I. Purpose of this SOP

The purpose of this SOP is to set forth the procedures to be followed in the continuing review of IRB approved human subjects research conducted under the auspices of Brandeis University.

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 procedure of Brandeis University that all non-exempt human subjects research conducted under its auspices must be reviewed by the IRB at an interval determined by the IRB at the time of its initial review or last requested modification, and based upon the nature of the study, the level of risk to subjects, and the vulnerability of the subject population, but no less than annually.

IV. Procedures

The continuing review timetable is indicated on the research application approval letter by the end date of the IRB’s initial approval of the research. If the research will continue beyond this end date, the principal investigator must submit a continuing review request at least 30 days prior to this end date. The research is considered continuing if the investigators are 1) continuing to recruit human subjects and/or are planning to continue data collection, or 2) are analyzing data collected for the research.

Continuing review approvals must include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting continuing review, the IRB will review, at a minimum, the protocol and any amendments as well as a status report on the progress of the research, including:

- The number of subjects originally approved to be enrolled in the research
- The number of subjects currently approved to be enrolled in the research
• The number of subjects currently enrolled in the research
• The total number of subjects currently planned to be enrolled in the research
• The number of subjects who refused to participate at the time of screening/informed consent
• The number of subjects who withdrew their participation after informed consent was given
• A description of any complications, adverse events, or unanticipated problems involving risks to subjects or others; withdrawal of subjects from the research; or complaints about the research
• An explanation of any unapproved modifications made to the research since last review
• A summary of changes in the literature that would affect the research

Full Committee Review
Continuing review requests for research whose initial review was subject to full committee review, or whose last approved modification upgraded the review status to full committee review, are reviewed by the full committee no less than annually.

Expedited Review
Continuing review requests for research whose initial review or last approved continuation was subject to expedited review, or whose last approved modification upgraded or downgraded the review status to expedited, are reviewed by the original reviewer or another member of the IRB designated by the chair no less than annually.

Exempt Status Research
Research whose initial review deemed the research exempt, or whose last approved modification downgraded the review status to exempt, is not subject to continuing review.

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 involving the procedures for the continuing review of research previously approved by the IRB:

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. [§ 46.109(e)]