If you wish, your child may remove any makeup before receiving TMS in this study. When TMS has been delivered to other parts of the brain, there have been reports of temporary dizziness, fainting, brief changes in attention, thinking, or mood, and visual changes. These are considered extremely rare and highly unlikely to occur with the type of TMS protocol being used in the current study. Assessment of your child's well-being will occur before and after each session to ensure safety and minimize their risk of experiencing these side effects.

- **Risk of Hearing Changes or Loss**

Changes in hearing or hearing loss are theoretical risks of TMS, although this does not present a risk when TMS is administered with standard earplugs. Your child will be asked to wear earplugs to minimize the risk of hearing loss. However, there may be some risk of temporary or permanent hearing changes or loss if an earplug should loosen, become detached, or fall out. We will ask your child to tell us immediately if an earplug loosens or falls out; we will stop TMS immediately if this happens.

- **Risk of Seizure**

It is estimated that in ordinary clinical use, standard TMS applications (delivered in the same general location of the brain and with the approximate strength that will be used in this study) have caused a seizure in approximately 1 out of 1,000 of patients. The TMS applications in this study will be given by doctors and staff who have extensive experience with the safe delivery of TMS and who are trained in steps to prevent and manage seizures. Medical personnel and equipment are available to monitor subjects and apply first-aid procedures if a seizure occurs at Butler Hospital. Most seizures last only a few minutes and spontaneously end, with the patient in a somewhat confused state that resolves over several hours. Management of a seizure during a TMS session may involve transferring patients to a local emergency room or to another facility for further evaluation, if that is determined to be necessary by the study doctor. Having a seizure may lead to a potential effect on a person's future employability and ability to drive. Should your child experience a seizure that is related to TMS application in this research, a doctor will provide you with a letter stating that the seizure was produced under specific brain stimulation condition in this study, and that there is no reason to expect another seizure would occur when they are not receiving TMS application.

There may be other risks that are currently unknown. Although TMS has been used for many years, the long-term effect of TMS on individuals are not completely known. If your child has any medical issues you should first contact your child's primary care physician, psychiatrist, or another mental health professional. A TMS-trained physician will oversee all TMS research sessions and is available immediately for urgent medical issues. You will be given information about how to contact the TMS medical staff outside of regular work hours.

- **Risks of Cognitive Testing/Questionnaires**

Your child may feel tired or frustrated during the tests and questionnaires. Your child will be given breaks as needed. Some of the questions we will ask your child as part of this study may make him or her feel uncomfortable. Your child may refuse to answer any of the questions

and/or may take a break at any time during the study. Your child may stop participation in the study at any time.

- **Risks of EEG**

The EEG cap leads will be in direct contact with your child's head and hair. This could cause skin irritation or allergic reactions. If your child experiences any discomfort while wearing the EEG cap, the cap will be removed.

- **Parents of Females Please Note**

TMS is not recommended for use during pregnancy. TMS may be harmful to a developing fetus. Testing for pregnancy will not occur as part of study procedures. Prior to beginning the study we will discuss with you in more detail the importance of avoiding pregnancy.

4. Benefits

Participation in the study may result in a temporary improvement in your child's response inhibition (lasting several hours to several days). However, there may be no benefit for your child.

5. Alternative Therapies

Taking part in this study is voluntary. The alternative is to choose not to participate in this study.

6. Refusal/Withdrawal

It is up to you whether you want your child to be in the study. You are not required to enroll your child or have them participate. If you decide you want your child to participate, you can always change your mind and remove them from the study at any time. If you decide not to have your child be in the study, or if you remove them later, your child will still be able to get the health care services they would normally get. If you enroll your child but later the researcher or your child's doctor feels being in the study is no longer good for your child, they may choose to take your child out of the study before it is over. If new information becomes available that might change your mind about whether you want your child to stay in the study the researcher will share this information with you as soon as possible.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If your child is injured by a medical treatment or procedure they would have received even if they were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If your child does experience a research injury, Lifespan or the study doctor can arrange medical treatment for them. Such treatment will be paid for as described below.

If you have insurance and your child has a research injury that is not covered by the study, it is possible that some or all of the cost of treating your child could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you or your child have any complaints about your child's participation in this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6897.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information

Your child's research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your child's information to someone outside of Lifespan) their health information for research purposes. If you sign this form you agree to have your child be in this research study and you permit the use and disclosure of your child's health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw your child from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, your child will stop taking part in the study and no new information will be collected about them. However, if you cancel your permission, it will not apply to actions already taken or information already collected about your child by the hospital or the researchers before you canceled your permission

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff at Butler Hospital and Bradley Hospital;
- The study sponsor: National Institutes of Health (NIH)
- Doctors, nurses, laboratories and others who provide services to your child or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The device companies: Magstim (rTMS) and ANT Neuro (EEG);

- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your child's health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your child's health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your child's information.

Your child's identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

You have the right to refuse to sign this form and not allow your child to participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, your child will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to have your child quit the study after signing this form (as described in Section 6), no new information will be collected about your child unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you removed your child from the study to complete analysis and reports of this research.

You will not be allowed to see or copy the information about your child's participation described in this form if the research study is open. You may see and copy the information when the study is completed.

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 your child. At most, the Website will include a summary of the results. You can search this Website at any time.

Contact for Future Studies: Your child's participation in **any research** is completely voluntary and you/ your child should feel no pressure to have them participate in another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about my child participating in other research projects studying OCD or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about my child participating in other research projects. **Do not** give my contact information to the staff of any other research studies.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT MY CHILD TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission for my child to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document expires on 5/17/2022.
DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

_____	_____	_____
Signature of Parent or Guardian	Date (MM/DD/YEAR)	Time when signed
_____	_____	_____
Signature of Second Parent or Guardian	Date (MM/DD/YEAR)	Time when signed

_____
Print name of participant

_____	_____	_____
Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**