

**Brown University**

**Application for Exemption**

**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**

**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**:**

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| **PART I. EXEMPT ELIGIBILITY SCREENING** |

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| **Exempt 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 this study *designed* 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 Exemption to the Brown HRPP.STOP |

**Complete the below section to identify study characteristics that DO NOT qualify for exemption.**

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| **Below are the specific characteristics that disqualify a study for exemption. Answer the following:** |
| [ ]  Yes [ ]  No | (a) Does this research involve the use of any FDA-regulated drugs, substances, biologics, or devices? |
| [ ]  Yes [ ]  No | (c) Does this research involve the use of any ionizing radiation (e.g, X-ray, DEXA scan, etc.?) |
| [ ]  Yes [ ]  No | (d) Does this research involve the use of genetic information and/or tests? |
| [ ]  Yes [ ]  No | (e) Does this research propose to study [prisoners](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#P) as a targeted population? |
| **In some circumstances, studies that would otherwise quality for exemption must undergo expedited or full board review by the IRB. These circumstances are study-specific. Please answer the following questions to determine if your study is ineligible for exemption:** |
| [ ]  Yes [ ]  No | (a) Is there a state, federal or other applicable law (e.g., tribal or international law) that prohibits an exemption determination for this research? [If “yes,” please identify the relevant law when submitting your Expedited / Full Board Application.] |
| [ ]  Yes [ ]  No | (b) Does the agency funding your research, or an agency with whom you are working, prohibit an exemption determination and require that you have IRB approval? [If “yes,” please provide written documentation of this prohibition when submitting your Expedited / Full Board Application.] |
| [ ]  Yes [ ]  No | (c) Are there any other study-specific requirements of which you have been informed that prohibit an exemption determination? [If “yes,” please provide written documentation of this requirement when submitting your Expedited / Full Board Application.] |
| **If you answered “YES” to any of the above eligibility screening questions, your study does not qualify for an Exempt review. Please complete the** [**Application for Full Board/Expedited Review**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#new)**. Otherwise, proceed to** [**PART II**](#PartII)**.** STOP |

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| **PART II. EXEMPTION CATEGORIES & WORKSHEETS** |

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| **1. Below are the Exemption Categories. Select one or more of the categories that are applicable to your proposed research. Fill out the Exempt Category Worksheet(s) that correspond with your selection(s) and submit the Worksheet(s) as part of your Application for Exemption.** |
| [ ]  [Exemption 1](https://www.brown.edu/research/exemption-categories#exempt1) | Research conducted in an established or commonly accepted educational setting that specifically involves normal educational practices. [Complete Exempt Cat. 1 Worksheet](#Exempt1) |
| [ ]  [Exemption 2](https://www.brown.edu/research/exemption-categories#exempt2) | Research that ONLY includes interactions involving:1. Educational tests (cognitive, diagnostic, aptitude, achievement); OR
2. Survey procedures; OR
3. Interview procedures; OR
4. Observation of public behavior; OR
5. Focus Groups

[Complete Exempt Cat. 2 Worksheet](#Exempt2) |
| [ ]  [Exemption 3](https://www.brown.edu/research/exemption-categories#exempt3) | Research involving ONLY benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording. [Complete Exempt Cat. 3 Worksheet](#Exempt3). |
| [ ]  [Exemption 4](https://www.brown.edu/research/exemption-categories#exempt4) | Secondary research using [identifiable private information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#I) or identifiable biospecimens, collected for a purpose other than this study. [Complete Exempt Cat. 4 Worksheet](#Exempt4). |
| [ ]  [Exemption 5](https://www.brown.edu/research/exemption-categories#exempt5) | Research and demonstration projects conducted or supported by a Federal department or agency that is designed to study, evaluate, improve, or otherwise examine public benefit or service programs. [Complete Exempt Cat. 5 Worksheet](#Exempt5). |
| [ ]  [Exemption 6](https://www.brown.edu/research/exemption-categories#exempt6) | Taste and food quality evaluation and consumer acceptance studies. **Brown does not typically review these types of studies. Please contact the** **Brown HRPP** **to discuss *before completing this application*.** |
| [ ]  [Exemption 7](https://www.brown.edu/research/exemption-categories#exempt7) | Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use for which [broad consent](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#B) is required.**Brown’s HRPP does not plan to implement this Exemption at this time. Limited exceptions may be considered.**  |
| [ ]  [Exemption 8](https://www.brown.edu/research/exemption-categories#exempt8) | Secondary research involving the use of identifiable private information or identifiable biospecimens for potential secondary research use for which [broad consent](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#B) is required.**Brown’s HRPP does not plan to implement this Exemption at this time. Limited exceptions may be considered.**  |
| **If you were unable to identify an applicable exemption category and/or the Worksheet(s) result in a determination that the study does not quality for exemption, please complete the** [**Expedited / Full Board IRB Application**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies)**.**STOP |

**Exempt Category 1 Worksheet**

*Research Conducted in Established or Commonly Accepted Educational Settings*

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| **1. Is the research being conducted in an established or commonly accepted educational setting?** |
| [ ]  Yes | Describe the [educational setting](#educationalsetting):  |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. Does this research involve** [**normal educational practices**](#normaledupractices)**?** |
| [ ]  Yes | Describe the educational practices:  |
| [ ]  No | This research does not quality for exemption under this category. |
| **3. Is the research on these educational practices NOT likely to** [**adversely impact students’ opportunity to learn**](#advimpactstudents) **required educational content?** |
| [ ]  Yes | Please explain:  |
| [ ]  No | This research does not quality for exemption under this category. |
| **4. Is the research on these educational practices NOT likely to** [**adversely impact the assessment of educators**](#advimpactedu) **who provide instruction?** |
| [ ]  Yes | Please explain:  |
| [ ]  No | This research does not quality for exemption under this category. |
| If you answered “yes” to all of the above questions, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to [PART III](#PartIII). If you answered “no” to any of the questions above, the research is not exempt under this category. |

Educational setting: The consistent interpretation of this term is that commonly accepted educational settings can be almost anywhere, as long as the setting is one where specific educational offerings normally take place or a setting where one would go in order to have an educational experience. Examples include: K-12 schools and college classrooms, after-school programs, preschools, vocational schools, an alternative education programs; professional development seminar for school district personnel; soccer practice field; Boy/Girl Scouts meeting; Medical school; Religious education settings; Training simulators (e.g., medical simulators, flight simulators, etc.).

Normal educational practices: Normal educational practices are those activities that are routinely used in similar educational settings and/or are considered proven educational practices with the population under study.

Adversely impact students’ opportunity to learn: Consider whether the proposed activity requires students to deviate from a curriculum that is aligned with any national or state-level indicators of student achievement (e.g., state end of grade testing) or if the activity will take instructional time away from students.

Adversely impact assessment of educators: Will participation, or the refusal to participate, in the research be a factor in the assessment of educators? Will the outcomes of the research be a factor in the assessment of participating instructors?

**Exempt Category 2 Worksheet**

*Educational Tests, Surveys, Interviews, Observations of Public Behavior*

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| **1. Is the research limited to interactions involving the following:*** **Educational tests (cognitive, diagnostic, aptitude, achievement); OR**
* **Survey procedures; OR**
* **Interview procedures; OR**
* **Observation of public behavior (including visual or auditory recording); OR**
* **Focus Groups**
 |
| [ ]  Yes | Please describe:  |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. If the research involves children as participants, are the research activities limited to educational tests (defined above) or** [**observation of public behavior**](#observepub) **where the investigator(s) will NOT participate in the activities being observed?** |
| [ ]  Yes | Please describe:  |
| [ ]  No | This research does not quality for exemption under this category. |
| [ ]  N/A | Children are not involved as participants in this study. |
| **3. Select the following conditions that apply to this research:** |
|  [ ]   | A. The information obtained is recorded in such a manner that the identity of the participants cannot readily be ascertained either directly or through identifiers linked to the participants.  |
|  [ ]   | B. Any disclosure of participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, [educational advancement](#eduadvancement), or reputation. |
|  [ ]   | C. Information obtained is recorded in such a manner that the identity of the participants **can be** readily ascertained, directly or through identifiers linked to the subjects, but adequate provisions have been made to ensure that the data collected are appropriate monitored and secured to ensure confidentiality. |
|   | Describe provisions to **protect the privacy of participants**: |
|  | Describe provisions to **maintain confidentiality of participant data**: |
| If you answered “yes” to questions 1 & 2 (or N/A to question 2) and were able to select an applicable condition(s) in Section 3, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to [PART III](#PartIII).If you checked 3C. (including if you are collecting audio/visual recordings) your application must also undergo a Data Security Assessment (“Limited IRB Review.”) Please complete [PART VI](#PartVI).If you answered “no” to any of the questions above, the research is not exempt under this category. |

Q: When is observation of public behavior without intervention or interaction human subjects research?

Observation of public behavior without intervention or interaction can be human subjects research when it satisfies the definitions of human subject and research. Within the framework of this exemption, it is possible that an investigator may be observing individuals in a setting where, while public, there is an expectation of privacy (e.g., classrooms, online group, or other venues where you would need permission to be there).  It is also possible under this exemption for an investigator to engage in public observation through which the investigator could capture information that would allow for the identification of observed individuals. In such circumstances, the IRB must conduct Limited IRB Review.

Q: How should one interpret “educational advancement” as something that potentially could be damaged?

Examples would be information learned in the study that would disqualify an individual from advancement.  For example, in a survey that collects data about academic integrity where respondents indicate whether they have engaged in misconduct (e.g., cheating on exams, plagiarism, etc.), the disclosure of the subjects’ responses outside the research could be damaging to the subjects’ educational advancement.

**Exempt Category 3 Worksheet**

*Benign Behavioral Intervention*

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| **1. Does the proposed research involve ONLY the participation of adults with adequate decision-making ability to agree to participate in the research?** |
| [ ]  Yes | Please continue to question 2.  |
| [ ]  No | This research does not qualify for exemption under this category. |
| **2. Does this research involve the use of** [**benign behavioral interventions**](#benign)**?** |
| [ ]  Yes [ ]  No | If “no,” this research does not qualify for this exemption. |
| **3. Is the intervention brief in duration?** |
| [ ]  Yes [ ]  No | If “no,” does not qualify for this exemption.If “yes,” please explain:  |
| **4. Is/are the intervention(s) harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on participants, and neither offensive nor embarrassing?** |
| [ ]  Yes [ ]  No | If “no,” does not qualify for this exemption.If “yes,” please explain:  |
| **5. Does the benign behavioral intervention include** [**collection of information**](#collectionofinfo) **only through verbal or written responses (including data entry) or audiovisual recording?** |
| [ ]  Yes | Please continue. |
| [ ]  No | This research does not qualify for exemption under this category. |
| **6. Will participants *prospectively* agree to the intervention and information collection?** |
| [ ]  Yes | Please explain: |
| [ ]  No | This research does not qualify for exemption under this category. |
| **7. Select the following conditions that apply to this research:** |
|  [ ]   | A. The information obtained is recorded in such a manner that the identity of the participants cannot readily be ascertained either directly or through identifiers linked to the participants.  |
|  [ ]   | B. Any disclosure of participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. |
|  [ ]   | C. Information obtained is recorded in such a manner that the identity of the participants **can be** readily be ascertained, directly or through identifiers linked to the subjects, but adequate provisions have been made to ensure that the data collected are appropriate monitored and secured to ensure confidentiality. Audio and visual recordings are considered identifiable. |
|   | Describe provisions to **protect the privacy of participants**: |
|  | Describe provisions to **maintain confidentiality of participant data**: |
| **8. Does this research involve deception or misleading participants about the nature or purpose of the research?** |
|  [ ]  Yes [ ]  N/A | Please explain, including when/how participants will be informed of the deception.*Note that to qualify for this exemption, there* ***must be*** *prospective agreement by the participant in which the participant is informed that he/she/they will be unaware of or misled regarding the nature or purpose of the research*. *Describe the process for documenting that participants have been informed.* |
| If you answered “yes” to all of the above questions and were able to select an applicable condition(s) in Section 7, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to [PART III](#PartIII).If you checked 7C. (including if you are collecting audio/visual recordings) your application must also undergo a Data Security Assessment (“Limited IRB Review.”) Please complete [PART VI](#PartVI).If you answered “no” to any of the questions above, the research is not exempt under this category. |

Benign behavioral interventions: Interventions that are harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on participants and are neither offensive nor embarrassing (taking into account the participant population and research context). Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of this exemption. Medical interventions, including medical tests, procedures and devices, may not be used under this exemption.

Accepted methods of data collection: Only certain data collection methods can be used under this exemption category. Even very low risk physical procedures (e.g., blood pressure monitoring, EEG, wearable activity trackers), minimally invasive procedures (e.g., blood draws), and the collection of bodily fluids via introduction of a tool or sensor into the body (e.g., buccal swab), are not allowed. Data entry via a device (e.g., a Fitbit) would not meet the requirements of this exemption.

**Exempt Category 4 Worksheet**

*Secondary Research Use*

*(Identifiable Private Information/Biospecimens)*

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| **1. Does the proposed research involve** [**secondary research use**](#secondaryuse) **of identifiable private information or identifiable biospecimens?** |
| [ ]  Yes | Please continue to question 2. |
| [ ]  No | This research does not qualify for exemption under this category. |
| **2. Select any of the following provisions applicable to this research:** |
|  [ ]   | **A.** The identifiable private information or identifiable biospecimens are [publicly available](#publiclyavailable). Please explain where this information is publicly available:  |
|  [ ]   | **B.** The information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; **the investigator does not contact the subjects; the investigator will not re-identify subjects.**Please explain how the data are recorded:  |
|  [ ]   | **C.** The research involves **only** information collection and analysis involving the investigator’s use of identifiable health information, when that use is regulated under HIPAA for the purposes of ‘‘health care operations’’ or ‘‘research’’ as those terms are defined at [45 CFR 164.501](https://www.govinfo.gov/content/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-501.pdf), or for ‘‘public health activities and purposes’’ as described under [45 CFR 164.512(b)](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html). Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information *obtained from* biospecimens).***\*\*Provision C cannot be selected in combination with any other provision (A, B or D)\*\**** |
|  [ ]   | **D.** The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. |
|  [ ]   | None of the above categories applies. |
| If you answered “yes” and were able to select an applicable condition in Section 2, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to [PART III](#PartIII). If you checked 2B. or 2C. you must also complete a Data Security Assessment ([PART VI](#PartVI))If you selected “None of the above…” the research is not exempt under this category.  |

Secondary research use: Private information and biospecimens no longer have to be in existence prior to the start of the research. Under the revised Common Rule, for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future, could qualify for this exemption if it meets at least one of the applicability provisions in Section 2.

Publicly available: Refers to data and/or specimens that are accessible to anyone in the general public, without the need for special permissions, payment or privileges.  In these cases, the participants do not have a reasonable expectation of privacy of their data/specimens. Examples include data/specimens searchable online, available at a library, or otherwise available to the public when an agreement is entered into with the data provider.

**Exempt Category 5 Worksheet**

*Research and Demonstration Projects on Public Benefit or Service Programs*

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| **1. Is the research or demonstration project conducted or supported by a federal department or agency designed to study, evaluate, improve, or otherwise examine public benefit or service programs?** |
| [ ]  Yes | Please continue to question 2. |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. Does the federal department or agency conducting or supporting the research have a publicly accessible website or other manner for publishing a list of the research and demonstration projects that are conducted or supported under this provision?** |
| [ ]  Yes | Your research may be exempt under this category. To be exempt, the research or demonstration project must be published on this list prior to commencing research with human subjects.Identify the federal department/agency and where the research/demonstration project is published:  |
| [ ]  No | This research is not exempt under this category. |
| If you answered “yes” to both questions, please provide the requested information in Section 2. This will become part of your Exemption Application. Proceed to [PART III](#PartIII). |

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

1. Provide a lay summary of the proposed research.

2. Succinctly describe the study aims and objectives.

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

3. Describe your research population. Include target number of participants to be enrolled, age range, sex, and any other pertinent demographic information.

4. Describe your recruitment methods.

5. Research activities.

1. Describe the research activities.
2. Time involved for participants in each activity.

1. Form(s) of compensation.

1. Describe how and when compensation is provided to participants.

6. Describe all potential research risks or discomforts to participants resulting from study procedures.

7. Describe any potential **direct** benefits of the research to participants.

8. Describe how privacy will be protected and confidentiality maintained.

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| **Proceed to** [**PART IV. INFORMED CONSENT**](#PartIV) |

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| **PART IV. INFORMED CONSENT** |

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| **Researchers are strongly encouraged to use Brown HRPP’s** [**informed consent guidelines and templates**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#Consents)**. At minimum, an informed consent process must include disclosure of the following to prospective participants:*** That the activity is a Brown University research study.
* A description of the procedures.
* That participation is voluntary.
* Name and contact information of the researcher.
 |
| **1. Does the research involve** [**interaction**](#interaction) **with participants?** |
| [ ]  Yes [ ]  No | If “yes,” please provide a description of the informed consent process or justification for not obtaining informed consent.  |
|  [ ]  | Informed consent form / script is attached |

Interaction: Communication or interpersonal contact between an investigator or his/her/their research staff and the research participant or the participants’ private identifiable information.

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| **PART V. USE OF SECONDARY DATA / BIOSPECIMENS** |

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

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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. 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.

4. 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)*.*

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| **PART VI. DATA SECURITY ASSESSMENT (“LIMITED IRB REVIEW”)** |

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| **1. Do the data / biospecimens include identifiers?**  |
| [ ]  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:1. 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?  |
| 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, **the investigator 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.

**Proceed to** [**PART VII. INTERNATIONAL RESEARCH**](#PartVII)

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| **PART VII. INTERNATIONAL RESEARCH** |

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| **1. Does the research involve human subjects activities outside of the United States?** |
| [ ]  Yes [ ]  No | a. If “yes,” please list the countries. If “no,” you are not required to complete this Part of the application. Proceed to [PART VIII](#PartVIII).-------------------------------------------------------------------------------------------------------------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: |

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| **PART VIII. ATTACHMENTS** |

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| **Please attach the following materials to this Application for Exemption, 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.) |
|[ ] [ ]  Data Use Agreement from data provider(s) |
|[ ] [ ]  HIPAA Authorization |
| [ ]  | [ ]  | Data Safety Monitoring Plan |
|[ ] [ ]  Other:  |

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| **PART IX. CONFLICT OF INTEREST**  |

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| [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. |

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

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| 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)*** |

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| **PART X. 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 subjects [CITI training](https://about.citiprogram.org/en/homepage/) before any work with participants or identifiable data / biospecimens begins.
8. 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 Exemption that may impact the study’s classification as exempt 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 the Investigator and/or Advisor Responsibilities in PART X.**

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



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**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 HRPP/IRB Use Only***

**Signature of the HRPP:**

**Date of HRPP determination/Limited IRB Review approval:** Click here to enter a date.