

Protocol #7006- Child Assent- Ages 7-11

Version Date: 11-14-22

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ASSENT FORM-Cover Sheet
Overlapping Neural Circuits Implicated in Pediatric OCD

Overview of the Study

Below is some information about the study that you are asked to be involved in. This does not replace the assent form, which you will have to sign if you decide to be involved in the study. The assent form includes many details about the study.

Purpose of the Study:

Children with and without Obsessive-Compulsive Disorder (OCD) will complete the study so we can look at differences in the brain. We are also trying to learn how the brain works in children with OCD before and after treatment.

Procedures:

You and your parent will be asked questions about your thoughts and feelings, we will take pictures of your brain through a magnetic resonance imaging (MRI) scan, and ask you to do some puzzles and games. We may ask you to come back after 12-16 weeks to answer more questions about your thoughts and feelings and to repeat the games and the MRI scan. If needed, you will meet with a study doctor for up to 16 weeks between the two MRI scans to talk about your thoughts and feelings.

Risks:

This study includes some risks and discomforts. These include: The interviews and puzzles and games may make you feel uncomfortable or tired; Therapy may make you feel worse or not help you; You may find it uncomfortable in the MRI scanner

Your Privacy:

All records will be private.

Your Rights:

During the study, you may not want to be in the study any more. This is ok. You may stop being in the study at any time and you do not have to finish the study. If you do not want to be in the study, we can help you find other doctors to talk to about your thoughts and feelings.

You may contact the study doctor, Dr. Rachel Marsh at 646-774-5774 with any questions.

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**ASSENT FOR PARTICIPATION IN A RESEARCH PROJECT NEW YORK STATE PSYCHIATRIC
INSTITUTE**

**Study Title: Overlapping Neural Circuits Implicated in Pediatric OCD Principal Investigator: Dr.
Rachel Marsh, Ph.D.; 646-774-5774**

WHY IS THIS STUDY BEING DONE?

We are asking you to take part in a research study. In this study, we are trying to learn how the brain works in children with Obsessive-Compulsive Disorder (OCD) before and after treatment. Children with and without OCD will complete the study so we can look at differences between the groups. You may be asked to speak to a doctor in this study about your thoughts and feelings so that we can see if anything in the brain changes when children talk to doctors about their feelings. We will also ask you questions, have you play games and solve puzzles, and take some very special pictures of your brain. These pictures are called magnetic resonance imaging or “MRI scans.” In the future, we might use your answers to questions, your puzzles and MRI scans from this study to learn more about the brain in other studies, too.

DO I HAVE TO BE IN THIS STUDY?

You do not have to be in our study if you do not want to. You can get an MRI from your doctor without being in our study today. We can also help you find other doctors to talk to about your thoughts and feelings.

WHAT WILL I DO IN THIS STUDY?

This study may last up to 16 to 20 weeks and it will have many different parts:

1. Questions- You and your parents will be asked some questions about your thoughts and feelings. These questions will take between 2 and 3 hours to finish. You don't have to answer any questions that you don't want to. After you and your parent finish answering them, our research team may decide that the study is not a good fit for you. If this happens, we will give your parents the names of other doctors to speak to about your thoughts and feelings. You will also get a gift card for the questions you answered.
2. Games and Puzzles- You will be asked to play some games and puzzles. If you wish to stop playing these games, please let us know and we will stop immediately.
3. Pregnancy Testing- If you are a girl and have had your first period, the doctors who work on this study want to be careful that you are not pregnant. Someone who works on this study will test your urine for pregnancy right before your MRI scan. If you would like, you can have your pregnancy test done by your own doctor or a different doctor's office. If the test says that you are pregnant, you cannot be in the study, and you and your parents will be told what the test says. Also, we will talk to you and your parent about where you can go to get some help.
4. MRI Scan- When we are ready to take pictures of your brain, we will ask you to lie down on a padded table that can move into the MRI machine. The MRI machine is shaped like a doughnut,

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with a round hole in the middle like a tunnel. When you are inside the MRI machine, you will hear knocking or buzzing sounds. These sounds are OK, they just mean that the machine is taking pictures. We will give you ear plugs to make it less noisy, but you will still be able to hear us talking to you. Your parent or someone that works on the study can stay in the room with you while we are taking the MRI pictures. It will take us between 1 and 1 1/2 hours to finish taking all the MRI pictures. When you are in the MRI machine, we will give you a rubber squeeze ball to hold in your hand. If you squeeze this ball, you will send a signal that tells us you want to stop right away. If you squeeze the ball, we will take you out of the scanner immediately. You can ask to stop the scan at any time if you feel uncomfortable or just don't want to be in there anymore.

Before we start taking the pictures, a member of our study team will tell you about everything that we are going to do. If you have any questions about what is happening, it's OK for you to ask and that person will answer you. The pictures we are taking are like the pictures that you take with a regular camera: you have to stay really still so that the pictures don't come out blurry. But we will ask you to do things like wiggle your finger, watch a TV screen, or push a button.

5. Therapy- After you finish all study questions, puzzle/games, and the MRI scan, you may meet with a study doctor in the Youth Treatment and Evaluation of Anxiety and Mood (Y-TEAM) Program. You will come to the study office for 12 weekly sessions. At each visit, the study doctor will speak to you for about one hour about your thoughts and feelings. If you do not want to finish therapy or participate in the study any more, you can still come to the Y-TEAM Program for 3 months to meet with doctors to talk about your thoughts and feelings. We will also give your parents the names of other doctors you can speak to about your thoughts and feelings.

6. End of Study Visit – We may ask you to come back for another visit 12-16 weeks after your first MRI scan so that we can see if anything in the brain is different after children talk to doctors about their feelings. We want you to have another MRI and play games/puzzles again. Your second visit will be almost the same as the first one.

7. Follow-up- We may call you and your parent 9-12 months after the you first come in for an MRI scan. We will also send your parent a survey. The phone call and survey will include some questions about your thoughts and feelings.

Audio recording – We would like to record your voice for some of the time you spend with the research team or therapist. We would like to do this to make sure we are doing our job well. If you say no to being recorded, you can still be in the study.

WILL ANYTHING IN THIS STUDY BE BAD FOR ME?

Nothing we do in this study will be bad for you. But if you feel uncomfortable during any part of this study, tell the study team, and we can stop what we are doing right away.

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Sometimes, people say that during the MRI scan, they feel a "tingling" or "twitching" feeling (or, very rarely a little painful feeling). Also, some people feel nervous when they are inside the scanner because the space is small. If you have any uncomfortable feeling in your body or get nervous while you are in the MRI scanner, tell a member of the study team or squeeze the ball in your hand, and we will stop the scan immediately.

Having an MRI doesn't hurt, but you might not like having to lie still inside of the machine. Also, you might get tired or upset if you are asked to do certain tasks, such as looking at pictures, pressing buttons, moving a joystick, or moving one of your fingers while you are in the scanner. Again, if you want to stop the scan at any time, just squeeze the ball in your hand and we will take you out of the machine.

When we ask you to do problems and puzzles, you might feel a little tired after having answered a lot of questions. If you feel tired, you can ask to take a break at any time. If you don't feel like answering some questions or doing some puzzles, you don't have to.

If you meet with the study doctor for treatment, you may feel that your thoughts and feelings are getting worse. You may also feel very nervous when your doctor asks you to face scary ideas and situations.

If you take part in this study, the doctors and the study staff will check with you and will ask you questions to make sure that you are OK. If you ever have thoughts about hurting yourself or anyone else, you should tell your parent(s)/guardian(s) right away. You should also tell someone on the study team. The study doctor will give your parent(s)/ guardian(s) names of other doctors to talk about these thoughts and feelings if needed to help keep you safe.

CAN THIS STUDY HELP ME?

The study may or may not make you feel better. The study doctor does not know this for sure. Being in this study, though, might help us to learn more about the brain, and this might be able to help other people later.

WILL I GET ANYTHING AFTER I AM FINISHED?

Once you finish all parts of the study, you will receive a gift card for your time. We will give you gift cards for \$150 after you finish the study. If you do not finish all parts of the study, you will be given a gift card for the parts that you complete (\$75 for the interviews/games/puzzles, and \$75 for the MRI scan).

If you come back for a second MRI scan and the end of treatment visit, you will again receive gift card for being in the study. We will give you another gift card for \$125.

If you complete the follow-up phone call and questions, we will mail a \$25 gift card to your address. You can expect it to arrive within 3 weeks of answering these questions.

WHERE WILL INFORMATION ABOUT ME BE KEPT?

All of the information we have about you will be kept private and in a special place. You do not have to take part in this study if you don't want to. Whether you say "yes" or "no" to

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being in this study will not change the way the study team treats you, and they will still give you the help you need. Our team or a different study team may use some of the information we have collected from you for future research studies, but your name and other personal information will not be used in this way.

If your answers indicate a serious problem that may jeopardize your safety or health, then the researchers will contact your parents. New York State law requires us to report any cases of suspected child abuse or neglect to state officials. Most of the things you talk about with the study team will not be told to your parent(s)/guardian(s). But if the study staff thinks that you are in danger of hurting yourself or someone else, they will have to tell your parent(s)/guardian(s) or your emergency contact. Research staff may not be able to discuss this with you first. In the case of a safety emergency, we may have to take you to an Emergency Room or community resources, such as 911 or 988.

If you would like to know any of the results from this research, including results from your interview, let us know, and we can provide them. Also, your MRI scan will be reviewed by a doctor, and we will share the doctor's findings with your parent(s) and/or your doctor.

QUESTIONS?

Please feel free to ask questions about any part of this form or this study that you don't understand. Take as long as you need to decide if you want or do not want to participate in the study. The doctor running this study, Dr. Rachel Marsh, will answer any questions you have now or later about this study. You can ask your parents to help you call her at (646) 774-5774. You will be given a copy of this assent form to keep.

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DOCUMENTATION OF ASSENT

I have read this assent form, and I agree to take part in this research study because I want to. I understand that I don't have to be in this study if I don't want to. All of my questions have been answered.

Signature of Child

Date

Printed Name of Child

Voice Recording:

Do you agree to the audio recording described above? If you say no, you can still be in this study.

_____ **Yes**, I agree to recording

_____ **No**, I do not agree to recording

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To be completed by the person administering assent:

Check those that apply:

☐

The participant is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.

☐

The participant is not capable of reading the assent form; however, the information was explained verbally to the subject, who has verbally given assent to take part in this study.

I have discussed the proposed research with the participant, and, in my opinion, this individual understands the benefits, risks, and alternatives (including non-participation) and is capable of freely assenting to participate in this research study.

Signature of Person Obtaining Assent

Date

Print Name