

Approved by IRB Executive Committee: July 16, 2008  
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AAHRPP Element II.2.A.

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## **POLICY**

Continuing review must occur no 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. Expired Studies**

The IRB recognizes that not all IRB approved research protocols are reviewed prior to the expiration date. The Principal Investigator is sent two automatic notifications from the ERICA system regarding the need to apply for continuing review prior to the expiration date. Once a study expires IRB approval an expiration notification from the ERICA online system is sent to the Principal Investigator. The expiration notification states that no research activity may continue.

Conducting any study-related procedures after the study expires IRB approval must be requested in writing to the IRB Chair for review and approval. Documentation will be retained in ERICA.

- 2.1. 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.
- 2.2. If the Principal Investigator wishes to continue with the study, he/she must submit a new study application for initial review and approval.