

Approved by IRB Executive Committee: March 11, 2009
Supersedes Document Dated: July 16, 2008, N/A (originally approved under SOP 302: Review of Submissions)
AAHRPP Element II.2.A.

POLICY

Continuing review must occur at intervals appropriate to the degree of risk, but not less than one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study. For a study approved using expedited review procedures, continuing review must occur within one (1) year from the date the IRB Chair or designated expedited reviewer gives final approval to the protocol. Determination of the length of the approval period is made by the IRB considering the degree of risk. The determination is documented in the board member checklist and if reviewed by the convened board, in the minutes. The expiration date is the last date of approval.

Review of a change in a protocol (i.e. modification or amendment) ordinarily does not alter the date by which continuing review must occur because continuing review is review of the full protocol, not simply a change to it.

PROCEDURES

1. Procedures for Assignment of Determined Expiration Date

The approval period of a study, whether during initial or continuing review is determined by the IRB. The assignment of the expiration date is based the type of review and the determination of approval period.

- 1.1. For research reviewed by a convened board, the ERICA system automatically assigns the expiration date as one day earlier in the following year than the date the convened board approves the research. The IRB coordinator is responsible for verifying the correct expiration date. If the IRB determines the study requires continuing review more frequently than annually, the IRB coordinator enters the expiration date manually in the ERICA system according to the IRB determination.
- 1.2. For research reviewed using the expedited review procedure, the ERICA system automatically assigns the expiration date as one day earlier in the following year than the date the IRB Chair or designated expedited reviewer approves the research. The IRB coordinator is responsible for verifying the correct expiration date. If the expedited reviewer determines the study requires continuing review more frequently than annually, the IRB coordinator enters the expiration date manually in the ERICA system according to the IRB determination.
- 1.3. For research which is expired and is reviewed after the expiration date, the new expiration date will be within one year from the date the study expired. The IRB coordinator is responsible for entering the expiration date manually in the ERICA system.

2. Expiration of Approved Studies

- 2.1. The IRB sends the Principal Investigator two automatic notifications from the ERICA system regarding the need to apply for continuing review prior to the expiration date. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted.
- 2.2. A continuing review form must be submitted within the ERICA online system to be reviewed by the IRB even if the continuing review cannot be conducted before the expiration date. If the Principal Investigator fails to apply for re-approval by the expiration date, the study will be administratively closed by an IRB staff member. Once the study is closed, the Principal Investigator must submit a new study application for initial review and approval if he/she wishes to continue with the study,.
- 2.3. Once IRB approval for a study expires, an expiration notice is automatically generated and sent from the ERICA online system to the Principal Investigator. The expiration notice informs the investigator the research is expired. No research activity may continue until the application for continuing review is approved by the convened IRB or, if expedited, the IRB Chair or designated expedited reviewer. The notice also informs the investigator that no new participants may be enrolled.
- 2.4. For VA research, the investigator must immediately submit a list of participants for whom stopping research activities will cause harm to the IRB Chair and report the expiration to the sponsor. The VA Research Compliance Officer receives a copy of expiration notices for studies involving the VASLCHCS and may contact the investigator for follow-up of the required actions.
- 2.5. Conducting any study-related procedures after IRB approval expires must be requested in writing to the IRB Chair for review and approval. If the IRB Chair determines that subjects participating in an expired study would suffer a hardship because research procedures/medication must be discontinued, appropriate research procedures may continue beyond the expiration date for a reasonable amount of time. For VA studies, the IRB Chair will consult with the VA Associate Chief of Staff to make such a determination. The IRB Chair will address on a case-by-case basis those rare instances where failure to enroll new subjects would seriously jeopardize the safety or well being of an individual. Prospective research data cannot be collected until a continuing review application or other progress report is reviewed and approved. The IRB Chair will notify the Investigator of the decision by way of written documentation and this documentation will be attached permanently to the continuing review report form, accessible by all IRB members. Documentation will be retained in ERICA.
- 2.6. Expiration of IRB approval does not require a report to OHRP as a suspension or termination of IRB approval.