Post Approval Monitoring Program for the Protection of Human Subjects in Research

PI Self-Assessment: Non-Exempt Studies

Purpose:

The goal of Post-Approval Monitoring (PAM) of studies involving human subject research is to confirm by observation and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with an Institutional Review Board (IRB)-approved protocol. An additional goal of the program is to provide education to the investigators on best practices for conducting their human subject research study in compliance with their IRB-approved protocol, Iowa State University (ISU) IRB policies and guidance, and Federal regulations. The program is also designed to help investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

Preparation:

Perhaps the most effective way to prepare for a Post-Approval Monitoring visit is to carefully and objectively review your approved protocol and make sure that you and your staff are performing the research activities as described and approved by the IRB. Many variables can play into the need for adjustment in the design, procedures, etc., of your protocol. Any change to a non-exempt study must be reviewed and approved by the IRB prior to implementation. A modification may seem trivial to a researcher, but it may be of great concern to the IRB, federal regulators, funding agencies, or auditors.

The staff of the ORE is always willing to assist in answering questions, or to help facilitate modifications to your protocol. Staff can be reached at 515-294-7792 or irb@iastate.edu.

Suggested areas to examine when assessing your study:

- How many participants are currently enrolled in the study? Is the number enrolled in line with the number approved? Is a modification to add participants needed?

- Are key personnel performing duties as described and approved? Are modifications needed?

- Have there been early withdrawals from the study? Participant complaints?

- Have there been any adverse events? Were they reported?

- Who is responsible for conducting study procedures?

- Are procedures being conducted in accordance with the IRB protocol?

- Have any changes been made to the approved materials (recruitment fliers, questionnaires, interview questions, etc.)? Has IRB approval been sought prior to implementing these changes?

- Who is responsible for training study personnel on IRB-protocol specific procedures? Are records of training maintained?

- Are all research team members that have contact with participants or the participants' identified data listed as personnel on the study? Is a personnel modification needed?

- Are all personnel (i.e., PIs, Co-PIs, research staff) aware of all IRB-approved modifications?

- Is the informed consent document being used the current version? Does it have the IRB stamp?

- Are you using the IRB stamped recruitment advertisements/flyers?

- Are study records (e.g., approval letters, informed consent) maintained for 3 years after the close of the study?

- Are documents, records, and data stored as outlined in the IRB-approved protocol?

Common Findings:

Below are examples of common findings from post-approval monitoring visits:

- The IRB-approved version of the informed consent or assent document is not used.

- Dates of consent occur prior to IRB approval of study.

- Informed consent documentation problems (when applicable):

  - No real time signatures by individuals obtaining consent (missing, or postdated).

  - Signatures are illegible; this is particularly important when determining if individual giving consent for minors is authorized to do so (i.e., parent or legal guardian, not a grandma, uncle, aunt, sibling, etc.) ORE recommends "Printed Name" lines in informed consent or parental permission documents.

- The informed consent document retained by research team is not complete (i.e., only the page containing the signature is on file).

- Changes have been made to the IRB-approved survey questions or interview questions:

  - Questions have been added prior to IRB review and approval

  - Questions have been removed prior to IRB review and approval

- Recruitment methods have been changed prior to IRB review and approval

- Methods have changed (e.g., from paper versions to online versions, individual interviews to group interviews)

- Compensation plans or amounts have been changed prior to IRB review and approval

- Study Records

  - Study records are not stored as indicated

  - Persons reviewing study records that are not approved or trained to do so

If you have identified discrepancies between your current practices and those outlined in the approved protocol and these questions, please make the appropriate corrections. This may require submitting a modification to your protocol, or simply implementing better documentation practices.

Remember, the goal of Post-Approval Monitoring is not to "catch" researchers. Rather, it is designed to facilitate research by making sure it is conducted in a manner where the conditions of Federal Regulations and University Policy are met, and by assisting researchers to identify and correct any deficiencies.

Document History

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