SOP#: PM-13b	**Monitoring and Audit Visits by ASRC (Arctic Slope Regional Corporation)**
Version #: 1.1	**Next Review Date: 09/2026**
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NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.09.23 11:37:05 -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.

Note**:** Arctic Slope Regional Corporation (ASRC) monitors/auditors have view-only access to CRIS and the protocol's regulatory file

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 being reviewed by ASRC, the CCR's contract group.

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

RESOURCES

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Efficacy Guidelines website
    - E6 Good Clinical Practices (R2)
- NIH Clinical Center Health Information Management Division (HIMD) Medicolegal Section homepage
    - Clinical Center Medical Record Department's Regulatory Audit Guide
- 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 Clinical Research Coordinator (CRC) will negotiate visit dates with monitor with a minimum of 10 business days confirmation notice.
    - Remember: ASRC monitors have view-only access to CRIS do not need to schedule a remote visit with HIMD. Also, an Audit Record Request Form is NOT needed.
    - Notify the CCR OCD of the scheduled visit by forwarding a copy of 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 research records

- To share source research records (e.g., participant diary) not in CRIS, please send directly to ASRC monitor via their NIH email using encrypted email.
- Remember: ASRC monitors have view-only access to the protocol's regulatory file.

STEP 3: Prepare for monitoring visit

- Most monitors will send a letter/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,)
    - Individuals with whom the monitor will want to meet (e.g., PI, CRC, data manager).
    - Forward the letter or email confirmation to the Protocol Support Office (PSO) Manager as soon as possible, so they can ensure the electronic Regulatory Files are updated.
- The CRC will:
    - Notify the Data Manager (DM) so they can assist in preparation.
    - 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: research records must be sent via encrypted email directly to the monitor
    - 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 PSO Manager to ensure the electronic regulatory file is complete, including an updated Delegation of Activities 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

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 CRC will:
  - Ensure the monitor has all contact information need (email, phone number) for CRC, DM and other team members as needed.
- The CRC 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 CRC and DM will:
  - Meet with the monitor and PI or designee at the end of the visit to discuss issues and answer questions as needed. The monitor will discuss when a site visit report will be sent.

STEP 6: Responsibilities after the visit

- The monitor will send a site visit report or other follow-up communication (e.g., email) to the PI and research team. The CRC 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 CRC will:
  - Forward the letter to relevant staff (e.g., DM, 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 CRC 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 – typically 4 weeks from the date of the letter.
  - Review written site visit report response letter with the PI before finalizing.
  - Send the site visit report response 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.