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# Audit Preparation Timeline

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CALGB Audit Preparation Workshop, November 2008

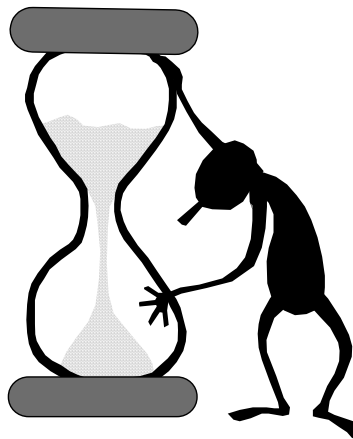
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# Audit Preparation Timeline

- CALGB Audit Preparation Workshop

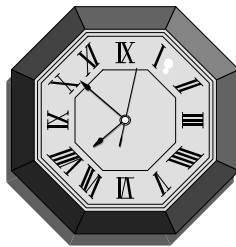


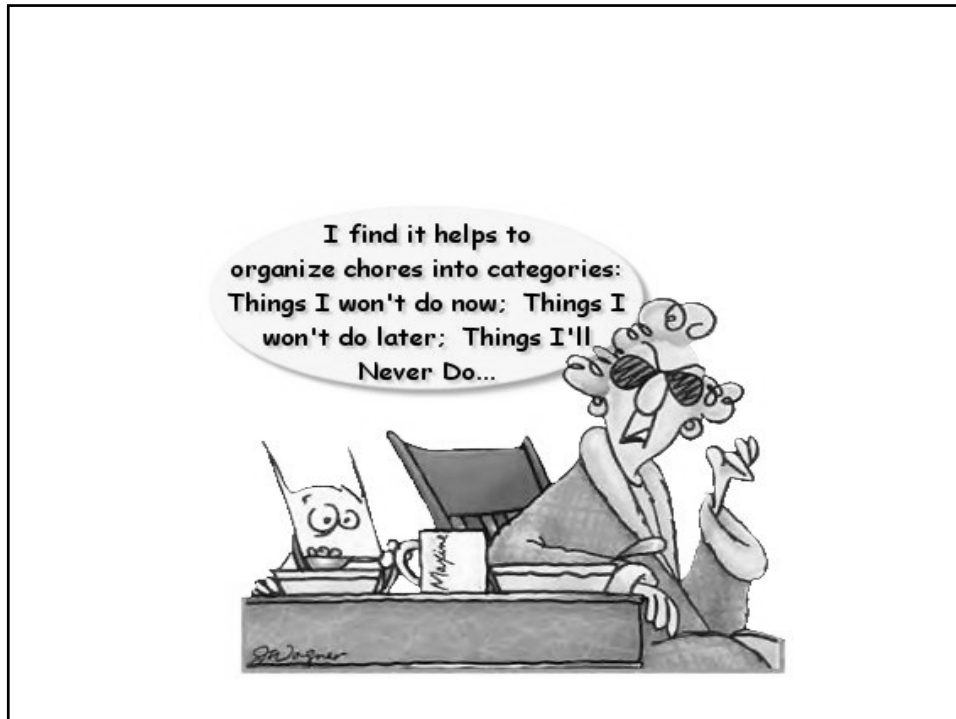
# Audit Preparation Timeline

- **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 & 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 & affiliate institutions at least twice a year (quality assurance)
- Be aware that all sites need complete sets of IRB documents
- *Submit* materials to the DOC as required per protocol
- *Monitor* submission of required slides, blocks, & x-rays

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Slide 7

## When do I prepare?

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

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Slide 8

## Audit Date(s) Identified

- *Obtain* the “PI Letter” & read carefully- start a correspondence folder
- *Notify & schedule* date with PI, Co-PIs, all CRAs, pharmacists, IRB & medical record 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)
- *Secure access* for viewing of radiology films
- *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

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

## 1 Month Before Audit

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

## 1 Month Before Audit

- *Provide specific directions to team leader*
- *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.

## 1 Month Before Audit

Expectations for electronic medical records (EMR):

- 1) site has reviewed EMR on all patients to assess that all required documents are available for review.
- 2) Print a hard copy of documents that may be hard to find or take 1-2 minutes to load.

## 1 Month Before Audit

- 3) Prepare a History Page for a summary of relevant dates.
- 4) A computer work station will be needed for each team of physicians and CRAs.
- 5) A “driver” will be needed for each computer set-up.

## *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 Central Office
- *Contact* the specified audit team leader to verify time of arrival and confirm directions to audit room

## 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

- *Organize* charts for audit by protocol in audit room
- *Organize* IRB records 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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*Slide 23*

## *The Audit Day(s)*

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



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*Slide 24*

## 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 & 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**- “Don’t change that dial!”

# 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.

