# HRPP SOP #101
## Initial Review of Research

**Responsible Office(s):** Office of Research Administration  
**Responsible Official(s):** Associate Provost for 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 in the initial review of human subjects research applications submitted to the Brandeis University IRB for research to be 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 human subjects research conducted under its auspices must be reviewed by HRPP staff for determination of its review status (exempt, expedited, full) and, if non-exempt, by the IRB for approval.

## IV. Procedures

IRB applications must be submitted electronically via email and in hard copy, with all relevant signatures attached.

**Administrative Review:**

All IRB applications undergo an initial administrative review by HRPP Staff. At this time the IRB administrator may request additional information about the research, additional documentation, and/or revisions to the application. Once all additional information, additional documentation, and/or revisions are submitted, HRPP staff reviews the application for an initial review category determination.

**Exempt Review**

Projects that meet the requirements for one or more of the exempt status categories specified in the federal regulations; involve no more than minimal risk to subjects; do not place subjects at risk for criminal or civil liability, or damage their financial standing, employability, or reputation; do not involve deception (incomplete disclosure may be allowed if subject agrees to the incomplete disclosure prospectively); do not
involve children unless expressly allowed by the category of review; and do not involve prisoners (or their data), undergo review by a qualified HRPP staff member and/or by an IRB member designated by the Chair.

Possible outcomes of review for exemption status:

- **Exempt**: The application is exempt and research may proceed.
- **Does not Qualify for Exempt Status**: The application does not qualify for exempt status and the applicable review process is observed.

**Exempt Status Categories**

**Exempt Category 1**
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

1. Research on regular and special education instructional strategies.
2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Note:** This category may be applied to research involving children

**Exempt Category 2**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
   —and—

2. Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

**Note:** Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review.

**Note:** This category may be applied to research involving children provided it is 1) research involving educational tests, or 2) public observation involving no interaction between the investigators and the children.

**Exempt Category 3**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

1. The human subjects are elected or appointed public officials or candidates for public office.
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Exempt Category 4**
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**Exempt Category 5**
Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs.
2. Procedures for obtaining benefits or services under those programs.
3. Possible changes in or alternatives to those programs or procedures.
4. Possible changes in methods or levels of payment for benefits or services under those programs.

**Exempt Category 6**
Taste and food quality evaluation and consumer acceptance studies:

1. If wholesome foods without additives are consumed.
2. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

*Note: This category may be applied to research involving children.*

**Expedited Review:**
Projects are eligible for expedited review if they involve no more than minimal risk to subjects and meet one of nine categories specified by the federal regulations. For applications qualifying for expedited review, the IRB chair or his/her designee assigns one or more designated reviewers to evaluate the submission and make a final determination about the acceptability of the research protocol. IRB members are assigned to review applications based on relevant disciplinary and regulatory knowledge and experience with study contexts and populations.

Possible outcomes of an expedited review are:

- Approval: The application is approved and no changes are required or recommended. Research may proceed.
- Conditional Approval: The application is approved contingent on minor revisions being made.
- Requires Revision: The application cannot be approved without revisions, clarifications, or additional documents. Once these are submitted, the review process is repeated.
- Does not qualify for Expedited Review: The application does not qualify for expedited review and the applicable review process is observed.

*Note that assigned reviewers of an expedited review may not disapprove a research application. If the reviewer believes the research should not be approved, it must be referred to the full committee for a final determination.*

**Expedited Review Categories**

**Expedited Category 1**
Clinical studies of drugs and medical devices only when

- Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required; or
- Research on medical devices for which (i) an investigational device exemption application (21 CR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Expedited Category 2**
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:

- Healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- Other adults considering the age, weight, and health of the subjects, the collection procedures, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects,
the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**Expedited Category 3**  
Prospective collection of biological specimens for research purposes by noninvasive means.

**Expedited Category 4**  
Collection of data on subjects 18 years of age or older through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves as well as procedures involving general anesthesia or sedation. Where medical devices are employed, they must be cleared/approved for marketing.

**Expedited Category 5**  
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes such as medical treatment or diagnosis.

**Expedited Category 6**  
Collection of data from voice, video, digital, or image recordings made for research purposes.

**Expedited Category 7**  
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior); or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Expedited Category 8**  
Continuing review of research previously approved by the entire IRB as follows:

- Where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
- Where no subjects have been enrolled and no additional risks have been identified; or
- Where the remaining research activities are limited to data analysis.

**Expedited Category 9**  
Continuing review of research in which the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Full Committee Review:**  
Projects that involve more than minimal risk or prisoners, or those that do not fit into one or more of the categories for expedited review or exempt status, must be reviewed by the full board at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific.

In the event the IRB lacks the appropriate expertise to assess scientific merit and the research is judged by the IRB to have greater than minimal risk, the IRB may seek outside expertise to assist its evaluation of the proposed research.

Approximately one week prior to the next scheduled board meeting, all application materials scheduled to be reviewed are distributed to the full board. It is the expectation that all members of the committee review the application materials prior to the meeting and be prepared to participate in the discussion of the significant concerns, raise additional concerns, provide necessary clarifications, and/or propose resolutions.

The meeting is called to order by the board chair once a quorum of committee members is reached. If a quorum of members is not reached or is lost once the meeting has begun, all proposals not reviewed are
tabled and reviewed at the next scheduled meeting or the meeting is rescheduled for such a time that a quorum of members are present.

Once the application has been sufficiently discussed by a quorum of committee members, the members present vote on the review determination. In order for a given project to be approved, it must receive the approval of a majority of the members present at the meeting.

Possible outcomes of a full committee review are:

- Approval: The application is approved and no changes are required or recommended. Research may proceed.

- Conditional Approval: The application is approved contingent on minor revisions being made.

- Requires Revision: The application cannot be approved without revisions, clarifications, or additional documents. Once these are submitted, the review process is repeated (at this point a subset of the committee may be designated by the chair to review the revised application on a rolling basis).

- Disapproval: The application cannot be approved due to issues the committee believes are non-revisable and inherent in the research.

Note: For an application to be approved, a majority of the committee members present must vote to approve the application.

In addition to determination of approval/disapproval of the research application, the reviewer(s) of non-exempt research will assess the level of risk to subjects involved in the research and determine a continuing review schedule that will be no less than annual.

Note: Any application approved by the IRB may be subject to further review by officials of the institution. The institution may not, however, override the IRB’s decision to disapprove an application.

Once the review process is complete, the IRB administrator notifies the investigator electronically of the determination and next steps. A signed hard copy is available upon request by the principal investigator.

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 initial review of IRB applications:

1. In order to fulfill the requirements of this policy each IRB shall [§46.108]: Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. [§46.108(b)]

2. An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. [§46.109(a)]

3. An IRB may use the expedited review procedure to review either or both of the following:

   a. Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.
b. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

4. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b). [§46.110(b)]

5. Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. [§46.112]