I. Purpose of this SOP

The purpose of this SOP is to set forth the parameters for the jurisdiction of the Brandeis University IRB.

II. Scope of this SOP

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

III. Key Definitions

**Human Subject**: A living individual about whom an investigator conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens
   — or —
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

**Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

**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**: Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject’s environment that are performed for research purposes.

**Interaction**: Communication or interpersonal contact between investigator and subject

**Identifiable**: The identity of the subject is or may readily be ascertained by the investigator or associated with the information
**Private Information:** 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.

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

Examples of systematic investigations are:
- Surveys
- Questionnaires
- Interviews
- Focus groups
- Participant observation
- Existing data analysis
- Program evaluation
- Social or psychological experiments
- Drug trials

**Generalizable Knowledge:** Data designed to apply to a population beyond the research subjects themselves and contribute to current academic understanding.

Generalizable knowledge generally refers to:
- Published papers
- Oral presentations
- Posters at a conference
- Dissertation or thesis

Projects being conducted solely for a class are not considered generalizable knowledge.

**IV. Statement of SOP**

It is the standard operating procedure of Brandeis University that all human subjects research conducted under its auspices, regardless of funding, be reviewed by Brandeis University IRB members (expedited, full review, or limited IRB review research) or staff (non-limited IRB review exempt research).

**V. Procedures**

The federal regulations stipulate that all federally funded human subjects research must be conducted under a Federalwide Assurance or contract entered into by the institution with oversight for the research and the Office of Human Research Protections (OHRP) under the Department of Health and Human Services (HHS). This contract stipulates that all federally funded research conducted under the auspices of that institution will comply with the federal regulations. Brandeis University operates under Federalwide Assurance #FWA00004408.

While the regulations apply only to federally funded research, Brandeis University believes the protection of human subjects in research is vital and has determined that all research conducted under the auspices of the university or by any member of the Brandeis community will be held to the same standards, whether federally funded or not.

Human subjects research conducted under the auspices of Brandeis University, that requires IRB review and approval prior to its initiation, includes that which falls into the following categories:

- Human subjects research conducted by Brandeis University faculty, staff, or students
• Human subjects research performed with or involving the use of facilities or equipment belonging to Brandeis University
• Human subjects research performed in fulfillment of a Brandeis University degree, such as a thesis or dissertation

VI. Applicable Regulations and Guidance

The US government code of federal regulations for the protection of human subjects (45 CFR 46) contains the following requirements involving the jurisdiction of the IRB:

1. Except as detailed in §___104, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy. [§46.101(a)]

2. Each institution engaged in research which is covered by this policy, with the exception of research eligible for exemption under §___104, and that is conducted or supported by a Federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for Federal-wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by and IRB (if such certification is required by §___103(d). [§46.103(a)]