Expired Study
January 2017

Background:
The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of the IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when the IRB approval expires.

It is the Principal Investigator's (PI) responsibility to make sure that continuing reviews are submitted to the IRB for each active Expedited or Full Board protocol. Continuing Reviews should be submitted six weeks prior to expiration of the protocol, regardless of whether or not a renewal reminder letter or notification was received from the IRB.

Q: What happens if the study expires?
When IRB approval has expired you may not do any of the following: (1) enroll or screen any new subjects, (2) perform any study interventions, unless the IRB finds that it is in the best interest of individual subjects to continue participating in research interventions or interactions, (3) collect or use, any data, and/or (4) receive or distribute any study funding.

Q: What do I do if the study has expired?
If a study expires and enrolled subjects are undergoing study interventions, the PI must contact the IRB Chair who will determine if it is in the best interest of the subject to continue participation. For VA research the PI and IRB will follow the guidelines as outlined in VHA Handbook 1200.05 and the NF/SGVHS Human Research Protection Program Procedures for the Protection of Human Subjects in Research.

Once a study expires, IRB review and re-approval must occur before re-initiation of the research occurs. The PI is given an additional 30 days from the expiration date to submit the Continuing Review/Study Closure Report.

For any expired study for which a Continuing Review or Study Closure has not been submitted to the IRB within 30 days of expiration, the project will remain permanently “expired.” The only option available at that point is to submit a Study Closure. To conduct further research on a project that has permanently expired, the PI must re-submit the project as a new study to the IRB.

Q: Does the IRB notify investigators of upcoming expiration dates?
As a service to Investigators, the myIRB electronic submission system will send email notifications to the PI and any staff with the coordinator role 90-days, 45-days, and 7-days prior to study expiration. Another notification will be sent on the day the study actually expires. The electronic system will track the recipients of these notifications.
The ultimate responsibility is on the investigator to make sure continuing reviews are submitted at least 6 weeks prior to the expiration date.