**Brown University**

**Collaborative Research Application**

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

**Brown 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)*.*

1. **Research Activities**

*Describe activities constituting* [*engagement*](https://www.brown.edu/research/engagement-human-subjects-research) *to justify the enactment of a reliance agreement.*

* 1. What activities will **Brown researchers** conduct?

Click or tap here to enter text.

* 1. What activities will **collaborating researcher(s)** conduct?

Click or tap here to enter text.

1. **Collaborating Investigator**

Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

Phone: Click or tap here to enter text.

Email: Click or tap here to enter text.

1. **External Investigator Affiliation**

*Select the option that best describe the Collaborating Investigator’s external affiliation*

[ ]  Associated with an institution or organization covered by another IRB (IRB Authorization Agreement – IAA)

[ ]  Associated with an organization requesting coverage by the Brown University IRB (Organizational Authorization Agreement - OAA)

[ ]  Not associated with another institution or organization and will be covered as an individual under Brown University (Individual Investigator Agreement – IIA) **(END HERE)**

1. **Collaborating Institution**

Name: Click or tap here to enter text.

FWA #: Click or tap here to enter text.

IRB #: Click or tap here to enter text.

IRB Contact Name: Click or tap here to enter text.

Phone: Click or tap here to enter text.

Email: Click or tap here to enter text.

Signatory Official Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

1. **Who will be the IRB of Record?**

[ ]  Brown University [ ]  Collaborating Institution [ ]  Independent IRB

1. **How will the Reliance be Documented?**

[ ]  SMART IRB Portal

[ ]  Letter of Agreement

[ ]  Advarra Master Agreement

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

1. **Participants**

**Describe any local participant populations.**

Click or tap here to enter text.

**Select all applicable targeted populations**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ☐ | Brown Faculty, Staff, or Students |[ ]  Children (30 days – 17 years) |[ ]  Justice-Inolved |[ ]  Decisionally- Impaird |[ ]  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 |

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

*Recruitment procedures occurring at Brown must comply with University policy.*

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

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

**Will Brown University researchers be involved in the consenting process?**

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

**If Yes, explain the informed consent process**Click or tap here to enter text.

1. **Will data be collected, analyzed or stored at Brown?**

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

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. **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. **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.*

Click or tap here to enter text.

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.

1. **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.
This data sharing intent **must** be described as part of your consent process / form. Note that an Outgoing Data Use Agreement may be 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.

|  |
| --- |
|  **PRINCIPAL INVESTIGATOR AGREEMENTS & RESPONSIBILITIES**  |

 **A. Conduct of the Research**

1. I accept responsibility for the ethical conduct of the Brown University 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 Brown University 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 Brown University 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.**