SOP#: PM-12	**NCI CTEP and Network Audits**
Version #: 5.1	**Next Review Date: 07/2025**
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NCI Clinical Director Signature/ Effective Date:	James Gulley Digitally signed by James Gulley Date: 2023.07.31 16:34:16 -04'00'

POLICY

Clinical trials conducted in the Center for Cancer Research (CCR) will be monitored and audited as required by federal regulations. Protocols sponsored by NCI Cancer Therapy Evaluation Program (CTEP) or one of the NCI Networks (including Consortiums) will have audits as defined by CTEP, Network and Consortiums policies and in the specific protocol.

Audit notification will be sent to the CCR Clinical Director, Deputy Clinical Director, or a designated site contact. The audit notification will be forwarded to the applicable research team(s). The CCR Office of Education and Compliance (OEC) coordinates the administrative aspects of the audit, including any audit responses.

All monitoring and auditing visits will adhere to the Clinical Center (CC) Regulatory Audit Guidelines. Remote access to CRIS is available via the Clinician Portal. Scheduling the audit with HIMD as well as other administrative aspects of the audit (e.g., securing CVs, required training, etc.) will be coordinated by the OEC.

PURPOSE

To describe the steps required to coordinate an audit visit by CTEP or a Network to ensure the visit is conducted in an efficient, organized and effective manner. This policy covers studies sponsored by CTEP and Networks. For audits/monitoring visits for industry or CCR-sponsored studies, please see SOP PM-13 *Industry-Sponsored Studies Monitoring and Audit Visits* and PM-13a *Center for Cancer Research Sponsored Studies Monitoring and Audit Visits*.

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)

- NCI Cancer Therapy Evaluation Program (CTEP) website -- Information about Network and Consortium polices is also found on this website, under "Initiatives/Programs"
    - Clinical Trials Monitoring Branch (CTMB) website
- CCR Standard Operating Procedures website
    - PM-6: *Guidelines for the Development and Maintenance of Regulatory Files/Binders*

PROCEDURES:

The CTEP monitoring contractor (e.g., Theradex) and the Network/Consortium auditors will communicate directly with the CCR Office of the Clinical Director staff regarding dates of audits. Audit preparation activities are shared by the CCR Office of Education and Compliance (OEC) liaison and the protocol Study Coordinator as outlined below.

STEP 1: Set Date for Audit Visit

OEC liaison will:

- Negotiate the visit dates with auditor(s)
    - For Theradex audit, the next visit dates are typically set at the end of the previous audit.
- Contact Health Information Management Department (HIMD) to determine if auditors have an updated CV on file.
- Contact Investigational Pharmacy if a pharmacy visit is required during the audit and negotiate a day/time for the visit. Typically, a pharmacy visit is only required once per year during the annual review of CTEP protocols.
- Complete audit request dates via the Regulatory Audit Schedule portal. Updated CVs for each auditor will be sent if necessary. Coordinate location for on-site visit or remote meeting as needed.
- Provide information to the auditors regarding access to the NIH campus and/or access to the Clinician Portal (for remote CRIS access) as needed.
- Schedule a room for exit interview or a remote meeting on the last day of the audit, if required.

Note: For NCI Network/ Consortium audits, the CCR OCD will typically be notified several months prior to the audit. The OEC liaison will notify the PI/team(s) selected for the audit at that time and schedule access to the Clinical Portal as in Step 1 above.

In addition, information will be requested by the Network/Consortium auditors prior to participants being selected for review. The OEC liaison will work with the research team and PSO manager to collect and send requested information to the auditors and others by the date requested.

STEP 2: Notify PI, Research Team, Protocol Support Office and Investigational Pharmacy of Upcoming Audit

OEC liaison will:

- Notify the particular PI and research team if their protocol and study participants are selected for the audit
    - The CCR OEC is typically notified of the selected studies and study participants to be audited 4 weeks prior to the audit and that audit confirmation letter will be forwarded to the PI/teams.
- Notify the Investigational Pharmacy of protocols selected for review and requested pharmacy documents
    - Confirm date/time and length of pharmacy visit if required
- Upload audit confirmation letter and other applicable documents into the protocol regulatory file, in the "Monitoring" folder.
- Download protocol participant registration list from the Patient Registration and Enrollment System (PRES) and send to individual teams for review.

STEP 3: Prepare for Audit Visit

Study Coordinator will:

- Review the PRES participant registration list sent by the OEC liaison to ensure accuracy and update PRES as needed.
    - If previously entered participant information is inaccurate, the Study Coordinator will contact PRES support by clicking on **Need Assistance** button present at bottom of the every page or through email ncipres@nih.gov .
- 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.
- Prepare electronic regulatory file
    - Work with the protocol's PSO Manager to ensure the electronic regulatory file is complete, including an updated Delegation of Task/Signature Log.
    - Ensure any paper regulatory files are up to date (e.g., screening/enrollment logs, site visit log) and send to PSO manager for uploading into the regulatory file as appropriate.

OEC liaison will:

- Complete the *Audit Record Request Form* for all protocols and participants selected for the audit and send to HIMD via encrypted email no later than the Wednesday to week prior to the audit.

- Make a list of protocols being reviewed during the audit, including PI and Study Coordinator (SC) names and SC email. If source data and database information is going to be reviewed, include the Data Manager (DM) and contact email should any questions arise during the audit.
- Create an NCI Box folder "Theradex Audit [date]" with individual protocol folders for each protocol being reviewed and upload requested documents into those protocol folders.

Note: *See CCR Supplemental Guidance for Remote Regulatory Audits/Monitoring Visits* under PM-13 for acceptable, secure ways to share information with the auditors.

STEP 4: Provide Assistance as Needed During the Audit

ON-SITE VISIT

- Both the Study Coordinator and OEC liaison should meet with the auditors at the beginning of the visit and periodically throughout the visit.
    - The OEC liaison will meet the auditors upon arrival to the Clinical Center and escort them to the meeting room.
    - Provide the auditors with team contact information at the beginning of the visit.
    - If there are paper research records, the Study Coordinator is responsible for bringing those to the meeting room by 9am each day of the audit and pick the records up at the end of each audit day.
- The OEC liaison will attend the exit interview, as required.

REMOTE VISIT

- The morning of the first day of the audit, the OEC liaison will give auditors access to the NCI Box file "Theradex Audit [date]."
- If requested by the auditor, the OEC liaison will set up a virtual meeting at the beginning of the audit to discuss audit activities. This meeting should include the Study Coordinator and Data Manager with their team leads as needed. The OEC liaison will also attend this meeting.
- The auditors should contact the protocol SC and DM should any questions arise during the visit.
- The OEC liaison will set up an exit interview for each protocol team at a day and time agreeable to both the team and the auditors.
    - The OEC liaison will attend the exit interview, as required
- The OEC liaison will remove auditors' access to NCI Box folder at the end of the audit. Access may be extended if needed.

STEP 5: Responsibilities After the Visit

- CTEP monitoring contractor (e.g., Theradex) or Network Auditor will send a site visit report to the CCR OCD contact person. The OEC liaison will forward the site visit report to pertinent research teams and Investigational Pharmacy, as needed.

- The site visit report may contain action items that require a response by the research team. Each discrepancy will require a response and/or corrective action plan. If the site visit report contains Data Discrepancy Reports, the Study Coordinator and Data Manager will complete the response for each data discrepancy. The completed form(s) must be forwarded to the OEC liaison several days prior to the due date specified on the report so the OEC liaison can review and provide feedback to the team as needed prior to the response being finalized. The OEC liaison will specify the date due to the liaison when the report is forwarded to teams.

Note: The OEC liaison is available to review the audit visit report with the team and to assist with the site visit report responses.

- The OEC liaison will collate responses and forward to the CTEP monitoring contractor or Network Auditor by the response due date.
- The OEC liaison will uploaded the report and response and other applicable documents into the protocol regulatory file, in the “Monitoring” folder.