**BROWN UNIVERSITY**

**PARENT PERMISSION ADDITIONAL LANGUAGE**

1. [Researcher](#Researchers) **|** 2. [Study Sponsor](#Study_sponsor) **|** 3. [What is this study about?](#What_is_this_study_about) **|** 4. [What will my child be asked to do?](#What_will_I_be_asked_to_do) **|** 5. [Will my child be paid?](#Will_I_be_paid) **|** 6. [What are the risks?](#What_are_the_risks) **|** 7. [What are the benefits?](#What_are_the_benefits) **|**

8. [How will my child’s information be protected?](#How_will_my_information_be_protected) **|** 9. [Are there any alternatives to this study?](#Are_there_alternatives) **|**

10. [What if my child wants to stop?](#What_if_I_want_to_stop) What if I no longer want my child to participate? **|** 11. Can my child’s participation end without permission? | 12. [Who can my child or I talk to if we have questions about this study?](#WhocanItalktoifIhavequestions) **|**

13. [Who can I talk to if I have questions about my child’s rights as a participant?](#HRPP_questions) **|**

14. [Permission to Participate](#Consent_to_participate)

1. **Researcher(s)**

No additional language at this time

1. **Study Sponsor(s)**

No additional language at this time

1. **What is the study about?**

No additional language at this time

1. **What will my child be asked to do?**

[Blinding](#Blinding) | [Device Provided for Study Use](#Device) | [EEG](#EEG) | [EMG](#EMG) | [FDA-Regulated Studies](#FDA) | [MRI](#UseofMRI) | [Placebo](#Placebo) | [Randomization](#Randomization) |

**Blinding**: [Choose either **Option A** or **Option B**, depending on the design of the study.]

**Option A: Single Blind**:

“You and your child will not know which group your child is in. The researchers *will* know. This information needs to be kept secret so that the study is based on scientific results, not on peoples’ opinions. However, we can give this information out if your child has a medical emergency.

If your child has a medical emergency, make sure you tell the medical staff that your child is in a research study. They can contact us, and we will give them all relevant information.”

**Option B: Double Blind**:

“You and your child will not know which group your child is in. Neither will the researchers. This information needs to be kept secret so that the study is based on scientific results, not on peoples’ opinions. However, we can give this information out if your child has a medical emergency.

If your child has a medical emergency, make sure you tell the medical staff that your child is in a research study. They can contact us, and we will give them all relevant information.”

**Device Provided for Study Use:** [If you provide a device (e.g. tablet, pedometer, sleep monitor, activity tracker, etc.) to child participants for data collection, describe how child participants or their parents will pick up/receive the device from the study team and how child participants or their parents will drop off/return the device to the study team at the end of data collection. For example, will the child participants or their parents pick up and drop off the device from Brown campus or will the study team mail the device to the child participant’s home and, later, mail a pre-paid return envelope.]

**“ Use of Electroencephalography** **EEG:** Electroencephalography (EEG) is a non-invasive method of measuring brain activity which means there are no injections, drugs or radioactive tracers used.

The EEG procedure requires putting on an “electrode cap,” which looks similar to a swimmers cap. The electrodes do not deliver electrical shocks, but instead will measure brain activity. Your child’s hair and face may get wet while they are wearing the cap. Conductive paste is applied to each sensor and your child’s scalp may be rubbed gently with an instrument similar to a Q-tip to ensure there is good contact between your child’s scalp and the electrode.”

<Include this language *only if* EEG and MRI are described on the same parent permission.>

“\_\_\_\_\_\_\_ EEG recordings will be done while in the MRI scanner”

“\_\_\_\_\_\_\_ EEG recordings will be done separately from MRI”

**“ Use of Electromyography** **(EMG):** We will place <insert number> of electrodes to your child’s <insert location on body where electrodes may be placed, if applicable>. The electrodes do not deliver electrical shocks, but instead will measure muscle contractions.”

**FDA-Regulated Studies**: “This <insert name of drug or device> is regulated by the FDA. <insert **Option A** (off-label use) or **Option B** (on-label use) listed below>

**Option A**: “This <name of drug or device> is being used differently from its approved/regulated labeling. [Describe how the research will use the drug/device from its labeling.]

**Option B**: “This <name of drug or device> is being used as approved/regulated.”

**“ Use of Magnetic Resonance Imaging (MRI):** To study how the brain works, we use Magnetic Resonance Imaging (MRI). This is a non-invasive method of imaging, which means there are no injections, drugs or radioactive tracers used while a person <choose as applicable:> “is in the scanner” or “performs a task in the scanner.” The brain images collected are used to answer research questions about how the brain works.

Before MRI, you will need to fill out a questionnaire about your child’s health <insert “and handedness” if inquiring>. Your child will be screened for “MR Safety” by answering questions about surgeries they have had, and any medical devices or metal they may have on or in their body.

[If performing a task:] “During the MRI procedure visual stimuli will be visible through a mirror positioned comfortably above your child’s head. Auditory stimuli will be presented through noise-canceling headphones. Depending on the task, your child may respond by pressing <insert whatever is applicable: button on a keypad, speaking aloud, using a joystick, touching a screen or other response methods that could be encountered in everyday life.>”

The MRI session will last <insert hours>, which includes up to <insert hours/minutes> of screening, set-up, and training outside of the scanner and up to <include hours/minutes> of physically being in the MRI scanning.”

**[**If there are repeat sessions to the study, where child participants and/or their parents will need to come back for the same procedures**]**: “You and your child will be asked to return for up to <insert number> sessions on different days to complete MRI procedures.”

**Placebo**: “A placebo is a pill or a liquid that looks like medicine but is not real. It should have no physical effect on your child.”

**Randomization**: “This study will have <insert number> different groups of research participants. To decide which group your child will be in, we will use a method of chance. This method is like flipping a coin [use for 2 groups] or rolling dice [use for 3 or more groups].”

1. **Will my child be paid?**

[ClinCard](#Clincard) **|** [Compensation (gifts)](#Compensationgifts) **|** [Compensation (money)](#Compensationmoney) **|** [Compensation (raffle/lottery)](#compensationraffle) **|** [Compensation in Case of Injury](#Compensationinjury)

**ClinCard:** “Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card.

We will <choose: give/mail> your child the card. Your child will be given one card for the entire time of their participation and this card may be used to pay them in any future Brown University studies that use ClinCard. Your child will also get information about how to use this card and whom to call if you or they have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your child’s card based on the study’s payment schedule. Your child may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways your child can use the card, some of which may involve fees that will reduce the amount of money on the card.

If your child earns $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your child’s social security number to correctly identify them in the payment system and issue them an IRS 1099 Form. You may also be asked to complete a Form W9 for your child. This may affect their taxes. Only payments for being in research studies will be used to decide if your child should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your child’s name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your child’s health status or the study in which your child is participating.

If your child’s card is lost or stolen, please call the study coordinator for a free replacement card. If your child requests a replacement card from Greenphire directly, they may be charged a fee.”

**Compensation (gifts):** “Your child will receive <insert gift & amount worth of the gift> for <insert task>. If your child leaves the study early, or if we have to take your child out of the study, they will only be given <insert gift and amount it is worth > for the visits they completed.”

**Compensation (money):** “Your child will be paid $XX.XX for each visit in this study, <if the amount will vary from visit to visit, state the different amounts and visit types.> This will add up to a total of $XX.XX, if your child completes all of the visits <if some participants undergo a particular procedure while others do not, break this into different amounts and explain.> If your child leaves the study early, or if we have to take your child out of the study, they will only be paid for the visits they completed.”

[Include the following language when compensation is $600 or more, but consider using when at ≥ $400:] **“**It is important to know that payment for participation in a study is taxable income. If your child earns $600 or more in this study, or across a combination of studies at Brown University within one calendar year, they will be taxed on this income. We are required to give Brown University your child’s name, address, social security number, and amount paid. The university uses that information to issue 1099 statements (IRS tax statements) to study participants. This is an IRS requirement with which we must comply.”

**Compensation (raffle/lottery):** [Describe the raffle/lottery: the item, its value, how a participant can win, and when a participant will receive it.] “Your child will be entered to win <insert number of items the participant can win> of <insert number of total items available in the study>. Your child’s odds of winning are <insert number> out of <insert maximum number of participants approved by the IRB>.”

**Compensation in case of injury:** [Include for all greater than minimal risk studies and any minimal risk studies in which injury may be likely to occur.]

“Many kinds of research involve some risk of injury. Even though the investigators are careful to prevent any harm, your child might develop medical problems from being in this study. If your child does have problems, the researchers will give you and your child information that may be of help in getting proper medical care, if you or your child ask for it. Brown University does not pay for medical or other costs. Signing this form does not mean that you or your child give up any liability rights for personal injury.”

1. **What are the risks?**

[Coercion and/or Undue Influence](#coercion) **|** [COVID-19 Countermeasures](#COVID19) **|** [Device Provided for Study Use](#RisksDevice) **|** [EEG/EMG](#EEGEMG) **|** [MRI](#MRI) **|** [Sensitive Questions](#sensitivequestions) **|**

**Coercion and/or Undue Influence**: [Address how coercion and/or undue influence will be mitigated based on the child population and study procedures.]

**COVID-19 Countermeasures:** [Include **verbatim** if your study uses a COVID-19 covered countermeasure.]

"Due to the coronavirus public health emergency, the U.S. government issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act. This Declaration may apply to this study if it involves procedures or other actions that are related to or in response to coronavirus. If it applies, this Declaration limits your and your child’s right to sue the researchers, healthcare providers, study sponsors, manufacturers, distributors, and potentially others that are involved with this study. However, the U.S. government has a program that may provide compensation to you or your family if your child experiences serious physical injuries or death related to procedures or other actions taken in this study. To find out more about the 'Countermeasures Injury Compensation Program,' please visit <https://www.hrsa.gov/cicp>. "

**Device Provided for Study Use:** [If you provide a device (e.g. tablet, pedometer, sleep monitor, activity tracker, etc.) to child participants for data collection, include what will happen if child participants lose or damage the device. For example, will the study replace the device at no charge, will the child participant’s total study compensation be reduced by a specific amount to recompense the cost of the device, if child participants will be withdrawn if the study cannot replace the device.]

**EEG/EMG**:

“There are minimal risks associated with the use of the <insert EEG or EMG> in this study. There is a small possibility that your child may experience some tenderness or reddening of the skin where the electrodes are placed, as your child’s head will be mildly scraped. This feels similar to scratching your head with your hand. Your child may also feel slight irritation from the gel solution, but the irritation commonly dissipates soon afterwards. The electrode cap may feel tight on your child’s head.

Researchers will wear latex-free gloves and have received extensive procedural training to minimize the possibility of the reddening of skin while preparing participants for recording. All equipment in direct contact with your child will be chemically sterilized with an FDA-approved solvent immediately after each use.”

**MRI**: “There may be some discomfort from being in the MRI scanner because your child will be asked to lie down and be very still for a long time. The research team will try to make your child as comfortable as possible before the imaging begins. If your child feels claustrophobic or anxiety, they should let the researcher know immediately. MRI scanning risks and discomforts are discussed in further detail in the MRI addendum to this consent form.”

**Sensitive questions**: “In this study we will ask your child about <list whatever applies>. Some of these questions may make them uncomfortable, or bring up unpleasant feelings or memories.”

1. **What are the benefits?**

[Clinical Research](#clinical) [**|** Justice-Involved Research](#prisoner)

**Clinical Research**: “This is not a treatment study or designed to improve your child’s health.”

**Justice-Involved Research**: “Participating in this study will not affect your child’s <list whatever applies: case, court proceedings, sentence, etc.> or relationship with the <justice or court> system.”

1. **How will my child’s information be protected?**

[Certificate of Confidentiality (CoC)](#CoC) **|** [Clinical Trial](#Clinicaltrial) **|** [FDA-Regulated Studies](#FDAconfidentiality) **|** [Focus Groups](#focusgroups) **|** [Genetic Information Nondiscrimination Act (GINA)](#GINA) **|** [Third-Party Applications, Software and Devices](#thirdparty)

**Certificate of Confidentiality:** “This research is covered by a Certificate of Confidentiality. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or suit unless your child says it is okay. They also cannot provide them as evidence unless your child has agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.  
  
There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats that your child may harm themself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child’s information from being used for other research if allowed by federal regulations.  
  
Researchers may release information about your child when you and your child say it is okay. For example, you and your child may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you and your child from willingly releasing information about your child’s involvement in this research. It also does not prevent you child from having access to your child’s own information.”

**Clinical Trial: “**A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You and your child can search this Web site at any time.”

**If the permission covers procedures that do not involve “clinical trial procedures,” but is part of a clinical trial**:“This <list applicable study procedures, for example: focus group/interview/survey, etc.> is part of a larger clinical trial.”

**FDA-regulated Studies**: “Because this research involves the use of an FDA-regulated product, the Food and Drug Administration (FDA) may choose to inspect, and copy medical or research records that identify your child.”

**Focus Groups**: “Due to the nature of focus groups, your child’s confidentiality cannot be guaranteed. We ask all participants to respect each other’s privacy by not repeating conversations that are shared in the focus group.”

**GINA**: “A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against anyone based on their genetic information. This law will protect your child in the following ways:

 • Health insurance companies and group health plans may not request your child’s genetic information that we get from this research.

 • Health insurance companies and group health plans may not use your child’s genetic information that we get from this research when making decisions regarding your child’s eligibility or premiums.

 • Employers with 15 or more employees may not use your child’s genetic information that we get from this research when making a decision to hire, promote, or fire them or when setting the terms of their employment.

Be aware that this federal law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect your child against genetic discrimination by all employers.”

**Third-Party Software, Applications or Devices:** “Participation in this study requires the use of <insert name of third party product>, a product of <Insert owner of product>, for data collection. Brown University will protect your child’s research data but has no authority over the management of any data collected through <insert name of third party product> or <insert name of product>. Before agreeing to participate, please review the data and privacy policies of <insert name of third party product> and <insert name of product>. <Insert link to data and privacy policies> “

1. **Are there any alternatives to this study?**

No additional language at this time

1. **What if my child wants to stop? What if I no longer want my child to participate?**

No additional language at this time

1. **Who can my child or I talk to if we have questions about this study?**

[Researcher Financial Conflict of Interest](#ResearcherFCOI)

**Researcher Financial Conflict of Interest:** “<insert applicable consent language from the table below>”

“You are being given this information, so that you and your child can decide if this <interest/relationship> affect(s) whether you want your child to participate in this study. If you have any questions, please contact <insert the name and contact information for the appropriate research personnel, other than the researcher with the conflict>. They will answer any questions you may have.”

|  |  |
| --- | --- |
| Situation Recommended Consent Language | |
| Researcher received compensation for consulting work | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and receives consulting payments from [name of company], the company that is funding this research.  Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and receives consulting payments from [name of company], a company that has similar interests to the company that is funding this research. |
| Researcher is a Scientific Advisory Board member | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and is also a Scientific Advisory Board member of the company/foundation that is funding this research. Dr. \_\_\_\_\_\_ does not [does] receive money for serving on the Scientific  Advisory Board.  Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and is also a Scientific Advisory Board member of a company/foundation that does research in the same are as this study. Dr. \_\_\_\_\_\_does not [does] receive money for serving on the Scientific Advisory Board. |
| Researcher has stock/equity in the company | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and has stock/equity in [the company/foundation funding the research], the company that is funding this research.  Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and has stock/equity in [name of company], a company that has similar interests to the company that is funding this research. |
| Researcher is on Board of Directors | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and is a member of the Board of Directors of the company that is funding this research [or a company or foundation that is performing research in the  same area as this study]. |
| Researcher is an inventor on a patent or an author on the copyright | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and is an inventor of the [drug, compound, device, etc.] being studied. He/she may benefit financially if the [drug, compound, device, etc.] is found  to be helpful and is made available for sale. [Brown University may also be involved in the patent and marketing process and, therefore, also has a financial interest in the drug, compound, device, etc.]. |
| Researcher received honoraria or travel reimbursement | Dr. \_\_\_\_\_\_ is [the lead researcher] [a researcher] on this study and has [received payments or had travel paid for] during the past 12 months from [study sponsor]. [Study sponsor] is funding this research. |

1. **Who can I talk to if I have questions about my child’s rights as a participant?**

[Non-English speaking/English as the non-primary language participants](#nonenglish)

**Non-English speaking/English as the non-primary language:** [Include, if Brown’s HRPP is the primary regulatory contact.] “If English is not your or your child’s first language, the HRPP will find someone who is able to speak with you.”

1. **Consent to Participate:**

[Permission to re-contact](#Permission_to_recontact)

**Permission to re-contact:** “After the study ends, could the research team contact you in the future about other studies for which your child may be eligible? By agreeing to be contacted, you or your child are not obligated to participate, and you or your child may remove your names from our re-contact database at any time.

Yes, you may contact me in the future  No, I do not want to be contacted about

other studies