**HOW TO USE THIS TEMPLATE: Instructions are marked in [shaded brackets]. In [*italicized, shaded brackets*] is additional language specific to certain types of studies (for example, an intervention or a study funded by the FDA).**

**All plain text without shading should be included in your consent document without modification.**

**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, research population, or funding.**

**You can find** [**additional consent language**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms#Consents)**, with definitions and examples of when/why they may be appropriate, by clicking on individual section headers below.**

**BROWN UNIVERSITY**

**CONSENT FOR RESEARCH PARTICIPATION**

[Title of study]

[Version #, date]

**KEY INFORMATION**:

[**This section is required for ALL consent documents**.

“Key Information” must briefly summarize the important aspects of the research study that will help a reasonable person understand why they may or may not want to participate in the research. This section should be no longer than half a page in length. Provide a justification in the protocol if more than half a page is needed to complete this section.

The rest of the consent document after this section should expand on the “Key Information” section in detail.]

You are invited to take part in a Brown University research study. Your participation is voluntary.

* PURPOSE: The study is about … [state the purpose(s) of the research.]
* PROCEDURES: You will be asked to … [state the procedures to be followed.]
* TIME INVOLVED: The study will take XX [state the total minutes, hours, days, etc.] of your time.
* COMPENSATION: You [will/will not] receive XX [state the total compensation] for your time.
* RISKS: [State the reasonably foreseeable risks to the prospective participant.]
* BENEFITS: [State the direct benefits to the prospective participant that may reasonably be expected from the research, if any.]
* ALTERNATIVES TO PARTICIPATION: [*For studies involving an intervention*: Describe the standard of care and/or other alternative procedures available.]

[The informed consent information must be presented in language that is understandable to the participant. To the extent possible, the language should be understandable by a person who is educated to 8th-grade level and layman’s terms should be used in the description of the research.]

1. **[Researcher(s):](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Researchers)**

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

1. **[What is this study about?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_is_this_study_about)**

The purpose of the study is … [Provide a brief explanation of the activity in lay language (8th grade reading level or below).]

You are being asked to be in this study because you are … [State the age of the participants to be involved and any inclusion criteria.]

1. **[What will I be asked to do?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_will_I_be_asked_to_do)**

[Describe the tasks/procedures involved in the study using separate paragraphs for each task/procedure.

Describe any questionnaires, surveys, and interviews with examples of the most personal and sensitive questions participants will be asked. State that participants may refuse to answer or skip any question asked of them.

If there are multiple procedures/visits, a study flow chart or table may be helpful.

If applicable, include the use of any medical, academic, or other records, photographs, audio or visual recording.]

Your participation in this study may last up to \_\_\_\_\_ [hours, minutes].

1. **[Will I be paid?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Will_I_be_paid)**

[Add any compensation per procedure and/or reimbursement for participant expenses, and list the possible total amount. If creating a table of procedures, add any compensation to the table.]

1. **[What are the risks?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_risks)**

[All studies have risk (physical, psychological, social, legal, or financial, etc.). Do not state that there are no risks or that risks “should be” minimal.

Describe any side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. Assess each risk’s likelihood and seriousness.

Describe the procedures for protecting against or minimizing any potential risks. State whom participants should contact in the event of study-related injury, illness, or distress.

State that the procedures (and audio/video recording, if applicable) can be stopped at any time.]

1. **[What are the benefits?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_benefits)**

[[](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_benefits)*If appropriate, include]*: You may not directly benefit from being in this research study.

[Provide a description, if there are direct benefits to the participant. Compensation and/or reimbursement for travel are not study benefits.]

1. **[How will my information be protected?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "How_will_my_information_be_protected)**

[State whether data will be identifiable (identifiers collected), coded (identifiers collected, but linked to data by code or pseudonym) or anonymous (no identifiers collected).

Describe the physical, administrative, and technical safeguards used to protect the identities of research participants and research data. This should include a discussion of the privacy protections (referring to space/location) of the consent process and study procedures, and the confidentiality (referring to information) of research data.

For example, conducting a procedure in private, locking file cabinets and the office, or a computer not connected to the Internet are physical safeguards; random number coding of research data, or password protection of computers and electronic files are administrative safeguards; encryption of research data is a technical safeguard.

State if study data and audio/video recordings (if applicable) will be kept indefinitely, shared with other researchers, or used in presentations/publications.

Describe arrangements for destroying identifiable data after the data are no longer needed.

Where applicable, list the state, federal, regulatory, or funding agencies that will have access to identifiable data.

*For all studies in which links between participant identities and data will be kept, add:* Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.]

1. **[Are there any alternatives to this study?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Are_there_alternatives)**

[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?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_if_I_want_to_stop)**

**Taking part in research is voluntary.** You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University [or any other name of organization, Dr., if applicable] or [academic standing, job status, reputation, etc., if applicable] will not be affected.

1. **[Who can I talk to if I have questions about this study?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Study_questions)**

If you have any questions about your participation in this study, you can call [(name) at (phone #) or email [XXX@Brown.edu](mailto:XXX@Brown.edu) or (if applicable) my advisor (name) at (phone # or email)].

1. **[Who can I talk to if I have questions about my rights as a participant?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "HRPP_questions)**

If you have questions about your rights as a research participant, you can contact Brown University’s Human Research Protection Program at 401-863-3050 or email them at [IRB@Brown.edu](mailto:IRB@Brown.edu).

1. **[Consent to Participate](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Consent_to_participate)**

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date / PRINTED NAME

[Optional, *unless the study is FDA-regulated*.]

Research Staff Signature and Date / PRINTED NAME