Standard Operating Procedures for Expired Protocols

Notifications

1. All investigators shall receive via email and/or hard copy notices of pending expiration of his/her research study approximately 90, 60, 30 days prior to the expiration date.

2. Within 30 days of expiration a letter will be sent via email and/or hard copy to the PI, all co-investigators, and the Department Chair from the Campus-IRB Director notifying them of the expiration.

3. Within 30 to 60 days of expiration a letter will be sent by the Campus IRB Director to the IRB Chair and Executive Director, HSPP1 notifying them that the study is being referred to the Executive IRB committee2. A copy of this letter will be sent to the PI, and the Depart Chair, or the Research Dean if the PI is a Dept Chair. This letter will include the deadline for submission of required documents and the Executive Committee meeting date at which the protocol will be reviewed. The date of the meeting to which investigators will be referred will be identified by determining the next deadline that provides the PI will at least 15 business days to respond.
   a. Investigators who do not submit an application for continuation or closure prior to their expiration date will be referred to the Executive Committee. The study will be reviewed by the Executive Committee for continuation or closure at the request of the principal investigator if it is received by the meeting deadline. The study will be referred for administrative termination if no application is received by the meeting deadline.
   b. Investigator submit a continuation or closure request prior to expiration, but whose protocols expire during the review process:
      i. Before assignment to an Executive Committee meeting date, a careful review of the study file will be conducted to access the timeliness of submission, the turn-around time of IRB reviews, and the amount of time IRB staff have taken to provide comments and/or other necessary materials and guidance to the investigators.
         1. In case where expiration of the protocol is due to IRB reviewer turn-around and/or IRB staff time, the protocol will not be assigned an Executive Committee review date. The file will be reviewed again for inclusion on an Executive Committee agenda in the following month if the study status is still at that time “Expired.” No notice will be generated.
         2. In cases where expiration of the protocol is due to the principal investigator’s failure to submit a response to an IRB debriefing memorandum, a notice of referral to the Executive Committee will be generated and accompanied by a copy of the outstanding debriefing memorandum. If the principal investigator does not respond to the debriefing memorandum prior to the submission deadline, the protocol will be included on the Executive
Committee agenda for administrative termination. If the principal investigator responds to the debriefing memorandum prior to the submission deadline, the protocol will be included on the Executive Committee agenda for closure or continuation at the request of the principal investigator.

c. **Investigators who have left the institution:** Following administrative closure of protocols of investigators who have been found to have left the institution, notification of the closure and referral for future follow-up will be made to the appropriate school research dean.

Any exception to these procedures will be made through special permission by the IRB Chair and/or Director.

**Executive IRB Committee Actions:**

1. The Executive IRB shall take action based on the following Categories of Expired Protocols:

   **Category 1: Unfunded minimal risk protocols – no submission of continuation application.**
   1. Protocols in this category may be voted upon as a group.
   2. Protocols will be administratively closed.
   3. Investigator is placed on probation.

   **Category 2: Funded minimal risk protocols – no submission of continuation application.**
   1. Protocols in this category may be voted upon as a group.
   2. Protocols will be administratively closed.
   3. Sponsors will be notified of protocol status.
   4. Investigator is placed on probation.

   **Category 3: Unfunded greater than minimal risk protocols – no submission of continuation application.**
   1. Protocols in this category will be voted upon individually.
   2. All these studies present greater than minimal risk to participants, the Executive Committee of the IRB will make a determination as to whether a for-cause audit will be required.
   3. Investigator is placed on probation.

   **Category 4: Funded greater than minimal risk protocols – no submission of continuation application.**
   1. Protocols in this category will be voted upon individually.
   2. As these studies present greater than minimal risk to participants, the Executive Committee of the IRB will make a determination as to whether a for-cause audit will be required.
   3. Sponsors will be notified of protocol status.
   4. Investigator is placed on probation.

   **Category 5: Unfunded minimal risk protocols with submission of continuation application.**
   1. Protocols in this category will be voted upon as a group.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. Failure to provide adequate response by the stated deadline will result in administrative closure.
4. Investigator is placed on probation.

**Category 6: Funded minimal risk protocols with submission of continuation applications.**

1. Protocols in this category will be voted upon as a group.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. Failure to provide adequate response by the stated deadline will result in administrative closure.
4. Sponsor will be notified of protocol status.
5. Investigator is placed on probation.

**Category 7: Unfunded greater than minimal risk protocols with submission of continuation application.**

1. Protocols in this category will be voted upon individually.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. All these studies present greater than minimal risk to participants, the Executive Committee of the IRB will also make a determination as to whether a for-cause audit will be required.
4. Investigator is placed on probation.

**Category 8: Funded greater than minimal risk protocols with submission of continuation application.**

1. Protocols in this category will be voted upon individually.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. All these studies present greater than minimal risk to participants, the Executive Committee of the IRB will also make a determination as to whether a for-cause audit will be required.
4. Sponsors will be notified of protocol status.
5. Investigator is placed on probation.

4. Continuing non-compliance:

An investigator who has been brought before the Executive IRB more than once for expired protocols will be considered for a determination of continuing non-compliance, subject to reporting to OHRP.

5. Exceptions may be granted by the IRB Executive Committee on a case by case basis.

**Designation of Investigator-on-probation:**
1. Implications of designation as Investigator-on-probation:
   a. Investigators-on-probation may not submit new protocols for review to Rutgers IRB or Western IRB, nor can they be added as study personnel to other existing or new protocol submissions.
   b. Investigators-on-probation may submit review requests for continuation of other protocols.
   c. IRB members who are determined to be investigators-on-probation may be suspended from membership on the IRB until they have complied with the conditions set forth to return to good-standing.

2. Steps investigators-on-probation must take to regain good standing.
   a. Investigators-on-probation must present a final report for each study that has been administratively closed by the Executive Committee of the IRB.
   b. Investigators-on-probation must present a detailed corrective action plan addressing the reasons why protocols were allowed to fall out of review and explaining what steps will be taken to prevent future occurrences.
   c. Once administratively closed by the IRB, Principal Investigators may not resume study activity on that protocol. The protocol must be submitted and reviewed as a new submission, and new approval granted prior to the initiation or continuation of research activities.