EXPIRATION OF IRB APPROVAL AND SUBSEQUENT NOTICE TO CEASE STUDY ACTIVITY

4/4/2021

In compliance with the federal regulations governing research with human subjects and Duke policy, all active research studies involving human subjects conducted at DUHS or by DUHS employees or agents must have ongoing DUHS IRB approval. For the purposes of this policy, an active research study is defined as a study in which any of the following study activities is occurring:

- preliminary activities:
  - advertisement
  - ascertainment for which identifiable private information is recorded for research purposes
- interaction or intervention with research participants or potential research participants:
  - recruitment
  - enrollment
  - protocol-directed intervention or interaction
  - participant follow-up
  - notification of subjects concerning their randomization status or study results
- use of identifiable private information for research purposes:
  - data analysis
  - data transmission
  - preparation of a study publication
  - internal or external audit
  - any other activity involving the use of identifiable private information for research purposes.

The expiration date for an IRB protocol is the first date that the protocol is no longer approved. When a protocol is nearing its expiration date, the Principal Investigator must submit an application for continuing review, according to the policy titled “Continuing Review”. If the IRB has not approved the protocol by 12:00 AM (midnight) on the expiration date cited on the most recent Notice of IRB Approval, IRB approval expires automatically. All study activity as described above, including recruitment of new subjects, advertisement, screening, enrollment of new subjects, conducting the consent process, interventions and/or interactions with existing subjects, the collection of identifiable private information from existing subjects, and the analysis of existing identifiable private information, must cease.

Expiration Reminder Notices

At 60, 45, and 30 days prior to the expiration date, electronic Pending Expiration of DUHS IRB Approval reminders of approaching protocol expiration will be sent through the iRIS system. The PI must submit either a continuing review submission or final progress report for closure of an IRB-approved study to the IRB between 60 and 45 days prior to the expiration date of the study to ensure continued IRB approval and to permit the IRB sufficient time to conduct a complete review before the study’s expiration.

Expiration Action Notices
At 14 days prior to expiration, if IRB approval of the Continuing Review is not complete, another electronic Pending Expiration Action Notice will be sent. If the Continuing Review Progress Report or a Final Progress Report for Closure has been submitted to the IRB, the PI must contact the IRB to resolve any outstanding issues and ensure that IRB final approval is received before expiration. If neither report has been submitted, and the PI believes that continued research participation during this lapse in approval would be in the best interests of individual subjects (such as to avoid creating an overriding safety concern or ethical issue), the PI must request this in writing to the IRB Executive Director Jody Power and the Lead IRB Chair Sharon Ellison or designees. The correspondence must contain the following:

1) A brief (2-4 sentences) description of the study
2) A description of the study activity that the PI wishes to continue until IRB approval has been reinstated, with a justification for why its continuation would be in the individual subject's best interest
3) A listing by study number of each current subject for whom continued research participation would be in the person's best interest
4) A description of the effect of the activities described in #2 above on risks and benefits to subjects
5) An explanation for why the PI failed to complete the timely renewal of the protocol, and the plan to prevent such a recurrence.

If the IRB final approval for closure or renewal has not been issued by the expiration date, after 12:00 AM (midnight) on the expiration date an electronic Notice of Expiration of DUHS IRB Approval is issued. The Vice Dean for Clinical Research or designee will also contact the PI and instruct him/her to stop all research related to the protocol. Under no circumstances may participants be enrolled into expired research unless the activity meets the criteria for emergency use of a test article in a life threatening situation without prior IRB review.

If the protocol approval lapses, the IRB may require either re-consent of affected subjects for continued study participation, or documentation of written permission from the affected subjects for use of any research data collected during the period of approval lapse, as solely determined by the IRB.

The IRB may also require that the PI submit a Protocol Deviation/Violation Report that will explain the circumstances of the approval lapse and the plan to prevent a future lapse.

This expiration of IRB approval is not reported to OHRP or FDA as a suspension or termination of IRB approval under DHHS or FDA regulation. If no written reply is received from the PI to the Notice of Expiration of DUHS IRB Approval within 60 days post-expiration date, a Notification of Study Termination is issued. The study is then permanently closed; it may not be re-opened. For any other request for changes or required modifications without PI response, a parallel process will be used.

The current content (templates) of all expiration-related notices, and the distribution list for each notice, are maintained in iRIS.

Previous Version Date(s): 8/18/2008, 2/2/2011, 2/29/2016