

## 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

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. Electronic files that are well organized are also acceptable.

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 since the last audit date. **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.** If applicable, a copy of the IRB policy of an alternate method for handling submission/approval of external safety reports.
- 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.
- 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.

Additional documents:

A **Trial Master File** should be available for potential FDA registration studies (**LUNGMAP, S1418, S1806 and S1914**). The CTSU **Delegation of Task Log (DTL)** will be verified for applicable studies. A copy of the local **Site Authority Log** must be available for the audit team if studies without a DTL are being audited.

### DRUG ACCOUNTABILITY & PHARMACY REVIEW

The site should verify the following prior to the pharmacy audit:

- **Drug Accountability Record Forms (DARFs)**
  - 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**
  - The balance on the DARF matches the physical inventory and account for any discrepancies.
  - All study drugs are stored separately by protocol, strength and formulation and labeled as such.
  - All study drugs are stored in a secured, limited-access area that is monitored for temperature.
- **Tracking and Disposition**
  - Shipping receipts, transfer forms, and drug return forms for each protocol must be on file.
  - If drugs may be destroyed on site per protocol, destruction records must also be on file.
  - 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, 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 all major study parameters tagged in the source documents to facilitate the review of eligibility, treatment administration, toxicity evaluations, disease assessment and supplemental documents (i.e., consent forms, questionnaire, specimen submission, etc.)

### **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 #

- If auditors will review data in the electronic medical record (EMRs), a computer must be made available for each auditor and access obtained prior to the audit. **See Policy on Review of EMRs.**
- 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, tumor measurement grids, 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.

## **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.

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.