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1. **POLICY:**

In accordance with 45 CFR 46.109(e), Institutional Review Boards (IRBs) must conduct continuing review of approved research at intervals appropriate to the degree of risk. Continuing review must be substantive and meaningful. When considering whether to renew a study, the IRB revisits the same criteria used to grant initial approval. For a detailed description on review criteria, see SOP 302: Initial Review.

These policies and procedures apply to all reviewed research conducted under the jurisdiction of the Purdue University IRB.

2. **DEFINITIONS**

- 2.1** *Continuing Review* - Review of a protocol conducted for purposes of determining the appropriateness of granting continued approval and renewal.
- 2.2** *Expedited Review* - Review procedures for certain categories of research established by the Department of Health and Human Services and/or the Food and Drug Administration which do not require review by a convened quorum of the full IRB.
- 2.3** *Expedited Reviewers* - Experienced (by serving one year or more on the IRB, training by HRPP staff or a board member, or through daily job duties) reviewers who are voting IRB members assigned to conduct Expedited Review. All voting and alternate IRB members serving for one year or more on the IRB are automatically Expedited Reviewers, unless indicated to the IO by the IRB Chair.

3. **PROCEDURES**

3.1 Continuing Review Notification to Investigators

- 3.1.1** HRPP Support Staff generate a continuing review reminder notice and sends to Principal Investigators, ideally two months prior to the study's expiration date, with a due date approximately 1 month prior to current study approval expiration. The Principal Investigator is ultimately responsible for completing a Continuing Review form and submitting it to the HRPP Office for processing by the due date.
- 3.1.2** If a Continuing Review form is not submitted by the return due date, a second notice is sent to the PI along with a memo noting this is a final notice and that without return of a Continuing Review form, the protocol's approval will expire at the end of the day (11:59 p.m.) on the expiration date.

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- 3.1.3 On the protocol's expiration date, or as soon as possible thereafter, an Expiration Notice is sent to the Principal Investigator notifying him/her to cease and desist from all research activities.

3.2 Submission Requirements for Continuing Review

In order to ascertain the current status of the study, the following materials are required for submission and review:

- 3.2.1 Completed Continuing Review form;
- 3.2.2 Documented or electronic system authorization by the Principal Investigator;
- 3.2.2 A copy of the current informed consent document(s) or any newly proposed consent document(s) if enrollment is ongoing;
- 3.2.3 A copy of current recruitment material(s) or any newly proposed recruitment material(s) if enrollment is ongoing;
- 3.2.4 A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- 3.2.5 A summary of any relevant information about risks associated with the research; and
- 3.2.6 Any relevant multi-center trial reports.

3.3 Continuing Review – General Review Procedures

- 3.3.1 Beginning July 19, 2018, annual Continuing Review is no longer required by default for ongoing research originally approved through Expedited Review. This release from pre-2018 Common Rule requirements also applies to studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. However, the Purdue IRB maintains the authority to mandate Continuing Review on these protocols if necessary, for purposes of monitoring risk to participants and/or in cases of noncompliance.
- 3.3.2 No less than every (3) years, the PI will receive notification from the HRPP regarding the open study. At this time, the PI will be notified of his/her responsibilities and provided with the most up to date processes and forms. The IRB may elect to require more frequent continuing review

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as a condition of initial approval or may impose such requirement at a subsequent time.

- 3.3.3 For those studies requiring Continuing Review, HRPP Support Staff forwards a Continuing Review form and relevant materials to a Protocol Analyst or Expedited Reviewer for administrative review. Either the HRPP Support Staff or Protocol Analyst enters the submission data into the data management system.
- 3.3.4 A Protocol Analyst conducts administrative review on the submission to determine if the Investigator has submitted all of the necessary documentation and ensures that all the required elements are complete. The Protocol Analyst documents any concerns in the data management system. Once complete, the Protocol Analyst routes the submission and protocol to the IRB for review.
- 3.3.5 The continuing review submission and the protocol are reviewed by the convened IRB or an Expedited Reviewer (if necessary, for an Expedited Review). The criteria for approval of research with continuing review are the same as for initial review (see SOP 302: Initial Review). The IRB considers any significant new findings that may relate to participant's safety or willingness to continue participation.
- 3.3.6 For review of multi-center trials monitored by a Data Safety Monitoring Board, Data Monitoring Committee, other similar body, or sponsor whose responsibilities include review of adverse events, interim findings, and relevant literature, the IRB may rely on a current statement from the DSMB or sponsor indicating that it has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB.

3.4 Continuing Review – Full Board Review Procedures

- 3.4.1 For continuing review requests, a primary reviewer and a secondary reviewer are assigned to the protocol submission. The primary reviewer is responsible for conducting the continuing review, reporting his/her assessment to the convened IRB and documenting their review. The secondary reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB and, in the event the primary reviewer cannot fulfill his/her responsibilities, documenting their review.
- 3.4.2 Both the primary and secondary reviewers receive copies of the original continuing review request and access to the original protocol file.

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- 3.4.3 All IRB members receive a copy of the continuing review request including all submitted materials and, as needed access to the original protocol file.

3.5 Lapse in Continuing Review

- 3.5.1 If an Investigator fails to provide a completed continuing review submission to the IRB, or the IRB has not reviewed and approved a research study by 11:59 p.m. on the continuing review date specified by the IRB, the current approval expires automatically and research activities including (but not limited to) recruitment, enrollment, data collection, and data analyses must stop, unless the IRB finds that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.
- 3.5.2 Such expiration of IRB approval does not need to be reported to federal regulators at the Office of Human Research Protections (OHRP) within the US Department of Health and Human Services (DHHS) as a suspension of IRB approval under DHHS regulations.
- 3.5.3 For an expired protocol to regain approved status, the IRB must conduct continuing review within 60 days of the protocol's expiration date and approve the protocol in accordance with Section 3.

3.6 Exceptions to Continuing Review Requirement

- 3.6.1 Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
- (a) The research is eligible for expedited review, as described in SOP 303: Expedited Review;
 - (b) The research was reviewed by the IRB in accordance with Limited IRB Review, as described in SOP 301: Exemption Determination; or
 - (c) The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - (i) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - (ii) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

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4. RESPONSIBILITY

HRPP Support Staff is responsible for generating Continuing Review reminder notices, Final Notices, and Expiration Notices and sending them to Principal Investigators. Additionally, HRPP Support Staff is responsible for processing of the Continuing Review form and forwarding the request to a Protocol Analyst for administrative review.

The Protocol Analyst is responsible for conducting administrative review of Continuing Review submissions and routing them to the full board for review.

The IRB Administrator in consultation with the IRB Chair and HRPP Director is responsible for establishing and implementing processes for conducting continuing review of research.

The Primary Reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB, and documenting the review on the Checklist.

The Secondary Reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB and, in the event the primary reviewer cannot fulfill his/her responsibilities, documenting the review on the Checklist.

The Institutional Official or designee is responsible for conducting further appropriate review and granting Institutional approval.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.110, 45.111

45 CFR 46.108, 46.109, 46.110, 46.111

[OHRP Guidance on Continuing Review](#)

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

204 Protocol Closure