



Audit Preparation Timeline

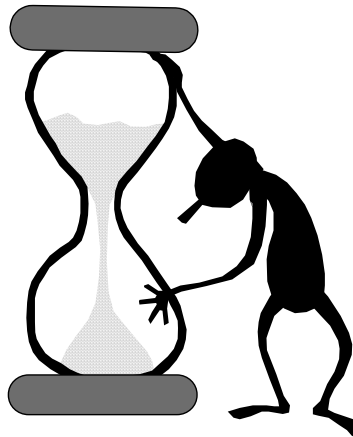
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CALGB CRA Orientation, April 2008

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Audit Preparation Timeline

- CALGB Audit Preparation Workshop



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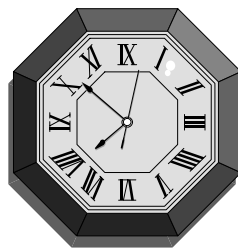
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Audit Preparation Timeline

- **When** do I start preparing?
- **How** do I prepare?
- **Who** should I contact?
- **What** arrangements need to be made?
- **Who** attends the audit from our institution?

When Do I Prepare?

- **Start NOW!**





Start Audit Preparation Now

- *Review* the Audit Guidelines from the CALGB Policy and Procedures 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

Start Audit Preparation Now

- *Do* a mock audit of your institution and affiliate institutions at least twice a year (quality assurance)
- *Submit* materials to the CALGB Statistical Center, Data Operations as required per protocol
- *Monitor* submission of required slides, blocks, and x-rays

When Do I Prepare?

- Start NOW!
- **Audit Date(s) Identified**

Audit Date(s) Identified

- *Obtain* the "PI Letter" and read carefully.
- *Start* a correspondence folder
- *Notify* and *schedule* date with PI, Co-PIs, all CRAs, pharmacists, IRB and MR staff
- Ditto above for your affiliates
- *Reserve* adequate space for the audit date(s)

Audit Date(s) Identified

- *Reserve* adequate space for audit preparation
- *Order* supplies needed to tag charts (i.e., several colors of post-its)
- *Reserve* x-ray view box
- *Arrange* access to food for audit day(s)

When Do I Prepare?

- Start NOW!
- Audit Date(s) Identified
- **1 Month Before Audit**

1 Month Before Audit

- *Compile* list of patients to be audited in organized fashion (i.e., expired, off tx, active tx)
- *Make* POA with Medical Records department
- *Make* POA with Radiology
- *Make* at least 2 copies of each protocol to be audited (IRB and chart audit)

1 Month Before Audit

- *Tag* protocols for chart audit
- *Begin* IRB review and tagging of each protocol to be audited
- *Anticipate* "problem cases"
- *Block* time on schedule of PI for touching base and exit interview

1 Month Before Audit

- *Tag* medical records.
- Original consents ONLY.
- If a form mistake is discovered, the form can be amended, but needs to be held until after the audit to be submitted.

When Do I Prepare?

- Start NOW!
- Audit Date(s) Identified
- 1 Month Before Audit
- **2 Weeks Before Audit**

2 Weeks Before Audit

- *Continue* contact with affiliate institutions to monitor their progress
- *Touch base* with pharmacist
- *Be aware* of any new correspondence from the CALGB Central Office

2 Weeks Before Audit

- *Review* any audit special studies reports to check for accuracy
- *Expect* arrival of data packets for the auditors
- *Forward* any affiliate packets to the affiliates, if the audit is taking place there.
- ***DO NOT OPEN Marked Envelopes!***

When Do I Prepare?

- Start NOW!
- Audit Date(s) Identified
- 1 Month Before Audit
- 2 Weeks Before Audit
- **1-2 Days Before Audit**

1-2 Days Before Audit

- *Gather* supplies needed for auditors (i.e., calendars, calculators, BSA calculators, pencils, post-its, etc)
- *Obtain* the last of medical records to be tagged
- *Remind* pharmacist of need for at least 1/2 hour of time availability

1-2 Days Before Audit

- *E-mail* the specified audit team leader to verify time of arrival and provide directions
- *Organize* charts for audit by protocol in audit room
- *Organize* x-ray jackets for audit by protocol in audit room
- *Organize* IRB reports by protocol

When Do I Prepare?

- Start NOW!
- Audit Date(s) Identified
- 1 Month Before Audit
- 2 Weeks Before Audit
- 1-2 Days Before Audit
- **The Audit Day(s)**

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The Audit Day(s)

- *Plan* to arrive early and stay late
- *Plan* for a CRA to be present at ALL times
- *Take* 3 deep breaths and *SMILE* - you've done the best you can do!



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The Audit Day(s)

- *Let* the Audit Team Leader set the agenda for the day(s), advise of special times needed for pharmacy, etc.
- *Have* a phone and fax available
- *Take* notes throughout the day
- *Take* notes at the Exit Interview
- *Arrange* for return to airport, if necessary

When Do I Prepare?

- Start NOW!
- Audit Date(s) Identified
- 1 Month Before Audit
- 2 Weeks Before Audit
- 1-2 Days Before Audit
- The Audit Day(s)
- **After the Audit**

After the Audit

- *Submit* corrected data sheets to CALGB Statistical Center, Data Operations, if appropriate
- *Read* carefully the Audit Report when it arrives
- *Write* response to Audit Report

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Audit Preparation

Please remember the mission of CALGB. You are an important team member in the climb toward our goals. View the audit as the learning experience that it is.



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