I. Purpose of this SOP

The purpose of this SOP is to set forth the conditions under which Brandeis University undergraduates, graduate students, and postdoctoral scholars (student researchers) must conduct human subjects research under the auspices of Brandeis University.

II. Scope of this SOP

This SOP applies to human subjects research projects conducted by students and postdoctoral scholars under the auspices of Brandeis University.

III. Key Definitions

Principal Investigator 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

Human Subject is a living individual about whom an investigator obtains one or both of the following:

1) Data through intervention or interaction with the individual
2) Identifiable private information about the individual

About Whom refers to information the subject discloses about him/herself (including his/her opinions), as opposed to information/facts the subject shares regarding an external topic (such as a program, product, or procedures) about which the subject can be considered an expert

Intervention refers to physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes

Interaction refers to communication or interpersonal contact between investigator and subject
Identifiable refers to when the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Private Information refers to information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Research refers to a systematic investigation designed to develop or contribute to generalizable knowledge.

Systematic Investigation refers to a project that methodically tests (quantitatively or qualitatively) a hypothesis or research question, by gathering and analyzing data with the intention of drawing conclusions.

Generalizable Knowledge refers to data designed to apply to a population beyond the research subjects themselves and contribute to current academic understanding.

IV. Statement of SOP

It is the standard operating procedure of Brandeis University that all human subjects research conducted by Brandeis University students and postdoctoral scholars under its auspices must be overseen by a Brandeis University faculty or staff member, who will act as principal investigator, and that all such student researchers complete required training in human subjects research.

V. Procedures

Projects conducted by students for educational purposes within a course alone do not fall within the purview of the IRB, as it is not considered to be research as defined by the federal regulations. Such projects occur in a course designed, at least in part, to provide training in research methodology. These projects are commonly conducted as part of a research methods course or research practica, which involve the supervised practical application of previously studied theories of research methods.

*Note that this does not apply if a student plans to use the data collected for future human subjects research activities (as a pilot study, for example), in which case the project will require IRB review, as IRB approval is not retroactive.*

Independent projects conducted by undergraduate students/graduate students/postdoctoral scholars that include human subjects research as defined by the federal regulations do fall within the purview of the IRB. Such projects include, but are not limited to, honors theses, graduate theses, and doctoral dissertations.

Research initiated by undergraduate students, graduate students, and postdoctoral scholars (including staff conducting human subjects research in fulfillment of a degree program) requires a Brandeis University faculty or staff advisor to serve as Principal Investigator. In these cases the student/scholar serves as Student Researcher.

Students and postdoctoral scholars planning to conduct a research project involving human subjects must submit a protocol through their faculty or staff advisor, who is then responsible for ensuring the application is complete and accurate. All interactions, from original submission through the termination and final report will take place between the IRB staff and the Principal Investigator.

It is Brandeis University’s policy that all students involved in human subjects research must complete the online CITI training prior to initiating or participating in human subjects research.
Note that, to the extent that students will be interacting with human subjects, regardless of whether their project meets the federal regulations definition of human subjects research, care must be taken to ensure that those subjects are treated with respect and courtesy, do not have their privacy invaded, and are not subjected to unnecessary discomfort (physical or emotional). It is important that the instructor fully understand the classroom projects that are proposed and conducted by his/her students, and that s/he provide clear and unambiguous guidelines to those students with respect to their interactions with their subjects.

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]