SOP#: PM-13	**Industry-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 07:48:22 -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. A Curriculum Vitae (CV) for each industry monitor/auditor must be on file with the Medicolegal Section. The CV must be updated annually. In addition, the monitor/auditor must sign a Confidentiality Agreement prior to being allowed to access the electronic medical record (Clinical Research Information System [CRIS]). This agreement must be signed annually.

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.

On-site monitoring should be limited to those visits that require in-person pharmacy and/or research laboratory visits. On-site monitoring is no longer required to take place in HIMD as the monitor will use the Clinical Portal to access medical records. On-site visits can take place in a meeting room scheduled by the research team via "CC-CRC Hatfield Conference Rooms" in Global.

PURPOSE

To describe the steps required to coordinate an industry monitoring and/or audit visit to ensure the visit is conducted in an efficient, organized and effective manner. For Cancer Therapy Evaluation Program (CTEP)-sponsored studies and NCI Network studies, see CCR SOP PM-12: *NCI CTEP and Network Audits*. In addition, the mechanism to notify the CCR OCD of monitoring/audit visits will be defined.

For studies sponsored by Center for Cancer Research (CCR), please see SOP PM-13a: *Center for Cancer Research Sponsored Studies Monitoring and Audit Visits*.

For those studies being monitored by ASRC, please see SOP PM-13b: *Monitoring and Audit Visits by ASCR (Arctic Slope Regional Corporation).*

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)
- CCR Policies/Standard Operating Procedures (SOPs) website
    - PM-6: *Guidelines for the Development and Maintenance of Regulatory Files/Binders*

PROCEDURES:

REMOTE VISIT

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.
    - For a new industry monitor, request their CV and forward it to email "CC-HIMD Regulatory Audits" in Global.
- 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 Monitoring Visit."
    - 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: Provide information about access to research records, pharmacy documents and regulatory file

- To share source research records (e.g., participant diary) not in CRIS, pharmacy records and/or regulatory files, a secure method must be used, preferably the NIH Box sharing platform. Please see *CCR Supplemental Guidance for Remote Regulatory Audits/Monitoring Visits* for more information.

ON-SITE VISIT

STEP 3: Set date for monitor visit

- The Study Coordinator (SC) will:
    - Negotiate visit dates with monitor, with a 10-business day minimum for confirmation of visit.
    - Secure meeting room for visit via "CC-CRC Hatfield Conference Rooms" in Global.
    - Confirm investigational pharmacy staff availability for a monitoring appointment during proposed visit date. The Investigational Pharmacy requests at least **six weeks'** notice to schedule monitoring visits. They may not be able to accommodate visits if less than six weeks' notice is provided
    - Confirm research laboratory staff and other groups are available as requested by the monitor.
    - Notify PSO Manager of upcoming monitoring visit as soon as possible, so they can ensure the electronic Regulatory Files are updated.
- 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 Monitoring Visit."
    - 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.
- For a new industry monitor, request their CV and forward it to email "CC-HIMD Regulatory Audits" in Global.
- The SC will organize a meeting place for the exit interview at the end of the monitoring visit. Confirm with monitor that this will be needed. The PI's office can be utilized if the PI is available or email "CC-CRC Hatfield Conference Rooms" for availability of meeting space.

STEP 4: Provide information about access to the NIH campus to external monitor, if needed

- All external monitors must go through the NIH security checkpoint at the NIH Gateway Center each day of the visit.
- All monitors must wear an NIH visitor's badge while on NIH property.
- More information can be found at the NIH Visitor Information website.

See Appendix A for a sample introductory email that can be sent to the monitor.

REMOTE VISITS and ON-SITE

STEP 5: 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, pharmacy records)
    - Individuals with whom the monitor will want to meet (e.g., PI, pharmacist, study coordinator, data manager).
    - 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.
    - 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: for remote visit these documents must be sent in a secure fashion. For use of NIH Box, please see *CCR Supplemental Guidance for Use of NIH Box*.
    - 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 the e-regulatory file.

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 6: Provide support during the monitoring visit

- For remote visits, 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. Please verify with monitor that all requested patients are listed for review. For any issues, please contact (301) 496-3331 or via email "CC-HIMD Regulatory Audits."
    - Verify that monitor has access to required research records, pharmacy 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.
- For on-site visits, the Study Coordinator will meet the monitor on their arrival to the Clinical Center and escort them to the scheduled meeting room.
    - Provide any paper source documents (i.e., research records) and the electronic and paper regulatory files to the monitor.
    - Discuss monitor expectations of study team. Provide contact information for SC and DM.
    - Review appointment information for meetings with investigational pharmacy, research labs and/or PI. Escort the monitor to various meeting locations.

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 7: 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 required. If the visit occurs for multiple days, each day should be a separate entry. Site personnel will initial/sign the log as required.
    - Return any paper source documents and paper regulatory files to the research team office.

STEP 8: 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 – 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.

APPENDIX A

Below is a sample email that can be sent to the monitor/auditor explaining the process required to visit the NIH campus. This information is particularly helpful for those who have never visited the NIH campus. Attach a map of the NIH campus and a map of the first floor of the Clinical Center.

Subject: Information Pertaining to Monitoring [*Audit*] Visit

Dear _____:

I look forward to meeting with you on [*visit date*] for the monitoring [*audit*] visit for protocol [*protocol title*]. The following information will be helpful for preparing for your visit to the National Institutes of Health (NIH).

The NIH campus is a secure federal facility and as such, you will need to undergo a security check each day that you visit the campus. The time to complete security screening can vary widely depending on the volume of visitors that need to be screened. You should plan at least 30 minutes for this process. Please visit the NIH Visitor Information website (www.nih.gov/about-nih/visitor-information) for more information about the security screening process and required forms of identification. You will be given an ID badge that must be worn at all times while on campus.

This monitoring [*audit*] visit will take place in the NIH Clinical Center, room XXXX. See the attached NIH campus map – the Clinical Center is located on the top center of the map.

I will meet you at [*time if visit*] in the north main lobby of the Clinical Center. See the attached Clinical Center floorplan map – the main lobby is located on the top center of the map. If the security screening process is taking longer than expected, please call my cell [*pager*]: xxx-xxx-xxxx. I will escort you to the meeting room.

Please let me know if you have any questions.

Sincerely,