Purpose
This document describes the policy used when performing an initial review of proposed research activities involving human research participants, including exempt and non-exempt research. Additionally, the policy describes the procedures which the IRB will follow for reporting its findings and actions to investigators and the institution.

Regulatory Background
Proposed research may be reviewed by full committee or by an expedited review procedure. In accordance with DHHS regulations at 45 CFR 46.108(b), initial review of proposed research activity must be conducted by the IRB 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, except where research activities fall under one of the categories for exemption or expedited review published by DHHS regulations at 45 CFR 46.101 and at 45 CFR 46.110(b)(1). Approval of research is by a majority vote of the quorum of voting IRB members.

Initial review using expedited review procedure 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 reviewer(s) 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 at a convened meeting.

Scope
These procedures apply to all investigators at Princeton University, including faculty, professional researchers, staff and students conducting research involving human research subjects.

Responsibilities
Principal Investigator (PI): An individual who has ultimate responsibility for the overall conduct of the study. When research is initiated by a student, a faculty advisor must act in the capacity of principal investigator for the study. All other individuals involved in the study, including the students, are considered research personnel. Federal regulations and the Princeton IRB recognize only one individual as the PI of a study.

Research personnel: all other individuals involved in the design, conduct, or reporting of the research.

IRB Member(s): review research at convened IRB meetings or by expedited procedures. Each IRB member receives one vote at convened meetings.
Definitions

Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Harm: Anything that has negative effect on the welfare of research participants; the nature of the harm may be social, behavioral, psychological, physical, economic, legal, and reputational.

Approval Date: The approval date is the first date that research can be performed.

Approval Period: The Princeton IRB follows OHRP guidance in determining the approval period. An approval period for initial review cannot be longer than one year.

Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period. An expiration date may not be longer than one year from the date the approval period begins.

Quorum: means that greater than half of the IRB members are present at an IRB meeting and the following criteria are met: at least one member whose primary concerns are in scientific areas is present at the meeting; at least one member whose primary concerns are in non-scientific areas is present at the meeting; and at least one unaffiliated member is present at the meeting. A Board member may fulfill more than one criterion.

Policy

In order to approve research, the Princeton IRB must consider and determine that all of the requirements of federal regulation 45 CFR 46.111: Criteria for IRB Approval of Research specified below are satisfied.

Criteria for Approval

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

2. 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) as among those research risks that fall within the purview of its responsibility.
3. 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.

4. 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 the Federal Regulations.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by the Federal Regulations.

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

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Exempt Research

The Code of Federal Regulations at 45 CFR 46.101 identifies six categories of minimal risk research as being exempt from federal oversight. However, these categories of research are not exempt from review by the Princeton IRB, the ethical guidelines of the Belmont Report, or Princeton IRB policies.

Exempt studies must be submitted to the IRB for an exempt determination. Investigators are not authorized to make this determination. Once the IRB Chair, Assistant Director of RIA, or other Board member designated by the Chair determines that the proposed research activity meets an exempt category below, an “Exemption Notice” will be issued to the Principal Investigator.

Continuing review is not applicable to exempt research. Therefore, no expiration date will appear on the “Exemption Notice.” However, the activity is still human subjects research subject to Princeton IRB oversight. For example, investigators must submit proposed changes, issues of noncompliance, Unanticipated Problems, and notification of study closure to the IRB for exempt studies. If the investigator does not notify the IRB of an exempt study’s closure, the IRB will contact the investigator 3 years after the last action for the study to determine whether the study can be closed (“last action” is defined as the last submission.
Categories of Exempt Research

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. 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.

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 section 2 immediately above, if:
   a. The human subjects are elected or appointed public officials or candidates for public office;
   b. Or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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.

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:
   a. Public benefit or service programs;
   b. Procedures for obtaining benefits or services under those programs;
   c. Possible changes in or alternatives to those programs or procedures;
   d. Possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies,
   a. If wholesome foods without additives are consumed
   b. Or 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 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 U.S. Department of Agriculture.

Limitations and Exceptions:

Children: Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply when research involves children, except for observations of public behavior when the investigator does not participate in the activities being observed.

Prisoners: Exemptions do NOT apply when prisoners are involved.

Procedure

Initial IRB Application

The IRB must receive sufficient information from investigators to provide adequate review of proposed research and to make the required determinations for IRB approval. The following materials must be submitted for initial review. Submission requirements are the same for reviews performed by the convened IRB and for reviews using expedited procedures.

Initial Submission

1. A completed IRB application which is signed by the PI. If the study is conducted by a student, the faculty advisor (serving as the principal investigator) and the student must sign the application.

2. Informed consent document(s), if applicable.

3. Recruitment materials, i.e., flyers, posters, web-pages, email messages, etc.

4. Copies of all study measurements, e.g., questionnaires, surveys, or interview guides

5. If the study is federally funded, the grant number or the grant.

6. Human subjects training verification. The IRB requires that the PI and all research personnel complete human subjects training. This is a one-time training requirement. Retraining is not required unless issues of noncompliance are found or there are major revisions to the regulations or policies/guidelines affecting human subjects research.
The training can be from any source if the training directly addresses human subjects research. For example, training in conflicts of interest, biosafety, animal research, or responsible conduct of research work will not be recognized.

The IRB recommends the following training options:

Option #1: obtaining a passing score on one of the following Collaborative Institutional Training Initiative (“CITI”) courses:

“Social & Behavioral Research Investigators” (3 hour course)

“Biomedical Research Investigators” (3 hour course)

“Social Behavioral Faculty Advisors” (if the research is student-led and the PI is the student’s faculty advisor) (1 hour course)

“Biomedical Faculty Advisors” (if the research is student-led and the PI is the student’s faculty advisor) (1 hour course)

CITI instructions can be found at:

CITI-LOGIN-AND-REGISTRATION-INSTRUCTIONS

Option #2: attend an in-person training session by IRB staff (30 minutes). The training can be done on a one-to-one basis or small or large group setting. Please contact the IRB to schedule an in-person training session.

Expedited Review Procedures

The IRB Chair, Assistant Director of RIA, or other Board member designated by the Chair uses the expedited review procedure to review the following:

1. Research appearing on the list of categories of research eligible for expedited review and found by the reviewer(s) to involve no more than minimal risk.

2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Categories of Research Eligible for Expedited Review

Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the categories below, may be reviewed by the IRB through the expedited review procedure.

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. Additionally, the categories in this list apply regardless of the age of subjects, except as noted.
The expedited review procedure cannot be used when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The standard requirements for informed consent (or its waiver or alteration) apply regardless of the type of review.

Expedited Research Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which an investigational device exemption application (21 CFR Part 812) is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. From healthy, non-pregnant 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
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, 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.

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

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection
an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging, (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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).

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

7. Research on individual or group characteristics or behavior (including, but not limited to, search 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.

Board members will be advised of the research proposals which have been approved under the expedited review procedure via a monthly expedited review report.

**Possible Actions after Expedited Review**

When reviewing proposed research activities using expedited procedures, IRB reviewers may take one of the following actions:

- Approve
- Require modifications to secure approval
- Assign the item to a convened meeting
Full Board Committee Review Procedure

Pre-Meeting Distribution of Documents
IRB staff will prepare and distribute IRB meeting materials to Board members 7-10 days before each convened meeting. If an ad hoc IRB meeting is convened, Board members will receive the meeting materials such that they have adequate time to review the materials.

Primary and Secondary Reviewers at Full Board meetings
Once the IRB Administrator has determined that the item is not eligible for exempt status or expedited review, the IRB Administrator selects a primary and secondary reviewer. Primary and secondary reviewer(s) are selected using the IRB roster and an assessment of their expertise as documented in their Curriculum Vitae or resume.

A primary and secondary reviewer will be assigned to initial review applications; other agenda items typically receive one reviewer. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the Board.

The primary and secondary reviewers are responsible for:
1. Performing an in-depth review of the proposed research.
2. Having a thorough knowledge of the details of the proposed research.
3. Leading the discussion of the proposed research at the convened meeting.
4. Recommending one of the motions noted in this policy.

IRB members who are not assigned as primary or secondary reviewers are expected to review the meeting materials such that they can meaningfully participate in the Board discussion.

Presentation and Discussion of Protocols at Full Board Meetings

To be properly discussed at a full board meeting, a quorum of the members must be present. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, or absence of a nonscientist or unaffiliated member), the IRB cannot take further actions or vote until quorum is restored.

Possible IRB Actions at a convened IRB meeting:

Approve: The submission meets the criteria for approval. Research activities may commence without conditions.

Require modifications to secure approval: The submission will meet the criteria for approval with minor changes or if the investigator’s response meets certain parameters that are set by the Board.
Defer: The IRB is unable to approve the submission according to the criteria for approval, but the IRB can suggest modifications that might make the research approvable.

Disapprove: The IRB determines that it is unable to approve the initial application according to the criteria for approval and the IRB cannot describe modifications that might make the research approvable.

Suspend: Based on new information, the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.

Terminate: Based on new information, the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.

Lift Suspension: Based on a modification submission or new information, the previously suspended research meets the criteria for approval.

Communication of IRB Actions
After an IRB meeting, IRB staff draft the minutes and submits them to the IRB Chair. After the IRB Chair approves the minutes, IRB staff issue correspondence to the investigators based upon the approved minutes. The correspondence includes the required revisions. For research that is disapproved, the correspondence includes the reasons for disapproval and a description of how the investigator can respond. For studies that are approved, the correspondence includes the approval date; the approval period; the approval end date or expiration date; reminders to submit modification requests before implementation; and instructions on how to close a study.

Reviewing Investigator Responses
If the Board defers the agenda item, the investigator’s response will be reviewed at a convened IRB meeting.

If the Board indicates that an agenda item requires modifications to secure approval, the Board may designate one or more Board members to review the investigator’s response. If the Board does not specify who will review the investigator’s response, the Assistant Director of RIA will review the response.

Administrative Closure of Submissions
If the IRB does not receive the principal investigator’s response within 90 days of the IRB correspondence, the IRB will administratively close the submission. If the investigator wishes to pursue approval of the submission, the investigator must re-submit the item.
RetentionPolicyIRBRecords

IRB records will be retained by the IRB for at least 3 years after completion of the research. Records relating to research which is conducted will be retained by the investigator for at least 3 years after completion of the research per DHHS regulations at 45 CFR 46.115(b). All records will be accessible for inspection and copying by the IRB and by authorized representatives of DHHS at reasonable times and in a reasonable manner.

References

45 CFR 46.111, 45 CFR 46.116, OHRP “Guidance on Written IRB Procedures” (07/01/11)

Version History

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<th>Version Number</th>
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<tr>
<td>Add 1.0</td>
<td>June, 2013</td>
<td>Added exempt research, regulatory background &amp; retention of IRB records.</td>
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<tr>
<td>2.0</td>
<td>March, 2016</td>
<td>Added administrative closure of submissions; editorial revisions</td>
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<tr>
<td>3.0</td>
<td>April 2016</td>
<td>Revised training requirements</td>
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