**BROWN UNIVERSITY**

**ADDITIONAL CONSENT LANGUAGE**

*Beyond the*[*basic elements of informed consent*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/consent-process)*, there may be additional elements that should be included based on the study design or research population.*

*Each additional consent language topic is listed under its section header from the*[*Brown consent template*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/guidance-human-subjects-research/consent-process/consent-templates)*, with definitions and examples of when/why they may be appropriate.*

*This list is not all inclusive and will be updated often. There may also be additional language required by other institutions/organizations involved in a research study.*

1. **Researcher(s)**

List names and contact information of principal investigator, contact person(s) for participants, faculty advisor(s) for student research only.

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

Provide a brief explanation of the activity in lay language (8th grade reading level or below).

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

**Experimental Design (Randomization, Blinding, Recordings):**

**Definitions:**

\* **Randomization:** The process by which participants are assigned to a group of study procedures by chance rather than by choice.

\* **Blinding:** Process by which researchers and/or participants do not know to which study group they are assigned. There are single (participant is blinded) or double blind (participant and researcher are blinded) studies.

**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.”

**Blinding**:

**Single**: “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.”

**Double**: “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.”

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

**FDA-Regulated Studies (Drug, Placebo)**:

**Definitions:**

**\* Off-label Use:** The use of prescription and over-the-counter drugs or devices for an unapproved indication or in an unapproved age group, dosage, or route of administration.

**\* On-label Use:** The use of prescription and over-the-counter drugs or devices for the approved indication.

**\* Placebo:** A substance that has no therapeutic effect, used as a control in testing new drugs.

**FDA-Regulated Studies**: “This <insert name of drug or device> is regulated by the FDA. <insert *choice 1* (off-label use) or *choice 2* (on-label use) listed below>

*Choice 1:* “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.>

*Choice 2:* “This <name of drug or device> is being used as approved/regulated.”

**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.”

1. **Will I be paid?**

**Compensation (money, gifts, reimbursement):**

**Definitions:**

**\* Compensation (money):** cash, gift card, reloadable cards, check

\* **Compensation (gifts):** food, items, educational programs, course credit

\* **Reimbursement:** food, travel, accommodations, parking

**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 non-FDA study only>) for the visits you completed for $XX.XX.”

**Include the following language when compensation is ≥ $599, but consider using when at ≥ $400: “**It is important to know that payment for participation in a study is taxable income. If you earn more than $599 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 (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.”

1. **What are the risks?**

**Coercion, Undue Influence, Sensitive Questions:**

**Definitions:**

**\* Coercion:** Occurs when an overt or implicit ***threat of harm*** is intentionally presented by one person to another in order to obtain consent.

 - e.g. an investigator might tell a prospective subject that they will lose access

 to needed health services if they do not participate in the research.

**\* Undue Influence**: Occurs through an offer of an ***excessive or inappropriate reward*** or other overture in order to obtain compliance.

- e.g. an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, the investigator offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

**Coercion and Undue Influence**: <Address how coercion and/or undue influence will be mitigated based on the population and study procedures, if applicable.>

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

1. **What are the benefits?**

**Medical Research, Prisoner Research:**

**Definition:**

**Clinical Research**: Medical research that involves people to test new treatments and therapies.

**Medical Research**: “This study is not designed to treat any illness or 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?**

**Recordings, Certificate of Confidentiality, Clinical Trial, FDA-Regulated Studies, Focus Groups:**

**Definition:**

**\* Certificate of Confidentiality**: A Certificate of Confidentiality (CoC) helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive health-related research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. If interested in getting a CoC, please visit: (https://humansubjects.nih.gov/coc/contacts).

**\* Clinical Trial**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**\* Placebo:** A substance that has no therapeutic effect, used as a control in testing new drugs.

**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:** “<Enter required CoC language based on the specific NIH agency.>”

**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 (focus group/interview/survey, etc.) is part of a larger clinical trial.”

**FDA-regulated Studies**: “Because this research involves articles regulated by the Food and Drug Administration (FDA), the 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.”

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

For studies involving interventions (behavioral, educational, social, medical, or other), include a description of alternative procedures or standard care that are available if a participant chooses not to be in the study.

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

**Taking part in research is voluntary.** A participant does not have to be the study if they do not want to be. Even if they decide to be in the study, they can change their mind and stop at any time. If they refuse to participate or to leave the study, their current or future relationship with Brown University will not be affected.

1. **Who can I talk to if I have questions about this study?**

Provide the name, phone number, and email of a PI/staff member/etc. that can answer any questions a participant may have specific to the study design and/or their participation. Additionally, if an advisor is involved, their contact information should also be included.

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

If a participant has a question specific to their rights as a participant in a research study, but not a question specific to the research design, they can contact Brown University’s Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

1. **Consent to participate:**

Waiver of documentation of Consent:

**Definition:**

**Waiver of Documentation of Consent (verbal consent process or online consent process):** If appropriate, the IRB may approve to waive the requirement for an investigator to obtain a signed consent document if:

1. The consent document would be the only record linking the participant to the research and (b) the **principal risk** of the research would be a potential harm from a breach of confidentiality; OR
2. The research presents **no more than minimal risk** of harm to participants, and (b) involves no procedures for which written consent is normally required outside of the research context."

**Online consent**:“Clicking the link below confirms that you have read and understood the information in this document, are <insert age range> and that you agree to volunteer as a research participant for this study.”

You can print a copy of this form.

< provide URL>”

**Phone/Verbal consent**:“Do you agree and understand the information in this document? Do you agree to volunteer as a research participant for this study?”

Would you like a copy of this form?”