1.0 Policy Purpose

This Policy defines who is eligible to serve as a Principal Investigator ("PI") on an Institutional Review Board Authorization Agreement ("IAA"), or an Exempt, Expedited, or Full Board human subjects research study that has been granted exemption (hereafter referred to as “approved”) by the Brown University Human Research Protection Program ("HRPP") or that has been approved by the Brown University Institutional Review Board ("Brown IRB").

2.0 To Whom the Policy Applies

This Policy applies to any individual who submits an application to the HRPP for an IAA or Exempt determination, or an application to the Brown IRB for Expedited or Full Board approval.

3.0 Policy Statement

The HRPP and Brown IRB recognize one PI for each human subjects research study. While the PI may delegate certain responsibilities to other research personnel on a project, the PI retains ultimate responsibility for all aspects of the research and for compliance with all Brown policies and procedures and federal and state requirements.

The HRPP adheres to the Brown University Policy on Principal Investigator Eligibility for Externally Sponsored Awards ("the Eligibility Policy") when making a determination regarding who is eligible to submit a human subjects research application for approval by the HRPP or Brown IRB. The below information identifies situations where it may deviate from the Eligibility Policy and the process to request exceptions.

3.1 Hospital-based Faculty Holding a Clinical Appointment at Warren Alpert Medical School

In general, human subjects research conducted by a hospital-based faculty member with a clinical appointment at Warren Alpert Medical School ("AMS") falls under the purview of that faculty member’s affiliated hospital-based IRB. If such an individual receives a sponsored award through Brown University to conduct a human subjects research study, that individual is eligible to serve as a PI on a human subjects research study submitted to the HRPP or Brown IRB. Any exceptions to these requirements will be considered through the exceptions process on a project-by-project basis as defined in Section 3.6 of this Policy.
3.2 Warren Alpert Medical School Medical Students and Brown University Graduate Students

AMS medical students and Brown University graduate students who are in good standing with AMS or the University and are not on leave, are eligible to serve as PIs on human subjects research applications. The individual must name an Advisor on the human subjects research application and the Advisor must complete the Advisor Appendix. The Advisor Appendix is available on the Office of Research Integrity’s website, and must be submitted with the human subjects research application.

Students must close any active studies approved by the HRPP or Brown IRB prior to graduation and in any other instance that will result in discontinued enrollment as a student at AMS or the University. Students are responsible for promptly identifying an alternate Advisor and amending their IRB applications accordingly if a named Advisor no longer meets criteria set forth in the Advisor Appendix.

3.3 Undergraduate Students

Undergraduate students are responsible for reviewing and adhering to available guidance on Undergraduate Work Involving Human Subjects and submitting an Undergraduate Project Application, when applicable. Undergraduate projects involving human subjects must name an Advisor. Undergraduate students are not eligible to serve as PIs on human subjects research applications. An Advisor on an undergraduate research study that meets the definition of human subjects research and therefore requires a human subjects research application will serve as the PI of the study and must meet PI Eligibility criteria.

3.4 PI and Advisor Qualifications

All PIs and Advisors must demonstrate sufficient qualifications to conduct and/or oversee the design, conduct, and/or reporting of the research involving human subjects. Human subjects research studies that require skills beyond those held by the PI must be modified to meet the PI’s qualifications, or have one or more additional qualified faculty act as co-investigator(s).

3.4.1 Studies involving the administration of a drug or use of a device for research purposes

Human subjects research studies that involve the administration of a drug or use of a device for research purposes must include a licensed medical provider as the PI or as a co-investigator. This licensed medical provider must have relevant qualifications in the area of research inquiry.

3.5 Restrictions

If a PI has an approved study that has fallen out of compliance with Brown policies or procedures, or state or federal laws (e.g., failure to submit a continuing review when required, lapsed IRB approval or human subjects research training, failure to register a clinical trial and/or maintain a clinical trial record in good standing), the PI may be restricted from submitting a new human subjects research application or a modification to an existing approved study until the noncompliance issue(s) have been resolved.
3.6 Exceptions process

Individuals that do not meet eligibility criteria must request written permission from the Office of the Vice President for Research or the Dean of Medicine and Biological Sciences (as outlined in the Eligibility Policy) for an exceptional approval to serve as PI after securing approval from the faculty sponsor, department chairperson, and senior officer in the relevant school, department, center, institute, or library. Such requests must use the Brown University Request for Approval to Serve as Principal Investigator on an IRB Application form. The completed and signed form must be included in the PI’s submission of a human subjects research application.

4.0 Definitions

For the purpose of this Policy, the terms below have the following definitions:

Advisor: The supervising faculty mentor to the student researcher who shares the responsibility for the ethical conduct of the research with the student. An Advisor must discuss the general principles of research ethics prior to the initiation of any project involving human subjects, help the student researcher determine whether the project requires HRPP or Brown IRB review, and guide the student researcher through the IRB application process. Advisors to undergraduate student researchers will serve as the PI of the study, and will take on the role and responsibility of the PI.

Exempt: Category of human subjects research that is minimal risk, and not subject to review and approval by an IRB. Categories of Exempt research activities are defined by federal regulations. Researchers conducting Exempt research must comply with the requirements of the HRPP and Brown University.

Expedited: Category of review of human subjects research that is minimal risk, and subject to IRB review and approval. Categories of Expedited research activities are defined by federal regulations.

Full Board: Category of review of human subjects research that is greater than minimal risk, and subject to IRB review and approval. Whether a research study requires Full Board review is determined by HRPP policy and practice.

Principal Investigator: An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, providing technical and administrative oversight of the research and making important study-related decisions. For purposes of this Policy, only one individual is designated as the Principal Investigator of a human subjects research study.

5.0 Responsibilities

All individuals to whom this Policy applies are responsible for becoming familiar with and following this Policy. University supervisors are responsible for promoting the understanding of this Policy and for taking appropriate steps to help ensure compliance with it.
6.0 Consequences for Violating this Policy

Failure to comply with this and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the University, in accordance with applicable (e.g., staff, faculty, student) disciplinary procedures, or for non-employees, may result in the suspension or revocation of the user’s relationship with Brown University.

7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, Brown’s Anonymous Reporting Hotline allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

7.1 Related Policies:
- Brown University Policy on Principal Investigator Eligibility for Externally Sponsored Awards

7.2 Related Procedures:
- Undergraduate Work Involving Human Subjects

7.3 Related Forms:
- Brown University Request for Approval to Serve as Principal Investigator on an IRB Application
- Advisor Appendix

7.4 Frequently Asked Questions (FAQs): N/A

7.5 Other Related Information:
- Exemption Categories
- Expedited Categories

8.0 Policy Owner and Contact

8.1 Policy Owner: Vice President for Research
8.2 Policy Approved by: Vice President for Research
8.3 Subject Matter Contact: Brown University Human Research Protection Program
   - Telephone: 401-863-3050
   - Email: IRB@Brown.edu

9.0 Policy History

9.1 Policy Effective Date: May 21, 2020
9.2 Policy Last Reviewed: N/A
9.3 Policy Update/Review Summary: N/A