

INSTITUTION GUIDANCE FOR A REMOTE NRG QUALITY ASSURANCE AUDIT

- Review NCI Audit Guidance, Section 2.4.2, Auditing Patient Cases Utilizing the Source Document Portal (SDP) and Section 4.3, Off-site/Remote Audit prior to scheduled audit.
 - [HTTPS://CTEP.CANCER.GOV/BRANCHES/CTMB/CLINICALTRIALS/DOCS/CTMB_AUDIT_GUIDELINES.PDF](https://CTEP.CANCER.GOV/BRANCHES/CTMB/CLINICALTRIALS/DOCS/CTMB_AUDIT_GUIDELINES.PDF)
- Regulatory and Pharmacy components of the audit continue to be reviewed off-site by NRG Oncology QA staff. This process is unchanged and will remain in place regardless of the location of the patient case component of the audit.
 - However, for pharmacy review of security, storage and shelf counts determine in advance of the audit if inspection may be done via a scheduled video call (e.g. FaceTime) with the audit team.
- If EMR access will be provided for the patient case component, ensure access is established in advance and local support is available for initial account set-up to prevent delays in the start of the audit.
 - Auditors should not be asked to provide PII per NRG Oncology and the CTMB. Please refer to Section 4.3 of the NCI Audit Guidelines.
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 - Guidance documents on where to find records on EMR system is helpful for the audit team.
- If EMR access is not possible, redacted patient case documents may be provided using a shared portal (e.g. Box, SharePoint) or by uploading redacted patient case documents to the CTSU audit portal. <https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-CM>
- If utilizing a shared document portal, organize when possible, by protocol timeline/schedule of events not by document type. File naming conventions that follow the protocol and EDC (RAVE) structure are helpful when possible.
- Have staff available to provide support to audit team during the scheduled audit.
- For scheduling questions contact: Janet Famiglietti famigliettij@nrgoncology.org
- All other questions contact: Mary Jo Antonelli antonellim@nrgoncology.org