**Brown University**

**Human Subjects Research Application**

*Instructions on how to complete this application can be found in our guidance tool.*

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

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

*If PI is a graduate/medical student, please upload* [*Appendix I: Human Subjects Research Advisor*](https://www.brown.edu/research/sites/research/files/9.%20Appendix%20I_Human%20Subjects%20Research%20Advisor_v%2001.24.2023.docx)*.*

**1. Provide the scientific background of the study.**   
Click or tap here to enter text.

**2. Identify the research question(s) of the study and how the study will contribute to generalizable knowledge.**   
Click or tap here to enter text.

**3. Describe each participant population for the study and list all eligibility criteria.**

Click or tap here to enter text.

**3.1 Select all vulnerable populations you intend to target for recruitment.**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Brown Faculty, Staff, or Students |  | Children (30 days – 17 years) |  | Justice-Involved |  | Decisionally- Impaired |  | At Risk for / Experiencing Substance Use Disorder |
|  | Students |  | Known Interpersonal Relationships |  | At Risk of / Experiencing Homelessness |  | Unauthorized Immigrants |  | Refugees |
|  | LGBTQ+ |  | Pregnant People |  | Fetuses / Neonates |  | American Indian / Alaskan Native |  | Disabled People / People with Disabilities |

**4. Describe the recruitment methods.  N/A**

Click or tap here to enter text.

**5. Explain the informed consent process.  N/A**Click or tap here to enter text.

**5.1 To request a waiver or alteration of consent, at least one box must be checked  N/A**

The research involves public benefit and service programs, is conducted by or subject to the approval of state or local officials, and could not practicably be carried out without the waiver or alteration;

The research meets all requirements for a general waiver or alteration of consent

For the purpose of screening, recruiting, or determining eligibility of prospective participants, the investigator will obtain information or biospecimens either through oral or written communication with participants, or by accessing records or stored identifiable biospecimens.

**5.2 To request a waiver of documentation of consent, at least one box must be checked  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.

Participants 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.

**6. Describe if the study design involves deception or incomplete disclosure.  N/A**Click or tap here to enter text.

**7. Describe the study procedures.**

*If study procedures involve asking participants about depression, suicide, or the risk of harm to self or others; may result in participants experiencing emotional distress; include populations at high risk for self-injury; administer study medications with a side effect of suicidal ideation, or involve other research components that could increase suicidal risks, please upload* [*Appendix F: Mental Health Safety Plan*](https://www.brown.edu/research/sites/research/files/Appendix%20F_Mental%20Health%20Safety%20Plan_v%2001.09.20.docx)*.*

Click or tap here to enter text.

**8. Describe the compensation.  N/A**Click or tap here to enter text.

**9. Is the study a clinical trial?  Yes  No**

**10. Describe the possible research risks to participants.**Click or tap here to enter text.

**11. Describe the anticipated benefits to participants.**

Click or tap here to enter text.

**12. Does the study involve the use of secondary data (identifiable information or identifiable biospecimens)?  Yes (complete Questions 12.1-12.3)  No (skip to Question 16)**

**12.1 Provide the source of the data.**

Click or tap here to enter text.

**12.2 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.

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

Click or tap here to enter text.

**13. Does the study involve the use of PHI from a HIPAA-covered entity?**

**Yes (complete Question 13.1-13.2)  No (proceed to Question 14)**

*If “yes,” please upload* [*Appendix G: Use of Protected Health Information (PHI) in Research*](https://www.brown.edu/research/sites/research/files/Appendix%20G_Use%20of%20PHI%20in%20Research_v%204.22.2020.docx)*. If applicable, upload a* [*HIPAA Authorization*](https://www.brown.edu/research/sites/research/files/Brown%20HIPAA%20auth%20V8.6.19.doc) *form.*

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

Click or tap here to enter text.

**13.2 Is the data considered a limited data set?  Yes  No**

**14. Does the study involve the use of Family Educational Rights and Privacy Act (FERPA) or Protection of Pupil Rights Amendment (PPRA) data?**

**Yes (complete 14.1-14.2)  No (proceed to Question 15)**

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

Directory information

Education records

Instructional material

Personally identifiable information (PII)

Data involving a PPRA-protected category

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

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

Click or tap here to enter text.

**15. 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?**

**Yes  No**

*If “yes,” please upload a copy of the Agreement(s) (draft or executed).*

**16. What type of data will be collected?**

Identifiable biospecimens

Personally identifiable Information (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

Publicly available data

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

**17. Briefly describe your plan for managing the integrity of the data and monitoring the safety of participants.  N/A**

Click or tap here to enter text.

**18. How will you protect the privacy of participants?**

Click or tap here to enter text.

**19. Does the study have or will you apply for a Certificate of Confidentiality (CoC)?**

**Yes  No**

**20. How will you maintain the confidentiality of participant data?**

Click or tap here to enter text.

**21. Who will have access to your identifiable 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.   
**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.

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

Click or tap here to enter text.

|  |
| --- |
| **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) and all applicable federal and state regulations and requirements pertaining to human subjects research, including but not limited to the Department of Health and Human Services’ [Protection of Human Subjects (45 CFR 46)](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46), and the Food and Drug Administration’s [Protection of Human Subjects (21 CFR 50)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50) and [Institutional Review Boards (21 CFR 56)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56).
2. I accept responsibility for ensuring that all members of the research team comply with all Brown policies and procedures pertaining to human subjects research.
3. I accept responsibility for ensuring that all members of the research team have or will complete the appropriate education and training to protect participants before any work begins with participants or identifiable information / biospecimens.

**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 will notify the Brown HRPP when I have completed all activities involving human subjects or identifiable participant information or identifiable biospecimens.
3. I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.
4. 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.

**By submitting this document, I certify that I have read and agree to uphold all of the Agreements and Responsibilities in this application.**