

**BROWN UNIVERSITY**

**APPENDIX I**

**ADVISOR APPENDIX**

**Protocol Title:** Click here to enter text.

**Protocol # (if amendment):** Click here to enter text.

**Principal Investigator (PI):** Click here to enter text.

**Date of submission:** Click here to enter a date.

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| **The research advisor must complete and sign this form when a graduate or medical student is the Principal Investigator.** |
| PART 1: Advisor name and contact information.  Advisor: Click or tap here to enter text.  Department: Click or tap here to enter text.  Phone number: Click or tap here to enter text.  Email address: **Click or tap here to enter text.** |
| **PART 2: Affirm human subjects education**  Human Subjects CITI training 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 |
| **PART 3: 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.”  I have 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).)  **Significant Financial Interest (SFI) related to this research study**  “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.  Choose one option from the two below:  I do not have a [significant financial interest](https://www.brown.edu/research/COIFAQ#interest) that is related to this research protocol.  I have a [significant financial interest](https://www.brown.edu/research/COIFAQ#interest) that is related to this research protocol. Please identify the SFI and explain the relatedness:  Click or tap here to enter text. |
| **PART 4: Conduct of the Research**  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.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), and Brown University policies.  I accept responsibility for ensuring this research is conducted in accordance with:   1. Sound research design and methods; 2. The parameters of the research plan and activities described in this Application; 3. The applicable terms of the grant, contract, or other signed funding agreements; 4. Applicable laws and regulations, including those protecting the rights, safety and welfare of human subjects.   I certify that I am 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.  I accept responsibility to directly supervise this research. I certify that I have sufficient time and resources to properly supervise this research. |
| **PART 5: Ensuring and Maintaining Compliance**  I will comply with relevant regulatory and institutional reporting requirements, including Brown University’s [*Reportable Events Policy*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc#reportableevent).  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 (of the Application), are reported promptly to Brown’s HRPP.  I will ensure informed consent is obtained and a copy is provided to participants, when appropriate.  If there are changes to the research described in the Application that may impact the study’s review category, I will promptly notify the Brown HRPP of such changes.  I will notify the Brown HRPP when I have completed all activities involving human subjects or identifiable participant data or identifiable biospecimens.  I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.  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. |
| **PART 6: Study records, Reports and Documentation**  I will comply by Brown’s [*Research Data and Research Materials Management, Sharing and Retention Policy*](https://www.brown.edu/research/content/research-data-team#Brown%20Policies).  I will maintain all research protocol materials and consent materials for the duration of this study.  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.  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).  I will ensure that the data security measures for acquisition, collection, transfer and use of study data described in PART VI. Data Security Assessment (of the Application) are adhered to by all members of the research team. |
| PART 7: Certifications and Signature  By my signature below, I certify that I have read and agree to uphold all of the Advisor Responsibilities.  As the Advisor:  I have permission from my Dean, Chair, or Direct Supervisor to serve as an advisor to the student conducting the proposed study.  I have read the complete protocol and approve this study.  I will remain available to advise the student throughout the course of the proposed human subjects research, or I will transfer responsibilities to another advisor if unable to advise for the entirety of the study.  **Advisor’s name (please print):** Click or tap here to enter text.  **Advisor's signature:** **Date:**  Click here to enter a date. |