Human Research Protection Program Departmental Policy And Procedure

2.2 Continuing Review of Research

Effective Date: January 21, 2026

I. Policy Statement

a. The Institutional Review Board (IRB) conducts substantive and meaningful continuation review at intervals appropriate to the degree of risk. The research protocol must continue to satisfy the criteria set forth in 45 CFR 46.111 or 21 CFR 56.111 for the IRB to approve the protocol for continuation.

b. In accordance with federal requirements, the IRB approval period can extend no longer than one year after the start of the approval period in which the study was approved or conditionally approved. The Principal Investigator (PI) may not continue research after expiration of IRB approval; continuation is a violation of federal requirements specified in 45 CFR 46.103(a), 21 CFR 56.103(a).

c. If the IRB approval has expired, the PI must cease all research activities and may not enroll new subjects in the study after the expiration of the IRB approval.

d. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the IRB determines the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects.

e. During continuing review, the IRB determines whether the submission contains information that may indicate that a study has been modified or changed without prior IRB approval.

f. At the time of continuing review the IRB will determine whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's previous conclusion (see 6.2 IRB

APPROVAL OF RESEARCH).

g. Unless the UT Southwestern IRB determines otherwise, continuing review of research is not required for research approved on or after January 21, 2019 which meet one of the following criteria:

    i. Research eligible for expedited review in accordance with 45 CFR §46.110;

    ii. Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); or

    iii. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

        1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
        2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

h. The UT Southwestern IRB may determine and document that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine and document that continuing review is required when:

    i. Required by other applicable regulations (e.g., FDA);

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

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

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

    v. An investigator has a history of noncompliance

i. The UT Southwestern HRPP will require an annual update when

continuing review is not required for studies approved via expedited or convened board review and may close studies if the annual update is not submitted in a timely manner.

II. Scope

a. This policy and procedures applies to all Investigators, the Human Research Protection Program Department (HRPPD) and IRBs for continuing review of research submitted and approved by the convened IRB.

III. Procedures For Policy Implementation

a. Continuing Review (CR) and Annual Updates (AU) Requests, Submissions, and Screening

   i. Reminders are generated by ETHOS and automatically sent to the PI (and a coordinator, if designated) before the IRB approval period expires (e.g., approximately eight weeks, six weeks and four weeks prior to expiration). The PI is responsible for responding to those requests in a timely manner.

   ii. The PI is responsible for completing the application for CR or AU according to the instructions in ETHOS.

   iii. The PI must submit CR and AU reports (approximately one month prior to expiration) for studies as long as the research:

      1. Remains open to enroll new subjects; or

      2. Continues to carry out research procedures or interventions; or

      3. Remains active for long-term follow-up (even when the research is permanently closed to enrollment and all subjects have completed all research-related interventions); and/or

4. Requires analysis of data with identifiers; or
5. For research externally supported, the project is still being funded locally.

iv. See 1.4. Study Closure And Inactivation for details on circumstances in which a PI may close a study.

v. Upon receipt of the CR or AU materials, the HRPPD staff screen the application to determine whether the study is eligible for expedited or administrative review and to determine whether the submission is complete.

vi. HRPPD staff also screen the application to ensure compliance with selected federal requirements, such as need for prisoner representative review.

vii. If the CR or AU submission includes information to indicate changes were made without IRB approval the HRPPD staff flag the study for further analysis and consult the Institutional Review Board Director (IRBD), or IRB Chair, for guidance. The HRPPD staff may contact the investigator to clarify the statement, request submission of a report of non-compliance or other appropriate actions. If the information indicates possible noncompliance, the HRPPD staff requests submission of a reportable event and follows guidance provided in 9.3 Noncompliance Review.

viii. When the HRPPD receives the CR or AU materials, the HRPPD staff conducts a preliminary screening of the materials submitted to ensure the materials are complete and consistent with IRB requirements. The CR or AU materials are compared with the IRB's protocol records to identify inconsistent, inaccurate or omitted information. HRPPD staff makes corrections when appropriate and contacts the PI, or other study team member, for any remaining issues and asks the PI to review the changes made by HRPPD staff. Corrected reports are requested prior to

final review, if time permits.

ix. Research involving prisoners:

1. Research involving interaction with prisoners must undergo continuing review using the same procedures required for the initial review of prisoner research. The prisoner representative must review the continuing review materials and participate in the convened IRB meeting during the review. For research eligible for expedited continuing review under Expedited Category 8(b), the prisoner representative must review the continuing review materials and concur that no prisoners have been enrolled and that no additional risks have been identified since the previous IRB review.

2. Research not involving interaction with prisoners may hat was initially approved through the expedited review procedure may be conducted through the expedited review procedure when the research continues to satisfy the criteria for expedited review and continues to involve no greater than minimal risk to the prisoner population being studied. 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. Expedited continuing review will follow the same review procedures applicable to the initial review determination.

x. During screening, the HRPPD staff compares answers in the CR materials with the data in the existing ETHOS record.

xi. The HRPPD staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family

Educational Rights to Privacy Act (FERPA) concerns.

xii. The HRPPD schedule CRs for a convened meeting date (if applicable) or route to designated reviewer.

xiii. The HRPPD, IRB Chair, or designee serves as the administrative designated reviewer for AUs when continuing review is not required as per I.G above.

xiv. The HRPPD staff contact ad hoc and cultural consultants regarding issues for which the IRB does not have the appropriate expertise, using the same procedures as outlined in the 2.1. INITIAL REVIEW OF RESEARCH.

xv. The HRPPD may request additional information or materials from the PI if the application is not complete or if requested by the reviewer. If the PI does not respond, HRPPD staff makes several attempts to contact the PI and/or research staff for additional information/materials, provided there is sufficient time before the end of the approval period.

xvi. If the HRPPD does not receive a response from the PI, the HRPPD sends the CR to the IRB. If the approval period limits the amount of time available to resolve outstanding issues, the HRPPD staff may schedule the protocol for IRB review “as is” to avoid a lapse of approval caused by further administrative procedures. The HRPPD staff forwards any applicable notes detailing the missing or incomplete materials to the IRB.

b. Continuing Review Procedures by a Convened IRB

i. UT Southwestern has designated all UT Southwestern IRBs to review non-exempt human research conducted under its Federalwide Assurance (FWA). Continuing review of research will be performed by any of the designated IRBs. The comprehensive administrative/regulatory 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).

ii. The HRPPD staff assigns a primary reviewer to each CR based on the IRB member's educational background and expertise. For research requiring expertise in multiple areas of science or ethics, additional reviewers may be assigned as determined by the HRPPD staff, IRBD or Chair. Reviewers may request the HRPPD provide additional expertise as well. Generally, the HRPPD staff make the reviewer assignments, if needed, the Regulatory Specialist, IRBD or IRB Chair may assist with this process. 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 shared drive.

iii. In selecting the reviewers, he/she must have appropriate scientific or scholarly expertise. If necessary, ad hoc or cultural consultants with appropriate expertise will be asked to participate in the pre-review and/or IRB review process. Ad hoc or cultural consultants are generally recruited from the membership of other UTSW IRBs, UTSW schools or affiliated institutions. This determination may be made by the IRB Chair/Alternate Chair or the IRBD. If, during the meeting, the Primary reviewer is absent IRB Chair/Alternate Chair/Regulatory Specialist may serve as the primary reviewer with input of the members present.

iv. Approximately 5 days prior to the meeting, the IRB members scheduled to attend the meeting receive access to the following items, but not limited to:

1. The completed CR including a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval and status report of the progress of the research;
2. Attachments (e.g., updates/changes, explanations, any relevant multi-center trial reports);
3. A copy of the current consent/assent form for which the investigator is seeking IRB re-approval;
4. Reviewer checklist.

v. All IRB members are responsible for reviewing all information in the review packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) 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.

vi. When documentation of informed consent is required, the IRB reviews the informed consent document(s) submitted for re-approval to ensure accuracy and completeness and any newly proposed consent document.

1. The IRB can observe or request observation of a research participant(s) being consented. The HRPP Regulatory Monitoring Analyst will observe and report findings back to the IRB. Protocols selected for observation may include those that involve:
    a. High risks to participants;
    b. Particularly complicated procedures or interventions;
    c. Potentially vulnerable populations (e.g., ICU patients, children);

d. Study staff with minimal experience in administering consent to potential study participants;

e. Other situations where the IRB has concerns that consent process might not be proceeding well.

vii. The HRPPD staff ensure that the complete IRB protocol record is available to all IRB members prior to and, if requested, during the convened meeting. All IRB members have the opportunity to discuss each research protocol during the convened meeting.

viii. The convened IRB assesses the CR materials using the federal criteria for approval (45 CFR 46.111, 21 CFR 56.111) (See 6.2 IRB Approval Of Research).

ix. When the IRB reviews research that involves categories of subjects vulnerable to coercion or undue influence, the HRPPD staff ensures that adequate representation or consultation is present for discussions of research involving vulnerable human subjects (6.2 IRB Approval Of Research).

x. The IRB/HRPPD staff conducts the convened meeting in accordance with 6.3 Conduct Of Full Board Meetings. Members who have a conflict of interest follow procedures outlined in both 6.3 Conduct Of Full Board Meetings and 6.4 IRB Member And Consultant Conflict Of Interest.

xi. The HRPPD staff serves as intermediaries between the PI and the IRB primary reviewer. However, the primary reviewer may contact the PI directly for clarification. The reviewer documents the issues discussed with the PI in the CR materials.

xii. Primary Reviewer review: continuing review of research at a convened meeting of the IRB relies on a single reviewer system. A reviewer from the membership is assigned to each business item. The primary reviewer system does not prohibit any member of the Board from obtaining, reviewing and providing input on any

business item scheduled for a convened meeting. Approximately 1 week prior to the convened meeting, the HRPPD staff make the following information available to the primary reviewer for review:

1. A completed CR for each study, which includes, when applicable, the number of subjects enrolled and withdrawn from the study; summary of unanticipated problems involving risks to the subject or others; recent literature; complaints about the research; and any new, significant findings (new findings and implications for subject participation);
2. A protocol summary and status report on the progress of the research;
3. A copy of the currently approved sponsor protocol for externally sponsored research (including any prior IRB approved modifications) and/or research description (summary which addresses all elements of criteria for approval);
4. And if applicable:
    a. A cover memo if it contains pertinent information to review of protocol;
    b. Attachments (e.g., updates/changes, explanations)
    c. Summary of data safety and monitoring reports;
    d. A copy of the current consent document and if different a copy of the consent form for which the investigator is seeking IRB approval;
    e. A revised grant application;
    f. Primary Reviewer Checklist for Continuation Review;
    g. The HRPPD staff recommendations;
    h. See the CR form for a complete list of information

and attachments the PI must submit.

xiii. The reviewer is responsible for:

1. Reviewing the CR and comparing with their review of the complete IRB record including any previous reports and protocol modifications previously approved by the IRB;
2. Informing the full IRB of any discrepancies in the materials provided for CR;
3. Reviewing new disclosures of protocol related conflict of interest disclosure, alerting the IRB if a disclosure is made. If a disclosure is made, the review will summarize the conflict and proposed management plan to the IRB (if a management plan is not provided from the Conflict of Interest Committee (COIC), the reviewer will provide recommendations to manage the conflict to the IRB;
4. Conducting an in-depth review (See 6.2 IRB Approval Of Research for details);
5. Identifying information in the CR that may indicate that changes or modifications to the study have been made without the IRB's approval and should have an external reviewer verify whether any material changes have occurred. If the information indicates possible noncompliance, the IRB follows guidance provided in 9.3 Noncompliance Review.

xiv. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. The minutes of the meeting document the information provided by the consultant. (See 8.1 IRB Minutes).

xv. Primary reviewers provide recommendations to the IRB at the convened meeting on issues which they determine do not meet

the federal criteria for approval, are controverted, need additional information, or concern compliance with federal regulations, IRB approval or the UTSW human research protection program policies. If the information indicates possible noncompliance, the IRB follows guidance provided in 9.3 Noncompliance Review.

xvi. If the primary reviewer is unable to attend the meeting, the reviewer's written comments or recommendations are presented by the Chair or Regulatory Specialist to the IRB at the convened meeting.

xvii. The IRB considers each CR scheduled for full review separately for approval. At the meeting, the IRB reviews the CR report and any controverted issues and their resolution prior to voting. During discussion, the IRB members only raise those controverted issues that the IRB determines do not meet the federal criteria for approval as specified in 45 CFR 46.111, and 21 CFR 56.111. IRB approval of the CR materials documents that the IRB agrees with the PI assessment of any specific findings included in the CR report that were not previously addressed by the IRB.

xviii. The IRB ensures the PI provides any significant new findings that might relate to the subject's willingness to continue participation in accordance with regulations.

xix. The convened IRB makes the final determination on the outcome of the review. The meeting deliberations are documented in the meeting minutes.

c. Expedited Continuation Review

i. The IRB may only use expedited review procedures for continuation review (CR) under the following circumstances:

1. The study was initially eligible and continues to be eligible for expedited review procedures including;

a. Category 1: Clinical studies of drugs and medical devices
b. Category 2: Collection of blood samples
c. Category 3: Prospective collection of biological specimens by noninvasive means
d. Category 4: Collection of data through noninvasive procedures
e. Category 5: Research involving materials collected for nonresearch purposes
f. Category 6: Collection of data from voice, video, digital, or image recordings
g. Category 7: Research on individual or group characteristics or behavior, OR

2. The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects (Expedited Category 8a); OR
3. Where no subjects have been enrolled at the UTSW and no additional risks have been identified either at the UTSW or at any site if the research involves a multi-site study (Expedited Category 8b); OR
4. The only remaining research activities are limited to data analysis (Expedited Category 8c) ; OR
5. The IRB previously determined and documented at a convened meeting that the research is no greater than minimal risk (Expedited Category 9), and all of the following are true:
    a. No additional risks have been identified, and

b. If the research involves the study of drugs and/or medical devices the research:

i. Does not require an Investigational New Drug (IND) (21 CFR Part 312) and/or

ii. Does not require an Investigational Device Exemption (IDE) (21 CFR Part 812) application and/or

iii. The device is approved for marketing and being used in accordance with the approved labeling.

ii. The IRBD, IRB Chair, or designated reviewer reviews expedited CR protocols. If the individual performing expedited review has a conflict of interest (e.g., is study personnel on a protocol for continuation review), is unavailable, or does not have the appropriate expertise to review the CR, the HRPPD staff may re-assign responsibility for the CR to another Chair, Alternate Chair, or designated reviewer. If no other reviewer is available, the HRPPD staff may assign the CR to the convened IRB.

iii. The HRPPD staff provides the expedited reviewer access to the same information provided to a convened IRB including the following, but not limited to:

1. A completed CR for each study, which includes, when applicable, the number of subjects enrolled and withdrawn from the study; summary of unanticipated problems involving risks to the subject or others; recent literature; complaints about the research; and any new, significant findings (new findings and implications for subject participation described);

2. A protocol summary and status report on the progress of the research;

3. A copy of the currently approved sponsor protocol for

externally sponsored research (including any prior IRB approved modifications) and/or research description (summary which addresses all elements of criteria for approval); and

4. If applicable:
    a. A cover memo if it contains pertinent information to review of protocol;
    b. Attachments (e.g., updates/changes, explanations)
    c. Summary of data safety and monitoring reports;
    d. A copy of the consent form for which the investigator is seeking IRB approval;
    e. A revised grant application;
    f. Primary Reviewer Checklist for Continuation Review;
    g. The HRPPD staff recommendations.

iv. The designated expedited reviewer(s) is responsible for reviewing 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 determine whether the research meets the regulatory criteria for approval.

v. The designated expedited reviewer(s) is responsible for making the final determination that the protocol meets the criteria for expedited review as outlined above. If the expedited reviewer determines full review is necessary, (s)he documents this requirement in ETHOS. Upon receipt of the reviewer's recommendation, the HRPPD staff forwards the submission to the convened IRB for review.

vi. The designated expedited reviewer(s) applies the same criteria for approval as outlined above for full review (i.e., applies 45

CFR 45.111, and 21 CFR 56.111), and documents the determination in ETHOS.

vii. When documentation of informed consent is required, the expedited reviewer reviews the informed consent document(s) submitted for re-approval to ensure accuracy and completeness.

viii. The HRPPD staff serves as intermediaries between the PI and the IRB expedited reviewer. However, the expedited reviewer may contact the PI directly for clarification. The reviewer documents in the CR materials the issues discussed with the PI.

ix. The expedited reviewer documents in the CR materials any determination pertaining to specific findings, as mandated by federal regulations that were not previously addressed by the IRB. (Expedited reviewer approval of the CR materials documents that the reviewer agrees with the PI's assessment of the specific findings).

x. The expedited reviewer ensures the PI provides any significant new findings that might relate to the subject's willingness to continue participation in accordance with regulations. The reviewer uses the IRB Continuation Review Checklist as a prompt.

xi. If the approval might lapse before completion of the CR, the expedited reviewer can make a determination to allow subjects currently participating to continue in accord with procedures described in the section below on lapses of approval.

xii. HRPPD staff list expedited CRs on the Expedited Report to advise the IRB of the expedited CR approvals.

d. Administrative Review of Annual Updates

i. The HRPPD may only administratively review annual updates if the study did not require continuing review as per I.G

above.

ii. The HRPPD, IRBD, IRB Chair, or designee reviews AUs. If the individual performing administrative review has a conflict of interest (e.g., is study personnel on a protocol for annual update), is unavailable, or does not have the appropriate expertise to review the AU, the HRPPD staff may re-assign responsibility for the AU to another Chair, Alternate Chair, or designated reviewer. If no other reviewer is available, the HRPPD staff may assign the AU to the convened IRB.

iii. The HRPPD staff provides the administrative reviewer access to the following information but not limited to:

1. A completed annual update form for each study, which includes, when applicable, the number of subjects enrolled and withdrawn from the study; summary of unanticipated problems involving risks to the subject or others; recent literature; complaints about the research; and any new, significant findings (new findings and implications for subject participation described);
2. A protocol summary and status report on the progress of the research;
3. If applicable:
    a. A cover memo if it contains pertinent information to review of protocol;
    b. Attachments (e.g., updates/changes, explanations)
    c. Summary of data safety and monitoring reports;
    d. A copy of the consent form for which the investigator is seeking IRB approval;
    e. A revised grant application;

iv. The administrative reviewer(s) is responsible for reviewing all information submitted in enough depth to be familiar with the protocol, to determine whether the research is eligible for annual update, and to determine whether the research meets the

regulatory criteria for approval.

v. The administrative reviewer(s) is responsible for making the final determination that the protocol meets the criteria for annual update as outlined above. If the administrative reviewer determines expedited or full review is necessary, (s)he documents this requirement in ETHOS. Upon receipt of the reviewer's recommendation, the HRPPD staff forwards the submission to the convened IRB for review.

vi. The administrative reviewer(s) applies the same criteria for approval as outlined above for full review (i.e., applies 45 CFR 45.111, and 21 CFR 56.111), and documents the determination in ETHOS.

vii. When documentation of informed consent is required, the administrative reviewer reviews the informed consent document(s) submitted for re-approval to ensure accuracy and completeness.

viii. The administrative reviewer documents in the AU materials any determination pertaining to specific findings, as mandated by federal regulations that were not previously addressed by the IRB.

ix. The administrative reviewer ensures the PI provides any significant new findings that might relate to the subject's willingness to continue participation in accordance with regulations.

x. HRPPD staff list expedited AUs on the Expedited Report to advise the IRB of the expedited CR approvals.

e. Review Outcome(s)

i. Convened Review

1. Generally, the primary reviewer makes a motion; another member seconds the motion, and then the convened IRB votes for or against or abstains from the motion. The motion may be one of the following four actions:

a. Approved - IRB approval indicates that the IRB has concluded that the research (including the research plan and consent forms) continues to meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the information/materials submitted for continuation of the protocol and/or specific findings described in the CR report by the PI.

b. Conditional Approval – IRB conditional approval indicates that the IRB has approved the protocol for continuation. The investigator must submit minor revisions or clarifications to the CR, consent, or any other applicable documents identified during the review. The submission of revisions required by the IRB must be provided within the time period specified by the IRB. Depending upon the nature of the required conditions, the IRB could designate the IRB chair, a specific IRB member with appropriate expertise, an IRB administrator, or a qualified HRPPD staff person to review the changes and determine whether the conditions of approval have been satisfied. The HRPPD staff sends the investigator a letter describing the revisions requested by the IRB.

    i. The HRPPD staff track the status of response to conditions. If a response is not received within a reasonable time period (with the exception of extenuating circumstances), the HRPPD forwards the protocol to the convened IRB. The convened IRB determines whether additional action (including suspension or termination) is appropriate.

ii. The PI responds to each of the IRB's conditions and sends the response to the HRPPD, who gives the response to the designated reviewer. 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.

c. Deferred/tabled - A vote of tabled or deferred indicates that the IRB withholds continuing approval pending submission of major revisions/additional information. The IRB considers whether the deferral of the study may result in a lapse of approval and follows the guidelines provided in that section of this policy. The HRPPD staff sends the investigator a letter listing the reasons for deferring 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.

i. The HRPPD staff track the status of response to tabling in the IRB minutes and agenda. The convened IRB determines whether additional action (including suspension or termination) is appropriate if a response is not received within a reasonable time period.

ii. The PI responds to the IRB's reasons for deferring and sends the response to the HRPPD, who prepares the item for review by the same IRB which deferred the continuing review.

d. Disapproved – A vote to disapprove research indicates that the IRB will not allow the research to continue. 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 major revisions to the application will not correct the issues preventing approval. The HRPPD staff sends the investigator a letter describing the reasons for disapproving the protocol.

2. Duration of approval

   a. 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 (unless anniversary date is used, see below).

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

      i. high risk protocols or protocols with unanticipated problems (UPIRSOs);

      ii. protocols with high risk/low potential benefit ratios;

      iii. studies involving the first use of an experimental drug or device in humans where safety data is limited;

      iv. studies involving research procedures not normally reviewed by the IRB;

      v. research with a history of noncompliance issues; or

      vi. any other study the Board determines a

shorter approval period and the resultant continuing review are appropriate.

ii. For expedited CR, the expedited reviewer may make the following determinations:

1. approved;
2. conditional approval; or
3. review by the convened Board required.
4. The expedited reviewer exercises all the authority of the IRB except the reviewer may not disapprove the CR. Only the convened IRB may disapprove the CR.
5. The expedited reviewer determines the duration of approval in the same manner as the convened review (as described above).

iii. For annual updates, the HRPPD administrative reviewer may make the following determinations:

1. Accepted – Acceptance indicates that the annual update has no issues and that the research can continue for another year. Designated Reviewer has concluded that the research (including the research plan and consent forms) continues to meet the federal criteria for approval. Designated Reviewer acceptance verifies that the Designated Reviewer agrees with the information/materials submitted for continuation of the protocol and/or specific findings described in the AU report by the PI.
2. Conditional Acceptance – Conditional acceptance indicates that the annual update has been accepted. The investigator must submit minor revisions or clarifications to the annual update, consent, or any other applicable documents identified during the review. The submission of

revisions required must be provided within the time period specified (usually about 30 days).

a. The HRPPD staff track the status of response to conditions. If a response is not received within a reasonable time period (with the exception of extenuating circumstances), the HRPPD staff forwards the status report to the Designated Reviewer for consideration of closure of the study.
b. The PI responds to each of the conditions and sends the response to the HRPPD. The Designated Reviewer may forward the responses to the IRB for additional review, request additional information from the investigator, or accept the response.

3. Defer to IRB – If significant concerns are identified during the review of a annual update, the Designated Reviewer may defer review of the annual update to the IRB (expedited or convened). The Designated Reviewer will provide the IRB with the reasons for deferring to the IRB.
4. The administrative reviewer determines the duration of approval in the same manner as the convened review (as described above).

iv. Use of anniversary dates when CR or AU is determined to occur annually – CR approved or conditionally approved (or AU accepted or conditionally accepted) for one year by either the convened board or expedited review may retain the current expiration date (day and month) as the date by which the next continuing review must occur (expiration date), if the approval/conditional approval occurs within 30 days before the IRB approval period expires. For convened review of CR, the HRPPD staff includes the approval period in the meeting minutes.

1. When CR is conditionally approved by the convened IRB, the HRPPD staff issue final approval after the IRB Chair or designee reviews and approves the PI's response.
2. When CR is tabled/deferred by the convened IRB 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.
3. Upon request, HRPPD staff also sends the PI and funding agency Certification of Approval form.

v. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns to the IRB in writing with a justification for altering the IRB decision. The IRB reviews the request using the standard IRB review procedures.

f. Lapse of Approval

i. The length of approval determined by the IRB results in an approval period (effective date and an expiration date). The expiration date is the last date of approval for the protocol. One day after the expiration date, if the IRB has not reviewed and re-approved the research, all research activities must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

ii. It is the Principal Investigator's responsibility to conduct research under a current IRB approval. The PI is responsible for planning ahead to meet the required continuing review dates and prevent a lapse in approval. The PI is also responsible for stopping

research that has lapsed unless it is in the best interest of the subjects. If research is conducted on or after the expiration date without IRB approval, the PI must submit a report of noncompliance (see 9.3 Noncompliance Review).

iii. If a PI fails to return the CR or AU or the IRB has not completed review by the end of the current approval period, the HRPPD staff promptly notifies the PI that the approval will lapse or has lapsed. The HRPPD staff will inform the PI that research must cease and no new subject enrollment may occur after the date of lapse. The HRPPD staff also inform the PI that he/she should, if appropriate, notify subjects that the study approval has lapsed and that, if applicable, it is his/her responsibility to notify the funding agency of the expiration of the IRB approval.

iv. The PI may ask the IRB for permission to allow subjects currently participating to continue due to overriding safety concerns, ethical issues, or because it is in the best interest of the individual subjects. The Board reviews the possible implications of stopping research and whether other actions should be taken to avoid a lapse in approval due to overriding safety concerns, ethical issues, or because it is in the best interest of the individual subjects. In either case, the IRB makes the final determination of whether research activities (e.g., continued administration of a study drug) may continue after the current expiration date. The HRPPD or IRB notifies the PI in writing of that determination.

v. In the case of a study was deferred and the PI is actively pursuing renewal, but he/she could not respond to the IRB request for changes before the end of the approval period, which resulted in a lapse of approval, HRPPD staff send the resubmitted materials to the same IRB that requested the changes. The IRB may subsequently approve the study for continuation.

vi. If a protocol approval has expired due to failure of the PI to submit a continuation review report or to respond to the IRB's request for

revisions and the PI subsequently submits the CR or AU materials/revisions after the study has expired, the HRPPD requests from the PI a written summary of events that occurred in the interim (if any). If the PI submitted the materials/revisions less than three months after the expiration date, HRPPD staff forward the PI's summary and the CR or AU materials/revisions to the IRB. The IRB reviews the materials/revisions following procedures outlined in this policy and may re-approve the study if no research activity has occurred after the expiration date. The new approval period will take into account the previous expiration date and not approve the study for a full year, rather the original expiration date will be used to avoid the potential for positive reinforcement for allowing a study to lapse.

vii. If a protocol approval has expired due to failure of the PI to submit a CR or AU, or respond to the IRB's request for revisions the study records may be administratively inactivated (see 1.4. Study Closure and Inactivation).

viii. A lapse of IRB approval does not constitute a suspension of approval under Food and Drug Administration and Department of Health and Human Services.

II. Definitions

See Glossary Of Human Research Terms

III. 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]

IV. Revision And Review History

a. October 2026; HRPP; Updated to Accessible Format

b. September 2026; HRPP; Added Expedited Review Categories and

clarified verification from other sources that material changes have not occurred. Updated review procedures for prisoner populations.

c. June 2026; HRPP; Updated eIRB to ETHOS

d. November 2021; HRPP; Defined expedited categories 8(a-c) and 9

e. June 2021; HRPP; Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

f. August 2021; HRPP; New Policy Development

g. March 2012; IRB Office; IRB Written Procedures