I. Purpose of this SOP

The purpose of this SOP is to set forth the procedures to be followed by the Brandeis University IRB for a determination of the necessity of an audit of 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 the Brandeis University IRB may determine at any time that verification from sources other than the principal investigator is necessary to ensure no material changes have occurred since the last review of a human subjects research project being conducted under its auspices.

IV. Procedures

Any member of the IRB may request monitoring of approved projects in the form of routine, targeted, or random audits. Possible reasons for such audits include, but are not limited to:

- Complaints received from research subjects
- Concerns raised by a third party
- Research involves a high risk of harm to subjects
- An occurrence of an unanticipated problem or adverse event
- A history of noncompliance by the investigator
Any member of the IRB may request an audit be conducted. Such an audit may be conducted by one or more members of the IRB, and/or an independent person designated by the IRB.

Audit activities may include, but are not limited to the following:

- Requesting progress reports from investigators
- Examining research records
- Contacting research subjects
- Dispatching observers to the sites where research involving human subjects and/or the informed consent process is being conducted
- Auditing advertisements and other recruitment materials

Results of the audit are reported at the next convened IRB meeting. If the auditors believe the subjects are being put at immediate risk due to the occurrence of material changes a special meeting may be called.

A report of the committee’s review of the audit is communicated electronically to the principal investigator, the institutional official, and the department or agency head as appropriate. A copy is placed in the IRB file and a signed hard copy is available upon request.

If the auditors suspect noncompliance by the research team, procedures for the reporting of noncompliance are initiated.

**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 determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review:

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]