Continuing Review and Expiration of IRB Approval

When do I have to submit my Continuing Review (Renewal) to the IRB?

We encourage you to submit your renewal within the 60 to 45 day window prior to your IRB approval expiration date. CLICK HERE to see the timeline requirements for your Continuing Review (Renewal) submissions to the IRB (scroll down to the bottom). Note that the investigator will be required to submit a deviation report for a late submission.

What should I do if I have submitted an IRB application for renewal and indicated on it that we have had no new enrollment to date, but then we enroll a new participant while we are awaiting IRB approval of our renewal?

If you have submitted an IRB application for renewal and indicated on it that you have had no new enrollment to date, but then you enroll a new participant while you are awaiting IRB approval of your renewal, please notify your Board Specialist immediately.

How is the expiration date for IRB approval determined?

The initial expiration date for a study can be no more than one year from the date of initial review. For example, a study was initially reviewed on April 1, 2015; therefore, its expiration date can be no later than April 1, 2016. The IRB sets the date for expiration of IRB approval, usually based on the risk level of a study. Current regulations specify that the period of time until expiration of IRB approval may be no more than one year.

Why does the review date, but not the expiration date, vary each year?

Federal regulations allow the same anniversary date for expiration to be maintained each year provided IRB review occurs within a 30-day window prior to the most current expiration date. The review date for continuing review will vary, but will never be more than 30 days prior to the current expiration date. For example, a study will expire on April 15 each year, but can have review dates anytime between March 17 and April 15.

When does IRB Approval for my study expire?

DUHS IRB Approval expires at 12 AM on the expiration date listed on the Notification of Approval.
If the IRB Approval for my study expires, what must occur?

At the time of expiration of IRB Approval, all study activities, including ascertainment, recruitment, consent, data collection and data analysis, must cease. If you wish to continue certain activities directly related to subject safety, e-mail Sharon Ellison and Dr. Geeta Swamy to request permission to continue those activities until IRB approval is reinstated. The e-mail must contain a specific description of the activities to be continued, how those activities directly relate to subject safety, and a brief description of the subject(s) affected by these activities. The regulations make no provision for enrollment to continue during a lapse in IRB approval.