SOP#: PM-13a	**Center for Cancer Research Sponsored Studies Monitoring and Audit Visits**
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NCI Clinical Director Signature:	James Gulley Digitally signed by James Gulley Date: 2022.05.19 07:48:46 -04'00'

POLICY

Clinical trials conducted in the Center for Cancer Research (CCR) will be monitored and audited as required by federal regulations and sponsor policies.

As part of an overall CCR Quality Management plan, the Office of the Clinical Director (OCD) must be notified of monitoring and audit visits, as well as subsequent monitoring/audit visit reports. If the visit report requires action by the research team, that visit report response must also be forwarded to the CCR OCD. Communications regarding monitoring/audit visits (e.g., confirmation letters, reports, responses) must be filed in the protocol electronic regulatory file.

All monitoring and auditing visits will adhere to the Clinical Center (CC) Regulatory Audit Guidelines.

For remote monitoring, CRIS is available via the Clinician Portal. Industry monitors/auditors are required to complete training "Information Security Awareness for New Hires." Training is available on the Clinical Portal website.

Note: For CCR-sponsored studies, the monitoring activities in this SOP refer to monitors contracted by the Office of Sponsor and Regulatory Oversight (OSRO) and the OSRO monitoring group has the acronym SROS (Sponsor and Regulatory Oversight Support).

PURPOSE

To describe the steps required to coordinate a monitoring and/or audit visit to ensure the visit is conducted in an efficient, organized and effective manner. This policy covers studies sponsored by the Center for Cancer Research (CCR). In addition, the mechanism to notify the CCR OCD of monitoring/audit visits will be defined.

For this SOP, the term "monitor" is synonymous with "auditor."

RESOURCES

- NIH Clinical Center HIMD Medicolegal Section homepage
- HIMD: Building 10, Room B1L400, (301) 496-3331, 7 a.m. to 5:00 p.m., Monday through Friday (excluding federal holidays)
    - Clinical Center Medical Record Department's Regulatory Audit Guide
    - Regulatory Audit Scheduling Form
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Efficacy Guidelines website
    - E6 Good Clinical Practices (R2)
- Office of Sponsor and Regulatory Oversight website
    - Clinical Trials records policy #203
    - Clinical Site monitoring policy #205
- CCR Policies/Standard Operating Procedures (SOPs) website
    - PM-6: *Guidelines for the Development and Maintenance of Regulatory Files/Binders*

PROCEDURES:

STEP 1: Set date for monitor visit

- The Study Coordinator (SC) will negotiate visit dates with monitor with a minimum of 10 business days confirmation notice.

Note: SROS monitors will contact pharmacy directly to set up the visit.

Note: Regarding CVs, Clinician Portal training and HIMD confidentially agreements, SROS/OSRO will manage these independently.

- Once visit dates are confirmed with industry monitor, the SC will complete "Regulatory Audit Scheduling Form" on the left side of the HIMD page in Resources. This will link to a portal to schedule your visit. You must use your PIV card to access this system. Select "Schedule New Audit – Remote." This should be done within 2 business days of receiving the confirmation email.
    - HIMD will send an email to confirm the audit dates
    - Notify the CCR OCD of the scheduled visit by forwarding a copy of the above email to "NCI CCR QA" listed in the global address book. Or forward the visit confirmation letter/email to NCI CCR QA mailbox.
- An exit interview can be conducted virtually through an NIH-approved platform. You must use one of these platforms to ensure participant privacy and confidentiality is protected.

STEP 2: Access to regulatory file and research records

- The SROS monitors will access the protocol's regulatory file via a file sharing platform called Veeva Vault. The PSO Manager will ensure that all required regulatory files are upload to the site.
- To share source research records (e.g., participant diary) not in CRIS, , the NIH Secure Email File Transfer (SEFT) system will be used. See *CCR Supplemental Guidance for Use of NIH Secure Email File Transfer (SEFT) System.*

STEP 3: Prepare for monitoring visit

- The SROS monitors will send an email verifying the visit date(s). This letter/email will include:
    - Protocol number
    - Participant study-specific ID be reviewed
    - Information to be reviewed (e.g., regulatory binder/file)

      Note: If the monitor has not sent a visit confirmation letter within 2 weeks of the visit, contact the monitor and request above information in writing.
    - Forward the letter or email confirmation to the PSO Manager as soon as possible, so they can ensure the electronic Regulatory Files are updated.
- The Study Coordinator will:
    - Notify the Data Manager (DM) so they can assist in preparation.
    - O order medical records for the requested participants not later than the Wednesday the week prior to the visit.
        - Complete the Audit Record Request Form and return via encrypted email to "CC-HIMD Regulatory Audits".
    - Organize any paper source documents (e.g., participant diary, QOL surveys) needed for the visit. The majority of source documentation should be in the electronic medical record.
        - Research records ARE allowed as source documents as they contain participant-completed or other study-specific forms that are not in the medical record. Research records should not contain printouts from CRIS.
        - Remember: these documents must be sent to the monitor via SEFT
    - Review the case report forms/research database to ensure that the data are complete, accurate and up to date as compared to the source documents and update/correct as needed.
    - Prepare regulatory file
        - Work with the protocol's Protocol Support Office (PSO) Manager to ensure the electronic regulatory file is complete, including an updated Delegation of Tasks/Signature Log. Any paper documents for the regulatory file (e.g., screening/enrollment logs, site visit log) need to be up-to-date and sent to the PSO manager for uploading into Veeva Vault.

Important: Do not provide any personally identifiable information (e.g., medical record numbers, names) to the monitor prior to the visit.

Note: For questions or assistance with preparing for the visit, contact your Team Lead or email the "CCR OEC" mailbox.

STEP 4: Provide support during the monitoring visit

- The Study Coordinator will:
  - Ensure the monitor has all contact information need (email, phone number) for SC, DM and other team members as needed.
  - Ensure the monitor has appropriate access to the NIH Clinician Portal.
  - Verify that monitor has access to required research records and regulatory files.
- The SC and/or the DM should check in with the monitor throughout the day to respond to queries or arrange a time to meet to discuss findings. Resolve queries if possible.

IMPORTANT: For questions about regulatory documents, please consult with the PSO Manager to ensure the correct document is given to the monitor. The monitor may email the PSO Manager directly with the question to help avoid confusion.

STEP 5: Conclude monitoring visit

- The Study Coordinator and Data Manager will:
  - Meet with the monitor and PI or designee at the end of the visit to discuss issues and answer questions. The monitor will discuss when a site visit report will be sent.
  - Ensure each monitor signs the Site Visit Log. If the visit occurs for multiple days, each day should be a separate entry. Site personnel will initial/sign the log as required.

STEP 6: Responsibilities after the visit

- The monitor might send a site visit report or other follow-up communication (e.g., email) to the PI and research team. The SC will forward a copy of that report or communication to "NCI CCR QA" mailbox and the PSO Manager for uploading into the protocol electronic regulatory file.
- If the site visit report contains action items and requires a response, the SC will:
  - Forward the letter to relevant staff (e.g., data manager, pharmacy) if they were not copied on the original letter. Arrange to meet with staff to review if necessary.
  - Ensure that the action items are completed in a timely fashion that will allow the SC time to collate responses in a written site visit report response letter, if needed. The site visit report will specify the timeframe in which to complete the actions.
  - Send the site visit report response, if any, to the monitor by the due date in the report and copy the "NCI CCR QA" mailbox and the PSO Manager.

Note: The CCR OCD is available to assist with site visit report responses - please email the "NCI CCR QA" mailbox with questions or request for assistance.