Northwestern University IRB Office

Remote Post-Approval Monitoring and Directed (for cause) Audit Guide

The purpose of this guidance is to assist Investigators and research teams prepare for and successfully navigate remote IRB assessment.

Contents

Background

The IRB Office Compliance Team conducts periodic routine reviews of research after approval and directed (for cause) audits. When performing post-approval monitoring activities or directed reviews, the compliance analysts (Reviewer) are responsible for monitoring the progress of the research study to ensure (1) participant data that is collected is accurate and complete, (2) regulatory requirements are satisfied, and (3) the Principal Investigator (Investigator) and the research team are adhering to the approved research protocol.

Monitoring and directed review activities may be limited due to restrictions on in-person research activities and any additional restrictions placed by the facility where the activities will occur. The Investigator is required to make research records available for review (HRP-103 – Investigator Manual) and to comply with university, hospital, and institutional policies governing data security, storage, and access. See the Resources section at the end of the guidance for links to institutional policies.

Keys for Success

Preparing for a remote visit may pose no additional burden above that of an in-person visit for those study teams conducting research where all records are maintained electronically. It is appropriate to provide the Reviewer remote access to the research records. However, for those study teams whose research includes paper records, additional preparation is required.

Paper records should be scanned and saved to an appropriate cloud storage location for review. The records, including regulatory and participant files, should be saved so that the file names are readable and relevant to the document's content. Titles such as "DCIM_0238251.PDF" do not provide information pertinent to a Reviewer. Like documents should be saved in a logical nested folder structure that aids in ease of access and comprehension. (See Examples at the end of this guidance)

If research records are stored in multiple systems by multiple entities (e.g., paper participant records, research data in the participant medical record in EPIC, drug accountability logs in the investigation pharmacy), it is the Investigator's responsibility to either collect and centralize the electronic data for the review or provide documentation and support for accessing the information. If research data is housed in a proprietary system(s), the Investigator is responsible for granting the Reviewer access to the system(s) and for facilitating a brief introduction and training on how to navigate the system(s).

Investigators are encouraged to provide general or overarching guides to university or hospital systems or policies that they would provide to external monitors, where applicable.

While all regulatory records must be available for review, reviewing all participant files or all abstracted data may be infeasible. The Reviewer will request the coded (HIPAA Identifiers removed) participant log to determine which records they will review. Investigators will provide the unredacted records for review. The Reviewer may include additional records after their initial selection based upon interim observations.

Order of Events

The Reviewer will send the Investigator and Primary Contact (if the Investigator selected someone in the eIRB+ system) an email notifying them that one or more of their studies will undergo routine monitoring or directed review. The notification will include a few proposed dates for the review, a request for the coded participant log, and other initial details.

The Investigator or designee should respond with a mutually agreeable date, provide the coded participant log, and begin preparing for the review.

The Reviewer will respond with the list of selected participant records.

The Investigator or designee should send the Reviewer a Microsoft Outlook calendar invite covering the review's duration, one week or more before the start date. The invite should include:

- The Primary Contact's information.
    - The Primary Contact for the review is the Investigator or a designated study team member who will be available during the entirety of the review to respond to questions and requests for information promptly. The Primary Contact for the review does not need to be the same person listed as Primary Contact in the eIRB+ system.
- Relevant supporting documents, such as guides to where data are stored or institutional policies typically provided to external monitors.
- A link to, or information on how to access, a video conference coordinated by the Primary Contact for the start of the first day of the review.
    - It is customary to begin the review with a brief video conference where all parties can ask and answer questions and provide last-minute details,

documents, and training on systems or locations where the data are stored. The Investigator is not required to attend the initial conference at the start of the review.

Before or during the initial meeting, the Primary Contact and the Reviewer will establish the method of contact for questions during the review. A review-specific Microsoft Teams chat is an effective and recommended option.

The Reviewer may shorten the allotted time for the review or notify the Primary Contact that additional time is needed to coordinate continued remote access to the study records. Near the review's completion, the Reviewer will contact the Primary Contact to schedule a video conference meeting to close the review.

While a close-out meeting is not required, it is an excellent opportunity for the Reviewer to discuss their observations, ask final questions, and set expectations for the next steps. Close-out meetings are generally 30 minutes or fewer in length.

At the review's conclusion, the Investigator should end the Reviewer's remote access to the study documents unless specified otherwise.

The Reviewer will follow-up with the Investigator and Primary Contact by email with the observations, to which the Investigator should respond. For most observations, the Reviewer will include required actions, recommended actions, or both. The Investigator should respond with a plan to correct observations and prevent future reoccurrence (CAPA Plan) in the manner requested by the Reviewer.

The review is complete for routine reviews when the Reviewer sends the Investigator the formal close-out email. For directed reviews, the review is complete when the Investigator submits the review letter and their response in an RNI submission and provides the RNI number to the Reviewer by email.

Resources

The following links are provided to assist Investigators and may not represent all relevant university, hospital, or institutional policies:

Northwestern University - Information Technology - Document Sharing and Storage

Northwestern University - Information Technology - Research Data Storage Service

Northwestern University - Feinberg School of Medicine - Data Security Policy for Information Used in Clinical Research

Northwestern University - Feinberg School of Medicine - Data Storage Policy

Northwestern University – Weinberg College of Arts & Sciences – Data and File Storage

Northwestern University - Human Research Protection Program Compliance

Northwestern University - Human Research Protection Program Plan

Northwestern University - IRB Office - Investigator Manual

Northwestern University - IRB Office - Study Support Resources and Templates

Northwestern University - IRB Office - Post-Approval Monitoring Checklists (Bottom of the Page)

File Folder Examples:

Participant_0378

- Eligibility Checklist
- Signed Informed Consent Form(s)
- Visit/Status Tracker
- Completed Questionnaires
- Payment Record
- Notes-to-File

Regulatory Record

- Protocol and Amendments
    - Current IRB approved protocol
    - Previous IRB approved protocol(s)
    - Protocol deviation log
- Informed Consent Documents
    - Current IRB-approved Informed Consent form(s) (this should have an IRB watermark at the top of the document with the approval period)
    - Previous IRB-approved Informed Consent form(s) (also with IRB watermark)
- Corrective and Preventive Action Plans
    - List of corrective and preventive actions mandated by the IRB through RNI review and supporting documents
- Other IRB Approved Documents
    - Currently approved study tools (i.e. debriefing script, questionnaires, telephone recruitment script, advertisements)
    - Archived_old versions of study tools
- Coded identifier list
- Enrollment and consent log
- IRB Documents
    - Initial Approval
        - Submitted Documents
        - Approved Documents (i.e. those containing the IRB watermark)
        - IRB Approval Letter
    - MOD0001
        - Submitted Documents
        - Approved Documents (i.e. those containing the IRB watermark)
        - IRB Approval Letter (or for automatic study team update approvals, a system screen shot or email notification)
    - RNI00002513
        - Submitted Documents

        - CAPA Plan
        - IRB RNI Acknowledgement Letter
    - CR0001
        - Submitted Documents
        - Approved Documents (i.e. those containing the IRB watermark)
        - IRB Approval Letter
- Study Personnel Documentation
    - Current human subjects training completion documentation for all study personnel (e.g. Human Research CITI Training)
    - Expired or inactive human subjects training (for the life of the study)
    - Current CVs for investigators and applicable study personnel
    - Expired or inactive CVs (for the life of the study)
    - Delegation of Authority Log