Guidance: Post Approval Monitoring

Overview

The mission of the Department of Human Research (DHR) Quality Assurance Program is to support the University's research enterprise by ensuring the protection of research participants; monitoring compliance with all applicable federal, state, and local laws and regulations; fostering the ethical conduct of human subject's research; and providing education and guidance to the University's researchers regarding regulatory requirements. One way in which these goals are met is by conducting ongoing oversight of human research activities.

The program aims to ensure research staff have the educational resources and guidance necessary to successfully conduct research; and provide the research community with the study support, tools, and other resources needed to perform compliant research.

Monitoring consists of a PI self-assessment followed by a site visit, either in-person or remote, by a member of the DHR team. All active human research subject protocols, including those who have IRB oversight by an external audit IRB are subject to routine monitoring. In addition, protocols closed within three (3) months of the notification may be subject to an audit.

The Principal Investigator (PI) and their research personnel must fully cooperate with all routine monitoring conducted by the DHR team. In addition, the PI must implement the appropriate corrective and preventative actions to resolve any observations and ensure that their research aligns with applicable federal regulations, state laws, and institutional policies.

Types of monitoring post-approval audits

Investigator-initiated audits

Researchers may request to schedule an audit to ensure compliance with research regulations and local policies. This is helpful in preparation for inspections or monitoring by federal agencies or sponsors, when a study reaches the point when data collection is complete, or just to ensure the project stays on track for large or multi-year studies.

For cause visits

For cause audits may be requested by the IRB, DHR, institutional officials, department chairs, and other senior leaders at the University. The visits are generally due to concerns regarding study compliance and/or research subject rights and welfare. For-cause visits may also be initiated due to complaints, repeated errors, or a lack of responsiveness by the principal investigator to IRB/DHR requests.

These visits may be focused on direct research subject impact (e.g., the informed consent process, recruitment procedures, etc.) Visits may be more investigative in nature whereby there is a more in-depth review of an investigator's studies or study conduct. The focus and scope will depend upon the nature of any noncompliance determinations and/or regulatory problems identified during review.

Routine visits

Routine audits are compliance reviews of the conduct of IRB approved studies that are meant to be educational to help improve research practices. An DHR staff member, who is internal to the IRB office, performs the audit. Routine audits typically consist of an in-person or remote review of adherence to the IRB approved protocol, assessment of study records and participant files, and evaluation of other research activities. All active studies are subject to routine audits. Studies may be selected based on any number of criteria, for example:

- Risk level of the study
- Studies enrolling vulnerable populations
- Studies involving investigational new drugs or devices
- Externally funded studies, including DoD-funded and FDA-regulated research
- Studies involving complex procedures
- A high number of studies conducted by a PI or managed by a study coordinator
- Random selection from all active studies

Protocols are subject to monitoring at any stage of the research including: protocols where subject accrual has been complete; study procedures are complete; only data analysis is being conducted; the protocol is ready to be closed with the IRB; or, the protocol was closed within the past 3 months. Studies must remain open during monitoring and the PI may submit the study for closure once the post-approval monitoring activity is complete.

Post approval monitoring process

Step 1: Contact and scheduling
The PI will be sent an Audit Notification via email. This will serve as formal notification of an audit as well as a request for availability. The notification will list the study selected for review. NOTE: For-cause audits may require an immediate or short turn-around with little notification depending on the level of concern for subject safety.

Step 2: Complete and submit protocol self-assessment checklist
The PI will be requested to submit a completed self-assessment checklist prior to the scheduled audit. After reviewing the checklist, the DHR may request additional materials to prepare for the audit.

Step 3: Prepare for the audit

During the audit, the DHR team may request study material. It is advised that the research team ensure all study documents are available and easily accessible. The following documents may be reviewed:

- Protocol files
- Regulatory and IRB documentation
- Study subject files or data
- Spreadsheets documenting recruitment, screening, and enrollment
- Study subject compensation and record keeping
- Signed informed consents
- Document linking subject identifiers with study codes

From the time of initial correspondence to the date of the visit, the research team is encouraged to contact DHR with any questions or concerns related to the activity.

4. Site visit [virtually or in-person]
At a mutually agreed upon date, the DHR will review the documents as requested with members of the research team. The monitoring visit will include, but not be limited to the following:

- Protocol adherence
- Documentation retention
- Participant recruitment, screening, and selection,
- Informed consent procedures
- Participant payment
- Document and data retention and storage practices
- Confidentiality and privacy practices and processes
- Sponsor and/or external IRB requirements

5. Audit report and PI response
The PI will receive a written report detailing observations made during the audit and a summary of findings. The report may include recommended or required actions such as, submitting an Incident, AE, or Reportable new information form or a Corrective and Preventative Action (CAPA) plan. Any issues identified that may pose an immediate threat to research subjects or constitutes serious non-compliance will be shared with the IRB and NU senior research leadership as appropriate.

6. Audit close out
The post approval monitoring audit will be closed once all required actions are addressed and the PI will be notified accordingly.