**BROWN UNIVERSITY**

**ADDITIONAL STANDARD CONSENT LANGUAGE**

1. [Researcher](#Researchers) **|** 2. [What is this study about?](#What_is_this_study_about) **|** 3. [What will I be asked to do?](#What_will_I_be_asked_to_do) **|** 4. [Will I be paid?](#Will_I_be_paid) **|**

5. [What are the risks?](#What_are_the_risks) **|** 6. [What are the benefits?](#What_are_the_benefits) **|** 7. [How will my information be protected?](#How_will_my_information_be_protected) **|**

8. [Are there any alternatives to this study?](#Are_there_alternatives) **|** 9. [What if I want to stop?](#What_if_I_want_to_stop) **|** 10. [Who can I talk to if I have questions about this study?](#WhocanItalktoifIhavequestions) **|** 11. [Who can I talk to if I have questions about my rights as a participant?](#HRPP_questions) **|** 12. [Consent to Participate](#Consent_to_participate)

1. **Researcher(s)**

No additional language at this time

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

No additional language at this time

1. **What will I be asked to do?**

[Blinding](#Blinding) | [Device Provided to Participant for Study Use](#Device) **|** [Digital Recordings](#DigitalRecordings) | [EEG](#EEG) | [EMG](#EMG) | [FDA-Regulated Studies](#FDA) | [MRI](#UseofMRI) | [Placebo](#Placebo) | [Randomization](#Randomization) | [TES (including tDCS and tACS)](#TES) | [TMS](#TMS)

**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.”

**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 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.”

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

**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 or rolling dice [use for 2 groups] or rolling dice [use for 3 or more groups].”

**Use of transcranial electrical stimulation (TES, including tDCS and tACS):**

[There are various TES procedures, including tDCS and tACS; make sure to only include the ones that are applicable for your study. If your study allows for more than one, add a checkbox before each procedure, so participants know which one applies.]

“We can study the way the brain works using transcranial electrical stimulation (TES). TES is a way of stimulating the brain without injections, drugs or surgical procedures of any kind.

*How TES works*

TES works by passing a low level <choose as applicable: direct or alternating> electric current through two or more electrodes that are placed on your body, with at least one electrode on your head. These electrodes look like <state how the electrodes look: rubber pads or smaller, round electrodes>. <If using rubber pad electrodes, state: “Rubber pad electrodes are either inserted into sponge pads that are moistened with salt water (saline) or covered with a thick paste before they are placed”>. <If using small, round electrodes, state: “The smaller, round electrodes will be covered with paste. The electrodes are held in place by either a rubber band or an EEG-like cap”>. When the electric current is turned on the electricity passes from electrode(s) to electrode(s) and everything in between including your brain to briefly affect the way the cells in your brain work for a period of time (up to 90 minutes). You may feel a tingly, itchy, or prickly feeling from the current, or you may not notice anything at all.

*Eligibility*

Before the TES procedure, you will be interviewed to see if you are eligible to participate in the procedure. The interview questions that determine your eligibility are chosen for both scientific and safety reasons. The interview will include some personal questions, such as questions about your health history, and any drugs or medications you might be taking. All your answers to our questions will be protected, as described in the “Confidentiality” section.

*For Women*: It is unknown if TES is safe during pregnancy. If you are, or you think you might be, pregnant, you cannot take part in this study.

*Location of TES*

The TES electrodes will be put on your head. Before the formal study begins, a member of the research team will show you the places we will put the electrodes. Example places are on your forehead above your eye, above your temple, or on the back of your head.

**Use of transcranial magnetic stimulation (TMS):**

[There are various TMS procedures; make sure to only include the ones that are applicable for your study. If your study allows for more than one, add a checkbox before each procedure, so participants know which one applies.]

“We can study the way the brain works using transcranial magnetic stimulation (TMS). TMS is a way of stimulating the brain, without injections, drugs or surgical procedures of any kind.

*How TMS works*

TMS works by passing an electric current through a “TMS coil” that is held against your head. A TMS coil looks like a wand with either a circle or a figure 8 at the end of it. Inside the coil are loops of wire. When the electric current goes through the coil, it creates a magnetic field that can safely go through your skull and your brain to briefly affect the way the cells in your brain work for a short time (1 second to 1 hour depending on the kind of TMS – described in detail below). The effects can be minor, such as a brief twitch, or you may not notice them.

TMS coils are not always “on,” so even if the coils are on your head, the experimenter needs to start the equipment. The procedures used in this study are described in detail below. You may or may not receive the actual TMS.

*Eligibility*

Before the TMS procedure, you will be interviewed to see if you are eligible to participate in the study. The interview questions that determine your eligibility are chosen for both scientific and safety reasons. The interview will include some personal questions, such as questions about your health history, and any drugs or medications you might be taking. All your answers to our questions will be protected, as described in the “Confidentiality” section.

*For Women*: It is unknown if TMS is safe during pregnancy. If you are, or you think you might be, pregnant, you cannot take part in this study.

*Location of TMS*

The TMS coil will be put on your head. Before the formal study begins, a member of the research team will show you the place(s) we will put the coil. Example places are on your forehead above your eye, above your temple, or on the back of your head.

*TMS Research Procedures*

The TMS procedure(s) pre-marked with an “X” in the box next to its title will be used in this study. We may continue to record the activity of your muscles for all the protocols listed below with an “X.” A TMS procedure typically lasts <insert amount of time>, including break time.”

“ *Motor Threshold*

*We will find your motor threshold (which is your baseline).* This TMS procedure is used to customize the strength of stimulation specifically for you and your brain.

You will be asked to sit comfortably in the chair in the TMS testing room. Your muscle may twitch or move without you telling it to move (involuntarily) from this test. TMS feels like tapping on your head. Muscles on your eyes, head, or neck may also twitch, if the coils are on the side of your head near those muscles.

Finding your motor threshold will take about <insert the # of minutes>.

When finding your baseline, there will be occasional short, single pulses of TMS (lasting a fraction of a second) delivered through the coils while you complete the task(s). You will get no more than <insert number of pulses per second>, and most pulses will have at least <insert number of seconds> in between them.

“ <choose: *Repetitive TMS, High-frequency Repetitive Stimulation, Offline Theta-burst Stimulation>*

You will be comfortably sitting up or reclining in the TMS chair and we will slowly stimulate your brain in one place with <insert number of pulses per second>. This stimulation will last <insert time in seconds/minutes, no longer than 6 minutes maximum>.

TMS feels like tapping on your head. Muscles on your eyes, head, or neck may also twitch, if the coils are on the side of your head near those muscles. After the stimulation, you will be asked to do a task and then there will be a break.

You may be asked to repeat the stimulation, task, and break pattern up to <insert number> of times during the study. There will be at least <insert minutes> in between the times when your brain is stimulated. This kind of slow TMS might change the way your brain works for only as long as the TMS lasted. For example, if the TMS lasted 6 minutes, there might be an effect for up to 6 minutes after the TMS ended.”

This kind of TMS might change the way your brain works for up to 1 hour after the TMS ended, and you will stay in the lab during this time. If you finish the task before 1 hour has gone by, we will ask you to stay in the lab until 1 hour has passed.”

1. **Will I 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> 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 (money):** “You 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 you complete all of the visits <if some participants undergo a particular procedure while others do not, break this into different amounts and explain.> If you leave the study early, or if we have to take you out of the study, you will only be paid for the visits you 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 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 <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>.”

**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, you might develop medical problems from being in this study. If you do have problems, the researchers will give you information that may be of help to you in getting proper medical care, if you ask for it. Brown University does not pay for medical or other costs. Signing this form does not mean that you 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 to Participant for Study Use](#RisksDevice) **|** [EEG/EMG](#EEGEMG) **|** [MRI](#MRI) **|** [Sensitive Questions](#sensitivequestions) **|** [TES](#TESrisks) **|** [TMS](#TMSrisks)

**Coercion and/or Undue Influence**: [Address how coercion and/or undue influence will be mitigated based on the 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 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 you experience 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 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.”

**TES:**

1. “TES carries a small risk of a skin burn under the electrode(s). This is rare. The stimulation parameters used have been chosen based on safety norms that minimize this risk. In addition, you will be screened for risk factors to avoid this risk, such as checking the skin for lesions, moles, or other possible problems.
2. However, if you feel that the skin under the electrodes start to feel warm you should tell the investigator and we will stop the stimulation.
3. When current is passed through the electrodes you may feel an itchy prickly or tingly sensation. You should let the experimenter know if you find the stimulation painful or too uncomfortable.
4. You might risk some reddening of the skin under the electrodes. This should go away within 20-30 minutes after stimulation.
5. If for some reason we would need to turn off the stimulation suddenly there is a chance that you notice a sudden flickering of light, similar to a broken fluorescent light bulb. This is due to the current being turned off.
6. Participants undergoing TES sometimes experience headaches. The cause of headaches can relate to the procedure set-up (for example, neck tension) as much as the stimulation itself. Headaches usually start after the session (about 20 mins. to 3 hours after TES). If you feel a headache coming on, we will stop the session and allow you to cope with the headache in your preferred way.
7. There is a risk of fatigue. We will give you regular breaks through the procedure.

TES is not regulated by the FDA. There may be other risks that are not yet known.

**TMS:**

1. “TMS carries a small risk of inducing a seizure. This is rare. The stimulation parameters used have been chosen based on safety norms that minimize this risk. In addition, you will be screened for risk factors related to seizure, such as epilepsy, history of prior seizure or convulsions, or a family history of seizures/epilepsy. A seizure may be thought of as a convulsion where a person’s body shakes. Many seizures are not like this. Some have very mild symptoms. Experiencing a seizure caused by TMS does not mean that you will have another seizure. The researcher is trained to manage the room and call for medical help in the unlikely event of a seizure.
2. It is possible that you could faint during TMS. This does not happen often, but can happen if you are anxious, nervous, or have not eaten. You should immediately tell the research staff if you feel dizzy or lightheaded.

If you have the above symptoms, the TMS study procedure will be stopped. You will be monitored until you are feeling better.

1. When current is passed through the TMS coil, it moves within its casing producing a loud “click.” It is possible that you could experience a temporary ringing in your ears. You will wear earplugs during the TMS to reduce the noise to prevent the risk of hearing problems.

We will ask you to let us know immediately if your ear plugs loosen or fall out.

1. The sensation of TMS is a tapping on the head at the site of stimulation. Depending on the site of stimulation, there can also be twitching in nearby muscles around the head, eyes and neck. The immediate effect of these sensations can range from mildly irritating to painful at high frequencies. Based on your feedback, we will adjust the stimulator output to a level that is not painful for you.
2. Participants undergoing TMS sometimes experience headaches. The cause of headaches can relate to the procedure set-up (for example, neck tension) as much as the TMS stimulation itself. Headaches usually start after the session (about 20 mins. to 3 hours after TMS). If you feel a headache coming on, we will stop the session and allow you to cope with the headache in your preferred way.
3. There is a risk of fatigue. We will give you regular breaks through the procedure.
4. Although TMS is an FDA regulated device, it is being used for research purposes and is considered an investigational device. There may be complications that are not yet known.
5. **What are the 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.”

1. **How will my information be protected?**

[Audio Recording, Video Recording, Photography](#audio) **|** [Certificate of Confidentiality (CoC)](#CoC) **|** [Clinical Trial](#Clinicaltrial) **|** [FDA-Regulated Studies](#FDAconfidentiality) **|** [Focus Groups](#focusgroups) **|** [Genetic Information Nondiscrimination Act (GINA)](#GINA) **|** [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.”

**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 you.”

**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.”

**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 you based on your genetic information. This law will protect you in the following ways:

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

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

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

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

**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).”

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

No additional language at this time

1. **What if I want to stop?**

No additional language at this time

1. **Who can I talk to if I 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 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.”

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

1. **Consent to participate:**

No additional language at this time