Audit Preparation Timeline and Medical Record Review

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Audit Preparation Timeline

• **When** do I start preparing?
• **Who** should I contact?
• **What** arrangements need to be made?
• **How** do I prepare?
When do I start preparing?

I find it helps to organize chores into categories:
Things I won’t do now: Things I won’t do later: Things I’ll Never Do...

When do I start preparing?

• Start NOW!
Start Audit Preparation Now!

- Review the Audit Guidelines from the CALGB Policy and Procedure Manual
- Review a copy of your institution’s last audit report
- Think “AUDIT” with each IRB file and patient documentation
- Audit your pharmacy on a regular basis

Patient Case Review FAQ

- I talked to the study chair on the phone and I was told it was ok to do XXXXX, but the protocol doesn’t say that it is ok. Do I need this in writing?
- The auditors will want to see documentation of correspondence with the study chair (print out of email preferred).
Start Audit Preparation Now!

- Do a mock audit of your institution & affiliate institutions twice a year
- Be aware that all sites need complete sets of IRB documents
- Submit materials to the SCDO as required per protocol
- Monitor submission of required slides, blocks, bloods and imaging records

Audit dates identified

- Obtain the “PI Letter” & read carefully-start a correspondence folder
- Provide copies of “PI Letter” to affected affiliates
Dear Dr.:

As previously arranged, the required routine or re-audit of (Institution Name (NCI #)) will take place on DAY, MONTH, DATE, YEAR. Patients at risk for audit are primarily, but not exclusively, those entered since the previous audit. The auditors will be:

[auditor name, affiliation] (Team Leader)
[auditor name, affiliation]

The audits will be conducted in the CALGB standard format. Please consult the CALGB Policies and Procedures Manual and the CALGB Audit Preparation Workshop slides for audit preparation instructions. Additional audit information can also be accessed on the CALGB Audit Resources Web page.

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Audit dates identified

Who should I contact?

- Notify & schedule date with PI, all Research Nurses and CRAs, Pharmacists & IRB
- Notify appropriate personnel at affiliates
Audit dates identified

How do I prepare?

• Reserve adequate space for audit preparation
• Reserve adequate space for the audit date
• Obtain supplies needed for chart review (i.e. several colors of post-it tabs)

Audit dates identified

How do I prepare?

• Secure access for viewing radiology exams
• Secure access to electronic medical records
• Arrange access to food for auditors
Patient Case Review FAQ

• A subject was re-consented because of a change in potential risks. Do auditors need to see the re-consent document?

• Yes, have all signed consents available for the auditors.

1 Month Before Audit

• Organize your list of patients to be audited (expired, off Tx, active Tx)
• Make plan of action (POA) with Medical Records Department if using paper charts
• Make POA with Radiology Department if using film
1 Month Before Audit

- Make a copy of each protocol to be audited
- Make a copy of the model consent form for each protocol audited
- Make a copy of your most recent IRB approved consent form for each protocol audited

1 Month Before Audit

- Begin IRB review & tagging of regulatory records
- Begin medical record review
- Discuss “problem cases” with PI
- Block time on PI schedule for introductions and exit interview
Medical Record Review

• What is a Source Document?
  – Medical Record Charts (paper)
  – Electronic Medical Record (EMR)
  – Shadow Charts
  – Study Flow Sheets: signed & dated in real time
  – Imaging Film
  – Digital Imaging

Patient Case Review

• Properly signed & dated informed consent
  – Original form strongly preferred
• Eligibility
• Correct treatment & treatment sequence
• Evaluation of disease outcome / response
• Adverse events related to treatment
• General quality of the data collected & submitted
  – PCO, LTB, LCTB: check submissions!
Tagging of Paper Charts

- Post-It type tags on relevant documents
  - Consent form
  - Eligibility / On study criteria
  - Treatment cycles
  - Re-staging scans
  - Required labs
  - Follow-up
  - Serious Adverse Events
CALGB 90401

Patient ID: [Redacted]
Patient Initials: [Redacted]
Date on Study: 07/03/07
A.M.N. Initials: [Redacted]

Cycle 1: 07/10/07
Cycle 2: 07/21/07
Cycle 3: 08/21/07
Cycle 4: 09/11/07
Cycle 5: 10/02/07
Cycle 6: 10/23/07

Date of Progression: 11/12/07
Date of Death: 06/10/08
NCI Chart Audit

This chart has been tagged for an NCI Audit.

Please do not remove the tags.

Return the chart to the CTO ASAP.
Please call xxx-xxxxx with questions.
Patient Case Review FAQ

- During audit preparation, I found errors in submitted data. Should I send in the amended CRFs?
  
  - Yes! Be aware that the auditors may not have the corrected CRF in their packet, so be prepared to show them your copy.

Electronic Medical Record

- Review EMR to assess that all required documents are easily obtainable for all patients
- Print a hard copy of items difficult to find/load
- Prepare a Summary page for each subject
- Arrange for a computer work station for each audit team and a “local driver”
### CALGB Summary Sheet

<table>
<thead>
<tr>
<th>Event</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5</th>
<th>Cycle 6</th>
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</thead>
<tbody>
<tr>
<td>Signed ICF</td>
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<td>Enrolled</td>
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<td>Eligibility</td>
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<td>H&amp;P</td>
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<td>Labs</td>
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<td>CT chest &amp; up abdomen</td>
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<td>Bone Scan</td>
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<td>Other</td>
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<td>Treatment</td>
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<td>Response</td>
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<td>Prior to Cycle 3 scan</td>
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<td>Prior to Cycle 3 scan</td>
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<td>End of treatment</td>
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<td>Relapse</td>
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<td>Last Follow-up</td>
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</table>

### Patient Case Review FAQ

- A subject should have had a dose reduction, but didn’t. Should I report this error to the IRB even though it happened a while ago?

- Yes! It’s never too late to report a deviation to the IRB.
2 weeks before audit

- Verify time of arrival with team leader
- Provide specific directions to team leader; provide contact information
- Continue with regulatory and medical record review
- Meet with pharmacist
- Be aware of any correspondence from Central Office

2 weeks before audit

- Continue contact with affiliate institutions
- Expect arrival of data packets (forward affiliate packets if needed) - DO NOT OPEN marked envelopes
1-2 days before audit

- **Gather** supplies: calendar, calculators, BSA calculators, pencils, post-its, CTCAE booklets, staging criteria
- **Organize** audit room
- **Remind** pharmacist
- **Finalize** regulatory and medical record review
Patient Case Review FAQ

• My doctors never document performance status. What can I do?

• As a Health Care Provider, you can document this yourself in a progress note that becomes part of the medical record.
• Develop PS documentation templates.

The audit day

• Plan to arrive early & stay late
• Do any final room prep
• Plan for a CRA to be present at ALL times
• Relax; we’ve all been in your shoes!
The audit day

• Let the Team Leader set the agenda for the day, advise of any special times needed for pharmacy
• Have a phone available if cell phone reception is a problem
• Take notes throughout the day & during exit interview
• Arrange for return to airport, if needed
After the Audit 😄

ILL MAKE YOUR LIFE MISERABLE! I’LL THwart YOUR EVERY MOVE!

HI. I’M THE NEW SADIST. WHAT HAPPENED TO THE OLD ONE?

HE WENT TO SADIST PARADISE.

THE AUDITING DEPARTMENT?