I. Purpose of this SOP

The purpose of this SOP is to set forth the determination process used by the Brandeis University IRB in its decision to cede review or become the IRB of record when human subjects research is being conducted by a Brandeis University investigator in collaboration with a non-Brandeis University investigator.

II. Scope of this SOP

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

III. Key Definitions

**Assured Institution** is an institution with an IRB working under a federalwide assurance (FWA) negotiated with the Office for Human Research Protections (OHRP) of the National Institutes of Health (NIH)

**Cede Review** refers to an agreement whereby one assured IRB relinquishes its oversight responsibilities to a second institution's assured IRB for collaborative human subjects research between investigators at both institutions

**Collaborative Research** refers to human subjects research conducted by an investigator at an institution with an assured IRB and an investigator not affiliated with this same institution

**Independent Investigator** is a collaborating investigator who is not acting under the auspices of any institution with respect to his/her involvement in the research

**Individual Investigator Agreement (IIA)** is a formal written agreement in which an assured IRB agrees to serve as the IRB of record for collaborative human subjects research between an investigator at its institution and an independent or institutional investigator

**Institutional Investigator** is a collaborating investigator affiliated with an institution without an assured IRB
IRB Authorization Agreement (IAA) is a formal written agreement in which an assured IRB agrees to serve as the IRB of record for collaborative human subjects research between an investigator at its institution and a collaborating investigator at another institution with an assured IRB.

IRB of Record is an agreement whereby one institution's assured IRB assumes oversight responsibilities of another institution's assured IRB, or an independent or institutional investigator.

Joint Review is when the assured IRBs of two or more institutions with investigators participating in collaborative research retain oversight of the portion of a research project in which their investigator is engaged.

IV. Statement of SOP

It is the standard operating procedure of Brandeis University that when a Brandeis University investigator collaborates with a non-Brandeis University investigator, the Brandeis University IRB may agree to become the IRB of record, may cede review to the IRB of the collaborating investigator's institution, or may retain oversight of only that portion of the research in which the Brandeis University investigator is engaged.

V. Procedures

When conducting collaborative research, the Brandeis University investigator must submit an IRB application clearly delineating the portion of the research each investigator – both Brandeis University investigator and non-Brandeis University investigator – will be conducting. After confirming that both Brandeis University and non-Brandeis University investigators are engaged in the research, the Brandeis University IRB has three options:

1. The Brandeis University IRB agrees to joint review of the research with the assured IRB of the collaborating investigator's institution.
2. The Brandeis University IRB agrees to become the IRB of record for the complete research project.
3. The Brandeis University IRB agrees to rely on the assured IRB of the collaborating investigator's institution.

Conducting Collaborative Research with an investigator at an assured Institution

When a Brandeis University investigator is conducting collaborative research with an investigator at an institution with an assured IRB, the Brandeis University IRB, in conjunction with the IRB of the collaborating investigator's institution, will determine whether joint review of the research is appropriate or whether one institution's IRB will cede review to the IRB of the collaborating investigator's institution, which then becomes the IRB of record. This decision is based on a number of factors, such as:

The level of risk to subjects associated with the research

- If funded, which institution is the prime recipient of the funding
- If funded, whether the funder specifies which IRB is to act as the IRB of record
- If a multi-site project, whether one institution is coordinating the research
- If the research is subject to the NIH Single IRB (sIRB) policy for multi-site research (NOT-OD-16-094)
- The components of the research being conducted at each institution
- If the majority of contact with research subjects is at one institution
• If one institution’s IRB has more appropriate experience and expertise to review the research
• If one IRB does not feel it has sufficient understanding of the context in which the research is being conducted

When the Brandeis University IRB agrees to either cede review or serve as the IRB of record, a formal IRB Authorization Agreement (IAA) is required and must be in place naming the Brandeis University IRB as IRB of record, or stipulating that the Brandeis University IRB cedes oversight to the IRB of the collaborating investigator’s institution.

Note that research may not commence by either investigator until an IAA has been signed by both institutions, and the IRB of record has approved the research.

If both institutions agree to joint review, the two IRBs will collaborate to ensure those aspects of the research that depend on both IRB’s approval (such as recruitment or consent procedures and materials), will meet the approval of both IRB’s.

**Conducting Collaborative Research with an Independent Investigator**

When conducting collaborative research with an independent investigator, Brandeis University must enter into an Individual Investigator Agreement (IIA) with the independent investigator naming the Brandeis University IRB as the IRB of record. To qualify for an IIA, the independent investigator must:

1. Not be an employee or agent of Brandeis University
2. Be conducting collaborative research activities outside the facilities of Brandeis University
3. Not be acting as an employee of any institution with respect to his/her involvement in the research being conducted.

It is the responsibility of the Brandeis University investigator to bring to the attention of the Brandeis University IRB administrator that s/he will be collaborating with an independent investigator.

Note that research may not commence by either investigator until an IIA has been signed and the Brandeis University IRB has approved the research.

**Conducting Collaborative Research with an Institutional Investigator**

When conducting collaborative research with an investigator at an institution without an assured IRB, the Brandeis University IRB must enter into an Individual Investigator Agreement (IIA) with the collaborating investigator naming the Brandeis University IRB as the IRB of record. To qualify for an IIA, the institutional investigator must:

1. Not be an employee or agent of Brandeis University
2. Be conducting collaborative research activities outside the facilities of Brandeis University
3. Be acting as an employee or agent of a non-assured institution with respect to his/her involvement in the research being conducted
4. Be employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

It is the responsibility of the Brandeis University investigator to bring to the attention of the Brandeis University IRB administrator that s/he will be collaborating with an institutional investigator.
Note that research may not commence by either investigator until an IIA has been signed and the Brandeis University IRB has approved the research.

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 research collaborations:

1. Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. [§46.114(a)]

2. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. [§46.114(b)(1)]

3. The following research is not subject to this provision:
   a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) [§46.114(b)(2)(i)]
   b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context [§46.114(b)(2)(ii)]

4. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. [§46.114(c)]