HRPP SOP #104
Determining which Projects Require Review More Often than Annually

Responsible Office(s): Office of Research Administration
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I. Purpose of this SOP

The purpose of this SOP is to set forth the procedures to be followed by the Brandeis University IRB in determining at what interval approved human subjects research being conducted under the auspices of Brandeis University should be reviewed.

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 when determining the appropriate interval for continuing review of non-exempt human subjects research conducted under its auspices, IRB members consider such things as the degree of risk to subjects, the vulnerability of the subject population, and the nature and novelty of the intervention.

IV. Procedures

Both expedited and full-committee reviewed research may be determined to require annual or more frequent than annual review. The determination to review a study more often than annually can be made at any time and as a response to such things as modifications in the research, noncompliance by the researcher(s), or an occurrence of an unanticipated problem or adverse event.

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 determination of the review schedule for approved applications:

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)]