

**Brown University**

**Application for Full Board / Expedited IRB Review**

**Protocol Title:**

**Principal Investigator:**

**Department:**

**Phone number:**

**Email address:**

**Is this a graduate student project?\*** [ ]  **Yes** [ ]  **No**

**If student PI, please provide the following:**

**Advisor:**

**Department:**

**Phone number:**

**Email address:**

**Is this an undergraduate student project?\*** [ ]  **Yes** [ ]  **No**

**If yes, name of undergraduate student:**

**Human Subjects CITI training is complete (PI, advisor (if student PI)):** [ ]  **Yes** [ ]  **No**

**Good Clinical Practice (GCP) training is complete (**[**clinical trials**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/clinical-trials) **only):** [ ]  **Yes** [ ]  **No** [ ]  **N/A**

**HIPAA training is complete (if using** [**PHI**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#PHI)**):** [ ]  **Yes** [ ]  **No** [ ]  **N/A \**

**Are there multiple sites involved with this study?** [ ]  **Yes** [ ]  **No**

* If “yes,” review the [Application for IRB Authorization Agreement](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#new)

**Funding Source(s):**

* If externally funded, provide the following:
Project title:
Grant/Contract #:
* If there is no external funding for the project, write "University;" if funded by a specific internal funding mechanism (e.g., Mellon Mays Fellowship, Royce Fellowship, UTRA, OVPR Seed funds, etc.) please specify**:**

|  |
| --- |
| **PART I. HUMAN SUBJECTS RESEARCH SCREENING** |

|  |
| --- |
| **Full Board/Expedited studies must meet the federal definition of “Human Subjects Research.” Answer the following questions to determine if your proposed study meets the federal definitions of both “Research” and “Human subjects.”** |
|  [ ]  Yes [ ]  No | Is this study a [systematic investigation](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#S)? |
|  [ ]  Yes [ ]  No | Is the *primary design intent* of this study to contribute to [generalizable knowledge](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#G)? |
|  [ ]  Yes [ ]  No | Is the information being obtained *about* living individuals? |
|  [ ]  Yes [ ]  No | Will you collect information through some type of intervention or interaction? **OR**Will you have access to [individually identifiable information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#I)? **OR**Will you have access to [private information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#P)? |
| If you answered “no” to any of the above questions, your study does not meet the definition of “Human Subjects Research.” You are not required to submit an Application for IRB review to the Brown HRPP.STOP |
| **Before proceeding, be sure to review the revised Common Rule** [**categories**](https://www.brown.edu/research/exemption-categories) **for** [**Exemption**](https://www.brown.edu/research/exemption-categories) **to determine if your study meets criteria for Exempt review and the** [**Application for Exemption**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#new)**.** |

|  |
| --- |
| **PART II. RISK ASSESSMENT & EXPEDITED ELIGIBILITY SCREENER** |
| **1. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.****Using this definition, do you believe this research presents:** |
|  [ ]  No greater than minimal risk (**Expedited**) | Briefly justify this selection (and proceed to Question 2):  |
|  [ ]  Greater than minimal risk (**Full Board**) | Briefly justify this selection (and proceed to [Part III](#PartIII)): |

|  |
| --- |
| **2. Below are Research Categories *eligible* for Expedited Review. Select one or more of the categories that are applicable to your proposed research, if any.** |
|  [ ]  Category 1 | Clinical studies of drugs and medical devices only when condition (a) or (b) is met (please select one): [ ]  (a) research on drugs for which an IND application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review); OR[ ]  (b) research on medical devices for which (i) an IDE exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
|  [ ]  Category 2 | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: [ ]  (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn must not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; OR[ ]  (b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. |
|  [ ]  Category 3 | Prospective collection of biological specimens for research purposes by noninvasive means. Examples may include:(a) hair and nail clippings in a non-disfiguring manner;(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;(c) permanent teeth if routine patient care indicated a need for extraction;(d) excreta and external secretions (including sweat);(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;(f) placenta removal at delivery;(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routing prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;(j) sputum collected after saline mist nebulization. |
|  [ ]  Category 4  | Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)Examples may include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;(b) weighing or testing sensory acuity;(c) magnetic resonance imaging;(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
|  [ ]  Category 5  | Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be Exempt. Review the [categories for Exemption](https://www.brown.edu/research/exemption-categories) before selecting this option. |
|  [ ]  Category 6 | Collection of data from voice, video, digital, or image recordings made for research purposes. |
|  [ ]  Category 7 | Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be Exempt. Review the [categories for Exemption](https://www.brown.edu/research/exemption-categories) before selecting this option. |

|  |
| --- |
| **PART III. RESEARCH DESIGN & METHODS** |

1. **Introduction and Background.** *In reviewing the protocol, the IRB must consider the rationale for the study and the importance of the knowledge that may reasonably be expected to result.*

* **Briefly** summarize the nature, scientific or scholarly rationale and significance of the proposed study and any relevant background information on the topic in lay language. Explain the relevance of the study to previous and/or continuing work in the field. Discuss why novel inquiry is necessary. If there is a gap in knowledge, explain how it is anticipated that this research will address the gap. If this research is intended to replicate previous research, provide rationale.

2. **Specific Aims and Study Objectives.** *The IRB must evaluate the objectives of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.*

* **Clearly** outline the specific research question(s). Include the study objective(s) and/or hypothesis.

|  |
| --- |
| STOP **If your study ONLY involves the use of identifiable secondary data / biospecimens, including coded data from which you may be able to ascertain identity,****skip to** [**PART VI**](#PartVI)**. Otherwise, please continue.** |

3. Materials, Methods and Analysis. *The study design, methods and procedures must be adequately described in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation.*

**NOTE: The focus of this section is on methods and procedures. Risks will be described later.**

**THE BLUE TEXT IN THE FOLLOWING SECTIONS IS A GUIDE TO ENSURE ALL RELEVANT INFORMATION IS INCLUDED IN YOUR APPLICATION. YOU MAY DELETE THE BLUE TEXT BEFORE SUBMISSION**

4. **Participant Population.** *In order to approve research, the IRB must determine that the selection of participants is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations. To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc.*

* Describe the participant population:
	+ Provide the rationale for including the participant population. When including any vulnerable populations in the study, explain why inclusion of this population is necessary to accomplish the research aims.
	+ List the inclusion criteria such as age range, race or ethnicity, gender, language and literacy, etc.
	+ List the exclusion criteria and rationale.
	+ Address whether or not participants must be fluent in English and/or if any of the study activities (i.e. recruitment, consent, assessments, etc.) will be carried out in a language other than English.
* Discuss the number of participants needed for the research including the following:

	+ Provide the targeted number of individuals to be included in the research. If more than one group, provide numbers needed for each group and total number for the entire study. This number should account for any attrition from participants who may withdraw from the study without completing the procedures.
* Provide rationale for targeted numbers.

**5. Recruitment Methods**

* Describe the process and/or method by which participants will be identified, approached, and recruited for the research, including the following:
	+ When and how will each step of recruitment occur (i.e., initial contact, introductions, follow-ups, etc.)?
	+ Describe how the participant population is accessed. Discuss relevant permissions needed to reach the population (e.g., access to listservs, online databases, etc.).
	+ List any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If no written recruitment materials will be used, explain.
	+ Explain which research roles (e.g., PI, Research Assistant, etc.) will recruit participants and how they will be trained.
	+ Describe any screening tests and/or procedures that will be used to ensure that potential participants are eligible to participate.
		- State if this information will be destroyed once eligibility is determined. If you intend to keep this information for research purposes, ensure that a screening consent process is described in Part V.
	+ If any part of the recruitment procedures involves a language other than English describe any differences in the recruitment procedures for non-English speaking participants.
		- Describe how the research team member(s) are fluent in the language of the participants or if a translator will be used.
		- Describe how materials will be presented in the language understandable to participants (e.g. will translated materials be used?). If the participant’s language is only verbal and not written, state this and explain translation.
* For research involving an intervention (e.g. behavioral intervention, drug/device studies, etc.):
	+ Describe how the intervention will be distinguished from regular (standard of care) treatment.
	+ Indicate whether the research staff who will recruit participants have provided or will provide treatment or clinical care to the prospective participants. If treatment providers also have a role in the research, describe measures to avoid or diminish their undue influence on participants.

6. **Compensation / Reimbursement**

* If participants are to receive compensation for their time, please describe the following or simply state “no compensation will be offered”:
	+ The amount and nature of the compensation (e.g., cash, gift card, course credit, etc.).
	+ Explain how and when compensation will be provided, including payment schedules, whether or not compensation will be reduced (non-FDA studies only) if the participant does not complete all activities in the study, and how any proration will occur.
	+ Explain how the method and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of study visits, travel expenses, age of participant population, etc.).
	+ Explain if participants will receive any reimbursement for travel costs or child care. Describe the amount and nature of the reimbursement, and when it will be provided.
* If there is the possibility that there will be costs to the participant or to a third party (e.g., an insurer), identify the specific expenses (e.g., drug tests, procedures, hospitalization, travel, etc.) and provide a justification for those costs.

7. **Potential Research Risks / Discomforts to Participants.** In order to approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated benefits to participants, as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of the risks or discomforts.

* Describe any reasonably foreseeable risks of harm or discomforts for individuals and/or groups that may result from participation in the research. While risks associated with participation may be minimal, *all* research carries some risk. Consider the following:
	+ Information risks (e.g., loss of privacy and/or breach of confidentiality).
	+ Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).
	+ Social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
	+ Physical risks or harms (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, or death, side effects and contraindications of drugs or substances used in the research).
	+ Legal risks (e.g., risk of prosecution, mandatory reporting).
	+ Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.).
* For each identified risk, explain all of the following:
	+ Likelihood of the risk occurring.
	+ Magnitude of the effects the risk would have should they occur.
	+ How the risk will be minimized.
* If the protocol involves intervention, describe the how the risks of the research intervention compares to the “standard of care” and/or the risks the participants experience in their daily lives.
* When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants.
	+ If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach.
	+ If there is an established Data and Safety Monitoring Board/Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP.

8. **Potential Benefits of the Research.** **NOTE: Compensation for participation is not a benefit and should not be included in this section.** *In order to approve this research, the IRB must determine that the potential benefits to research participants are reasonable in relation to the potential risks. Very often, research at Brown does not include potential direct benefits to participants, but may only benefit society as a whole by helping researchers.*

* Describe any potential benefits that may result from the research. Consider the following:
	+ Direct benefits that may result from participation (e.g., weight loss, results of clinical tests, etc.). If there are no direct benefits to participants, clearly state this.
	+ Benefits to the general participant population.

|  |
| --- |
| **PART IV. APPENDICES SCREENER** |
| **Please complete & attach the following Appendices to this Application, as applicable.****Incl. N/A**  |
|[ ] [ ]  [Appendix A. Children as Subjects](https://www.brown.edu/research/sites/research/files/Appendix%20A.%20Children%20as%20Subjects.docx)*To be attached when minors are included as participants [please be aware of the age of majority for your specific research site(s)]* |
|[ ] [ ]  [Appendix B. Prisoners as Subjects](https://www.brown.edu/research/sites/research/files/Appendix%20B.%20Prisoners%20as%20Subjects.docx)*To be attached when prisoners are included as participants.* |
|[ ] [ ]  [Appendix C. Use of Drugs](https://www.brown.edu/research/sites/research/files/policies/hrpp-form-drug-ind-investigator-checklist-v3-16-16.pdf)*To be attached when the research includes the use of FDA-regulated or unregulated drugs.* |
|[ ] [ ]  [Appendix D. Use of Devices](https://www.brown.edu/research/sites/research/files/Appendix%20E.%20Prescription%20Drug_Medication%20Management.docx)*To be attached when the research includes the use of FDA-regulated or unregulated devices.* |
|[ ] [ ]  [Appendix E. Prescription Drug / Medication Management](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#appendices)*To be attached when study procedures include administering prescription medications to study participants.* |
|[ ] [ ]  [Appendix F. Mental Health Safety Plan](https://www.brown.edu/research/sites/research/files/Appendix%20F.%20Mental%20Health%20Safety%20Plan.docx)*To be attached when participants may experience significant emotional distress, or be at risk of themselves or others.* |
|[ ] [ ]  [Appendix G. Use of protected health information (PHI) for Research](https://www.brown.edu/research/sites/research/files/Use%20of%20PHI%20in%20Research%20_Appendix%20G_%20V%208.9.19.docx)*To be attached when study procedures include a plan to access, use or disclose Protected Health Information (PHI) of participants.*  |

|  |
| --- |
| **PART V. INFORMED CONSENT** |

|  |
| --- |
| Informed consent is a *process*, not just a form. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation.Please review the [Consent/assent templates](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#Consents) and related guidance on the HRPP Forms & Templates page before developing your consent forms. |

1. **Describe the informed consent process, including:**

* How the required elements of informed consent will be conveyed to participants (i.e., informed consent document, verbal script, online consent, etc.). *In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent.*
* Where and when the informed consent process will take place (i.e., in-person in a private room, by phone, online etc.).
* Any cultural considerations (e.g., tribal or group permission requirements, age of majority, technological limitations, etc.).
* Steps that will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence.
* Which research roles (e.g., PI, Research Assistant, etc.) will conduct the consent process and how that person will be trained (e.g. previous experience or related training, one-on-one training with PI, etc.).
* If multiple participant groups or consent procedures are to be included, these need to be clearly delineated (e.g., consent process for eligibility screening, consent process for in-person main study, etc.).

 2. **Facilitate Understanding**

* Describe how you will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or encouraged to ask questions?)
* Describe any special provisions for individuals who might have trouble comprehending the consent information.
* If any participants do not speak English, describe:
	+ Whether or not the researcher is fluent in the language.
	+ Whether or not and how a translator will be used.
	+ Whether or not translated consent materials will be used.
	+ Whether or not there are any differences in the consent process for different populations based on the language they speak.
* Describe the process by which you will ensure ongoing consent.

3. **Documentation**

* Describe how the researcher plans to document that each participant has provided informed consent and/or assent.

4. **Additional Considerations**

     If the research involves:

1. To request a waiver of documentation of consent, so that participants are not asked to sign a consent document:
	* Detail how the consent document will be the only record linking the participant to the research, explain how the principal risk of the research will be a potential harm from a breach of confidentiality, and confirm that each participant will be asked if they would like documentation linking them to the research. Their wishes will govern their consent process; OR
	* Detail how the research involves no more than minimal to the participants and involves no procedures for which written consent is normally required outside of the research context; OR
	* If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, detail how the research involves no more than minimal risk to the participants and describe the appropriate alternative mechanisms for documenting that informed consent will be obtained.
2. To request a waiver or alteration of consent, so that participants are not asked to go through a full consent process:
	* Detail how the research involves no more than minimal risk to the participants; AND
	* Explain how the waiver will not adversely affect the rights and welfare of the participants; AND
	* Describe how the research could not practicably be carried out without the waiver; AND
	* If the research involves using identifiable private information or identifiable biospecimens, explain how the research could not practicably be carried out without using such information or biospecimens in an identifiable format; AND
	* Whenever appropriate, confirm that the participants or legally authorized representatives will be provided with additional pertinent information after participation.
3. Minors (those under the age of majority) or individuals of diminished capacity:
	* Describe the capacity of the participant and their ability to assent.
	* Describe how assent to participate will be obtained and documented.
		+ If a waiver of assent or waiver of assent documentation is being requested, provide justification.
	* Explain how the permission of the parent(s), guardian(s), or legally authorized representatives will be obtained and documented.
		+ If a waiver of permission or waiver of permission documentation is being requested, provide justification.
4. Deception:
	* Explain how participants will be deceived and why it is necessary for the study.
	* Deception is an alteration of informed consent; provide justification for how the use of deception meets the criteria for alteration of informed consent.
	* Describe the debriefing process and provide a script.

**Proceed to** [**PART VII. DATA SECURITY ASSESSMENT**](#PartVII)

|  |
| --- |
| **PART VI. USE OF SECONDARY DATA / BIOSPECIMENS** |

1. From what source(s) will you acquire or access the data / biospecimens?

2. Describe the type(s) of data and date range(s) of the data you will use and the characteristics of the study research population (e.g., age range, sex, and any other pertinent demographic information.)

3. To request a waiver of consent, so that participants are not asked to go through a consent process:

* + Detail how the research involves no more than minimal risk to the participants; AND
	+ Explain how the waiver will not adversely affect the rights and welfare of the participants; AND
	+ Describe how the research could not practicably be carried out without the waiver; AND
	+ If the research involves using identifiable private information or identifiable biospecimens, explain how the research could not practicably be carried out without using such information or biospecimens in an identifiable format; AND
	+ Whenever appropriate, confirm that the participants or legally authorized representatives will be provided with additional pertinent information after participation.

4. HIPAA and Protected Health Information (PHI):

* [Please review the HIPAA Privacy Rule Guidance for Brown University Researchers.](https://www.brown.edu/research/sites/research/files/Brown%20Guidance%20for%20researchers_%20V8.9.19.docx)
* If the research involves the use of PHI from a HIPAA-covered entity, describe how authorization from participants to access and use their information will be obtained.
* Complete [Appendix G. Use of Protected Health Information (PHI) for Research](https://www.brown.edu/research/sites/research/files/Use%20of%20PHI%20in%20Research%20_Appendix%20G_%20V%208.9.19.docx) and include with this application.

5. Do any of the source(s) require a Data Use Agreement (DUA) or other Agreement that requires institutional signature to obtain, access or use the data / biospecimens? [ ]  Yes [ ]  No

*If “yes,” please include a copy of the Agreement(s) with this submission and also follow the* [*Data Use Agreement review and signature processes*](https://www.brown.edu/research/content/data-use-agreements)*.*

**Proceed to** [**PART VII. DATA SECURITY ASSESSMENT**](#PartVII)

|  |
| --- |
| **PART VII. DATA SECURITY ASSESSMENT** |

|  |
| --- |
| **1. Do the study data / biospecimens include identifiers? Video and audio recordings are considered identifiable.** |
| [ ]  Yes [ ]  No\* | \*If “no,” I affirm that I have read and will abide by the [Level 1 Risk](https://it.brown.edu/computing-policies/risk-classifications) Minimum Security Standards: [ ]  Yes [ ]  No Proceed to Question #2.If “yes,” answer the following questions.A. Describe the identifiers associated with the data / biospecimens. B. Justify why identifiers are required to conduct the research.C. Described the proposed research use of the identifiable data / biospecimens.D. Self-classify the [Risk Level](https://it.brown.edu/computing-policies/risk-classifications) of these data / biospecimens (select the *highest level of risk* for all data / biospecimens being collected). [ ]  [Level 2 Risk](https://it.brown.edu/computing-policies/risk-classifications) [ ]  [Level 3 Risk](https://it.brown.edu/computing-policies/risk-classifications) |
| **2. How will study data / biospecimens be** [**collected**](#datacollection)**?** |
|  [ ]  Brown desktop [ ]  Laptop [ ]  [Departmental server](#departmentserver) [ ]  [CIS managed server](#departmentserver) [ ]  [Brown Qualtrics](#Qualtrics) [ ]  [REDCap](#REDCap); Please describe what instance of REDCap is being used (Brown does not have an instance of  REDCap):  [ ]  MTurk (AMT) [ ]  Text messaging 🡪 You must complete the [Text messaging](#textmessaging) section after completing Qs 3 – 5. [ ]  Mobile App (on tablet, iPad, Phone) 🡪 You must complete the [Mobile App](#mobileapp) section after completing Qs 3-5. [ ]  [Zoom](https://it.brown.edu/services/type/zoom-web-conferencing)  [ ]  Other audio / videoconferencing tool; please describe the tool:  [ ]  Paper records, including photographs. Please describe, including how you will securely store the paper records:  [ ]  Web-based site / survey / other tool not listed above 🡪 You must complete the [Web-based Other](#Webbasedother) section after  completing Qs 3 – 5. [ ]  Other; please describe:  |
| **3. Who will have access to the study data / biospecimens?** |
|  [ ]  A. Brown PI only. How will unauthorized access by others be prevented? [ ]  B. Brown PI and other Brown research team members. How will unauthorized access by others beprevented? [ ]  C. Data will be shared with research collaborators external to Brown. This data sharing intent **must** be described as part of your consent process / form. Please describe how you will securely share / transfer the data outside of Brown: *Note that an Outgoing Data* *Use Agreement* ***is required when sharing identifiable data external to Brown****. Please follow the procedures outlined* [*here*](https://www.brown.edu/research/content/data-use-agreements)*. You do not need to submit a copy of a DUA to the HRPP. This will be linked by the ORI administratively.* |
| **4. Where will the study data / biospecimens be stored?** |
|  [ ]  [Departmental server](#departmentserver) [ ]  [CIS managed server](#departmentserver) [ ]  [Stronghold](https://it.brown.edu/services/type/stronghold-research-environment-data-compliance) [ ]  [Campus file storage](https://it.brown.edu/services/type/campus-file-storage) [ ]  [REDCap](#REDCap)  [ ]  Other. Please describe:  |
| **5. If traveling with your data, describe how your data will be secured.** |
|  |
| **6. For how long will you retain identifiable data / biospecimens? How will you destroy identifiers when no longer required?** |
|  |
| **Text Messaging (only complete if instructed above.)** |
| 1. Are you using the current text messaging service available on the device? |
| [ ]  Yes [ ]  No | If “no,” you must also complete the [Mobile App](#mobileapp) section. |
| 2. Whose device will be used? [ ]  Participant’s personal phone [ ]  Brown-issued phone |
| 3. Content of messaging: (If brief, insert here; otherwise, please provide as an attachment) |
| 4. Is the communication one-way or two-way? [ ]  One-way [ ]  Two-way |
| **Mobile App (only complete if instructed above.)** |
| 1. Name of the mobile app:  |
| 2. Has this site / tool been reviewed by CIS IT Security?  |
| [ ]  Yes [ ]  No | If “no,” answer the following:a. Who created the site / tool (vendor name or off the-shelf app creator name)?b. Where is it hosted? c. Is the site / tool scanned for security vulnerabilities? [ ]  Yes [ ]  Nod. What version of software is being used, if applicable: [ ]  N/A or e. How are the data encrypted?  |
| 3. Whose device will be used? [ ]  Participant’s personal phone [ ]  Brown-issued phoneIf Participant’s person phone:a. How is the app downloaded to the device? b. Is a password or PIN required for the app? [ ]  Yes [ ]  No |
| 4. Will data be stored on the device for any period of time? |
| [ ]  Yes [ ]  No | a. If “yes,” please describe (i.e., queue on phone and then transmitted to server): b. Is the app data encrypted on the device? [ ]  Yes [ ]  No |
| 5. Device features mobile app can access [ ]  N/A [ ]  Device ID and call information [ ]  Identity [ ]  Contacts  [ ]  Camera [ ]  SMS or chat [ ]  Storage [ ]  Device and application history [ ]  Phone [ ]  Photo / media / files [ ]  Microphone [ ]  Location [ ]  Other; please describe:  |
| 6. Will a third-party have access to research data through this app? [ ]  Yes [ ]  No |
| 7. Is data transmitted by the device?  |
| [ ]  Yes [ ]  No | If “yes,” how is it encrypted in transit?  |
| 8. Are phone numbers or mobile identification numbers stored with the data? [ ]  Yes [ ]  No |
| **Web-based Other (only complete if instructed above.)** |
| 1. Name of the site / tool:  |
| 2. Has this site / tool been reviewed by CIS IT Security?  |
| [ ]  Yes [ ]  No | If “no,” answer the following:a. Who created the site / tool (vendor name or off the-shelf app creator name)?b. Where is it hosted? c. Is the site / tool scanned for security vulnerabilities? [ ]  Yes [ ]  Nod. What version of software is being used, if applicable: [ ]  N/A or e. How are the data encrypted?  |
| [ ]  Yes [ ]  No | If “no,” answer the following:a. Who created the site / tool (vendor name)? b. Where is it hosted? c. Is the site / tool scanned for security vulnerabilities? [ ]  Yes [ ]  Nod. What version of software is being used, if applicable: [ ]  N/A or e. How are the data encrypted?  |
| 3. Is informed consent being obtained via this site / tool?  |
| [ ]  Yes [ ]  No | If “yes,” how is re-identification prevented?  |
| 4. Does the technology allow for the explicit exclusion of the collection of IP address of the participant’s connection?  |
| [ ]  Yes [ ]  No | If “yes,” will you use this option to exclude the collection of IP address?[ ]  Yes [ ]  No |

Brown Qualtrics: CIS has pre-vetted [Brown Qualtrics](https://it.brown.edu/services/type/qualtrics-survey-tool) for collection/storage of up to [Risk Level III data](https://it.brown.edu/computing-policies/risk-classifications). Qualtrics is the preferred survey tool for all Brown research data collection.

REDCap: Brown does not currently have its own instance of REDCap. Access to REDCap through a Lifespan collaborator must be explicitly identified.

Data collection: The expectation is that data collection *devices* will only store data during active data collection. Data must then be transitioned to more secure long-term storage solutions.

Departmental/CIS managed servers: If data are collected/entered directly onto a Departmental or CIS managed server, **you must ensure** that the server meets the security standards described in the [Minimum Security Standards for Servers](https://it.brown.edu/protected/minimum-security-standards-servers-network-switches) based on the Risk Level of the data identified in 1D.

|  |
| --- |
| **PART VIII. INTERNATIONAL RESEARCH** |

|  |
| --- |
| **1. Does the research involve human subjects activities outside of the United States?** |
| [ ]  Yes [ ]  No | If “yes,” please list the countries:If “no,” you are not required to complete this Part of the application. Proceed to [PART IX. ATTACHMENTS](#PartIX).-------------------------------------------------------------------------------------------------------------b. What is the status of permissions / approvals from local ethics boards or committees? [ ]  Received; please append to this Application. [ ]  Pending  [ ]  N/A. Please explain: -------------------------------------------------------------------------------------------------------------c. Will this research take place in a non-public setting (including a school, hospital or clinic) for which local permission is required? [ ]  Yes [ ]  NoIf “yes,” please append a letter(s) of support or permission(s) to this Application. -------------------------------------------------------------------------------------------------------------d. Describe how you have taken into account any social, political, or cultural issues that may impact participants.  |
|  [ ]  | I have reviewed the current version of the [*International Compilation of Human Research Standards*](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html)and agree to abide by relevant local laws, regulations and guidelines. |
|[ ]  I have reviewed the [*General Data Protection Regulations guidance*](https://www.brown.edu/research/sites/research/files/14.%20GDPR%20v120318.pdf) and will abide by any requirements. |
|[ ]  I have reviewed ORI’s export control guidance on [international travel](https://www.brown.edu/research/international-travel), [international collaborations](https://www.brown.edu/research/international-collaborations), and [international shipping](https://www.brown.edu/research/international-shipping) (*if applicable*) |
|  |  |
| **2. Local Contact (*student research only*)** [ ]  N/A |
| Provide the name and contact information of your local contact:Name:Organization:Address:Phone Number:E-mail address: |

|  |
| --- |
| **PART IX. ATTACHMENTS** |

|  |
| --- |
| **Please attach the following materials to this Application for Full Board / Expedited IRB Review, as applicable.****Incl. N/A**  |
|[ ] [ ]  Informed consent documents / scripts |
| [ ]  | [ ]  | Data collection materials (questionnaires, surveys, interview scripts, etc.) |
| [ ]  | [ ]  | Permissions, approval documents, and/or support letters identified in PART VII. |
| [ ]  | [ ]  | Recruitment materials (emails, flyers, letters, scripts, posters, brochures, etc.) |
| [ ]  | [ ]  | Application for IRB Authorization Agreement |
| [ ]  | [ ]  | Data Use Agreement from data provider(s) |
| [ ]  | [ ]  | HIPAA Authorization |
| [ ]  | [ ]  | Data Safety Monitoring Plan |
|[ ] [ ]  Other:  |

|  |
| --- |
| **PART X. CONFLICT OF INTEREST**  |

|  |
| --- |
| [The *Brown University Conflict of Interest Policy for Officers of Instruction and Research*](https://www.brown.edu/research/COIpolicy) *(“COI Policy”)* defines the term “Investigator” as “the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research.” |
| Using this definition of “Investigator,” please ensure that all Investigators on this protocol answer questions (1) and (2) below. Attach additional sheets for any Investigators who are not the PI; additional sheets are available on the HRPP website. |

|  |
| --- |
|[ ]  I am affiliated with Rhode Island School of Design and will abide by policies and procedures set forth by my institution.  |

|  |
| --- |
| 1. Have you completed a conflict of interest disclosure (i.e. *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by Brown’s [COI Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-policy)? (You may access the InfoEd system [here](https://infoed.brown.edu/EnableWeb/Portal/Home) to confirm.) |
| [ ]  Yes [ ]  No | If “no,” please do so before submitting this Application |
| 2. Do you have a [significant financial interest](https://www.brown.edu/research/COIFAQ#interest) (SFI) that is related to this research protocol? “Related” could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI. It could also mean that the SFI could be affected by the proposed research or its results.  |
| [ ]  Yes [ ]  No | If “yes,” please identify the SFI and explain the relatedness:  |
|[ ]  [Additional COI sheets](https://www.brown.edu/research/sites/research/files/Additional%20Investigator%20COI%20v0607019.docx) for Investigators are attached to this Application.***(Required for Advisors)*** |
|  **PART XI. INVESTIGATOR & FACULTY ADVISOR AGREEMENTS / PRINCIPAL INVESTIGATOR RESPONSIBILITIES**  |

 **A. Conduct of the Research**

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), [Common Rule](https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf), and Brown University policies.
2. I accept responsibility for ensuring this research is conducted in accordance with:
3. Sound research design and methods;
4. The parameters of the research plan and activities described in this Application;
5. The applicable terms of the grant, contract, or other signed funding agreements;
6. Applicable laws and regulations, including those protecting the rights, safety and welfare of human subjects.
7. I certify that I am, or my faculty advisor is, sufficiently qualified by education, training and experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that all member of the research team have or will complete human
8. subjects [CITI training](https://about.citiprogram.org/en/homepage/) before any work with participants or identifiable data / biospecimens begins.
9. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research.

**B. Ensuring and Maintaining Compliance**

1. I will comply with relevant regulatory and institutional reporting requirements, including Brown University’s [*Reportable Events Policy*](https://www.brown.edu/research/sites/research/files/18.%20Reportable%20Events%20Policy%20%28Final_12Nov18%29.pdf).
2. I understand that it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct or reporting of the research declares any conflicts of interest related to this research. I will ensure that any changes that impact my or other research personnel’s answers to the questions in PART IX. Conflict of Interest, are reported promptly to Brown’s HRPP.
3. I will ensure that prospective agreement and/or informed consent is obtained and a copy is provided to participants, when appropriate.
4. If there are changes to the research described in this Application for Full Board / Expedited IRB Review that may impact the study’s classification as Full Board or Exepdited research, I will promptly notify the Brown HRPP of such changes.
5. I will notify the Brown HRPP when I have completed all activities involving human subjects or identifiable participant data or identifiable biospecimens.
6. I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.
7. I will cooperate with any post-approval monitoring or auditing of study activities and/or study records as requested and/or required by the Brown ORI, the Brown IRB, funding entities, sponsors, and/or any federal or state regulatory agencies.

**C. Study records, Reports and Documentation**

1. I will maintain all research protocol materials and consent materials for the duration of this study.
2. I will maintain research records for at least three years following the end of this research, or for a longer length of time if specified in applicable regulations or sponsor requirements. I will take measures to prevent accidental or premature destruction of these records.
3. I will abide by all terms of any Data Use Agreement (or equivalent agreement) related to this study, including those agreed to electronically (through an online attestation).
4. I will ensure that the data security measures for acquisition, collection, transfer and use of study data described in PART VI. of this Application are adhered to by all members of the research team.

**By my signature below, I certify that I have read and agree to uphold all of you and/or Advisor Responsibilities in PART XI.**

**Principal Investigator signature:**  **Date:** Click here to enter a date.



===============================================================================

**An Advisor’s signature is required for all graduate/medical student projects**

**Advisor certifies the following:** Advisor has read the complete protocol, approves this project, and will remain available to advise the student throughout the course of the proposed human subjects research, or will transfer responsibilities to another Advisor if unable to advise for the entirety of the project.

**Advisor’s name (please print):**

**Advisor's signature:** **Date:**  Click here to enter a date.



***For IRB Use Only***

**Signature of the IRB:**

**Date of IRB approval:** Click here to enter a date.