HRPP SOP #204
Principal Investigator Requirements and Responsibilities

Responsible Office(s): Office of Research Administration
Responsible Official(s): Associate Provost for Research Administration
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I. Purpose of this SOP
The purpose of this SOP is to set forth the requirements and responsibilities of the principal investigator in conducting human subjects research.

II. Scope of this SOP
This SOP applies to human subjects research projects conducted under the auspices of Brandeis University.

III. Key Definitions
Principal Investigator (PI) is the faculty or staff scientist or scholar (as well as other staff with appropriate expertise and prior IRB approval) with primary responsibility for the design and conduct of a research project.

Student Researcher is the undergraduate or graduate student or postdoctoral scholar initiating the research under the supervision of the principal investigator.

Research Personnel are all non-PI/Student Researcher faculty, staff, students, and/or scholars participating on the research team.

IV. Statement of SOP
It is the standard operating procedure of Brandeis University that the principal investigator is solely responsible for ensuring the protection of the rights and welfare of participants, and that their human subjects research is conducted ethically and is in compliance with all applicable federal, state, and university laws, regulations, policies, and procedures. For this reason students and postdoctoral scholars may not be principal investigators.
V. Procedures

Principal Investigator responsibilities include, but are not limited to:

1. Requesting IRB guidance when uncertain whether a study is human subjects research and/or qualifies for exempt status.

2. Adhering to the principles of Respect for Persons, Beneficence, and Justice as set forth in the *Belmont Report*, regardless of funding status.

3. Obtaining IRB review and approval prior to initiation of activities determined to be human subjects research, including recruitment, collection of data about and/or samples from human subjects, or engagement in interventions/interactions with human subjects.

4. Obtaining review and approval from all other applicable institutional committees such as the Institutional Biosafety Committee (IBC) prior to IRB review.

5. Replying to all Brandeis University IRB requests for additional information and/or clarification necessary to make a determination.

6. Disclosing to the IRB any real or apparent conflicts of interest involved with the study before the study begins and as they arise throughout the duration of the study.

7. Ensuring all research personnel are fully conversant in, and strictly abide by, the study procedures, informed consent requirements, data collection and management, and any additional requirements as approved by the IRB.

8. Ensuring the voluntary informed consent of every subject (including the opportunity to ask and have answered any questions regarding the study), unless this requirement has been waived by the IRB.

9. Ensuring any commitment to the maintenance of privacy and confidentiality of all participants and their data.

10. Promptly reporting to the IRB any injuries or other unanticipated problems involving risks to subjects or others as a result of their research.

11. Promptly reporting to the IRB any forms of non-compliance with Brandeis University policies, federal regulations, the protocol as approved by the IRB, or applicable provisions of the Brandeis University Federalwide Assurance.

12. Requesting a continuation of IRB approval for non-exempt status studies at the interval set by the IRB and no less often than once per year.

13. Requesting approval for all modifications to currently approved research.

14. The timely submission of all continuation and modification requests and ensuring that no research – including changes to formally approved research – takes place without current IRB approval, unless necessary to eliminate any unanticipated problems or risk of harm to subject participants.

15. Promptly reporting to the IRB any changes or new information that may affect the risks and/or benefits to participants.

16. Retaining and maintaining accurate records of research data and documented informed consent in the manner and length of time approved by the IRB.
17. Making all research records available for review by the IRB if the IRB determines an audit is appropriate and necessary.

18. The timely submission of a final report to the IRB at study closure.

19. Maintaining copies of the Brandeis University IRB’s written determinations as to the approval of their human subjects research.

In addition, faculty and staff serving as the principal investigator on student/fellow-initiated research are responsible for:

1. Ensuring the student researcher is familiar with the ethical practices, regulations, and policies that pertain to human subjects research.

2. Ensuring that the student researcher has sufficient training and academic preparation to conduct the proposed research.

3. Reviewing the initial protocol and all subsequent modification and continuation requests, ensuring these are complete and accurate.

4. Meeting with the student investigator on a regular basis to monitor the progress of the research.

5. Monitoring the research to ensure that no deviations from the approved protocol are made.

6. Remaining available, personally, to supervise the student researcher in solving problems should they arise during the course of the research.

7. Arranging for an alternate faculty or staff advisor to assume responsibility during periods of absence (e.g., sabbatical leave or vacation), and advising the IRB office by letter of such arrangements.

8. Being the primary contact in all IRB correspondence and interactions, from original submission through the termination and final report.

VI. Applicable Regulations and Guidance

The Nuremberg code for ethical research with human subjects contains the following requirements regarding the qualifications of the principal investigator:

The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. [Nuremberg Code #8]