

Post-Approval Monitoring and Education (PAM&Ed) Program for the Protection of Human Subjects in Research

Program Description

Purpose

The purpose of Iowa State University's Human Subjects Post-Approval Monitoring and Education (PAM&Ed) Program is to **promote ethical human subjects research** and to **support compliance** with relevant federal regulations, state laws, Iowa State policies, and the Institutional Review Board (IRB) approved procedures. The program serves as an internal process for proactive identification of potential compliance problems with an emphasis on education and training.

Objectives

The objectives of the Human Subjects Post-Approval Monitoring and Education (PAM&Ed) program are to provide Iowa State University, the IRB, and researchers:

- an **internal process** to confirm that human subjects research projects are conducted in accordance with Institutional Review Board (IRB)-approved protocols;
- **practical support and guidance on best practice for the conduct of human subject research** that facilitates research and optimizes compliance with the IRB-approved protocol, Iowa State IRB policies and guidance, and Federal regulations;
- **targeted researcher education** to address identified gaps;
- **a means to identify systemic educational and clarification needs** related to the conduct of human subjects;
- **identification of strengths and best practice** in the conduct of human subjects research at Iowa State.

The program is also designed to help Principal Investigators (PIs), research teams, and Iowa State in **preparation for external audits** by funding, regulatory, and accreditation agencies.

Targeted Education

Education is a primary goal of the PAM&Ed program. The one-on-one nature of the program allows for the sharing of targeted, individualized information. PIs are encouraged to ask questions throughout the monitoring process and beyond. The Post-Approval Monitor (PAM) is equipped to address questions related to IRB process, the importance of following the approved IRB-protocol, and what is expected from PIs and

their team. Additionally, the PAM may serve as a resource for investigators, sharing information and best practice ideas for conducting their human subjects research in compliance with ISU IRB policies/guidance and Federal regulations.

Roles

IRB

The purpose of the Institutional Review Board (**IRB**) is to help researchers ensure that the rights, well-being, and safety of human participants in research are protected and that research is conducted in compliance with relevant regulations, laws, and policies. Toward this end the IRB:

- **Advises** PIs in the design of research projects that minimize potential harm to participants,
- **Reviews** all planned research involving human participants prior to initiation of the research,
- **Approves** research that meets established criteria for protection of human participants, and
- **Monitors** approved research to ascertain that participants are protected.

The IRB has the authority to approve, require modifications, disapprove, suspend, or terminate human subject research activities at Iowa State. Federal Regulations explicitly grant the IRB authority to observe or have a third party observe the consent process and the research.¹

The IRB is administratively supported by the Office of Research Ethics (ORE), under the oversight of the Office of the Vice President for Research (OVPR).

Director, Office of Research Ethics (DORE)

The **Director, Office of Research Ethics (DORE)** provides oversight and management of the Human Subjects research compliance program and support to the IRB. The DORE assures that the IRB and the Institutional Official receive reports or updates on items of concern.

IRB Chair, IRB Vice-Chair, and IRB Co-Chair (Chair(s))

As part of Iowa State's PAM&Ed program, **the IRB Chair, IRB Vice-Chair, and IRB Co-Chair** in consultation with the DORE or the convened IRB committee, may determine if PAM&Ed is needed. Additionally, the IRB Chair, Vice-Chair, and Co-Chair review PAM&Ed reports in consultation with the DORE to determine if additional follow-up is needed.

Post-Approval Monitor (PAM)

The **Post-Approval Monitor (PAM)** is not a member of the IRB. The role of the PAM is to confirm through observation and documentation comparison that research activity is performed in accordance with IRB approved protocols and provide practical support and guidance for Iowa State researchers. The PAM reviews study records, observes research activity, prepares reports, provides recommendations for maintaining compliance, provides training or information on training options when needed, and assists in execution of

¹ 45 CFR 109(g)

corrective and preventative actions. The PAM also develops and delivers educational programming to the Iowa State research community.

IRB Compliance Subcommittee

A subcommittee of the IRB consisting of the IRB Chair, Co-Chair, Vice-Chair, DORE, and the PAM, reviews all finalized PAM&Ed reports. If protocol deviations or incidents of potential noncompliance are identified during the PAM&Ed process, the Subcommittee makes decisions regarding follow-up actions as outlined in the [IRB's Noncompliance policy](#).

Monitoring Types and Study Selection

All studies, including those determined to qualify for exempt status and those for which IRB oversight has been deferred to another institution, may be selected for monitoring through the PAM&Ed program.

Monitoring falls under one of three categories:

Routine Monitoring

Routine Monitoring (Not for Cause) – Studies chosen for **Routine Monitoring** are *primarily* randomly selected. However, emphasis may be placed on studies involving:

- vulnerable populations,
- deception,
- confidentiality concerns,
- waivers granted by the IRB (e.g., waiver of informed consent or waiver of documentation of informed consent),
- more than minimal risks to subjects,
- federal funding,
- Food and Drug Administration (FDA) regulation, or
- PIs with past compliance issues.

The aim of Routine Monitoring is to verify compliance, proactively identify, and if necessary, rectify potential problems. Routine Monitoring typically involves an in-depth process; however, more targeted verification (e.g., consent documentation review, observations of consent process, data security review) may occur.

Directed Monitoring

Directed Monitoring (For Cause) – **Directed Monitoring** is conducted at the request of the IRB Committee, IRB Compliance Subcommittee, IRB Chair(s), or the DORE.

Directed Monitoring is performed when:

- there are concerns regarding compliance, protocol adherence, subject safety or well-being,
- confirmation of corrective action implementation is needed,
- requested by external institutions in the context of a reliance agreement, or
- there are special circumstances as identified by the DORE.

Directed Monitoring may be limited to fact-finding related to a compliance concern, or may entail a full, in-depth review of study records, consent records, data confidentiality, file security, etc.

While Directed Monitoring is performed primarily to investigate concerns, it is hoped that PIs and their research teams come away from the process with increased knowledge and insights related to the conduct of research that prioritizes protection of human subjects and compliance with relevant regulations and policies.

PI Initiated Assessment

A PI or Supervising Investigator (SI) may also request an **PI Initiated Assessment** to aid in assuring records and procedures are in compliance with Federal regulations and Institutional policies, or to prepare for an external audit by a sponsor or federal agency. Assessments of this nature are encouraged, as an aim of the PAM&Ed program is to support researchers in meeting their obligation to conduct ethical and compliant research.

Scope

During the Routine and Directed Monitoring, the PAM verifies study procedures and practices are conducted in accord with the IRB-approved protocol.

The PAM assesses relevant study areas such as, but not limited to:

- Recruitment procedures and materials
- Screening procedures and materials
- Participant eligibility
- Informed consent process and materials
- Current enrollment
- Study procedures and materials
- Study publications
- Reports of adverse events
- Privacy and confidentiality protections including storage of documents and data
- Research subject payment
- Research team composition and training
- Study oversight by PI
- Research collaborations with non-Iowa State entities or individuals
- Drug/device documentation
- Compliance with federal, state and institution human subjects research reporting requirements (e.g. ClinicalTrials.gov, unanticipated problems)
- Compliance with any other relevant federal or state regulations or University policies and procedures as it pertains to human subjects research.

Areas of evaluation are primarily focused on those that mitigate risk to subjects and compliance with federal, state, and institutional requirements. This may include review of study records, visiting with the PI to review procedures being followed, observation of the consent process, etc. Directed Monitoring may focus on areas of concern specified by the IRB, DORE, or IRB Chair(s). The PAM may also review additional areas not specifically outlined above as applicable to the specific study context, or if they observe additional issues that

involve risk to subjects or indicate potential noncompliance. PI Initiated Assessments are primarily focused on areas identified by the PI; however, the PAM may expand the scope as needed.

The PAM does not assess unrelated areas such as personnel issues, financial management, research misconduct, etc.

Throughout the PAM&Ed process the PAM also aims to document notable best practices of the study's organization, process, and/or procedures. Noteworthy research team strengths are recognized within the report shared with the IRB.

PAM&Ed Process

Following a study's selection for Routine or Directed Monitoring, the PAM contacts the PI to schedule a meeting with PI(s) and their staff (when appropriate), making reasonable attempts to accommodate schedules. Monitoring may take place on-site or virtually via videoconference. The initial scheduling communication indicates the type of monitoring (Routine or Directed Monitoring) is and includes a copy of a "PI Self-Assessment" document to aid the PI in preparation for the meeting.

Depending on study complexity, the PAM may ask the PI to provide copies of materials used for the study (e.g., surveys, questionnaires, interview guides, informed consent forms), listing of enrolled subjects by ID (including date of enrollment), study specific data confidentiality/security materials (e.g. study policies for accessing data, staff training materials) in advance of the meeting. Prior review of these materials by the PAM allows for more a more efficient monitoring/verification process with meeting time reserved for discussion, feedback, and tailored education. In cases for which materials cannot be provided in advance, scheduling additional follow-up may be necessary.

For many studies, the PAM&Ed process can occur over the course of one meeting; however, study complexity and/or monitoring scope may necessitate additional meetings or follow-up. The PAM may seek additional information from the research team by phone or email to complete the review. Availability of records, study complexity, and emergent information impact the monitoring process and timeline.

The research team is expected to have materials used for the study records and materials available for PAM&Ed review. When monitoring is conducted remotely records may be shared electronically using secure Iowa State supported platforms (e.g., Cybox), on-site review of files, or through other methods as established with the PI.

At the conclusion of the initial PAM&Ed session, the PAM provides a preliminary summary of observations and outlines next steps. As time allows, this step may occur as part of the session or as follow-up via email. If findings warrant further review or discussion to resolve substantive issues prior to issuing the final report, the PAM may schedule a follow-up meeting.

Information Sharing and Follow-up

Significant Issues or Concerns

Uncovered issues that appear to pose an imminent risk to the safety, welfare, and/or rights of research participants or that may constitute serious noncompliance are promptly brought to the attention of the DORE or Chair(s) to determine whether immediate action is warranted to protect participants or others.

Report

Following the PAM&Ed process, the PAM prepares a written report to summarize the evaluation, recognize strengths, outline observed discrepancies (if any) from the IRB-approved protocol, and offer suggestions/recommendations for areas of improvement, including any suggested corrective actions identified during the assessment. The PI is provided an opportunity to verify report accuracy within a specified timeframe. This PI feedback is incorporated into the report. If a response is not received within the specified time, the PAM moves forward with finalizing the report. A copy of the finalized report is shared with the PI.

IRB Subcommittee Notification

The IRB Compliance Subcommittee reviews all PAM&Ed reports. The Subcommittee determines whether additional follow-up is needed. The Subcommittee directs follow-up according to the IRB policy on [IRB Review of Protocol Deviations and Noncompliance](#).

IRB Notification

The IRB Committee is informed of all PAM&Ed; however, the degree of detail shared is dependent on the type of monitoring. For Routine Monitoring and PI Initiated Assessments, the PAM shares only a brief verbal summary of the PAM&Ed during a regularly scheduled IRB meeting. The short summaries of these not-for-cause evaluations keep the IRB apprised of PAM&Ed activities and abreast of general findings. Contrastingly, the PAM shares the complete written PAM&Ed report for Directed Monitoring evaluations with the convened IRB.

Recordkeeping

A copy of the final PAM&Ed report is retained by the PAM and by ORE according to IRB record retention practices.

Document History

<i>Created/Approved:</i>	09/2009
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