**Brown University**

**Application for IRB Authorization Agreement**

**(Full Board / Expedited Studies Only)**

**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**

**How many total sites are engaged in the research study?**
**Names of all Collaborating Institutions:**       **\*If Brown is the IRB of Record, please fill out a separate application for each relying institution.**

**Does your study qualify for** [**Exempt review**](https://www.brown.edu/research/exemption-categories)**?** [ ]  **Yes** [ ]  **No**

 **If yes, DO NOT CONTINUE. Exempt studies are not eligible for IAA collaboration.**

\* Most Undergraduate student projects do not require IRB/HRPP review and oversight. Before completing this application, please refer to Brown’s [Guidance Regarding Undergraduate Work Involving Human Subjects Research.](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc)

|  |
| --- |
| **PART I. USE OF APPLICATION** |

|  |
| --- |
| **Please indicate the desired purpose of this application** |
| **New Protocol** |
| 1. | [ ]  | I want Brown to relinquish IRB oversight for a **new** study. Brown will cede review to a [collaborating institution](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#collaborating). (Continue to Part II.) |
| 2. | [ ]  | I want Brown to provide IRB oversight for a **new** study. Brown will be the IRB of Record for a [collaborating institution](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#collaborating). (Continue to Part II.) |
| **Amendment to my approved study at Brown.** |
| 3. | [ ]  | I want Brown to relinquish IRB oversight to my **current** study. Brown will cede review to a [collaborating institution](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#collaborating). (Continue to question 5) |
| 4. | [ ]  | I want Brown to provide IRB oversight for my **current** study. Brown will be the IRB of Record for a [collaborating institution](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#collaborating). (Continue to question 5) |
| 5. | Provide a brief lay summary of the overall project. | Enter text |
| 6. | Provide a detailed description of the changes being requested. | Enter text |
| 7. | State the reason (justification) for the requested amendment. | Enter text |

|  |
| --- |
| **PART II. ENGAGEMENT IN RESEARCH** |

|  |
| --- |
| **To be engaged, the activities conducted by researchers at Brown University must meet the federal definition of “**[**engagement in human subjects research**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)**.” Answer the following questions to determine if your proposed study is engaged in non-Exempt Human Subjects Research.** |
| 1. |  [ ]  Yes [ ]  No | Will Brown researchers collect information through some type of intervention or interaction? **OR**Will Brown researchers have access to [identifiable private information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#I)? **OR**Will Brown researchers obtain informed consent?  |
| 2. |  [ ]  Yes [ ]  No | Will Brown University be the [prime awardee](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#prime awardee) of a federal award to conduct this research (e.g. Advance-CTR, NIH, NSF, CFAR)? |
|  | If you answered “no” to both of the above questions, Brown University is not engaged in Human Subjects Research. You are not required to submit an Application for IRB Authorization Agreement to the Brown HRPP. |

|  |
| --- |
|   **PART III. BROWN UNIVERSITY FUNDING** |

|  |
| --- |
| **Please provide information specific to**  |
| 1. | Funding Type |  [ ]  External (e.g. NIH, NSF, CFAR)[ ]  Advance-CTR [ ]  IMPACT Collaboratory  [ ]  Internal Funding [ ]  No Funding (Skip to Part III) |
| **If funded, complete #2 and/or #3, as applicable.** |
| 2. | Is Brown the prime awardee?*(Funding issued directly to Brown)*[ ]  Yes *(Continue to 2a.)*[ ]  No *(Skip to 3.)* | 2a. Funding Source: Enter text. |
| 2b. Funding Proposal Title: Enter text. |
| 2c. Grant/Contract #: Enter text. |
| 2d. Grant/Contract Term: | Start date. | End date. |
| 2e. Does Brown **issue** a [sub-award](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#sub-award) to collaborating institution? |  [ ]  Yes [ ]  No |
| 3. | Does Brown **receive** a sub-award?*(Brown as sub-awardee*) [ ]  Yes [ ]  No | 3a. Institution ***issuing*** sub-award ***to*** Brown University: Enter text.  |
| 3b. Funding Source: Enter text.  |
| 3c. Funding Proposal Title: Enter text. |
| 3d. Grant/Contract #: Enter text. |
| 3d. Grant/Contract Term: | Start date. | End date. |

|  |
| --- |
| **PART IV. COLLABORATING INSTITUTION** |

|  |
| --- |
| **Information below should be specific to** [**collaborating institution**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#collaborating) **only.** |
| 1. | Name of Institution | Enter text. |
| 2. | Protocol Title | Enter text. |
| 3. | Protocol or Reference Number | Enter text. |
| 4. | Principal Investigator | Enter text. |
| 4a. | [ ]  Yes [ ]  No | Will the collaborating institution be the [IRB of Record](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#IOR) (Brown [cedes review](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#cede))? |
| 4b. | [ ]  Yes [ ]  No | Has the collaborating institution approved this study?Provide the collaborating institution’s approval memo.  |
| 5. |  [ ]  Yes [ ]  No | Is this institution a[“Smart IRB” member](https://smartirb.org/participating-institutions/)**?**  |
| **If yes to #5, PI from IRB of Record should** [**initiate reliance request**](https://www.google.com/url?client=internal-uds-cse&cx=000741335895712361513:s7gfmll2gx8&q=https://smartirb.org/sites/default/files/Reliance-Checklist.pdf&sa=U&ved=2ahUKEwi4zJqYrPHiAhWFmuAKHblaD4cQFjAAegQIBRAB&usg=AOvVaw3tJcuw9lbU06EW-iScSyOc) **within their** [**SMART IRB portal**](https://reliance.smartirb.org/users/sign_in)**. Skip to** [**Part V**](#PartV)**.** |
| 6. | IRB Contact | Name: Enter text. | Phone: Enter text. |
| Email: Enter text. |
| 7. | [Signatory Official](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#signatory official): | Name: Enter text. |
| Title: Enter text. |
| 8. | [FWA #](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#FWA) | Enter text. |
| 9. | [IRB Registration #](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#irb registration number) | Enter text. |
| 10. | [ ]  Yes [ ]  No | I have reviewed the collaborating institution’s regulations (including state and local policies) and will work with the Brown HRPP to provide information about local context considerations. |

|  |
| --- |
| **PART V. PROJECT INFORMATION** |

|  |
| --- |
| **Please provide specific and detailed information including specific research activities (i.e. recruiting, consenting, interviews, interventions), location of procedures and data storage. Please refer to** [**Full Board/Expedited Application**](https://www.brown.edu/research/sites/research/files/Full%20Board%20Expedited%20IRB%20Application%20v032119.docx) **as guidance (segments may be copied or attached to this application).**  |
| 1. | What activities will **Brown researchers** be conducting? | Enter text. |
| 2. | What activities will the **collaborating institution researchers** be conducting? | Enter text. |
| 3. | Where are research activities involving participant interactions taking place?  | Enter text. |
| 4. | [ ]  Yes [ ]  No | Will data be stored at Brown? |
|  | If yes to 4 | Please submit [Data Security Assessment](http://www.brown.edu/research/sites/research/files/Data%20Security%20Assessment.docx) |
| 5. | [ ]  Yes [ ]  No | Will data include [PHI](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#PHI)? |
|  | If yes to 5 | Which institution will be responsible for HIPAA compliance (i.e. authorization, waivers)? Enter text. |
| 6. | [ ]  Yes [ ]  No | Does the currently approved application/protocol at the [IRB of Record](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#IOR) include all research activities being conducted by [relying institution](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#relying institution)’s investigators? |
| 7.  | [ ]  Yes [ ]  No | Is research being conducted in a foreign country? If “no,” proceed to PART VI. |
| 7a. |  | Name of country(ies): Enter text. |
| 7b. | [ ]  Yes [ ]  No  | I have reviewed ORI’s [export control](https://www.brown.edu/research/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) |

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

|  |
| --- |
| [The *Brown University Conflict of Interest Policy for Officers of Instruction and Research*](https://www.brown.edu/research/COIpolicy) *(“COI Policy”)* defines the term “Investigator” as “the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research.” |
| Using this definition of “Investigator,” please ensure that all Brown Investigators on this protocol answer questions (1) and (2) below. Attach [additional sheets](https://www.brown.edu/research/sites/research/files/Additional%20Investigator%20COI%20v0607019.docx) for any Investigators who are not the PI; additional sheets are available on the HRPP website. |

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

|  |
| --- |
| 1. Have you completed a conflict of interest disclosure (i.e. *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by Brown’s [COI Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-policy)? (You may access the InfoEd system [here](https://infoed.brown.edu/EnableWeb/Portal/Home) to confirm.) |
| [ ]  Yes [ ]  No | If “no,” please do so before submitting this Application |
| 2. Do you have a [significant financial interest](https://www.brown.edu/research/COIFAQ#interest) (SFI) that is related to this research protocol? “Related” could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI. It could also mean that the SFI could be affected by the proposed research or its results.  |
| [ ]  Yes [ ]  No | If “yes,” please identify the SFI and explain the relatedness: Enter text. |
|[ ]  [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)*** |
| \*Advance CTR Only - When Brown is the prime awardee but our investigator(s) are not conducting any research activities and we are ceding review, the reviewing IRB will be responsible for conducting conflict of interest analyses for all investigators. |

|  |
| --- |
| **PART VII. FILING INSTRUCTIONS** |

|  |
| --- |
| **Please attach the following materials to this Application, as applicable.** |
| **Brown will be IRB of Record (New Application)** |
|[ ]  Please submit this form as an attachment to Full Board/Expedited Application along with all other applicable materials |
| **Brown will be IRB of Record (Amendment)** |
|[ ]  Revised protocol *(If collaboration affects approved procedures)* |
|[ ]  All new/revised documents |
|  | [ ]  | Consent/Assent documents |
|  | [ ]  | Instruments/Measures |
|  | [ ]  | Advertising/Recruitment Materials |
|[ ]  Data Security Assessment *(If applicable)*. |
|[ ]  Other: Enter text. |
| **Brown will relinquish IRB oversight** |
|[ ]  Approved protocol including study materials from IRB of Record |
|[ ]  IRB approval notice from other institution (most recent continuing renewal or initial submission) |
|[ ]  Data Security Assessment *(If applicable)*. |
|[ ]  Other: Enter text. |

|  |
| --- |
| **PART VIII. 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 reviewing institution’s 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 members 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 the reviewing institution’s relevant regulatory and institutional reporting requirements.
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, completes section VI of this form ("Conflict of Interest") and has submitted an up-to-date COI Reporting form. I further understand that it is my responsibility to remind all investigators to promptly report any changes to the COI section and/or COI Reporting form. I will notify the IRB of Record when I have completed all activities involving human subjects or identifiable participant data or identifiable biospecimens.
3. I will cooperate with any post-approval monitoring or auditing of study activities and/or study records as requested and/or required.

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

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



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

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

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

**Advisor’s name (please print):**

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

