Purpose

This document describes the procedures and processes used when reviewing all submissions for initial review of proposed research activities involving human research participants including exempt and non-exempt research. Additionally, the procedures which the IRB will follow for reporting its findings and actions to investigators and the institution are described.

Regulatory Background

Proposed research may be reviewed by full committee or by an expedited review procedure. In accordance with HHS 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 HHS regulations at 45 CFR 46.101 and at 45 CFR 46.110(b)(1). Approval of research is by a majority vote of this 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 including IRB Administrators. 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 at a convened meeting. Procedures which the IRB will follow for reporting its findings and actions to investigators and the institution must also be addressed as required by federal regulations at 45 CFR 46.103(b)(4)(i).

Scope

These procedures apply to all investigators under the jurisdiction of Princeton University, including faculty, staff and students conducting research involving human research participants.

Responsibilities

Principal Investigator (PI): An individual who has ultimate responsibility for the overall conduct of research activities including the scientific and technical direction of a research project. While student may be listed as an investigator, faculty advisors act in the capacity of “principal investigators” when research is initiated by a student.

Note:
The IRB considers the term “investigator” to include anyone involved in conducting a proposed research project. When multiple individuals are involved, student investigators and other key study personnel may be listed as co-investigators.

Key Personnel are individuals who contribute to the scientific development or execution of a research project in a substantive measurable way.

**IRB Administrators:** Responsible for conducting an initial assessment of proposed research activity, attending IRB meetings, determining that meetings are appropriately convened before the discussion and vote for each review and providing correspondence to principal investigators. Additionally, staff who are board members may review protocols as appropriate.

**IRB Member(s):** Designated by the IRB Chair and assigned by the IRB Administrators to review research at a full convened IRB meeting or by expedited procedures. Each IRB member receives one vote at convened meetings and must provide timely written comments on research undergoing review.

**Definitions**

**Minimal Risk:** 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.

- **Note:** When identification of research participants 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, “greater than minimal risk” to subjects may be involved.

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

**Preliminary review:** The process performed by IRB Administrators to determine that a submission for IRB review is complete, including the required materials, copies, appropriate signatures and, that institutional requirements such as completion of human subjects protection education have been met.

**Approval Date:** The approval date is the date that the research is approved or approved with stipulations by convened or expedited review or, when modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator. The approval date is the first date that research can be performed (following notification from the IRB).

**Approval Period:** For initial review, the cycle begins on the day research is approved by convened or expedited review or, if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator. The continuing review cycle begins on the day research is re-approved (by convened or expedited review) or when
required modifications are met. **Note:** An approval period for initial or continuing review may not be longer than one year.

**Expiration Date:** The date that the IRB’s approval of research has lapsed and research can no longer be performed. **Note:** An expiration date may not be longer than one year from the date the approval period begins.


**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: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) 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 disable 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 Human Subjects research as being exempt from the regulations. While research activity in which the only involvement of human subjects will be in one or more of the specific exempt categories described below may be exempt, this category of research is not exempt from the ethical guidelines of the Belmont Report.

When information or questions of a sensitive nature are involved, exemption may not apply (additional exceptions are noted below). All requests for “exempt status” must be reviewed by an IRB Administrator before commencement of study procedures. Investigators are not authorized to make this determination. Once an IRB Administrator determines that the proposed research activity meets at least one of the exempt categories below, an "Exemption Notice" will be issued to the Principal Investigator.

Continuing review is not required for exempt research therefore, no expiration date will appear on the "Exemption Notice" however, it will specify the category under which exemption is granted, among other things. Investigators must inform the IRB when research activity has concluded for each project. In that regard, when the PI leaves the University the project must be closed or it will be administratively closed.

Categories of Exempt Research

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 paragraph (b)(2) of this section, if:
(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) 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:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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, (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.

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. IRB review is required.

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 prior to IRB approval. The information listed below includes materials that must be submitted for initial or continuing review or for review of proposed changes to previously approved research. Except as noted, submission requirements are the same for reviews performed by the convened IRB and for reviews using expedited procedures.

Initial Submission

1. A completed original IRB application with signatures of the PI, co-investigator(s) (including students) noting faculty advisor, when student projects are proposed
2. A research proposal should describe the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, data and safety monitoring plan (DSMP) and other relevant information, that may be required.

3. Informed consent document(s) and assent document, when applicable

4. Human research training verification

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

6. Copies of all instruments if the study involves the use of questionnaires, surveys, or similar instruments

7. Letters of permission or support for external sites

8. Copy of the Health & Human Services (HHS) grant application, when applicable

When the research involves more than minimal risk, all required documents should be submitted by the submission deadline for inclusion on the IRB agenda. The submission deadlines for full board meetings are published on the IRB's website at www.princeton.edu/ria

**Preliminary Review**

An IRB Administrator will perform a preliminary review of each submission to determine completeness, level of risks and the accuracy of the information submitted. The submission will be considered complete when all applicable documents are included and when the description of the proposed work provides sufficient detail to make all required determinations.

If an application is incomplete or clarifications are needed, the principal investigator will be notified by e-mail, phone or in person of missing materials, as appropriate. If no response is received within 30 days, a reminder will be sent. If no response is received within 90 days, the PI is notified that the submission will be withdrawn.

**Primary and Secondary Reviewers**

A. Once the IRB Administrator has determined that the application is complete, the submitted materials will be entered into an electronic database, assessed for exempt status, assigned to a designated reviewer for expedited review, or a primary and secondary reviewer may be selected for full board review. The IRB Administrator will take into consideration the reviewer's area of expertise, representation for vulnerable populations and potential risk levels among other things. Primary and secondary reviewer(s) are selected using the IRB roster and an assessment of their qualifications and experience documented in their Curriculum Vitae or resume.

B. A designated reviewer will be assigned to each protocol and may be assigned to several protocols simultaneously. When the IRB is presented with a protocol which may be outside of the knowledge base or representative capacity of all of the IRB members, an outside consultant may be sought. Protocols for which appropriate expertise cannot be obtained for a given IRB meeting will be deferred to a future meeting when appropriate expertise can be
The primary and secondary reviewers are responsible for:

1. Having a thorough knowledge of the details of the proposed research,
2. Performing an in-depth review of the proposed research,
3. Leading the discussion of the proposed research at the convened meeting, presenting both positive and negative aspects of the research, leading the IRB through the regulatory criteria for approval and,
4. Recommending one of the actions noted below or suggestions for changes to the proposed research to secure approval, when necessary.

D. If both the primary and secondary reviewers are absent from the meeting, a new reviewer may be assigned, providing the new reviewer has reviewed the materials in sufficient time to provide meaningful comments. Additionally, an absent reviewer can submit their written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting, who can serve as the primary reviewer.

Pre-Meeting Distribution of Documents

The IRB Administrator will prepare and distribute protocol information to members at least 7-10 days before each convened meeting. There may be exceptions when an emergency meeting is necessary. In those cases, the board members will receive the materials at least the day before the meeting.

The primary and secondary reviewers are expected to review all materials for their assigned protocol(s). IRB members who are not assigned as primary or secondary reviewers are expected to review at least the application, protocol and consent forms for research studies being considered at the meeting but, of course, may review all submitted materials specified above:

Materials received by the IRB

Reviewer(s) and IRB Administrators from among the IRB membership will receive and review any relevant applications and associated documents, including the grant applications, when applicable. Any IRB member may request material provided to the primary and secondary reviewers by contacting the IRB Office.

The primary reviewers will document their review and assessment of the research by completing a Reviewer Sheet and submitting it to an IRB Administrator prior to or at the conclusion of the convened IRB meeting.

Expedited Review Procedures

Princeton IRB uses the expedited review procedure to review both of the following:

1. some or all of the 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 and,
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 may not 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 expedited review procedure may not be used for classified research involving human subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or convened utilized by the IRB.

Research Categories one (1) through seven (7) pertain to both initial and continuing IRB review:

(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, 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. [Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."] [45 CFR 46.402(a)]

(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 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 non-research purposes (such as medical treatment or diagnosis). [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 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 DHHS regulations for the protection of human subjects. See Exempt Categories and 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 as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

Please note: category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

If research activities involve multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

(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.

[Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (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. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

The protocol number, title, PI name, and the category of research for which each protocol that was approved using an expedited review procedure will be reported to the IRB at the next scheduled meeting.

Possible Actions after Expedited Review

When reviewing proposed research activities using expedited procedures, IRB reviewers may take one of the following actions:
An expedited reviewer can also request additional information and/or clarification from the investigator before taking one of the above actions.

**Presentation and Discussion of Protocols at Full Board Meetings**

To be properly presented and discussed at a full board meeting, a quorum of the members (which must include a non-scientist and a prisoner representative if research including prisoners is discussed) must be present for the entire presentation, discussion, and deliberation. 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 non-scientist member), the IRB may not take further actions or votes unless the quorum can be restored.

Members not present for a substantial part of the discussion and deliberations should abstain from voting. For those protocols undergoing initial review, the following are discussed in detail (this list is not all-inclusive):

1. The above mentioned regulatory criteria for approval at 45 CFR 46.111 are met.
2. Consent Requirements including whether requirements for a waiver of documentation is met.
3. The setting in which the research occurs
4. The scientific and ethical justification for including vulnerable populations (children, prisoners, pregnant women, fetuses, decisionally impaired adults), if applicable
5. Analysis of the procedures to minimize risk.
6. The procedures to be used to ensure protection of subject privacy and data confidentiality
7. The scientific qualifications and experience of the investigators and their research staff
8. The human subjects protection training of the investigators and their research staff
9. Potential or disclosed investigator conflict of interest

**Possible IRB Actions at a convened IRB meeting:**

**Approved:** Research activities may commence without conditions.

**Conditional Approval** (Modifications required to secure approval): An IRB action that
specifies conditions that requires satisfactory resolution before research can be approved.

**Approved with Stipulation:** An IRB action taken when the required determinations allows research involving human subjects to proceed pending resolution of a non-significant condition that does not affect the approval determination. This type of stipulation does not prohibit the initiation of research activity however, the condition(s) must be met.

**Deferred:** An IRB action taken when the IRB cannot fully evaluate the research under review and make the determinations required for approval without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research. This may also be the result of loss of quorum, lack of appropriate expertise or administrative issue. **Note:** Convened IRB review of the investigator's response(s) is required.

**Disapproved:** An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document. **Note:** Research cannot be disapproved by expedited review.

**Tabled:** An IRB action that indicates that significant substantive revisions are necessary and the review could not be completed, resulting in postponement of further IRB review. **Note:** Convened IRB review of the investigator's response(s) is required.

**Review of Investigator Responses**

A. When expedited reviewer(s) require modifications to research, investigators' responses will be reviewed to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this subsequent review/verification may be performed by the IRB Chair, one or more IRB members, a consultant with specific expertise, and/or qualified IRB Administrator (who may or may not be IRB members).

B. When substantial revisions are necessary, the board may require verification by a subcommittee, by full committee or by the initial reviewers that resolution of conditions are satisfactory.

C. When it is unclear whether the conditions for approval have been satisfied the review will be forwarded to the IRB Chairs, Vice-Chairs or a subcommittee, as appropriate. When the conditions for approval are not met, the submission may be referred to the convened IRBs for review (i.e., research cannot be disapproved except by convened review).

**IRB Approval Period**

A. The IRB may approve research for a period of up to one year. The initial and continuing review approval period for a study is determined as described below.

B. For initial review, the date that research is approved, or if modifications are required to secure approval, the date that the modifications/conditions are met by the investigator is the “start date” for the approval period.

- For example, if modifications were required for a study reviewed by the convened
IRB on May 1, 2011, and the required modifications/conditions were met by the investigator on May 15, 2011, the maximum approval period begins May 15, 2011, and ends May 14, 2012.

In the example above, the first date that the research can be performed (assuming that notification from the IRB is received) is May 15, 2011.

Length of Approval Period

The IRB will determine the interval for the continuing review of the research, appropriate to the degree of risks that will be experienced by research participants. The interval for continuing review will be at least once per year but may be shorter.

The following conditions are likely to require review more often than annually:

1. There is a high degree of risk to subjects
2. The stage of research is such that many of the risks are unknown
3. The proposed procedures have not been used in humans
4. There have been confirmed instances of serious or continuing noncompliance
5. An IRB member believes more frequent review is required

Communication of IRB Actions

A. After the IRB Chair (or designees) approves the minutes which reflect risk determination, approval period (review interval) and other actions of the convened IRB meetings, IRB Administrators prepare notification letters to inform investigators of IRB actions. Note: Approval letters may be sent prior to completion of the meeting minutes, when appropriate.

B. Notification letters include (minimally) the following information:

- Date of review
- Type of submission reviewed (e.g., initial review, exempt review, continuing review, or review of amendments to previously approved research)
- IRB action and review category
- Approval and expiration date (when applicable)
- Any associated approvals requiring specific regulatory findings (e.g., waiver of the requirement for obtaining informed consent), when applicable
- For Initial or Modifications, additional required clarifications, or other conditions that must be satisfied by the investigator, if any, for IRB approval
- Any stipulations that must be submitted for IRB records
- For research that is deferred, a statement of the reasons for deferral and a description of how the investigator can respond
For research that is disapproved, a statement of the reasons for disapproval and a description of how the investigator can respond.

**The Institutional Official (Dean for Research) will receive a copy of the approved minutes.**

**Retention of IRB Records**

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

**References**


**Version History**

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<td>Added exempt research, regulatory background &amp; retention of IRB records.</td>
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