AAH RSPP GUIDANCE

IRB approval dates and Expiration of Approval

PURPOSE
The purpose of this document is to outline how IRB approval and expiration of IRB approval is calculated. The guidance also outlines the consequences of a lapse in IRB approval.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE

What is the effective date of IRB approval?

The Effective Date of IRB Approval

Whenever the IRB approves a research study with one or more conditions at the time of initial review, the effective date of the initial approval is the date on which the IRB chairperson (or any other individual(s) designated by the IRB) has reviewed and accepted as satisfactory any revised protocol or informed consent documents or any other responsive materials required by the IRB from the investigator. [See OHRP Guidance: Approval of Research with conditions (2010), G.2]

No research activities involving human subjects may be initiated until the conditions have been satisfied in the manner set forth by the IRB and the approval becomes effective.

If the IRB approves a research study as submitted without conditions, the effective date of IRB approval becomes the date of the IRB meeting or expedited review.

How is the Expiration Date calculated?

Convened board studies. The expiration date is no greater than one year from the date of the IRB meeting at which the research study was approved as submitted or approved with conditions. [See OHRP Guidance: Continuing Review, 2010].

Expedited review studies. The expiration date is no greater than one year from the date of the expedited review at which the research study was approved as submitted or approved with conditions.

Therefore, the maximum allowable expiration date is calculated as one year minus one day after the date the study is reviewed (by convened board or expedited review) and approved as submitted or with conditions. Some studies may require more frequent than annual review. This will be determined by the IRB.

IRB approval of a study expires at 11:59 pm of the expiration date. (See more information below.)

Extensions beyond the expiration date are not allowed by regulations.
How does the IRB determine the Effective Date of Approval?
The initial approval and effective date of approval is determined in the following manner:

Protocols reviewed at a Full convened meeting:

- When a research study is approved without any conditions of approval being issued at a convened IRB meeting
  - Effective Date of Approval: the date of the committee meeting.
- When the research study is approved at a convened IRB meeting, but conditions of approval were issued by the IRB, and must be satisfied by the PI prior to issuance of IRB approval:
  - Effective Date of Approval: the date the conditions of approval were determined to be satisfied.
  - Expiration Date: Unless otherwise determined by the IRB, one year minus one day from the most recent IRB meeting date where the study was reviewed, and conditions of approval issued.

Protocols reviewed through the expedited review process:

- When a research study is reviewed by the Chair or his/her designee (Expedited Reviewer), and the research study is approved without any conditions of approval being issued:
  - Effective Date of Approval: the date that the Expedited Reviewer made his/her initial determination of approval.
  - Expiration Date (when applicable): one year minus one day after the Effective date of Approval.
- When a research study is reviewed by the Chair or his/her designee (Expedited Reviewer), and conditions of approval were issued:
  - Effective Date of Approval: the date that the Chair or his/her designee (Expedited Reviewer) determined that the conditions were satisfied.
  - Expiration Date (when applicable): Unless otherwise determined by the reviewer, one year minus one day after the Effective Date of approval.

Changes reviewed at a Full convened meeting:

- When a Change is approved at a convened meeting without any conditions of approval being issued by the IRB:
  - Effective Date of Change Approval: the date of the committee meeting.
- When a Change is approved at a convened meeting but conditions of approval are issued by the IRB:
  - Effective Date of Change Approval: the date the conditions of approval were determined to be satisfied.
NOTE the expiration date of the study does not change with approval of a modification or amendment.

Changes reviewed through the expedited review process:

- When a modification is reviewed by the Chair or his/her designee (Expedited Reviewer), and approves the project without any conditions of approval being issue:
  - **Effective Date of Change Approval**: the date that the Expedited Reviewer made his/her determination of approval

- When a modification is reviewed by the Chair or his/her designee (Expedited Reviewer), and conditions of approval were issued:
  - **Effective Date of Change Approval**: the date that the Chair or his/her designee (Expedited Reviewer) determined that the conditions were satisfied

NOTE the expiration date of the study does not change with approval of a modification or amendment.

**How is the date for second and all subsequent continuing reviews determined?**

Continuing reviews reviewed at a Full convened meeting

- The date of the convened meeting *at which the IRB conducts continuing review and approves the study (with or without conditions) becomes the Effective Date of Approval for the continuing review.*
  - Note that any conditions of approval that are issued during the IRB’s review of the continuing review must be satisfactorily met before study expiration date.

- When applicable, the new expiration date will be at least one year minus one day after the *Effective Date of Approval.*

Continuing reviews reviewed through expedited review process:

- The date that the Chair or his/her designee (Expedited Reviewer) conducts continuing review and approves the study (with or without conditions) *becomes the Effective Date of approval* for the continuing review.
  - Note that any conditions of approval that are issued during the expedited review of the continuing review must be satisfactorily met before study expiration date in order for a lapse in IRB approval not to occur.

- When applicable, the new expiration date will be at least one year minus one day after *Effective Date of Approval.*

**What if a study is not re-approved by the expiration date (lapse in IRB approval)?**

When required by federal regulations and the IRB, investigators are required to file either a continuing review application or a final report in advance of the expiration date of IRB approval.
• PIs are reminded of the need for continuing review by the IRB submission software at 60 days and 30 days prior to expiration. Attempts by RSPP staff to contact the PI may also be made.

• If no continuing review has been received by the date of expiration, the PI is notified by the IRB submission software that s/he must cease research activities at 11:59pm due to a lapse of IRB approval.
  o The PI is notified that all research activities must stop, including any research related interventions, recruitment, data collection, data sharing/reporting and analysis of data, and no new subjects may be enrolled.
  o Where subjects are patients in treatment studies, continuation of research interventions or interactions is only allowable if the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.
  o If the PI feels it necessary for any subject to continue receiving research interventions during a lapse in IRB approval, the IRB must be notified in writing of the need.
    ▪ An IRB Chair will review the request.
      ➢ If the IRB Chair considers the request to be warranted, the PI will be provided authorization to continue with the requested research interventions. NOTE that authorization to continue with research activities is not a certainty.

Lapses in IRB approval are not considered by OHRP to be a suspension or termination of IRB approval. Therefore, such expirations of IRB approval do not need to be reported to OHRP as suspensions or terminations of IRB approval under the HHS regulations at 45 CFR 46.113. However, the RSPP considers the lapse of IRB approval to represent noncompliance with the requirements of the IRB and are reviewed as noncompliance (per RSPP SOP #5 and 6). Noncompliance action will be taken in conjunction with the attempts to seek IRB re-approval.

• Repeated lapses and/or continuation of research activities during a lapse without IRB approval of the activity may represent serious and/or continuing noncompliance.

Once an IRB lapse in approval has been noted, the RSPP Office will make several attempts to contact the PI to rectify the lapse in IRB approval. Advocate Aurora Research Institute leadership and the Institutional Official will also be notified of the lapse in IRB approval. Communication attempts between the RSPP Office and the PI will be saved in the study file. The PI will be informed in writing that:

• s/he has 28 days from the IRB approval expiration date to submit the necessary continuing review or final report to the IRB.
• the 28-day period does not constitute an extension of the IRB approval period. Rather, as research activities have been halted, this period is meant to allow for continuing review or final report submissions that may be in process.
• if no continuing review or final report is received by the RSPP Office by the end of this 28 day period, action will be taken by the IRB to terminate the research at AAH.
If no correspondence/paperwork has been received from the PI after 28 days, the IRB will take action to terminate the research study. (See RSPP Guidance: Suspensions and Terminations of IRB Approval)

**REQUIREMENTS**

- Common Rule Regulations 45 CFR 46.113
- FDA Regulations: 21 CFR 56.113
- AAHRPP Accreditation Standards/Elements: II.2.E, II.2.F
- AAH System Policy: 2467
- AAH RSPP SOPs: 5, 6, 12