**BROWN UNIVERSITY**

**ADDITIONAL BULLETED CONSENT LANGUAGE**

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* RESEARCHER:

No additional language at this time

* PURPOSE:

No additional language at this time

* PROCEDURES:

[Blinding](#Blinding) | [Device Provided to Participant for Study Use](#Device) | [Digital Recordings](#DigitalRecordings) | [EEG](#EEG) | [EMG](#EMG) | [MRI](#UseofMRI) | [Randomization](#Randomization) |

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

**Option A: Single Blind**:

“You will not know which group you are 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 you have a medical emergency.

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

**Option B: Double Blind**:

“You will not know which group you are 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 you have a medical emergency.

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

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

**Digital Recordings (audio, video, photo):** “With your permission <insert procedure> will be <insert recording type>.” [State if participants can opt out of recordings and still enroll in the study.]

**“**[ ]  **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 hair and face may get wet while you are wearing the cap. Conductive paste is applied to each sensor and your scalp may be rubbed gently with an instrument similar to a Q-tip to ensure there is good contact between your scalp and the electrode.”

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

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

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

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

 **“**[ ]  **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 health <insert “and handedness” if inquiring>. You will be screened for “MR Safety” by answering questions about surgeries you had, and any medical devices or metal you may have on or in your body.

[If performing a task:] “During the MRI procedure visual stimuli will be visible through a mirror positioned comfortably above your head. Auditory stimuli will be presented through noise-canceling headphones. Depending on the task, you 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 your study, where participants will need to come back for the same procedures**]**: “You will be asked to return for up to <insert number> sessions on different days to complete MRI procedures.”

**Randomization**: “This study will have <insert number> different groups of research participants. To decide which group you 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].”

* TIME INVOLVED:

No additional language at this time

* COMPENSATION:

[ClinCard](#Clincard) **|** [Compensation (gifts)](#Compensationgifts) **|** [Compensation (money)](#Compensationmoney) **|** [Compensation (raffle/lottery)](#compensationraffle)

**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> you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that uses ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study’s payment schedule. You 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 you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you 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 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 health status or the study in which you are participating.

If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.”

**Compensation (gifts):** “You will receive <insert gift & amount worth of the gift> for <insert task>. If you leave the study early, or if we have to take you out of the study, you will only be given <insert gift and amount it is worth; this applies for non-FDA study only> for the visits you completed.”

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

[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 you earn $600 or more in this study, or across a combination of studies at Brown University within one calendar year, you will be taxed on this income. We are required to give Brown University your 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.] “You will be entered to win [number of items the participant can win] of [number of total items available in the study]. Your odds of winning are [XX] out of [maximum number of participants approved by the IRB].”

* RISKS:

[Coercion and/or Undue Influence](#coercion) **|** [Device Provided to Participant 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 population and study procedures.]

**Device Provided to Participant for Study Use:** [If you provide a device (e.g. tablet, pedometer, cellphone, etc.) to participants for data collection, include what will happen if participants lose or damage the device. For example, will the study replace the device at no charge, will the participant’s total study compensation be reduced by a specific amount to recompense the cost of the device, if 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 you may experience some tenderness or reddening of the skin where the electrodes are placed, as your head will be mildly scraped. This feels similar to scratching your head with your hand. You may also feel slight irritation from the gel solution, but the irritation commonly dissipates soon afterwards. The electrode cap may feel tight on your 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 you 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 you will be asked to lie down and be very still for a long time. The research team will try to make you as comfortable as possible before the imaging begins. If you feel claustrophobic or anxiety, 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 you about <list whatever applies>. Some of these questions may make you uncomfortable, or bring up unpleasant feelings or memories.”

* BENEFITS:

[Clinical Research](#clinical) [**|** Prisoner Research](#prisoner)

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

**Prisoner Research**: “Participating in this study will not affect your prison sentence or parole.”

* CONFIDENTIALITY:

[Audio Recording, Video Recording, Photography](#audio) **|** [Certificate of Confidentiality (CoC)](#CoC) **|** [Clinical Trial](#Clinicaltrial) **|** [Focus Groups](#focusgroups) **|** [MTurk](#MTURK)

**Audio Recording, Video Recording, Photography**: **“**In this study we will be <audio, video and/or photo> recording <list whatever task applies>. We will use <state medium of recording—e.g. notebook, computer files, digital recorder, smartphone>. We will keep this information confidential. We will store it for <state duration of storage>. At the end of that time, we will destroy it [if applicable].

**Certification of Confidentiality:** “To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally 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.”

[Use the following language as applicable] “The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You 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.”

[Language, such as the following, should be included if the researcher intends to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] “The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of such as child abuse and neglect, or harm to self or others.

**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 you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

**If the consent 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.”

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

**MTurk:** “Important information about your MTurk ID: Your MTurk ID does not directly identify you, but it can be linked to your public profile page. You may want to restrict what information you share on this public profile. We will not share your MTurk ID with anyone outside of our research team. If you ever contact us, Amazon.com will automatically insert your email address into the message, so that we can reply to you. We will use your name and email only to respond to your communication and will never distribute it to anyone outside of our research team. For more information about the privacy and confidentiality limitations associated with using MTurk, please refer to Amazon’s MTurk Privacy Notice and contact them for more information: [https://www](https://www.google.com/url?q=https://www&sa=D&source=hangouts&ust=1574450326518000&usg=AFQjCNFa7fM7bFqQSuzRGqlHwhNIJEotaQ).[mturk.com/mturk/privacynotice](http://mturk.com/mturk/privacynotice) and [https://www](https://www.google.com/url?q=https://www&sa=D&source=hangouts&ust=1574450326518000&usg=AFQjCNFa7fM7bFqQSuzRGqlHwhNIJEotaQ).[mturk.com/mturk/contact](http://mturk.com/mturk/contact).”

* VOLUNTARY:

No additional language at this time

* CONTACT INFORMATION:

[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 can decide if this <interest/relationship> affect(s) whether you want 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.”

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| 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 ScientificAdvisory 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 thesame 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 foundto 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. |

* YOUR RIGHTS:

[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 first language, the HRPP will find someone who is able to speak with you.”

* CONSENT TO PARTICIPATE:

No additional language at this time