

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.

## 6. QUALITY ASSURANCE: POST-APPROVAL MONITORING OF APPROVED HUMAN SUBJECT RESEARCH

This Standard Operating Procedure describes the policies and procedures for the post-approval monitoring of human subjects research under the NYU HRPP Post Approval Monitoring Program (PAM).

### 6.1 PURPOSE

The purpose of post-approval monitoring of studies involving human subject research is to confirm by observation, interviews with study staff and the PI, and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with the IRB-approved protocol. Through its evaluation process, the program educates investigators on best practices for conducting their human subject research to maintain compliance with their IRB-approved protocol, NYU HRPP, and IRB policies and guidelines, and Federal regulations. The program helps investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

### 6.2 ROLES

The purpose of the IRB is to help researchers ensure that the rights and safety of human participants in their research are protected and that they conduct their research in compliance with applicable regulations. To achieve this, the IRB:

1. advises investigators in the design of research projects that minimize potential harm to participants,
2. reviews all planned research involving human participants before initiation of the research,
3. only approves research that meets established criteria for protection of human participants, and
4. monitors approved research to ensure the protection of the research participants.

The IRB has the authority to approve, require modifications in, disapprove, suspend, or terminate all human subject research activities at NYU. The IRB may determine whether post-approval monitoring is needed.

The Human Research Compliance Director (HRCO), provides oversight and management of the Post-Approval Monitoring Program (PAM) and assures that the IRB and the Institutional Official receive reports or updates on items of concern.

As part of NYU's post-approval monitoring program, the IRB Chair or IRB Vice-Chair, in consultation with the HRCO or the convened IRB committee, may determine if post-approval monitoring is needed. This type of monitoring is considered "directed." Additionally, the IRB Chair or Vice-Chair review PAM reports, and in consultation with the HRCO, determine if additional follow-up is needed.

Additionally, the IO or HRCO may determine a need for routine monitoring of specific research programs.

The role of the PAM is to meet with investigators and their teams to confirm by observation and documentation comparison that research activities comply with approved IRB protocols. The PAM reviews study records, observes research activities, prepares reports, provides recommendations for maintaining compliance, provides training or information on training options when needed, and assists in the implementation of corrective and preventative actions.

#### Categories of Monitoring Reviews:

**Routine:** The HRCO, in collaboration with the IRB Chair, may select studies to be monitored. Selection may include monitoring only some aspects of the research, such as observation of the informed consent process, study procedures, or study records.

**Informed consent:** This review is intended to support researchers in conducting the informed consent process. It may include observation of the consent process and a thorough review of the consent records. Monitoring may also include reviewing the process of how Principal Investigators train study personnel on administering consent to participants.

**Directed (For-cause Audits):** Directed reviews (for-cause audits) are not a routine compliance review and may be directed by the IRB, the Vice Provost for Research, Institutional Official, or a designee. A directed review may include but is not limited to a full study audit, a Corrective and Preventative Action Plan Assessment (CAPA), consent

form observation, or evaluation of other research activities. The following may trigger a directed review:

- Reportable new information that might affect the rights and welfare of research participants
- Any review of materials submitted via Cayuse Human Ethics (IRB)
- An allegation of non-compliance (perceived or confirmed)
- A suspension or termination of IRB approval
- Participant and employee complaints
- Whistleblower

**Investigator-Initiated:** A PI may request a 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. Reviews of this nature are encouraged, as the goal of post-approval monitoring is to assist investigators in conducting compliant research. During these PI-requested reviews, the PAM focuses on areas of improvement, and if protocol deviations are found, counsels the PI on self-reporting the issue to the IRB, along with submitting a protocol modification, if needed.

### 6.3 PROTOCOL SELECTION

All studies, even those determined to qualify for exempt status, are subject to monitoring. Studies chosen for routine monitoring are randomly selected. However, emphasis may be placed on monitoring studies involving vulnerable populations, deception, confidentiality concerns, studies with more than minimal risks to subjects, or studies conducted by investigators with past IRB concerns.

### 6.4 THE POST-APPROVAL MONITORING PROCESS

The HRCO schedules monitoring with PI(s) and their staff, making every attempt to accommodate schedules. During scheduling, the HRCO staff provides the PI with a copy of the “PI Self-Assessment” to prepare for the visit.

During the post-approval monitoring visit, the monitor compares procedures conducted in the laboratory or study area with those listed in the IRB-approved protocol and any approved modifications. The visit may include activities such as reviewing study records, visiting with the PI to review current procedures and observation of the consent process.

The monitor brings documented discrepancies between observed and approved activities to the attention of the PI. The monitor reviews and assesses areas such as, but not necessarily limited to:

- Research team composition and training
- Recruitment procedures
- Screening procedures
- Consent process
- Study procedures
- Publications from the study
- Current enrollment and verification of informed consent
- Reports of adverse events
- Storage of study documents and data
- Privacy and confidentiality issues
- Subject payment
- Questions and concerns from the PI and research team

#### Post-Approval Monitoring as a Pedagogic Vehicle

The primary goal of the post-approval monitoring program is research compliance through education. The HRCO staff can explain the IRB process, the importance of following the IRB-approved protocol, and what the HRPP expects from investigators and their team. Additionally, the HRCO staff is a resource for investigators, providing best practice ideas for conducting their human subjects research in compliance with NYU HRPP policies and educating the research team on HRPP guidance documents, policies, and Federal regulations. The HRCO staff also assists the principal investigator in identifying any protocol deviations, unanticipated problems, provides guidance for self-reporting any deviations or unapproved changes to the IRB protocol, and implementing any necessary actions, such as submitting a protocol modification.

Most potential non-compliance issues uncovered during post-approval monitoring are a result of a lack of understanding of the roles and responsibilities of individuals involved in research and inadequate training of staff. In many cases, minor discrepancies observed during PAM can be addressed through modification of an existing protocol, or reverting to procedures that were originally approved; however, more serious discoveries such as protocol deviations and unanticipated problems must be reported to the HRCD and IRB (see the process below).

## 6.6 INFORMATION SHARING AND FOLLOW-UP

Issues that pose an immediate threat to research participants or that may constitute serious non-compliance are brought to the immediate attention of the HRCD, the IRB Chair, and Vice-Chair, as needed. The monitor prepares a written report of the post-approval monitoring. The goal of this report is to outline any discrepancies from the IRB-approved protocol and offer recommendations for areas of improvement, including any required protocol modifications identified. A draft copy of the report will be shared with the PI for their comments and review. The PI reviews the report, the report is finalized, and a copy is shared with the PI for their records. The final report is then shared with the HRCD, the IRB Chair, and Vice-Chair. They review the report to determine whether additional follow-up is needed. If warranted, the HRCD, or their designee, contacts the PI to investigate any potential non-compliance found during PAM. Following this investigation, the HRCD, or their designee, prepares a report of potential non-compliance to share with the IRB. The IRB discusses both the PAM report and the potential non-compliance report (if warranted) at a convened IRB meeting.

Any determinations of non-compliance or requests for additional follow-up are made at this time. In the case of non-compliance or protocol deviations, periodic monitoring may be necessary to ensure that required corrective and precautionary actions have been taken to prevent protocol deviations in the future, or as directed by the HRCD, IRB Chair(s), and IRB as needed. HRCO staff members assist investigators, if needed, in the completion of required actions resulting from the PAM or IRB-determined corrective actions. Assistance may include guiding protocol modifications and direction to appropriate training.

## 6.7 INVESTIGATOR APPEAL PROCESS

PIs who disagree with the findings of the post-approval monitoring or required actions are invited to address these concerns with the monitor during the discussion period at the end of the visit. If the monitor and the PI cannot reach a satisfactory resolution, the PI may then contact the HRCD to discuss these issues within 30 days of the visit. Again, if no satisfactory resolution is agreed upon, the PI may address the IRB in writing within a second 30-day period.

## 6.8 POST-APPROVAL MONITORING AND RECORDKEEPING

The HRCO retains a copy of the final post-approval monitoring assessment report by attaching it to the applicable Cayuse Human Ethics (IRB) study file or files.