

REVIEW OF ELECTRONIC MEDICAL RECORDS (EMRs)

SWOG recognizes that many institutions now collect and store research data electronically. Electronic data used to support NCTN studies must adhere to the same guidelines as a paper system and adhere to 21 CFR Part 11:

- When original observations are entered directly into a computerized system, the electronic record is the source document.
- Data entry should be designed so that individuals need to enter digitized or electronic signatures to ensure the data is attributable.
- Any change to a record should not obscure the original information. The record should clearly indicate that a change was made and clearly provide a means to locate and read the prior information.
- Changes to data that are stored electronically require an audit trail including who made the changes, when, and why they were made. Audit trails must be available for review during the audit, if requested.
- Data should be retrievable in such a fashion that all information regarding each individual subject in a study is attributable to that subject.
- Electronic data must meet the same applicable regulatory requirements for record keeping and record retention in clinical trials as paper systems.
- Electronic records related to SWOG-credited studies must be available for inspection by the FDA, NCI, and SWOG. SWOG auditors act as representatives of the NCI and have completed GCP, HIPAA and Human Subjects Protection training; therefore, they will not complete additional site-specific training on these topics prior to an audit. EMR-related training within reason will be accommodated.

SWOG will review EMRs during audits with the following restrictions and guidelines:

- 1) Original consent forms must be preserved and provided for auditors to review.
- 2) A computer(s) with EMR access must be available for each auditor in or near the conference room where the audit is taking place. EMR data from remote locations such as affiliates or NCORP components may also be reviewed if made available at the main member location during the audit.
- 3) Access to the EMR for each auditor must be arranged prior to the audit. It is important that access and any password requirements are verified prior to the audit date to ensure a smooth and efficient audit process. ***Failure to provide timely access to the auditors will require that audit documents be printed for review.***
- 4) Complete the attached EMR Source Document Locator Form and return to the auditor prior to the audit.
- 5) A CRA or other knowledgeable person must be available to guide the auditors in navigating the EMR the first morning of the audit.
- 6) It is important that a paper/shadow chart of documents that often are not part of the EMR be made available for auditor review. Some examples of such data include:
 - Original signed consent forms
 - Signed eligibility checklists, registration worksheets, etc.
 - Documentation of drug compliance such as nursing notes, patient diaries or calendars
 - Documentation of specimen submission (Specimen Tracking printouts, lab notes, etc.)
 - Documentation of calculations (BSA, calculated creatinine clearance, etc.)
 - Adverse event logs signed by the investigator
 - Documentation of tumor measurements/grids that are signed by radiologists or investigators
 - Documentation of communications (with SWOG, patient, etc.)
- 7) Regulatory documents may also be reviewed electronically provided files are labeled and a knowledgeable person is available to assist during the review.