Human Research Protection Program Departmental Policy and Procedure

2.1 Initial Review of Research

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: September 3, 2026

I. Policy Statement

a. The IRBs must receive sufficient information from investigators to provide adequate review of proposed research and to make the determinations required by regulations for IRB approval. This policy describes the submission requirements and initial review process for research requiring IRB review.

b. UTSW will apply the revised Common Rule only to research approved after January 21, 2019, unless it is determined that a study approved prior do this date, may be transitioned to the revised Common Rule.

c. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the UT Southwestern IRB does not require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.

d. In order to approve research, the IRB shall determine that all required determinations of approval (45 CFR §46.111) are satisfied. For certain exempt categories (2iii, 3i, 7, and 8), limited IRB review will ensure that 45 CFR §46.111(a)(7) has been met.

II. Scope

a. This policy and procedure applies to all on-going and future human participant research projects conducted by UT Southwestern Medical Center (UTSW) faculty, staff, or students or by anyone conducting a research activity supported by UTSW or its affiliates.

III. Procedures For Policy Implementation

a. Submission and Screening

i. The Principal Investigator (PI) or designee creates the study and the PI or designee completes the IRB application for initial IRB review (details available on the HRPP website).

ii. The PI indicates in the application what review type may be appropriate. The IRB makes the final determination regarding the appropriate review type.

iii. The PI submits a completed application to the Human Research Protection Program Department (HRPPD). Instructions for preparing the application are available on the HRPPD website. The investigator may contact the HRPPD staff with questions.

iv. Upon receipt of the application, the HRPPD staff screen for completeness and accuracy and make a preliminary determination as to whether the application meets the applicability criteria for expedited review including minimal risk and the expedited review categories. If the application was submitted for expedited review but does not meet the criteria for expedited review, the HRPPD staff consult with one of the HRPPD expedited reviewers or IRB Chair to make the final determination whether the study is eligible for expedited review. If appropriate, the HRPPD staff will advise the PI to submit the revised application materials for convened IRB or exempt review.

v. The HRPPD conducts a comprehensive Administrative Pre-review (see 1.1. Receiving, Routing, And Administrative Review Of IRB Submissions)

vi. After completing application screening, the HRPPD staff forwards the application to the appropriate reviewer(s).

b. Assigning Reviewers

i. Convened IRB Reviewers

1. The comprehensive pre-review allows the HRPPD staff to make reviewer assignments based on study's scientific or clinical focus area, significant ethical or regulatory issues, or issues related to local context of research (e.g., cultural issues). The HRPPD staff assigns a primary reviewer to each new study based on the IRB member's educational background, experience and expertise. For research requiring expertise in multiple areas of science or ethics, additional reviewers may be assigned as determined by the HRPPD staff, Institutional Review Board Director (IRBD), or IRB Chair. Reviewers may request the HRPPD to provide additional expertise as well.
2. Information on each IRB member's earned degrees, scientific status, representative capacity (e.g., knowledge related to children, pregnant women, prisoners, economically disadvantaged, educationally disadvantaged, cognitively impaired adults or students), and indicators of experience (e.g., scientific and clinical experience, certifications, licensure, etc.) are maintained in the HRPPD membership spreadsheet.
3. In selecting reviewers (for either scientific/ethical pre-review or final review), at least one person must have appropriate scientific or scholarly expertise.
4. If a reviewer with appropriate expertise is not available, the research will be scheduled for a future meeting when a reviewer is available. This determination may be made by the IRB Chair/Alternate Chair or the IRBD.
5. If additional expertise is needed, the IRB reviewer may request the assistance of an ad hoc or cultural consultant as described below.

ii. Expedited Reviewers

1. HRPPD Expedited Reviewers - HRPPD staff includes several

experienced IRB members that serve on all UTSW IRBs in the Regulatory Specialist position. These individuals include the IRBD and other senior regulatory staff. These HRPPD staff/IRB members by their education and experience are designated as expedited reviewers by the IRB Chairs.

2. IRB Chairs and IRB member expedited reviewers - The IRB Chairs and other experienced board members may also serve as expedited reviewers. The Chairs or other experienced members are often called on to perform expedited initial review when the HRPPD expedited reviewers have a conflict of interest, do not have the expertise to complete the review, or when the HRPPD reviewer requests assistance or another opinion on the research. Members must meet the definition of experienced by: serving as an IRB member for at least 1 year; holding a CIP certification; or has 1 year of work experience within the HRPPD.
3. In reviewing new research applications, the expedited reviewer considers whether they have the appropriate scientific or scholarly expertise. Given that all research eligible for expedited review must be minimal risk, the nature of the typical type of research can be adequately understood by most reviewers with appropriate experience.
4. The reviewer assigned to a specific study may consult with other expedited reviewers in the HRPPD, the IRB Chairs or experienced IRB members to ensure the protocol receives an appropriate scientific and scholarly review. In addition, the expedited reviewer(s) may consult with members of other research related committees, UTSW schools or affiliated institutions.
5. If a reviewer with appropriate expertise is not available, the research will not be approved until one is available or the study can be scheduled for a future convened meeting of the IRB.

6. If additional expertise is needed, the IRB reviewer may request the assistance of an ad hoc or cultural consultant as described below.

iii. Ad hoc Scientific or Cultural Consultants

1. Ad hoc scientific or cultural consultants with appropriate expertise may be asked to participate in the pre-review and/or IRB review process (expedited or convened). Ad hoc scientific or cultural consultants are generally recruited from the membership of other UTSW IRBs, UTSW schools or affiliated institutions.
2. HRPPD staff may ask an ad hoc or cultural consultant who has appropriate expertise in the discipline or with non-English speaking populations or locations to participate in the review.
3. The HRPPD maintains a list of potential cultural consultants qualified by cultural and/or linguistic knowledge or training to assist the IRB, as appropriate, and may also contact IRB members, UTSW faculty, or department chairs for advice in identifying appropriate scientific/clinical consultants.
4. The PI may also recommend cultural consultants provided that they are not directly involved in the study. These consultants may review consent forms, provide verifications of translated documents, provide guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted.
5. When initially contacting the potential ad hoc or cultural consultants, the HRPPD staff query the individual about possible sources of conflict of interest in accordance with the 6.4 IRB Member And Consultant Conflict Of Interest.

c. IRB Review Process

i. Documents available to review: IRB reviewers (Convened IRB Reviewers

and Expedited Reviewers) receive access to all application documents such as:

1. IRB application with research description;
2. Informed consent/assent process and forms combined with HIPAA Authorization language, including waiver requests, NIH sponsored sample consent documents (if applicable), translated consent document for non-English speaking subjects;
3. Informed consent or HIPAA Authorization waiver forms;
4. Additional materials, including advertisements, proposed data instruments (e.g., case report forms (CRF), data collection log, etc.), materials/letters for off-site research, information contained in the IRB application on the use of Investigational New Drug (IND) or use of approved drugs for unapproved use, or use of radioactive materials;
5. Vulnerable populations, including forms for research involving decisionally impaired individuals, pregnant women, fetuses and/or neonates, prisoners, or children;
6. Miscellaneous forms (as applicable) including grant application, and conflict of interest management plans;
7. Other required committee/review approvals (as applicable) – Radiation Safety Office (RSO) approval, Institutional Biosafety Committee (IBC) approval, etc.

ii. Convened IRB Review

1. The IRB conducts initial review for non-exempt human subjects' research at convened meetings unless a designated member of the IRB determines the research may be eligible for expedited initial review. Review by the convened IRB will be referred to as either "full review" or "full board review". See the procedures for conducting a

convened meeting, the definition of quorum, and the requirements for conducting a full review meeting in the 6.3 Conduct Of Full Board Meetings.

2. The Human Research Protection Program Department (HRPPD) and the IRB members perform a review of submission packages prior to the scheduled meeting. The HRPPD staff performs a screening to identify errors or omissions in the application and an identification of the regulatory issues as part of pre-review. IRB members may perform a targeted review to identify significant scientific and ethical issues during the “Scientific/Ethical Pre-review”. The findings of both pre-review processes are communicated to the investigator to allow corrections, clarifications and communication. The application is corrected/revised as necessary and scheduled for review by the full board.

3. All studies requiring convened IRB review may go through a two-step IRB review process. The first step is the scientific and ethical pre-review which occurs at the same time as the administrative pre-review. The purpose of this review is to identify scientific or ethical issues prior to review by the convened IRB. The second step is the convened IRB review.

iii. Targeted Scientific and Ethical Pre-Review

1. The HRPPD staff may decide to make a copy of the initial application available to one or more IRB member or consultant reviewers (when applicable) to complete the Targeted Scientific and Ethical Pre-review.

2. The Scientific and Ethical Pre-review is a joint effort by all assigned reviewers. The review is limited to specific concerns identified during the initial administrative pre- review related to substantive scientific and ethical/human subject protection issues, including those in both the protocol and informed consent document. Substantive issues are

those directly relevant to the seven determinations required for IRB approval (45 CFR 46.111 and/or 21 CFR 56.111, e.g., risks to subjects are minimized).

3. The reviewers are encouraged to communicate comments, questions or clarifications to the PI during the pre-review period. Once the review and communication process has been completed, a summary of the substantive issues identified by the reviewers is documented in an email from the primary reviewer to the HRPPD.

4. The substantive issues should be addressed prior to convened IRB review by making appropriate corrections, additions or clarifications to the submission package. The targeted scientific and ethical pre-review comments and responses are included in the package reviewed at the convened meeting.

iv. Review by the Convened IRB

1. The UTSW has designated four IRBs operated by UTSW to review nonexempt human research conducted under its Federalwide Assurance (FWA). Initial review of research may be performed by any of the designated IRBs.

2. The IRB reviews each initial full review application. The IRB may contact the PI or sub- investigator by phone during the convened meeting or ask the individual to attend the meeting if additional information is needed. The IRB reviews the application and discusses any controverted issues and their resolution prior to voting.

3. During discussion, the IRB members raise only those issues that the committee determines do not meet the federal criteria for approval as specified in 45 CFR 46.111, and 21 CFR 56.111, further discussed in 6.2 IRB Approval Of Research. In addition, the IRB determines the overall risk level for the study. Also, the IRB considers whether the PI's

preliminary assessment of federally mandated specific findings requirements (e.g., request for waiver of informed consent) is acceptable with respect to meeting federal requirements.

4. For research involving drug(s) or evaluating the safety or effectiveness of a device where the PI has not obtained an IND or IDE, the committee determines what action(s) is needed (whether the PI needs to get an IND/IDE or whether PI needs to contact the Food and Drug Administration [FDA] for guidance).
5. In conducting the initial review of the proposed research, the IRB utilizes the Full Board Reviewer Worksheet.
6. A member, ex-officio member, consultant, or others with a conflict of interest must leave the room during the vote and only participate in the review by providing information in accordance with 6.4 IRB Member And Consultant Conflict Of Interest.
7. Primary Reviewer System - review of research at a convened meeting of the IRB relies on a primary reviewer system. A primary reviewer from the membership is assigned to each business item. Generally, the same reviewers who performed the Scientific and Ethical Pre-review of the research also conduct the final review at the convened meeting. The primary reviewer system does not prohibit any member of the IRB from obtaining, reviewing and providing input on any business item scheduled for a convened meeting. The primary reviewer is responsible for:
    a. Comparing the detailed grant application or industry protocol with the IRB application;
    b. Informing the full IRB of any discrepancies between the detailed protocol and the summary application materials;
    c. Determining whether the project involves a NIH multi-center clinical

trial (e.g., cooperative group trial) and, if so, comparing the “Risks” and “Alternatives” section of the NIH-approved sample informed consent document with the UTSW proposed form to ensure that the NIH and UTSW sections of the consent are consistent;

d. Reviewing management plans issued by the Conflict of Interest Office. If a disclosure is made, the reviewer will summarize the conflict and the proposed management plan to the IRB and recommend any additional requirements if necessary;

e. Reviewing the other committee review/final approvals for consistency in human subjects protection (as available);

f. Conducting an in-depth review to ensure the protocol meets the required regulatory determinations for approval (see 6.2 IRB Approval Of Research for details);

g. Presenting the study to the convened IRB during the meeting including any concerns and comments they have;

h. Considering the IRB’s comments and concerns and make the motion for IRB determination using the Full Board Reviewer Worksheet;

i. If, during the meeting, the Primary reviewer is absent and no other member is present with the appropriate scientific or scholarly expertise who conducted an in-depth review, the research will be deferred to the next convened IRB meeting. This determination will be made by the IRB Chair/Alternate Chair with the input of the members present at the time the primary reviewer is marked as absent.

8. All IRB members receive access to submission documents being presented at the meeting (including those protocols for which the IRB member is not the primary reviewer).

9. All IRB members are expected to review all documents in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.

10. Ad hoc scientific or cultural consultants may provide comments or recommendations in writing to the HRPPD prior to the meeting or attend the convened meeting to participate in the review. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant. (See 8.1 IRB Minutes).

v. Expedited IRB Review

1. The Institutional Review Board (IRB) uses an expedited review process to review studies that meet the categories adopted by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) and that involve no greater than “minimal risk”. The expedited applicability criteria, including the definition of “minimal risk”, and federally mandated categories identified below.. Expedited review procedures allow the IRB Chair, IRBD or Designee to review and approve studies that meet the criteria in the attached document without convening a meeting of the full IRB. Collectively, these individuals will be referred to as “expedited reviewers” in this document. The federally mandated categories include:

   a. Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

      i. 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.)

ii. Research on medical devices for which:

iii. An investigational device exemption application (21 CFR Part 812) is not required; or

iv. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

i. From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, 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

ii. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

c. Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

i. hair and nail clippings in a non-disfiguring manner;

ii. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

iii. permanent teeth if routine patient care indicates a need for extraction;

iv. excreta and external secretions (including sweat);

v. 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;

vi. placenta removed at delivery;

vii. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

viii. 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;

ix. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

x. sputum collected after saline mist nebulization.

d. Category 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:

i. 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 participant or an invasion of the participant’s privacy;

ii. weighing or testing sensory acuity;

iii. magnetic resonance imaging;

iv. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Category 5: Research involving materials (data, documents, records, or specimens) that:

i. Have been collected for non-research purposes (such as medical treatment or diagnosis), or

ii. 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 participants.)

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

g. Category 7: Research on individual or group characteristics or behavior including, but not limited to:

i. Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or

ii. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

2. The expedited reviewer(s) does not participate in the review of research where the reviewer has a conflict of interest (see HRPP policy on 6.4 IRB Member And Consultant Conflict Of Interest). The reviewer(s) only approves research that meets the federal criteria for approval (45 CFR 46.111 and 21 CFR 56.111) when research involves only procedures listed in one or more of the specific nine categories published in the Federal Register and further explained in 6.2 IRB Approval Of Research. In addition, the expedited reviewer(s) ensures that the informed consent process and documentation as specified in 45 CFR 46.116 and 117, 21 CFR 50.25, are carried out unless the IRB can waive the requirements in accord with federal regulations. (See 3.1. Informed Consent Requirements).
3. The expedited reviewer(s) exercises all of the authority of the IRB except that the reviewers may not disapprove the research. If an expedited reviewer is unable to approve a study, the issue may be forwarded to the convened IRB for review. Only the convened IRB may disapprove a research study as provided in the DHHS regulations.
4. The IRB agenda report for convened meetings advises the IRB of research studies approved using expedited review procedures. Any member can request to review the entire IRB file for an expedited study.
5. The expedited reviewer(s) reviews all information in the expedited review packet in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review and to be prepared to determine whether the research meets the regulatory criteria for approval.
6. The expedited reviewer(s) can determine that the research is eligible for a less stringent mechanism of review (i.e., the project is exempt from requirements for review or the activities do not meet the

definitions of human subjects research according to DHHS or FDA). In these cases, the IRB does not require a new application provided the IRB, with assistance from the HRPPD staff, documents the exempt categories or the rationale for determining that the activities do not meet the federal definitions of research, clinical investigation or human subject.

7. The expedited reviewer(s) will contact the PI and/or other qualified study team member (i.e.—Clinical Research Coordinator) for any clarification needed and documents the issue(s) discussed on the expedited reviewer worksheet. The expedited reviewer(s) may also use the Expedited Reviewer Checklist to confirm that the research meets the federal criteria for IRB approval.
8. The reviewer(s) only approves research that meets the federal criteria for approval as specified in the common rule (e.g., 45 CFR 46.111 and 21 CFR 56.111) when research involves only procedures listed in one or more of the specific categories published in the Federal Register and further explained in 6.2 IRB Approval Of Research.
9. The expedited reviewer(s) ensures that the informed consent process and documentation as specified in 45 CFR 46.116 and 117, 21 CFR 50.25, are carried out unless the IRB can waive the requirements in accord with federal regulations. (See 3.1 Informed Consent Requirements and 3.3 Informed Consent Waivers And Alterations).
10. The expedited reviewer(s) will only raise those controverted issues or request changes that they have determined do not meet the federal criteria or HRPPD policies for approval.
11. Research involving prisoners:
    a. Research involving interaction with prisoners will be reviewed by the convened IRB. A prisoner representative must be assigned to

review the research, receive all review materials provided to the primary reviewer, and participate in the convened IRB review in accordance with Policy 6.3 Conduct of Full Board Meetings. Initial review of research involving interaction with prisoners is not conducted using expedited review procedures.

b. Research involving prisoners that does not include interaction or intervention with prisoners (e.g., existing records review or analysis of existing data) may be reviewed using the expedited review procedure when the reviewer determines that the research presents no greater than minimal risk to the prisoner population being studied and otherwise meets the criteria for expedited review. Review by a prisoner representative is not required; however, the IRB Chair or designee may assign a prisoner representative to serve as a reviewer or consultant when appropriate.

12. The expedited reviewer(s) documents his/her determinations in ETHOS regarding expedited eligibility, applicable expedited category, whether the research meets the federal criteria for approval, and one of the three outcome determinations as described below. If the expedited reviewer sends a study eligible for expedited review to the convened IRB for review and the convened IRB determines that the study is more than minimal risk, the rationale will be documented (45 CFR 46.110(b)(1)(i)).
13. If the expedited reviewer determines that a continuing review is required, the reasoning behind requiring continuing review will be documented. This may include studies such as:
    a. Continuing review is required by other applicable regulations (e.g., FDA);

b. The research involves topics, procedures, or data that may be considered sensitive or controversial;

c. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;

d. An investigator has minimal experience in research or the research type, topic, or procedures; and/or

e. An investigator has a history of noncompliance

vi. Review of Research Documentation in the Medical Record

1. If flagging of the medical record is standard for a specific institution, the IRB may:

a. With input from the PI, alter the study title to eliminate any content that may represent an increased risk beyond that ordinarily present in the medical record.

b. Waive the requirement if identification as a participant in the study would place the participant at a greater risk of harm.

d. IRB Review Determinations – The convened IRB or IRB expedited reviewer(s) will make one of the following determinations in regard to the protocol and consent forms:

i. Approved – (Convened IRB and Expedited Review) IRB approval indicates that the convened IRB or IRB expedited reviewer(s) has concluded that the application (including the research plan and consent forms) meets the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. The investigator will receive an approval letter documenting the IRB decision. (See 8.2 Reporting Policy And Procedure)

ii. Conditional Approval – (Convened IRB and Expedited Review) IRB

conditional approval indicates that the convened IRB or IRB expedited reviewer(s) has approved the protocol pending submission of minor revisions and that the IRB has given the individual chairing the meeting (in the case of convened review) or designee the authority to approve the minor revisions which do not involve substantive issues. The HRPPD staff sends the investigator a letter describing the revisions requested by the IRB. The PI responds to revisions requested by the IRB and sends the response to the HRPPD. The Chair or designee may forward the responses to the entire IRB for additional review (return to the convened Board), request additional information from the investigator, or approve the response (see Review of Responsive Materials below).

iii. Full Board Review Required - (Expedited Review). The IRB expedited reviewer may determine that the protocol requires full review by the convened IRB.

iv. Tabled/Deferred - (Convened IRB only) A vote of tabled or deferred indicates that the IRB withholds approval pending submission of major revisions/additional information. The HRPPD staff sends the investigator a letter listing the reasons for tabling and includes a description of the revisions or clarifications requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator.

v. Disapproved – (Convened IRB only) A vote to disapprove research indicates that the IRB will not allow the research to be conducted. Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval. Disapproval generally indicates that even with major revisions to the application the issues preventing approval will not be resolved. [Examples: part or all of the research is prohibited by a law, regulation or institutional

policy; there is insufficient preliminary research to justify the proposed study; there is insufficient expertise or resources locally to safety conduct the study; the nature of the research will adversely affect the rights or welfare of the subjects]. The HRPPD staff sends the investigator a letter describing the reasons for disapproving the protocol. Investigator responses to the IRB decision to disapprove research are reviewed at a subsequent convened meeting of the IRB.

e. Length of approval: For studies approved or conditionally approved by the IRB, the IRB determines the length of approval, as appropriate to the degree of risk but not longer than one year from the meeting date that the study was approved or conditionally approved.

   i. The IRB may set a shorter approval period for:

      1. high risk protocols;
      2. protocols with high risk/low potential benefit ratios;
      3. studies involving the first use of an experimental drug or device in humans where safety data is limited;
      4. studies involving research procedures not normally reviewed by the IRB; or
      5. Any other study the IRB determines a shorter approval period and the resultant continuing review are appropriate.

   ii. The date of the meeting (convened IRB review) or date of determination (expedited IRB review) becomes the first day (start) of the approval period with the expiration date being the first date that the protocol is no longer approved. However, studies conditionally approved by the IRB may not begin until the IRB's conditions of approval (revisions) are approved by the designated IRB reviewer (final approval).

   iii. If the research is approved for one year, the expiration date is determined

to be the same date one year from the date which the IRB (or IRB expedited Reviewer) approved the protocol or conditionally approved the protocol. For example: the IRB reviews and approves a protocol without any conditions or approves a protocol with minor conditions for one year at a convened meeting on October 1, 2002. September 30, 2003 is the last day that research may be conducted under this approval. October 1, 2003 is the first day that the study approval is expired.

iv. The expiration date is the first day that research is not approved and must stop unless the study has been re-approved (see 2.2. Continuing Review Of Research).

v. For studies that are tabled/deferred due to substantive issues identified during the review at one convened meeting and subsequently reviewed and approved by another convened meeting, the approval period starts with the date of the subsequent convened IRB meeting.

vi. Concerns with IRB decision – If the PI has concerns regarding the IRB decision/recommendations for changes in the study, they may submit his/her justification for changing the IRB decision to the IRB (or IRB reviewer(s)). The PI sends the request to the expedited reviewer and/or to the IRB Chair or Vice Chair for final resolution. If the investigator is still dissatisfied with the IRB decision, HRPPD staff send the protocol to the convened IRB for review.

f. Review of Responsive Materials

i. When the convened IRB approves the study with stipulations (conditional approval)), the following procedures are followed:

1. The PI submits a response to stipulations to the HRPPD that may include the following response materials:

a. a point-by-point response detailing how each IRB stipulation was addressed;

b. If applicable, an electronic copy of each document that was revised with the changes tracked;

c. electronic copies of additional documents requested

2. The HRPPD staff review the responsive materials to confirm the package is complete. The materials are provided to the stipulation reviewer. The stipulation reviewer may be Expedited Reviewer (IRBD, IRB Chair, other IRB member designated by the IRB), or an Administrative Reviewer (HRPPD staff member who need not be IRB members and can review responsive materials so long as all of the modifications for the protocol are limited to minor changes eligible for administrative review). See Tables 1 and 2 below for examples of each review type.

3. The stipulation reviewers verify that all of the modifications to the proposal have been completed. Since the modifications to secure approval are limited to minor changes that require a simple concurrence by the investigator, the responses received are generally affirming the modification was made.

4. If a response is contrary to the IRB's stipulation, the stipulation reviewer may:

a. Accept the investigator's alternative explanation/solution;

b. Require the original modification be followed; or

c. Make no determination of approval and forward the response materials to the convened IRB that originally reviewed the study following the scheduling procedures listed in this policy.

g. Examples of stipulation responses that may be approved by Administrative reviewer (a qualified HRPPD staff member who need not be an IRB member)

i. Examples of acceptable responses

1. Additional changes to documents (after IRB review) to correct typographical errors noted by the investigator, provided that such a change does not alter the content or intent of the statement;
2. Additional administrative changes (after IRB review) from the study sponsor, provided that such a change does not alter the content or intent of the statement; (e.g., updated mailing addresses for shipping samples, revised information in the sponsor protocol that does not affect the conduct of research locally);
3. Clarification from the investigator that items of omission were actually present in the application documents reviewed by the IRB;
4. Submission of documentation of endorsement or committee approval letter
5. Addition of language specified by the IRB to the consent document or other protocol forms (i.e., add “history of seizures” to the exclusion criteria).

ii. Examples of unacceptable responses

1. Addition of new study staff, study locations, or off-site research locations;
2. Addition of new risks or safety information that will directly affect the subjects willingness to participate (e.g., new unanticipated problems involving risks);
3. Addition of new information from another institutional committee (e.g., RSO) or official that changes the information originally reviewed by the IRB or may affect the subjects’ willingness to participate;
4. Modification stipulated by the IRB is not addressed in the responsive materials;
5. Modification was based on an incorrect assumption/conclusion that is

disproved in the application documents reviewed by the IRB and completely addresses the issue; (e.g., a modification to include a permission for tissue banking to the consent, when the study will not include banking)

6. Addition of language to the consent form or other protocol documents that was not specified by the IRB and is not a minor typographical or clarification change

h. Examples of stipulation responses that may be approved by the expedited reviewer (IRBD, IRB Chair, other IRB member designated by the IRB)

i. Examples of acceptable responses

1. Clarification from the investigator that items of omission were actually present in the application documents reviewed by the IRB;
2. Modification was based on an incorrect assumption/conclusion that is disproved in the application documents reviewed by the IRB and completely addresses the issue; (e.g., a modification to include a permission for tissue banking to the consent, when the study will not include banking)
3. An alternative modification than requested by the IRB that will correct the problem completely

ii. Examples of unacceptable responses

1. Addition of new study staff, study locations, or off-site research locations;
2. Addition of new safety information that will directly affect the subjects willingness to participate (e.g., new unanticipated problems involving risks);
3. Addition of new information from another institutional committee (e.g., Radiation Safety Committee) or official that changes the information

originally reviewed by the IRB or may affect the subjects' willingness to participate

4. Modification stipulated by the IRB is not addressed in the responsive materials;
5. Modifications stipulated by another institutional committee (e.g., Radiation Safety Committee) or official that changes the information originally reviewed by the IRB or may affect the subjects willingness to participate;
6. An alternative modification that fails to address the IRB issue or could worsen the acceptability of the risks in relation to the harms;
7. Removal of a direct benefit to the subjects enrolled;
8. An alternative modification based on stipulations from another institutional committee (e.g., Protocol Review and Monitoring Committee or RSO) or official that changes the information originally reviewed by the IRB or may affect the subjects willingness to participate

IV. Definitions

a. See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects
b. 45 CFR 46: Protection Of Human Subjects
c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)
d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: June 2026; Author: HRPP; Description: Minor clarifications regarding studies that transition to exempt under the Revised Common Rule

and updated reference to ETHOS.

b. Revision Date: June 2026; Author: HRPP; Description: Minor clarifications regarding studies that transition to exempt under the Revised Common Rule and updated reference to ETHOS.

c. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

d. Revision Date: January 2019; Author: HRPP; Description: Revision to reference 2019 common rule

e. Revision Date: July 2018; Author: HRPP; Description: New policy development

f. Revision Date: March 2012; Author: IRB Office; Description: IRB written procedures