I. Purpose of this SOP

The purpose of this SOP is to set forth the conditions under which modifications in human subjects research conducted under the auspices of Brandeis University must be reported to the IRB, and the procedures to be followed regarding such reporting.

II. Scope of this SOP

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

III. Statement of SOP

It is the standard operating procedures of Brandeis University that all modifications to currently approved human subjects research conducted under its auspices require HRPP staff (exempt research) and/or member (expedited and full-board research) review and approval prior to implementation.

IV. Procedures

All modifications must be approved by the IRB prior to any changes in research plan are implemented. If changes to currently approved research are initiated prior to IRB approval, the research will be out of compliance and must cease immediately unless it is determined by the IRB or principal investigator that it is in the best interest of individual subjects currently participating in the study to continue the research.

Examples of modifications include, but are not limited to:

- Change in principal investigator
- Addition or removal of personnel
- An increase in the number of subjects
- Changes to the procedures or study design
• Changes to the study instruments (surveys, questionnaires, etc.)
• Changes to the informed consent document or procedures
• Changes to recruitment materials
• Changes in location of research or agency
• Changes in funding sources

Modification requests must include:

• Change in risk level, if applicable
• A description of the proposed modification, including a discussion of the effects on the risks and benefits to the subjects and the procedures that will be taken to manage the risk(s)
• Revised consent forms, study instruments, and/or recruitment materials, if applicable
• Changes in personnel, including personnel being added and/or deleted, if applicable
• Changes in the facility/agency involved in the research activities and/or funding sources, if applicable

**Exempt Research**
Modification requests for research whose initial review or last approved modification request qualified the study for exempt status are reviewed by a qualified HRPP staff member unless it is determined that the requested modifications would result in an increase of risk level, in which case the modification request is reviewed in accordance with the change in risks to subjects.

**Expedited Review**
Modification requests for research whose initial review or last approved modification or continuation request qualified the study for expedited review are reviewed by the original reviewers or another member of the IRB unless it is determined that the requested modifications would result in a change of risk level, in which case the modification request is reviewed in accordance with the change in risks to subjects.

**Full Committee Review**
Modification requests for research whose initial review or last approved modification or continuation was subject to full committee review are reviewed by the full committee unless it is determined that the requested modifications would not increase the level of risk to participants, in which case the modification request is reviewed by the chair of the IRB or a member of the IRB designated by the chair.

Should the IRB become aware of research being conducted without, or not in accordance with, its approval, it has the authority to suspend or terminate the research through the withdrawal of its approval.

In addition, the Brandeis University IRB is required to report all “serious or continuing noncompliance” with the federal regulations for human subjects research to the Institutional Official, OHRP, and any applicable funding agencies.

The only exception is the rare circumstance in which a change is necessary to eliminate an apparent immediate increased risk to the research subjects. In this case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with the protection of human subjects.

Unanticipated risks to subjects or new information that may affect the risk/benefit assessment also must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of human subjects.

**V. Applicable Regulations and Guidance**
The US government code of federal regulations for the protection of human subjects (45 CFR 46) contains the following requirements for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects:

1. In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

   a. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

   b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) among those research risks that fall within the purview of its responsibility.

   c. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

   d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

   e. Informed consent will be appropriately documented or appropriately waived in accordance with, and to the extent required by §46.117.

   f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

   g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data [§46.111]

2. 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. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. [§46.113]