I. Purpose of this SOP

The purpose of this SOP is to outline the duty, authority, and responsibilities of the IRB and Institutional Official.

II. Scope of this SOP

This SOP applies to the Brandeis University IRB members and Brandeis University Institutional Official.

III. Key Definitions

**Institutional Official** is the university official responsible for ensuring the Human Research Protection Program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official, and assumes the obligations of the institution's Assurance.

IV. Statement of SOP

It is the standard operating procedure of Brandeis University that the IRB and Institutional Official have as their overriding responsibility the safeguarding of the rights and welfare of the human subjects participating in research conducted under its auspices.

V. Procedures

**IRB Authority**

The Brandeis University IRB, in its effort to safeguard the rights and welfare of human subjects in research, has the authority to review all human subjects research and:

- The IRB has the authority to approve, require modifications to secure approval of, or disapprove all human subjects research activities overseen and conducted under the auspices of Brandeis University.
• The IRB has the authority to suspend or terminate approval of human subjects research for instances of serious or continuing noncompliance and unanticipated problems involving risks to subjects or others

**Institutional Official Authority**
The Brandeis University Institutional Official, in his/her effort to safeguard the rights and welfare of human subjects in research, has the authority to review all human subjects research and:

• The Institutional Official has the authority to disapprove any research approved by the IRB

• The Institutional Official *does not* have the authority to approve any research disapproved by the IRB

**IRB Responsibilities**
The IRB, in its effort to safeguard the rights and welfare of human subjects in research, ensures its members:

• Seek appropriate expertise from non-members for the review of proposals that require knowledge or expertise beyond or in addition to that of the members of the IRB

• Participate in mandatory and ongoing training, including completion of the CITI course

• Understand the ethical principles, federal regulations, and institutional polices related to human subjects research

• Follow all applicable written policies and procedures

• Review all submitted non-exempt research applications, modification requests, and continuation requests according to federal regulations

• Attend monthly meetings and actively participate in discussions, each offering his/her unique point of view

• Avoid conflicts of interest by each member refraining from participating in an IRB meeting in which his/her research is being reviewed

• Keep confidential all documents and other information acquired as IRB members

• Review all allegations of investigator non-compliance and instances of unexpected serious harm to participants, and suspend or terminate approval when deemed necessary

**Institutional Official Responsibilities**
The Institutional Official, in his/her effort to safeguard the rights and welfare of human subjects in research, ensures:

• The IRB has the accumulated professional competency necessary to review all proposals

• The IRB members are selected based on appropriate diversity including consideration of race, gender, cultural backgrounds, and specific community concerns

• The IRB includes one member with formal education and training in scientific areas relevant to the research it reviews, one whose formal education and training are in non-scientific areas, and one who is not otherwise affiliated with the institution in any way, who is sensitive to and can represent community attitudes
• S/he participates in mandatory and ongoing training, including completion of the CITI course
• S/he understands the ethical principles, federal regulations, and institutional policies related to human subjects research
• S/he follows all applicable written procedures
• S/he reviews all allegations of serious investigator non-compliance and instances of unexpected serious harm to participants brought to his/her attention and for his/her action

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 IRB authority and responsibilities:

1. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. [§46.107(a)]

2. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession. [§46.107(b)]

3. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. [§46.107(c)]

4. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. [§46.107(d)]

5. In order to fulfill the requirements of this policy each IRB shall §46.108:
   a. Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by §46.103(b)(5). [§46.108(a)]

6. An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. [§46.109(a)]

7. Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. [§46.112]

8. An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. [§46.113]