**Brown University**

**Human Subjects Research Application**

**Study Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

*For more information on who may serve as a PI, see Brown’s* [*guidance*](https://www.brown.edu/research/pi-eligibility-advisor-qualifications) *and* [*PI Eligibility Policy*](https://policy.brown.edu/policy/human-subjects-research-principal-investigator-eligibility-policy)*.*

**Department:** Click or tap here to enter text.

**Student Research** [ ]  **N/A**

[ ]  Graduate student

Advisor name: Click or tap here to enter text.

Department: Click or tap here to enter text.

Email address: Click or tap here to enter text.

[ ]  Undergraduate student

Undergraduate student name: Click or tap here to enter text.

Department: Click or tap here to enter text.

**Education Affirmation**

Human Subjects [CITI training](https://about.citiprogram.org/) is complete: [ ]  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

**Collaboration Information** [ ]  **N/A**

*A reliance agreement may be required for IRB approved (Non-Exempt) studies. See HRPP’s* [*guidance*](https://www.brown.edu/research/collaborative-research) *on collaborative research for more information.*

List the site(s) involved: Click or tap here to enter text.

**Funding Information**  **☐ N/A**

*List the names of all external and internal sponsors funding the study.*

* Check if applicable:

[ ]  Advance-CTR

[ ]  IMPACT Collaboratory

* If externally funded, provide the following:
Sponsor: Click or tap here to enter text.
Project title: Click or tap here to enter text.
Institute Proposal #: Click or tap here to enter text.
* If internally funded by a specific Brown program (e.g., Mellon Mays Fellowship, Royce Fellowship, UTRA, OVPR Seed funds, etc.) specify**:** Click or tap here to enter text.
1. **Provide the scientific background of the study.**
Click or tap here to enter text.
2. **Identify the specific aims of the study and how the study will contribute to generalizable knowledge.**
Click or tap here to enter text.
3. **Participants**

Click or tap here to enter text.

**Select all applicable populations**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|[ ]  Adults (18+years) |  |[ ]  Children (30 days – 17 years) |[ ]  Justice-Involved |[ ]  Decisionally- Impaired |[ ]  Substance Users  |
|[ ]  Students |  |[ ]  Known Interpersonal Relationships |[ ]  At Risk of / Experiencing Homelessness |[ ]  Unauthorized Immigrants |[ ]  Refugees |
|[ ]  LGBTQ+ |  |[ ]  Pregnant People |[ ]  Fetuses/Neonates | [ ]   | American Indian / Alaskan Native |  |  |

1. **Recruitment** [ ]  **N/A**

*In order to approve research, the IRB must determine that participants are:*

* 1. *Respected and provided with adequate information to voluntarily enter the research.*
	2. *Selected for reasons directly related to the study aims and questions of the research, rather than due to their easy availability, their compromised position, or their manipulability.*

**Describe the recruitment methods.**Click or tap here to enter text.

1. **Consent** [ ]  **N/A***In order to approve research, the IRB must determine that informed consent will be:*
	1. *Sought from each prospective participant or their legally authorized representative, with sufficient information about the research, and be given the opportunity to choose what shall or shall not happen to them if they enroll.*
	2. *Presented in a manner and context, free of coercion or undue influence, to allow prospective participants time for consideration and opportunities to question researchers.*
	3. *Appropriately documented or appropriately waived.*

**Explain the informed consent process**Click or tap here to enter text.

**5.1 Request for a waiver or alteration of consent** [ ]  **N/A**

[ ]  The research involves public benefit and service programs conducted by or subject to the approval of state or local officials

[ ]  The research involves no more than minimal risk to the subjects;

[ ]  The research could not practicably be carried out without the requested waiver or alteration;

[ ]  The research involves using identifiable private information or identifiable biospecimens and could not practicably be carried out without using the data in an identifiable format;

[ ]  The waiver or alteration will not adversely affect the rights and welfare of the subjects;

[ ]  Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

[ ]  The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**5.2 Request for a waiver of documentation of consent** [ ]  **N/A**

[ ]  The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

[ ]  The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

[ ]  Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

1. **Deception/Incomplete Disclosure** [ ]  **N/A***In order to approve research, the IRB must determine that participants have authorized the deception or incomplete disclosure through a prospective agreement to participate in circumstances in which they are informed that they will be unaware of or will be misled regarding the nature or purposes of the research.*

**Describe if the study design involves deception or incomplete disclosure.**

Click or tap here to enter text.

1. **Procedures**

*In order to approve research, the IRB must determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety and protect the privacy of participants. The study design, methods and procedures for data collection must adequately describe all human subjects research activities. 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.* **Describe the study procedures.**Click or tap here to enter text.

1. **Compensation** [ ]  **N/A***In order to approve research, the IRB must determine that compensation for participation does not present an undue influence and interfere with prospective participants’ ability to give voluntary informed consent.***Describe the compensation.**

Click or tap here to enter text.

1. **Is the study a clinical trial?**

[ ]  **Yes** [ ]  **No**

1. **Does the study involve the use of drugs or substances?***If yes, Complete and upload Appendix C: Use of Drugs*

[ ]  **Yes** [ ]  **No**

**List the drugs or substances.**Click or tap here to enter text.

1. **Does the study involve the use of devices?***If yes, Complete and upload Appendix D: Use of Devices*

[ ]  **Yes** [ ]  **No**

**List the devices.**Click or tap here to enter text.

1. **Risk to Participants**In order to approve research, the IRB must determine that the possibility of harm to participants is:
	1. Minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on participants for diagnostic or treatment purposes.
	2. Justified and reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge that may reasonably be gained. *If research does not include anticipated direct benefits to participants, every effort must be made to reduce risks, secure the well-being of participants, and protect them from harm.*

**Describe the possible research risks to participants.**

Click or tap here to enter text.

1. **Benefits**

*In order to approve this research, the IRB must determine that the anticipated benefits to research participants are reasonable in relation to the probability and magnitude of possible harm.*

**Describe the anticipated benefits to participants.**

Click or tap here to enter text.

1. **Secondary Data (identifiable information or identifiable biospecimens)** [ ]  **N/A**
	1. **Provide the source of the data**

Click or tap here to enter text.

* 1. **Describe the type(s) of data / biospecimens 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.**

Click or tap here to enter text.

* 1. **Describe how will you use, study, or analyze the data / biospecimens**

Click or tap here to enter text.

1. **Use of PHI from a HIPAA-covered entity** [ ]  **N/A***Complete and upload Appendix G: Use of Protected Health Information (PHI) in Research. If applicable, upload a HIPAA Authorization form.*

**Describe how authorization to access the data will be obtained.**

Click or tap here to enter text.

1. **Use of Family Educational Rights and Privacy Act (FERPA) or Protection of Pupil Rights Amendment (PPRA) data** [ ]  **N/A**

**What type of FERPA or PPRA data will be accessed for this research?**

[ ]  Directory information

[ ]  Education records

[ ]  Instructional material

[ ]  Personally identifiable information (PII)

[ ]  Other, please describe: Click or tap here to enter text.

**Describe how authorization to access the data will be obtained.**

Click or tap here to enter text.

1. **Is a Data Use Agreement (DUA), Material Transfer Agreement (MTA), or other agreement required by the source to obtain, use, study, or analyze the data / biospecimens?** *If “yes,” please upload a copy of the Agreement(s) (draft or executed) to the study record.*

[ ]  **Yes** [ ]  **No** [ ]  **N/A**

1. **What type of data will be collected or received?**

[ ]  Identifiable health data (PHI) / biospecimens

 [ ]  Limited dataset

[ ]  Identifiable personal data (PII)

[ ]  Coded data and the study team has access to the linking file / key

[ ]  Coded data and the study team does not have access to the linking file / key

[ ]  Anonymous data

[ ]  FERPA-protected and/or PPRA-protected data

[ ]  Publicly-available data

[ ]  Other, please describe: Click or tap here to enter text.

1. **Describe the research plan for monitoring the data collected to ensure participant safety.**

*In order to approve research, when appropriate, the IRB must determine that the research plan makes adequate provisions for monitoring the data collection to ensure the safety of participants.*

 [ ]  **N/A**

 Click or tap here to enter text.

1. **How will you protect the privacy of participants?** *In order to approve research, when appropriate, the IRB must determine that there are adequate provisions to protect the privacy of participants.*
Click or tap here to enter text.
2. **Does the study have or will apply for a Certificate of Confidentiality (CoC)?***Studies funded by NIH are automatically issued a CoC.*

[ ]  **Yes** [ ]  **No**

1. **How will you maintain the confidentiality of participant data?**
*In order to approve research, the IRB must determine that there are adequate provisions to maintain the confidentiality of data.*Click or tap here to enter text.
2. **Who will have access to your study data / biospecimens?**

[ ]  Brown PI and other Brown research team members (including advisor).
**Describe how unauthorized access by others will be prevented.**

 Click or tap here to enter text.

[ ]  Data will be shared with research collaborators external to Brown.
This data sharing intent **must** be described as part of your consent process / form. Note that an Outgoing Data Use Agreement is required when sharing identifiable data external to Brown. **Describe how you will securely share / transfer the data outside of Brown.**
Click or tap here to enter text.

[ ]  Data will be shared with a data repository.

 This data sharing intent **must** be described as part of your consent process / form. (See Brown’s [Data Repository FAQs](https://www.brown.edu/research/guidance-and-faqs-sharing-information-data-repositories) for guidance).

 **Describe how you will securely share / transfer the data outside of Brown.**

 Click or tap here to enter text.

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|  **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. |
| 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)? (If you have not completed this disclosure, access the InfoEd system [here](https://infoed.brown.edu/EnableWeb/Portal/Home).) |
| [ ]  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: Click or tap here to enter text. |
| 3. Do you have an advisor or other Brown investigators working on this study? |
| [ ]  Yes [ ]  No  | [Additional COI sheets](https://www.brown.edu/research/sites/research/files/Additional%20Investigator%20COI%20v0607019.docx) for Investigators are attached to this Application. |

**Review the IRB Application guidance to identify any required attachments.**

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| **APPENDICES**  |

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| **Please complete & attach the following Appendices to this Application, as applicable.** |
| [Appendix A. Children as Subjects](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixa)*To be attached when children 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/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixb)*To be attached when prisoners are included as participants.* |
| [Appendix C. Use of Drugs](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixc)*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/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixd)*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-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixe)*To be attached when study procedures include administering prescription medications to study participants.* |
| [Appendix F. Mental Health Safety Plan](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixf)*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/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixghttps://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.*  |
| [Appendix H. International Research](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixh) *To be attached when study involves human subjects research outside the United States.*  |
| [Appendix I. Advisor Appendix](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#appendixi)*To be attached when a graduate or medical student is the Principal Investigator.* |

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| **ATTACHMENTS** |

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| **Please complete & attach the following materials to this Application, as applicable.** |
| Additional Investigator COI  |
| Application for IRB Authorization Agreement (IAA) |
| Data collection materials (questionnaires, surveys, interview scripts, etc.) |
| Data Safety Monitoring Plan |
| Data Use Agreement from data provider(s) |
| DSMB Charter Template |
| HIPAA Authorization |
| Informed consent documents / scripts |
| Permissions, approval documents, and/or support letters  |
| Recruitment materials (Today@Brown post, emails, flyers, letters, scripts, posters, brochures, etc.) |
| Request for Approval to Serve as Principal Investigator on a Human Subjects Research Application |

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|  **PRINCIPAL INVESTIGATOR AGREEMENTS & 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), [Federal Policy for the Protection of Human Subjects (45 CFR 46)](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46) , 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 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://policy.brown.edu/policy/reportable-events-and-noncompliance).
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 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 Human Subjects Research Application that may impact the study’s 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 comply by Brown’s [*Research Data and Research Materials Management, Sharing and Retention Policy*](https://policy.brown.edu/policy/rdm-management-share-retention-policy).
2. I will maintain all research protocol materials and consent materials for the duration of this study.
3. 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.
4. 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).
5. I will ensure that the data security measures for acquisition, collection, transfer and use of study data described in 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 Agreements and Responsibilities in this Application.**

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



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

***For IRB/HRPP Use Only***

**Protocol #:** Click or tap here to enter text.

**Signature of the IRB/HRPP:**

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