SOP 306: Post-Approval Monitoring

Terms and Abbreviations

IO: Institutional Official – individual who is legally authorized to act for the institution and ensures the effective functioning of the IRB

IRB: Institutional Review Board

IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually

Overview

The purpose of post-approval monitoring is to enhance the protection of human subjects and the oversight of approved research through reviews of ongoing research projects. The reviews will be completed to verify that IRB approved procedures are being followed. In addition, the IRB will use the results to develop researcher education and improve IRB processes/procedures/guidance.

Any active full board or expedited study involving human subjects may be selected for review. A PI will have no more than 1 study reviewed per fiscal year. Studies may be selected for review for any of the following reasons:

1. By request from a PI, SPI and/or coordinator
2. Studies that involve more than minimal risk
3. Studies involving medical devices, vulnerable populations, sensitive data
4. Studies that are Federally funded
5. Studies that were found to have non-compliance, a reportable event and/or deviation
6. Randomly selected studies

Details and Procedures

Selection and Notification

1. The IRB office will identify a study for review based on the reasons listed above.
2. The IRB office will determine who will review the study – IRB member(s) and/or IRB staff. A post-approval review event will be created in the study's IRB records system.
3. The IRB office will contact the PI via email to schedule the review. The email will include:
    a. A description of what a post-approval review is
    b. Why the study was selected
    c. How the post-approval review will be conducted and by whom

d. A reviewer checklist so the PI understands what is being reviewed
e. A list of items that will be discussed and/or reviewed:
    i. Current Study procedures and activities
    ii. Informed consent process and a review of signed consent forms (if applicable)
    iii. Visit of data collection site (if possible) to view equipment, devices, etc.
    iv. Review of subject data/records (paper and electronic)
    v. Training records of staff (if applicable)
f. A request to select a date/time/location to meet
g. A request to provide the current number of subjects enrolled

Review process

1. On the selected meeting day, the PI will be requested to provide access to study records (including, but not limited to, signed consent forms, study records/data, training records of study staff, access to equipment, etc.) and be available to answer reviewer questions.
2. The IRB will use a checklist to review study documents and procedures.
3. Throughout the meeting and with a summary at the end of the meeting, the reviewer(s) will verbally review positive observations, items that may require follow-up, and optional recommendations with PI, SPI, coordinator, etc.
4. The IRB will also review the IRB's study records in the electronic records system for completeness, accuracy, and compliance with relevant regulations and policies. This review may occur either prior to or after the on-site review, but should be completed no more than 2 weeks after the review date.
    a. Ideally this review would be completed by someone other than the original reviewer for the study. However, due to the small size of the IRB office, this will not always be possible.

Follow-up

1. The IRB will write up a summary report of observations and any corrective actions. The report will be sent to PI and filed with IRB study records.
2. If corrective actions are required, the PI will need to provide a corrective action plan by a specified date (typically within 4 weeks) to specify how issues will be resolved.
    a. The plan will specify how an item will be resolved and a target date for completion.
    b. Actions do not need to be completed by the deadline, but should be resolved in a timely manner. The IRB office staff will communicate with the PI to determine a mutually agreeable time frame.
    c. The PI's response will be filed with IRB study records.

3. After all corrective actions have been completed, the post-approval review will be considered completed/closed.
4. Post-approval review results will be reported to the IRB and the IO at IRB meetings.
5. Findings and observations from post-approval monitoring may result in new guidance, corrective actions, or training for researchers and/or IRB members. IRB office staff will create these materials and disseminate as appropriate.

References

None

Revision History

Version	Date	Summary of Changes
1	1 Feb 2022	Initial version