جامعة نيويورك أبوظبي

NYU | ABU DHABI

Post-Approval Monitoring Program

Introduction

Post- Approval monitoring (PAM) program is an educational process that assists investigators in meeting their compliance responsibilities. The IRB will randomly select approved studies for post-approval monitoring with a special emphasis being placed on studies that include vulnerable populations or have activities that may place participants at greater risk than what may be anticipated in ordinary circumstances. Because the revised Common Rule eliminates the need for annual continuation review, the PAM would serve as a mechanism for monitoring ongoing human subjects research projects.

Elements of Review

The principal investigator (PI) will receive a notification prior to the PAM review informing them that their study has been chosen for review. The PI will then contact the Reviewer, and a time will be scheduled.

The Reviewer will review the Study Protocol prior to the PAM review and all documentation related to the research study in the IRB file including:

- Approved IRB protocol, or Grant Application, if applicable;
- The IRB File that includes IRB Meeting issues (quorum, diversity, expertise, conflict of interest); adequacy of review; related correspondence/amendments, records of adverse events, and protocol deviations submitted by the investigator.
- Whether annual continuing review was completed (if applicable).
- Elements of Informed Consent/Assent documents, as well as review of the required elements of informed consent according to the IRB requirements.
- Subsequent publications resulting from IRB approved protocols may also be reviewed.

Investigators can prepare for the PAM review by referring to the checklist of questions below. (Please note that not all items on the checklist apply to all research studies).

Types of PAM review categories and notifications

The PAM review will be based on the nature of the research study. In cases where the safety of subjects is a concern, or where the IRB specifically requests an unannounced audit, a written notification will be sent from the Office of Research. An IRB member who has experience in the study topic may also be present during the PAM reviews. Visits will be scheduled based on the following estimated timeframes:

	PAM Review	Type of study selected	Notification Period
1.	**Routine**	Studies will primarily be randomly selected by the IRB Office. In routine reviews, the IRB Office may focus on the project as a whole or select certain elements of study activities to monitor.	At least two weeks' notice in advance of the initial meeting of the PAM review.

2.	**Informed consent**	This review is intended to support researchers in conducting the informed consent process. It may include observation (when possible) of the consent process and/or a thorough review of the process including training of people obtaining consent, and review of signatures and storing.	At least one week notice in advance of the monitoring.
3.	**For-cause**	Under 45 CFR 46.113 requirements, this review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB. This would be an on-site audit that may include a review of all or any related study activities.	At least twenty-four (24) hours' notice by a telephone call and email to the PI from the Institutional Official or his/her designee.
4.	**Investigator Initiated**	A PI may request an on-site review to help keep records and procedures in compliance with federal regulations and institutional policies or to prepare for an external audit by a sponsor or federal agency.	A time will be arranged by mutual convenience.

PAM review of Informed Consent/Assent Process

Investigators can request an overview of the consent process at any time before or during initiation of a study. During a PAM review of informed consent/assent process, the IRB Reviewer will examine:

- The timing of recruitment and screening in relation to informed consent.
- The appropriateness of the person obtaining consent.
- If the consent process meets the needs of vulnerable populations.
- Steps to aid participants with barriers to understanding or lack of capacity to consent (language, reading level, etc.)
- Steps to see if the participant understands the research purpose, risks, benefits, voluntary participation, withdrawal, confidentiality, costs/compensation, and contacts for questions or injuries.

Preparing for the PAM review: Questions for PI and research study team

Below are a sample of questions that can assist the investigators to prepare for the PAM review process.

- Does the researcher have the most recently approved protocol, consent form, and study documents?
- How many participants are currently enrolled? How many have been approved by the IRB?
- Are all key personnel listed on the protocol? Are personnel conducting procedures according to their role in the study?

- Have any participants withdrawn/dropped from study? If so, why?
- Have any adverse events occurred? Were any reported to the IRB?
- Are participants consented with the most recently IRB approved version? Have all the consent forms been signed and dated by the participant and the person obtaining consent?
- Have all study measures and procedures been approved by the IRB before implementation?
- Are all study records stored as indicated in the protocol?
- Are all advertisements and methods of recruitment being used IRB-approved?
- Are study documents maintained as outlined in the protocol?
- Are participant ID numbers generated per protocol (if applicable)?
- Have all enrolled participants met eligibility criteria? Is there documentation of eligibility?
- Have there been any protocol deviations? Have they been reported to the IRB?
- Have there been any unanticipated problems with protocol implementation?
- Has participant compensation been documented?
- Have there been any participant complaints?
- Are raw data files organized, complete, and legible?

During the PAM review:

A brief meeting will be set up to discuss the study between the Reviewer and the PI. The PI should provide the Reviewer access to related study files and a quiet space. Availability of the PI or designee during the PAM review will be required to answer any questions posed by the Reviewer. Documents pertaining to research will be held strictly confidential.

Review of Regulatory Compliance may include review of:

1. Roles and responsibilities of investigators and key personnel
2. Protocol file/regulatory documentation.
3. IRB Documentation.
4. Consent/Assent Forms.
5. Individual Participant Records. A random sample to determine if:
    - The participants met the inclusion/exclusion criteria for the study.
    - Study related procedures are performed according to the protocol.
    - Study related procedures are scheduled and performed per the study timeline.
    - Data are recorded and stored securely as described in the Consent Form.

- Adverse Events have been reported according to institutional policy.
- Protocol deviations have been reported to the IRB.
- Payments were made to participants as described in the protocol.
- Participant ID numbers are assigned according to the protocol.

Further to the PAM review, a brief summary of findings that includes recommendations, educational support on record retention, documentation, and other compliance related issues will be provided to the PI by the Reviewer.

Reports of Findings

A report identifying areas of improvement and recommendations will be drafted by the IRB Reviewer and sent to the PI for his/her review and responses. A copy of the signed report will be provided to the Assistant Director, Research Ethics and Governance, the PI, and the IRB Chair. The PI will be required to respond to each indication of non-compliance listed in the report along with a plan of corrective action for each item. The responses have to be submitted within 2 weeks of the date of the report being issued.

It is anticipated that in most cases serious violations involving risk of injury to participants will have already been reported to the IRB. However, if the PAM review demonstrates serious violation involving risk of injury to participants, it will be reported immediately to the IRB Chair, Assistant Director, Research Ethics and Governance, and to the Senior Vice Provost of Research (or his/her designee).

If you have any questions regarding the PAM review process or would like to schedule a time to meet with the Post Approval Reviewer for an individual or group education session please contact the IRB Office at Tel (UAE): +971 2 628 4743 or email your queries to irbnyuad@nyu.edu.au