

**Expiration of IRB Approval – Policy/Procedure:
1/1/2009**

1. Investigators are responsible for maintaining active IRB approval for ongoing studies. Without active IRB approval, there can be no intervention, interaction or follow-up with enrolled research participants. There can also be no advertising, recruitment, enrollment or continued collection of data or specimens, or analysis of data or specimens that have already been collected, or use of study data. In addition, no expenditures can be charged to the study fund code, meaning that no funds may be drawn down from the payment system and no obligations may be made against research trial accounts involving human subjects at Duke sites engaged in such research for any period not covered by IRB approval.
2. Investigators must have a procedure to track the status of studies and identify when information must be provided to the IRB for continuing review or study closure. The Clinical Trials Quality Assurance Office (CTQA) will include a review of the investigator's procedure as part of their monitoring procedures.
3. The expiration date for an IRB protocol is the first date that the protocol is no longer approved. IRB approval expires at 12:00 AM on the termination date.
4. A continuing review submission or final progress report should be submitted to the IRB between 60 and 45 days prior to the expiration date of the study to ensure continued IRB approval.
5. Investigators are responsible for ensuring that either a continuing review submission or final progress report is submitted to the IRB sufficiently far enough in advance to prevent the expiration of IRB approval regardless of whether or not they receive a reminder notice from the IRB. The IRB will send reminder notices at 60, 45 and 30 days prior to expiration of IRB approval. Notices go to PI, Co-PI and Study Coordinator.
6. IRB will send reminder notices at 14 days prior to expiration of IRB approval to PI, Co-PI, Study Coordinator, with a copy to: the Senior IRB Chair, IRB Executive Director, SBR Medical Director, and SBR Lead Coordinator.
7. At expiration of IRB approval, notice is sent to PI, Co-PI, Study Coordinator, SBR Medical Director, SBR Lead Coordinator, SBR Finance Manager, Departmental Business Manager, Office of Research Administration, and Clinical Research Support Office, with a copy to: the Senior IRB Chair, IRB Executive Director, Lead Board Specialist, and a designated Senior Board Specialist. The notice instructs the research team to **STOP** enrollment and all study activities, including stopping advertising and recruitment, and follow-up with enrolled research participants, continued collection of data or specimens, or analysis of data or specimens that have already been collected or use of study data, until IRB approval has been reinstated.
8. For protocols where IRB approval expires, the IRB Chair or designee contacts the PI or other study team member to confirm no ongoing research and assist with approval to continue specific study activities if the PI believes and the IRB concurs that continued research participation during this lapse in approval would be in the best interests of individual subjects. Documentation confirming contact with the PI or other study team member will be provided to the Associate Dean for Research Support Services.

- a. SBR Lead CRC or Medical Director will contact the study PI and Study Coordinator to ensure no ongoing research. Documentation confirming contact with the PI and Study Coordinator member will be provided to the Associate Dean for Research Support Services.
 - b. **The Associate Dean for Research Support Services will contacts PI, coordinator, Department Business Manager, SBR Finance Manager and SBR Medical Director to move all salary/fringe to a faculty discretionary or departmental fund code and to track all expenses incurred while IRB approval is expired.** Documentation of the salary/fringe change will be provided to the Associate Dean for Research Support Services. Associate Dean for Research Support Services will inform the Office of Sponsored Programs of the expiration.
 - c. Once continuing review or a final progress report for the study has been reviewed and approved by the IRB the department will send the Associate Dean for Research Support Services a copy of the IRB approval and a listing, signed by the Department Business Manager and SBR Finance Manager, of all non-salary/fringe expenses incurred while IRB approval was expired with a faculty discretionary or departmental fund code for each expense or a detailed explanation of why the expense is allowable. Any non-salary/fringe expenses incurred while IRB approval was expired will be reviewed by the Associate Dean for Research Support Services, the Office of Research Administration and Research Cost Compliance to ensure expenses are assigned to an appropriate funding source.
 - d. Any salary/fringe or expense removed from a fund code due to an expired IRB approval cannot be moved back to the study fund code.
9. If IRB approval expires because a failure in the IRB process, meaning the PI followed policy and provided a complete and correct continuing review submission or final report to the IRB 60 to 45 days before expiration of IRB, then the IRB will be responsible for all salary/fringe and non-salary expenses incurred during the period the IRB approval was expired.
 10. Exceptions or appeals will be made by the Associate Dean for Research Support Services, Vice Dean for Clinical Research and Executive Vice Dean for Administration.