# Parental Permission Document

**Title of Research Study:** *Neuromodulation augmented cognitive remediation to improve executive dysfunction in fetal alcohol spectrum disorder*

**Investigators:** *Jeffrey Wozniak, Ph.D. and Christopher Boys, Ph.D.*

**Supported By:** ***University of Minnesota – Department of Pediatrics***

## What is research?

Doctors and researchers are committed to your child's care and safety. There are important differences between research and treatment:

- The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.

## Why am I being asked to take part in this research study?

We are asking you and your child to take part in this research study because your child is between the ages of 10-16 and has a history of having been exposed to alcohol prenatally.

## What should I know about being in a research study?

- Someone will explain this research study to you.
- Whether or not your child takes part is up to you and your child.
- You can choose not to have your child take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

## Who can I talk to?

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

| | |
|---|---|
| **Researcher Name:** Jeffrey Wozniak, PhD<br>Phone Number: 612-273-9741<br>Email Address: jwozniak@umn.edu | **Study Staff:** Alyssa Krueger<br>Phone Number: 612-624-0127<br>Email Address: krueg654@umn.edu<br>**Study Staff:** Mariah Schumacher<br>Phone number: 612-624-0195<br>Email Address: schum605@umn.edu |

# Parental Permission Form

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your or your child's research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your or your child's rights as a research participant.
- You want to get information or provide input about this research.

## Why is this research being done?

(1) The purpose of this research is to test a form of brain stimulation called transcranial direct current stimulation (tDCS), combined with computerized cognitive training in children ages 10-16 with prenatal alcohol exposure (PAE).

(2) There are very few treatments available for children with developmental delays and learning problems as a result of PAE.

(3) Most of the benefits from this research will be to the field as a whole and not to you or your child as individuals. However, your child will receive computerized cognitive training and could potentially benefit from the experimental intervention as well.

(4) tDCS involves an investigational device. "Investigational" means that the device is not approved by the FDA for use in treatment.

## How long will the research last?

Your child's participation in this study will consist of six separate sessions over the course of four to eight weeks. Session 1 will be about 3 hours long. Sessions 2-5 will be only one hour. Session 6 will be about 2 hours long. In addition, we will complete one brief telephone follow-up about 30 days after the sixth session. We expect that your participation time will total about 9 hours.

## How many children / parents will be studied?

We plan to enroll 40 children in this research study.

## What happens if I say "Yes, I want my child to be in this research"?

We will ask you and your child to visit the University of Minnesota six separate times over the course of four to eight weeks, and we will complete the following procedures:

(Visit 1): We will conduct an interview to identify conditions that may exclude your child from participating, including certain neurological and psychiatric conditions.

(Visits 1 & 6): You will complete questionnaires about your child's behavior. Your child will complete cognitive tests. The cognitive testing is expected to take 60 minutes.

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(Visits 1 & 6): Your child will have an MRI scan which takes about 45 minutes. This involves taking pictures of your child's brain. The purpose of the MRI is to measure any changes in brain activity that may be related to the intervention. Beforehand, we will ask questions about your child's health history to ensure that it is safe to conduct the MRI scan. For the MRI, your child will be asked to remove all metal objects, change into scrubs (provided), and lie quietly in the scanner. There will be some noises like knocking or beeping sounds. We will give your child ear plugs and/or earphones to reduce the noise. We will also play a video for your child, if desired, to make the experience more pleasant.

We will be watching your child at all times and communicating by voice. Your child will be given a "panic button" to hold during the scan with which your child can signal the researcher that he/she wants to stop.

The MRI is designed to answer research questions, not for medical diagnosis. The MRI is not a substitute for one that a doctor would use. It may not show problems that would be picked up by a clinical MRI scan. However, if we believe that we may have found a medical problem in your child's MRI scan, we will ask a doctor who is trained in the reading of MRI scans (a radiologist) to review the scan. The pictures will not contain personal information except your child's age and pertinent medical history collected as part of the research. There will be no charge to you for having the radiologist review the MRI scan. If the radiologist thinks there may be an abnormality, we will help you obtain medical follow-up. However, further medical follow up is not a part of this study and the study does not have money set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

(Visits 1 – 5): Your child will complete some cognitive training exercises on a computer. During these exercises, your child will wear a battery-powered transcranial direct current stimulation (tDCS) cap on their head which will deliver either a very mild electric stimulation to the scalp or no stimulation (placebo). This will be determined by random chance (like the flip of a coin). If your child is in the "active" group, they will receive stimulation in two 13-minute periods per visit. If your child is in the non-tDCS "placebo" group, they will not receive tDCS stimulation but will still wear the cap. The experimenter, you, and your child will all be "blinded" to the group and will not know who is receiving real stimulation and who is not. Neither the experimenter nor you will be able to choose the group for your child.

During one of the visits, we will take a series of 3D facial images with a special digital camera. This will take 10 minutes.

During one of the visits, our clinician will perform a brief physical exam including measurements of height, weight, and measurements of the physical and facial features that are common in FASD. This will take 10 minutes.

We will complete a telephone follow up 30 days after visit 6.

| Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Follow up |
|---|---|---|---|---|---|---|
| (3 hours)<br>- Screening<br>- MRI scan<br>- Cognitive testing<br>- tDCS intervention | (1 hour)<br>- tDCS intervention | (1 hour)<br>- tDCS intervention | (1 hour)<br>- tDCS intervention | (1 hour)<br>- tDCS intervention | (2 hours)<br>- Screening<br>- MRI scan<br>- Cognitive testing | (telephone)<br>- Telephone survey 30 days after visit 6 |

### What happens if I do not want to be in this research?

You or your child may decline to participate and it will not be held against you.

### What happens if I say "Yes", but I change my mind later?

You and your child can leave the research at any time and it will not be held against you. If at any time you decide to leave the research, contact the investigator so that the investigator can discontinue your child's participation. Any remaining visits will be cancelled, but we will still use the information that we have already collected in the analyses and we will still call you approximately 30 days after the study to ask you about the child's functioning and health.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. In other words, your choice to not participate in this study will not negatively affect your child's right to any present or future medical treatment.

### What are the risks? Is there any way being in this study could be bad for me or my child?

<u>MRI:</u>

MRI machines use a strong magnet and radio waves to take pictures of the brain. MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Metal objects can be pulled into the magnet and turn into projectiles. To minimize this risk, we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel uncomfortable.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if your child does not wear hearing protection. Hearing protection is required and is provided.

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Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable your child should tell us.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. We will screen you and your child thoroughly for these devices.

Heating of Devices: The radio waves used in MRI can heat some materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. Your child will be asked to remove these items if possible. If they cannot be removed, your child will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will help us minimize the risks. Your child will be in constant contact with the investigator and should notify her/him immediately (panic button) it they notice anything unusual, become claustrophobic, think that the hearing protection is inadequate, or if they experience nerve tingling.

There is a risk of unknown effects related to MRI. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, go away shortly after leaving the MRI. If any sensations experienced during participation cause discomfort or pain, your child should notify the researcher right away, and their participation will stop and they will be taken out of the magnetic field. The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if your child is a female who is capable of becoming pregnant, and you or your child have any reason to believe that they might be pregnant, your child should not participate.

<u>Neurocognitive testing and questionnaires:</u>
We will ask you to complete questionnaires about your child's behavior. Some of the questions may be about topics that some people would consider sensitive and/or private. You only need to answer items to which that you are comfortable responding. We will be collecting private information including details about your child's prenatal alcohol exposure from the clinical record and physical measurements. To safeguard your child's privacy, we will remove all identifying information from these materials. They will be coded by number only.

<u>tDCS component:</u>
This study uses a battery-powered trans-cranial direct current stimulation (tDCS) device with a cap that goes on the head. tDCS is considered to be a safe brain stimulation technique that rarely results in adverse events. There have not been serious side effects reported from tDCS. Mild side effects that typically resolve upon discontinuation of tDCS include light itching under the electrode at the beginning of administration, headache, fatigue, and nausea. Your child may choose to discontinue stimulation at any time during the session if they experience discomfort or side effects. No other

risks are expected. Nonetheless, in order to minimize risks, study staff will be using standards of administration that have been shown to be safe in numerous other studies and across more than 2000 studies using tDCS.

### What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study records, to people who have a need to review this information. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. The video recording of the testing session is for data analysis purposes only. It will not be used in any presentations or publications.

Data will be handled by trained research staff members. Paper records will be stored in locked file drawers and electronic data storage will meet University security requirements (password protection, encryption, controlled access, audit trails of access, etc.). Protected Health Information will be separated from research data. Research data will be coded and, thus, de-identified. De-identified data will be stored in a local HIPAA-compliant RedCap database managed by the University of Minnesota. Signed consent forms will be scanned into the OnCore system as required by the University. Research information will not be placed into the individual's electronic medical record.

If you or your child tells us about ongoing child abuse or neglect, we are legally obligated to report it to state authorities.

### Will anyone besides the study team be at the consent meeting?

You may be asked by the study team for your permission for an auditor to observe the consent meeting (or a recording of the consent meeting). Observing the consent meeting is one way that the University of Minnesota makes sure that the rights of research participants are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not record any personal (e.g. name, date of birth) or confidential information about you or your child. The auditor will not observe the consent meeting (or a recording of the consent meeting) without your permission ahead of time.

### Will I have a chance to provide feedback after the study is over?

After the study, you might be asked to complete a survey about your child's experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

***If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the "Who Can I Talk To?" section of this form for study team and HRPP contact information.*** **What else do I need to know?**

You and your child will be paid $50 for the neuropsychological testing and parent rating forms, $50 for each MRI scan, $15 for the 3D facial image, $15 for the physical exam, and $25 for each tDCS session (up to $305 total) for participation in this study. We will also reimburse your travel expenses for the visits and we will pay for your parking.

# Parental Permission Form

If for any reason you and your child do not complete the whole study, you will receive payment for the portions that you have completed.

# Parental Permission Form

Your signature documents your permission for you and the named child to take part in this research.

_____
Printed name of child participant

_____ _____
Printed name of parent [ ] or individual legally authorized [ ] to consent for the child to participate — Date

_____ _____
Signature of parent [ ] or individual legally authorized [ ] to consent for the child to participate — Date

_____ _____
Printed name of parent [ ] or individual legally authorized [ ] to consent for the child to participate — Date

_____ _____
Signature of parent [ ] or individual legally authorized [ ] to consent for the child to participate — Date

_____ _____
Signature of person obtaining consent and assent — Date

_____
Printed name of person obtaining consent and assent

# Assent Form

## University of Minnesota

## Assent to Participate in Research

**Title of Research Study:** *Neuromodulation augmented cognitive remediation to improve executive dysfunction in fetal alcohol spectrum disorder*

**Researchers:** *Jeffrey Wozniak, PhD & Christopher Boys, Ph.D.*

## Why am I being asked to take part in this research study?

A research study is usually done to find a new or better way to help people. You are being asked to participate to help us test a new treatment for the brain.

## What should I know about being in a research study?

You do not have to be in this study. It is your choice. You can ask me or your parents any questions you have about the study. You can choose not to participate now or change your mind later. No one will be mad at you. You can ask questions before you decide.

## Why is this research being done?

I have some computer games that help you learn to concentrate and remember things better. I want to find out if a battery-powered cap that applies a very small amount of electricity to your scalp can help you learn during these games.

## How long will the research last?

Your first visit will be about 3 hours. Then, there will be 5 visits of about 1 hour each. The last visit will be about 2 hours.

## What happens if I say "Yes, I want to be in this study"?

I will ask you questions and give you tests that are like games that measure your memory and your attention. Some will be easy and some will be hard. I will give you breaks.

I will take pictures of your brain with an MRI scanner – a big camera in which you lie down. You won't feel anything and it won't hurt. It takes a while for the camera to work (about 45 minutes) and it's important that you lie still so that the pictures turn out well.

During some of the tests or games, you will be wearing a special battery-powered cap that might apply a very small amount of electricity onto your scalp. You will be placed in a random group (like the flip of a coin) to either play games with or without the small amount of electricity."

We will take pictures of your face with a special 3D camera

A doctor will examine your hands and face and measure your height and weight.

## Assent Form

During an MRI some people may feel dizzy or light headed and you will hear the clanking sound of the MRI. You might also feel a little uncomfortable because you need to lie still, but I will help you by giving you pillows and pads. You will be able to watch a movie or listen to music.

When you are wearing the special cap, you might be able to feel a tingling on your scalp. It won't be painful, but it might feel a little surprising or uncomfortable. If it gets too uncomfortable, I can adjust it to make it more comfortable or we can stop.

## Important information for girls

You cannot participate in this study if you are pregnant and you should not participate if you think you could be pregnant. If you think you could be pregnant you do not need to tell me. You can simply tell me you don't want to participate.

You have the right to not sign this form for any reason. You must sign to participate in this study.

## What else do I need to know?

You will be paid for each visit in the study (up to a total of $305).

_____ _____

Signature of child Date

_____

Printed name of child

_____ _____

Printed name of person obtaining assent Date

_____

Signature of person obtaining assent