Title of Research Study: tDCS and Cognitive Training as a Neurodevelopmental Intervention in FASD

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

Investigator Name: Jeffrey R. Wozniak, Ph.D.
Investigator Departmental Affiliation: Psychiatry and Behavioral Sciences
Phone Number: (612) 625-3817
Email Address: jwozniak@umn.edu
Study Staff Email Address: fasd@umn.edu

Supported By: This research is supported by National Institutes of Health, University of Minnesota.

Key information about this research study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

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

- The goal of research is to learn new things in order to help groups of people in the future. Investigators 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. Your child, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help your child get better or to improve your child's quality of life. Doctors can make changes to your child's clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why is my child 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 8 and 17 and has a diagnosis of fetal alcohol spectrum disorder (FASD), or having been exposed to alcohol prenatally.

What should I know about a research study?

- Someone will explain this research study to you.

- Whether or not you take part is up to you.
- You can choose not to 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.

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 8-17 with prenatal alcohol exposure (PAE). Cognitive training involves following a series of regular mental activities (brain exercises) designed to help maintain or even increase a person's cognitive (thinking) abilities. This is part of standard testing.

(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.

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

How long will the research last?

We expect that your child will be in this research study for a total of 11 separate visits. Visit 1 will last about 3.5 hours. Visits 2, 3, 4, 6, 7, 8, and 9 will each take about 1 hour. Visit 5 will last about 2.5 hours. Visit 10 will take 2 hours and visit 11 will last 1.5 hours. Visit 11 (follow-up) will be 2 months after completion of visits 1-10.

Study visits will be scheduled about 2 to 3 times per week for about 4 to 5 weeks. We expect that your child’s total participation time will be about 16.5 hours.

What will my child need to do to participate?

You and your child will be asked to come to the University of Minnesota for at least 4 visits and as many as 11 visits. Up to 7 of the visits may be done at home remotely with equipment that we will supply. At each visit, your child will complete a set of cognitive tests assessing memory, executive functioning, attention, reaction time and inhibition. In addition, your child will receive tDCS treatment for the first 10 visits. At visits 1 and 5 your child may receive an MRI scan if eligible to receive one.

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way that being in this study could be bad for my child?

There are a few general risks from MRI including projectiles, claustrophobia, hearing damage, nerve stimulation, disruption of devices, and heating of devices. We will make sure to minimize these risks through a pre-scan questionnaire, metal removal, ear plugs, and watching your child at all times.

The mild risks of tDCS include itching under the electrodes, headache, fatigue, and nausea. Trained study staff will minimize these risks by using safe administration standards.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me/ my child? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help my child in any way?

Cognitive training and tDCS are being utilized in the context of a research investigation as opposed to for clinical benefit. We cannot promise any benefits to your child or others from taking part in this research. The research is expected to benefit the population of individuals with FASD through the knowledge acquired.

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

There are no known alternatives, other than deciding not to participate in this research study. You and your child's decision will not be held against you.

Detailed information about this research study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 70 children with prenatal alcohol exposure will be in the study.

What happens if I say "*Yes, I want to be in this research*"?

We will ask you and your child to visit the University of Minnesota for at least 4 separate visits, up to 11 separate visits. As many as 7 visits may be completed at home. You and your child will complete the following procedures:

- **Screening:** We will conduct an interview to identify conditions that may exclude your child from participating, including certain neurological and psychiatric conditions (including seizure disorder).

- **Visits 1, 5 & 11:** You will complete questionnaires about your child's behavior. Your child will complete cognitive tests (executive functioning, memory, thinking, attention, etc.) The cognitive testing is expected to take 1 hour per visit.

- **Visits 1 & 5:** Your child will have an MRI scan (if eligible) which takes about 1 hour. 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/they 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 1-10:** Your child will complete cognitive training (CT) exercises on a computer at each session. During these exercises your child will wear a battery-powered transcranial direct stimulation (tDCS) cap or headband which will deliver either a very mild electric stimulation to the head (active-tDCS) for all 10 visits or active-tDCS for 5 visits and no stimulation (non-active tDCS) for 5 visits. This will be determined by random chance (like the flip of a coin) and your child will have an equal chance of receiving 5 or 10 active sessions. Stimulation will consist of approximately 20 minutes per active tDCS visit. During non-active tDCS visits, your child will still wear the cap/headband, but will not receive tDCS stimulation. This is a double-blinded study, meaning the experimenter, you, and your child will not know which group your child is assigned to (5 active sessions vs. 10 active sessions) and, at each session, nobody will know whether your child is receiving active or non-active stimulation. Each tDCS and CT session will take 1 hour. If your child will be doing any remote home sessions, we will have you sign a Study Device Loan Agreement, train you in person (at the University) to set up the devices, send you home with the devices, and we will control and supervise the sessions remotely by video and audio. The

home devices consist of a laptop computer, stimulation device, and headband/cap. We will ask you to have your child do these sessions in a quiet environment. We will guide you each time to help place the headband/cap on your child. We will remotely control the cognitive training and the stimulation through the computer; the system cannot operate without our real-time remote authorization and control. To your child, the training sessions will appear like video games in which they will be asked to pay attention, remember items, shift their attention, etc. Some participants will need parental supervision to ensure that they stay on task during the session and others will be able to work independently after learning the routines. When a session is finished, you will need to help remove the cap/headband, rinse it in a sink, and charge the equipment for the next session. We will schedule the sessions flexibly according to your needs.

- ☐ During one of the in person visits, we will take a series of 3D images of your child's face with a special digital camera. This will take 10 minutes.

- ☐ During one of the in person visits, we will take measurements of height, weight, and measurements of the physical and facial features that are common in FASD. This will take 10 minutes.

What are my responsibilities if I take part in this research?

If you take part in this research, you and your child will be responsible for: completing a consent process, answering behavioral questionnaires, completing a set of cognitive tests, undergoing tDCS treatment with cognitive training, and 2 MRI scans (if eligible)

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

If you and your child take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect you or your child's right to any present or future medical care.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you end the study early, we will help you to ship the equipment back to us at our expense.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or your child or loss of benefits to which you are both 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.

If you stop being in the research, information about you that has already been collected may not be

removed from the study database.

Can my child be removed from the research?

It is possible that we will have to ask your child to leave the study before they finish it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

If we end your child's participation early, we will help you to ship the equipment back to us at our expense.

What are the risks of being in this study? Is there any way being in this study could be bad for me/ my child? (Detailed Risks)

MRI:

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but 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: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that participants 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 claustrophobic.

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

- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.

- 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. If your child has any implanted device notify the investigator.

- Heating of Devices: The radiofrequency waves used in MRI can heat conductive 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 you 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 allow us to minimize the risk of device disruption and heating. Your child will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if they notice anything unusual, become claustrophobic, think that the hearing protection is not adequate, or if they experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. 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, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, your child can notify the researcher right away. Participation in the MRI will stop and your child will be taken out of the magnetic field.

Neurocognitive testing and questionnaires:

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 that you are comfortable answering. We will be collecting private information including details about your child's prenatal alcohol exposure from their clinical records 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.

tDCS component:

This study uses a battery-powered transcranial direct current stimulation (tDCS) device with a cap/headband that goes around/on the head. tDCS is a 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, irritation of the scalp, headache, fatigue, and nausea. There is no risk of burn and the long-term effects of tDCS in this age-range are unknown. 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 across more than 2000 studies using tDCS.

Privacy & confidentiality risks:

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will I receive any imaging results after an MRI?

The pictures created during this study are for research purposes only and are not intended to provide health care to your child. The investigator in charge of this study has decided that results from your child's scan will not be routinely shared with you or your child's physician. However, if a potential abnormality is identified in the MRI scan and the radiologist review indicates a clinical follow-up is needed, a full set of images will be prepared for sharing with the clinician doing follow-up. The pictures will not contain any 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 look at your child's pictures. Dr. Wozniak will contact you if the recommendation of the radiologist is to further investigate the unusual results of the MRI with your child's physician. However, further medical follow up is not a part of this study and the study does not have funds 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.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The risks of exposure to high magnetic fields are unknown for fetuses, but we will take steps to ensure that no pregnancies are exposed to MRI. If your child is capable of becoming pregnant, and your child has any reason to believe that they might be pregnant, they should not participate in this study (i.e., sexual intercourse without effective contraception taking place) There are no known risks for fetuses from tDCS, but we will take steps to ensure that no pregnancies are exposed to tDCS.

Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this study, which might affect your child's condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. (Charges may be incurred for use of mobile communication.)

What happens to the information collected for the research, including my child's health information?

We try to limit the use and sharing of your child's information, including research study records, any medical records and any other information about your child, to people who have a need for this information. We cannot promise complete confidentiality.

Overview

If your child participates in this study, your child's information, including your child's health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your child's information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form. If you sign this Consent Form, you are giving us permission to use and share your child's health information for these purposes, and if we are using your child's medical records, you are giving permission to any health care providers who are treating your child to share your medical records with us. As described elsewhere in this form, anytime we share your child's information, we remove all protected health information so that they cannot be identified.

NIMH Data Base:
De-identified data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism database (NIAAA-DA) at the National Institutes of Health (NIH). NIAAA-DA is a large database where de-identified study data from many NIH studies are stored and managed. De-identified study data means that all personal information about your child (such as name, address, birthdate, and phone number) are removed and replaced with a code number. Sharing your child's de-identified study data using Globally Unique IDentifiers (GUID) helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send de-identified study data about your child's health and behavior to the NIAAA-DA. Other researchers across the world can then request your child's de-identified study data for other research. Every researcher (and institutions to which they belong) who requests your child's de-identified study data must promise to keep your child's data safe and promise not to try to learn your child's identity. Experts at the NIH who know how to keep your child's data safe will review each request carefully to reduce risks to your child's privacy. Sharing your child's study data does have some risks, although these risks are rare. Your child's study data could be accidentally shared with an unauthorized person who may attempt to learn your child's identity. The study researchers will make every attempt to protect your child's identity.

Your child may not benefit directly from allowing their data to be shared with NIAAA-DA, however, the study data provided may help researchers around the world learn more about neuroscience and aid others who are contributing to the neuroscience field. Using NIAAA-DA data, NIAAA will also report information about the studies to Congress. When your child's data from NIAAA-DA are used in other studies, you will not be contacted directly.

You may decide now or later that you do not want your child's study data to be added to NIAAA-DA. You can still participate in this research study even if you decide that you do not want your child's data to be added to NIAAA-DA. If you decide any time after today that you do not want your child's data to be added to NIAAA-DA, contact the study staff, and they will tell NIAAA-DA to stop sharing your child's study data. Once your child's data is part of NIAAA-DA, the study researchers cannot take back the study

data that were shared before they were notified that you have changed your mind. If you would like more information about NIAAA-DA, it is available online at http://nda.nih.gov/niaaa.

____Yes, I agree to contribute my child's data to the NIAAA-DA

____No, I do not agree to contribute my child's data to the NIAAA-DA

What health information will be made available?

Health information about your child to be used and shared for the research includes those items checked by the research team below:

☒ Your child's medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your child's medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☒ My child's drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My child's HIV/AIDS testing records _____ (initial)

☐ My child's genetic testing records _____ (initial)

☒ My child's mental health diagnosis/treatment records ____ (initial)

☐ My child's sickle cell anemia records _____ (initial)

Who will access and use my health information?
If you agree to participate in this study, your child's information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);
- The National Institutes of Health
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Organizations that process any payments that may be made to you for participating in this study (including Greenphire) and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your child's information for mandatory reporting
If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my child's information be used in publications and presentations?
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify your child (such as your child's name and contact information, SSN and medical records number) will not be part of any publication or presentation. If your child has an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your child's identity even without these identifiers.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

What will be done with my child's data when this study is over?

If you agreed to allow your child's study data to be added to NIAAA-DA the data will be available for future research. They may be shared with researchers/institutions outside of the University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my child's information, including my child's health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, your child will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my child's health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my child's health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first

page of this Consent Form. If you cancel your permission, your child will no longer be in the research study. You may also want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel your permission, any health information about your child that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my child's health information after it is shared with others?
When we share your child's information with others as described in this Consent Form, privacy laws may no longer protect your child's information and there may be further sharing of your child's information.

Will I be able to look at my child's records?
Although MRI scans are sometimes done for clinical purposes, the scans your child will receive are being done for research. Because these scans are not designed for clinical reading, your child's scans will not receive a clinical interpretation.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include your child's name or any other direct identifiers such as your child's contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will I receive research test results?

NO Results will be shared
Most tests done in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your child's individual test results.

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

You may be asked by the study team for your permission for an auditor to observe your consent meeting or a recording of your consent. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant 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 document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting or a recording of your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. 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 rights as a research participant.
- You want to get information or provide input about this research.

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

The HRPP may ask you to complete a survey that asks about your 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, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if my child is injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your child's insurance company. If you think that your child has suffered a research related injury let the study physicians know right away.

Will I be compensated for my child's participation?

If you agree to have your child participate in this research study, you will be paid for your child's time and effort for each procedure your child attempts and/or completes. The payment schedule is as follows:

- Visit 1 ($75 to $125 total)
  - $50 for baseline cognitive testing
  - $25 for cognitive training and tDCS
  - $50 for MRI scan (if applicable)
- Visits 2, 3, & 4 ($25 total per visit)
  - $25 for cognitive training and tDCS
- Visit 5 ($75 to $125 total)
  - $50 for cognitive testing
  - $25 for cognitive training and tDCS
  - $50 for MRI scan (if applicable)
- Visits 6,7,8,&9 ($25 total per visit)
  - $25 for cognitive training and tDCS
- Visit 10 ($75 total)

    - $50 for cognitive testing
    - $25 for cognitive training and tDCS
- Visit 11 ($50 total)
    - $50 for cognitive testing

The total payment for all visits will be between $450 and $550.

If you and your child travel to the study center, you will also be reimbursed at the standard federal mileage rate. If you live more than 2 hours from Minneapolis, you may also be eligible for hotel reimbursement (one night per visit). If you live out of state, you may also be eligible for flight reimbursement (child plus one parent, actual cost with a maximum of $500 total per visit). You may also be reimbursed for parking costs at the study center (approximately $5-10 per visit). Please ask the study investigator or study staff if you have questions about any reimbursements for which you and your child may be eligible during the study.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name and address. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire and MasterCard will not receive any information about your child's health status or the study in which you and your child are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota

is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

The investigator may contact me in the future to see whether I am interested in participating in other research studies:

_____Yes, the investigator may contact me in the future about other research studies

_____No, the investigator may not contact me in the future about other research studies

Signatures:

Your signature documents your permission for your child to take part in this research. You will be provided a copy of this signed document.

_____

Printed Name of Child Participant

_____

Printed Name of Parent/Guardian Participant

_____ _____

Signature of Parent/Guardian Participant Date

_____

Printed Name of Parent/Guardian Participant

_____ _____

Signature of Parent/Guardian Participant Date

I attest that the individuals providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study and to the child's participation in this study.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date