**SITE PREPARATION FOR A SWOG AUDIT**

**AUDIT NOTIFICATION**

Four to six weeks prior to the site visit, a list of the patient records, IRB records, consent forms and drug accountability records that are to be audited will be sent by email. Main Members, LAPS and NCORPs must notify their affiliates/ components of their selected cases with audit instructions, including the date, time, place and requirements of the audit. Each affiliate/ component should prepare for the audit in the same manner as the parent institution.  Arrangements should be made for a representative from each site to be present or available by phone during the audit for questions.

**REGULATORY DOCUMENTS**

All IRB information pertinent to the protocols being audited should be reviewed prior to the audit to collect any missing information. The Regulatory files should be organized for easy access.  Colored tabs indicating the pertinent documentation (annual reviews, protocol updates, etc.) are recommended for flagging the files for the auditor's review.

Consent form documentation to be submitted to the SWOG Operations Office **prior** to the audit:
- Copies of the most current versions of consent forms for designated protocols on the case list.
- If using the CIRB, copy of the current approved boilerplate language (Study-Specific Worksheet About Local Context).

IRB/Consent documentation to be available **during** the audit:
- Local IRB: Documentation pertaining to initial review, continuing reviews, protocol updates, internal SAEs, and external Safety Reports.  ***Documentation may be in the form of minutes of the IRB meeting or an IRB approval letter that is signed by the IRB chairman or designate.  IRB Certification Forms are not considered acceptable documentation of IRB review.***
- CIRB:  A copy of the initial and subsequent revisions, if applicable, of the ***CIRB Approval of the Study-Specific Worksheet About Local Context*** giving approval to conduct the study as well as documentation of local implementation date for protocol updates and informed consent versions. CIRB protocol approval documents are available on the CTSU website and do not need to be printed for the auditors.
- If applicable, a copy of the IRB policy of an alternate method for handling submission/approval of external safety reports
- Copies of all versions of IRB approved/locally implemented consent forms or a detailed list of all versions for protocols that will be reviewed during the audit.
- Specimen collection/banking consents and HIPAA authorizations, if separate from the treatment consents.

Additional documents:
A copy of the local **Site Authority Log** must be available for the audit team. A **Trial Master File** should be available for potential FDA registration studies (**S1400/LUNGMAP, S1404, S1418, S1605 and S1806**). The CTSU **Delegation of Task Log** will also be verified for applicable studies.

**DRUG ACCOUNTABILITY & PHARMACY REVIEW**

The site should verify the following prior to the pharmacy audit:
- **Drug Accountability Record Forms (DARFs)**
  - o DARFs are present for all investigational agents being audited as well as any current inventory.  If any records for this audit cycle have been archived, these records must be retrieved prior to the audit.
- **Storage and Stability**
  - o The balance on the DARF matches the physical inventory and account for any discrepancies.
  - o All study drugs are stored in a secured, limited-access area that is monitored for temperature.
  - o Expiration dates of the drugs for confirmation of appropriate disposal, return of drug or transfer of drug for outdated and/or unused drug on closed or blinded studies.
- **Tracking and Disposition**
  - o Shipping receipts, transfer forms, and drug return forms for each protocol must be on file.
  - o If drugs may be destroyed on site per protocol, destruction records must also be on file.
  - o Procedures are in place to verify an investigator has an active investigator registration with CTEP prior to ordering investigational agents

Documentation to be submitted to the SWOG Operations Office **prior** to the audit:
- Drug accountability records (including DARFs, shipping receipts, drug return forms, and transfer forms) for all activity since the last audit date for select protocols including any satellite pharmacy records. Please see the case list for details. Records will be reviewed for compliance and compared to treatment administration data prior to the audit.

Documentation to be available **during** the audit:
- Originals of the drug accountability records that were submitted to SWOG as well as for any current inventory.
- The auditors will conduct a pharmacy inspection for all on-site audits. The site should make arrangements with the pharmacy prior to the audit.

## PATIENT CASE REVIEW

The following should be performed **prior** to the audit:
- Medical records and research charts must be obtained and kept in a secure location. If electronic medical records (EMRs) are used, computer access must be available to facilitate the retrieval of any information that is missing from the research chart.
- A review of all patient records being audited to verify that the following documents are available:
    - **Eligibility Criteria**
        - Documentation to support all eligibility criteria including operative and pathology reports, radiology reports, lab reports, medical history, doctor's notes, etc.
    - **Treatment**
        - Drug orders, prescriptions, chemo flowsheets, progress notes, intake calendars or other documentation of treatment administration;
        - Documentation to support and provide an explanation of modifications or delays in study treatment.
    - **Disease Outcome/Response Determination**
        - Documentation to support disease assessment/response evaluations as outlined in the protocol (physician notes, radiology reports, lab reports, etc.).
    - **Toxicity Assessment**
        - Documentation to support assessment of toxicities (i.e., signed AE logs with grade and attribution).
        - Supporting laboratory reports;
        - Copies of CTEP-AERs forms for reportable SAEs.
    - **Data Quality**
        - All records including the subject's primary care chart and copies of medical records from outside sources that are considered relevant to the subject's study participation must be accessible for review during an audit. If records are missing, all attempts to secure the records must be documented;
        - Supporting research documents (i.e., questionnaires, specimen submission);
        - Original records are preferred but shadow charts are acceptable if unable to obtain original records;
    - **Consent Forms**
        - Signed consent forms;
        - If applicable, documentation to verify patient was reconsented or notified of new information as instructed by the sponsor and/or local IRB.
- Tagging of all major study parameters in the source documents to facilitate the review of documents supporting eligibility requirements, treatment administration, toxicity evaluations, and disease assessment/tumor measurements

    **Examples of Color-Coding for Patient Charts**
    White       Operative and Pathology Reports: label tab with Op or Path and date
    Purple      H&P, Weight, Performance Status: label tab with Pre-study or Cycle # and date
    Orange      Treatment Records: label tab with Cycle # and date
    Yellow      Toxicity Evaluations: label tab with date range
    Red         Lab Tests: label tab with Pre-study or Cycle # and date
    Green       Tumor Measurements/Disease Assessment: label tab with Pre-study or Cycle # and date
    Blue        Specimen submission: label with pre-study or Cycle #

## AUDIT ACCOMODATIONS

A quiet room for the audit team to work and wireless internet access should be provided. There are a lot of charts, binders, and other materials present during the audit and it is important that adequate space be available. See **Policy on Audit of EMRs** if auditors will be expected to review any electronic data.

A regulatory representative and the persons who are most familiar with the patient charts should be available during the audit to assist with questions raised by the auditors. The Principal Investigator should also be available for the exit interview.