IRB Policy Number: 202	Version Number: 8.0	
Effective Date: January 21, 2019		
Title: Initial Review of Research Involving Human Participants		

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 46.104 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.

FDA-regulated research is reviewed only at a convened meeting. The FDA defines "research" as any experiment that involves a test article and one or more subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of The Federal Food, Drug, and Cosmetic Act ("Act"), or need not meet the requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. A test article is any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Act or under sections 351 or 354-360F of the Public Health Service Act.

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. The principal investigator must meet the criteria listed in the "Principal Investigator Qualification Chart by Rank" established by the Princeton University Research Board.

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, or reputational.

Approval Date: The approval date is the first date that research can be performed. The approval date is reflected on the Princeton IRB approval letter. Please see the "Communication of IRB actions" section of this SOP for more information.

Approval Period: The Princeton IRB follows OHRP guidance in determining the approval period.

Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

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. If the study is FDA-regulated, the convened Board must assess whether the investigator and/or sponsor determined that an investigational new drug application (IND) or investigational device exemption (IDE) is required for the proposed study, if applicable, and the basis for this determination. For FDA-regulated medical device research, the Board must make and document the significant/nonsignificant risk (SR/NSR) determination in the minutes.

The Princeton University IRB applies U.S. regulations, Princeton IRB policies, and ethical principles embodied in the Common Rule to all human subjects research, regardless of the state or country the study is conducted in. Any local, regional, federal, or country-wide regulations that impose an additional ethical standard must be considered.

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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decisionmaking capacity, 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.

In general, the IRB will not elect the option to transition individual studies to comply with the Final Rule. However, the IRB may, in its discretion, transition individual studies to comply with the new Rule.

Exempt Research

The Code of Federal Regulations at 45 CFR 46.104 identifies categories of minimal risk research as being exempt from federal oversight. In the event of an audit by a federal agency, exempt studies would not be audited. 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 and approves the study, an approval letter will be issued to the Principal Investigator.

Continuing review is not applicable to exempt research. Therefore, no expiration date will appear on the approval letter. 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. Exempt studies have a 3 year expiration date. If investigators would like to continue their exempt study after 3 years, a continuing review application must be approved before the expiration date. If a continuing review application is not approved before the expiration date, the IRB will close the study.

The Princeton University IRB does not adopt the concept of broad consent reflected in the Final Rule. Consequently, the following categories of exempt research are recognized by the Princeton University IRB:

Categories of Exempt Research

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §ll.111(a)(7).
3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §ll.111(a)(7).
   (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to

allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a

list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
   (i) If wholesome foods without additives are consumed, or
   (ii) 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.

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 that is submitted via eRIA. The PI indicates his/her understanding of the PI's obligations by signing the PI Assurance section of the application. If the study is conducted by a student, the faculty advisor (serving as the principal investigator) signs the PI Assurance section of 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. The IRB will not perform grant congruency due to limited utility unless the IRB, in its discretion, decides that performing a grant congruency would be appropriate for the study.

6. Human subjects training verification. The IRB requires that the PI and all Princeton-affiliated 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 and primarily 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" (only if the research is student-led and the PI is serving as the PI as a result of being the student's faculty advisor) (1 hour course)

"Biomedical Faculty Advisors" (only if the research is student-led and the PI is serving as the PI as a result of being 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 (60 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.

Verification of human subjects training is not required for research personnel who are not affiliated with Princeton. However, the PI must ensure that research personnel who are not affiliated with Princeton are qualified to perform the procedures and duties assigned to them during the study. Please see Princeton University SOP 207: Obligations of the Principal Investigator for Human Subjects Research for more details. The IRB encourages research personnel who are not affiliated with Princeton to contact their IRB as to whether IRB review is also required by their institution.

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

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 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 (i) an investigational device exemption application (21 CFR 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.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. 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
    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 nondisfiguring 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 gumbase 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 procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or 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 nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
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, 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB if the study status involves one or both of the following: data analysis (including analysis of identifiable private information or identifiable biospecimens), or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but 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.

10. The modification does not affect the design of the research; and the modification adds no more than minimal risk to subjects; and all procedures added as part of the modification (if applicable) fall into categories 1-7 on this list.

11. The modification does not meet category #10, but the study (which incorporates the modification) presents minimal risk to the subjects; and identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to the 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 risk; and all of the study procedures fall into categories 1-7 on this list.

If investigators would like to continue their expedited study after 3 years, a continuing review application must be approved before the expiration date. If a continuing review application is not approved before the expiration date, the IRB will close the study.

Board members will be advised of the research proposals which have been approved under the expedited review procedure via an expedited review report that is made available for each convened meeting. The Board will vote on the 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

Option for PIs to respond to IRB staff screening of agenda items

Once an agenda item is assigned to a convened IRB meeting and if there is sufficient time, the IRB staff will offer the option to PIs to screen the agenda item. The purpose of this screening is to minimize the Board deferring the agenda item. If the PI selects the screening option, the PI must submit the recommended revisions before the agenda is issued to the Board. Please see the flowchart at the end of this policy.

Pre-Meeting Distribution of Documents
IRB staff will prepare and distribute IRB meeting materials to Board members 7 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.

Option for Board members to contact the PI before the meeting

Board members have the option to contact the PI before the IRB meeting to resolve issues. The purpose of this option is to minimize the Board deferring the agenda item. If the Board member chooses this option, the Board member can either contact the PI directly or ask the IRB staff to contact the PI; IRB staff will maintain the Board member's anonymity. If the Board member contacts the PI before the IRB meeting, the Board member is encouraged to coordinate the communication with the presenter(s) and IRB staff. This coordination will minimize burden on the PI. Please see the flowchart at the end of this policy.

Presenters 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 two Board members ("presenters") to present the agenda item to the Board. The presenters are selected using the IRB roster and an assessment of their expertise. One of the presenters must be a scientist.

The IRB Administrator will assign two presenters to review initial applications; other agenda items typically receive one presenter. The IRB may, at 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 presenter(s) 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 presenters 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 upon receipt of the approval letter.

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. The Board may suspend the study in its entirety or may suspend aspects of the protocol, e.g., specified procedures or select study populations. The IRB Chair may also suspend the study before action can be taken through Committee Review if the IRB Chair determines that the rights and welfare of subjects may be at risk.

Table: the Board cannot review the item due to a loss of quorum or meeting adjournment. If an item is tabled, the item is placed on the agenda of the next IRB meeting.

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. The IRB Chair may also terminate the study before action can be taken through Committee Review if the IRB Chair determines that the rights and welfare of subjects may be at risk.

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 research that is tabled, the correspondence includes the date of the IRB meeting in which the item has been re-assigned. For studies that are approved, the correspondence includes the approval date; the approval period; the approval end date or expiration date.

IRB staff provide the approved minutes to the Institutional Official. IRB staff also provide the approved minutes to the next convened IRB. The Board will vote on the minutes.

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 IRB Chair will designate one or more Board members to review the investigator's response. If the IRB Chair 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.

Retention of IRB Records

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"

Principal Investigator Qualification Chart by Rank" established by the Princeton University Research Board:

https://www.princeton.edu/research/urb/pi-qualification-chart/Principal-Investigator-Qualification-Chart-by-Rank-updated-2013-7.pdf

Version History

	Version Number	Revision Date	Revisions
	1.0	June, 2013	Added exempt research, regulatory background & retention of IRB records.
	2.0	March, 2016	Added administrative closure of submissions; editorial revisions
	3.0	April 2016	Revised training requirements
	4.0	September 2016	Added pre-IRB meeting screening option and scientist requirement for review of full Board new studies
	5.0	April 2017	Application of regulations and policies to all research; extended in-person IRB training; the Board will vote on the expedited review report and the IRB meeting minutes
	6.0	October 2017	Edited to reflect the use of eRIA
	7.0	September 2018	Edited to reflect FDA-regulated research
	8.0	January 2019	Edited to reflect the Final Rule

Flowchart of Full Board review process