



Audit Preparation Timeline

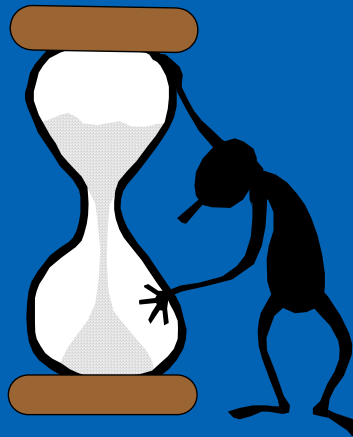
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University of Missouri – Columbia

CALGB CRA Orientation, April 2008

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Audit Preparation Timeline

- CALGB Audit Preparation Workshop



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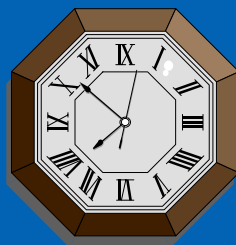
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Audit Preparation Timeline

- **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?

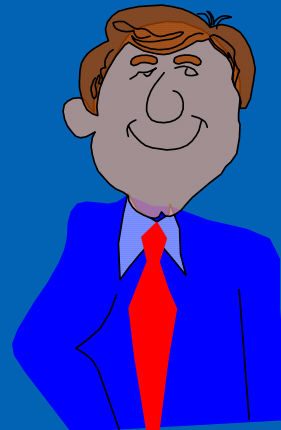
- Start NOW!
- Audit Date(s) Identified
- 1 Month Before Audit
- 2 Weeks Before Audit
- 1-2 Days Before Audit
- The Audit Day(s)

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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

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.



