

Clinical Research Enterprise (CRE)

Standard Operating Procedures

FDA Audits

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Purpose

The purpose of this SOP is to describe the process for FDA audits. The IND regulations establish authorization for FDA auditors to visit study sites and inspect study records. The Public Health Service has regulatory authority in cases where scientific misconduct is suspected. The PI, nurse research manager, regulatory coordinator, study coordinator, and other designated staff work together to prepare for an FDA audit

References

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Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is to be followed without deviation

I. Reasons for FDA audits

- Ensure adherence to protocol guidelines and regulatory requirements
- Check integrity of scientific testing and study conduct
- Check validity of data
- Ensure rights and safety of subjects

II. Types of FDA audits

- Routine inspections/surveillance inspections
 - Approximately 250 per year
 - Pivotal studies or studies with new product claims

- b. For cause inspections
 - i. Approximately 35 per year
 - ii. Suspicious data or possible infringement of rights and safety of human subjects

III. Notification-What to do when the FDA calls

- a. An FDA auditor may call for an appointment or arrive unannounced. The time span between initial contact and the actual audit should be as short as possible. Any due delay may affect the tone and conduct of the inspection
- b. Request the following information from the auditor
 - i. Name of auditor
 - ii. Study to be audited
 - iii. Scheduled visit date
 - iv. Length of visit
- c. Notify the nurse research manager immediately
- d. Call the sponsor immediately
 - i. Speak with the CRA or Project manager for the study. If it is necessary to leave a message, be sure the message includes the fact that it regards an FDA audit. A team from the sponsor may come to the site prior to the FDA visit to help prepare for the audit
- e. The nurse research manager, study coordinator, and regulatory coordinator will work together to prepare all relevant information
 - i. Reserve an undisturbed work area
 - ii. Place participant records in the work area
 - iii. Place CRF binders and regulatory binders in the work area
 - iv. Notify pertinent hospital departments (pharmacy, lab, IRB) as the auditor may ask to visit any of these departments during the course of the visit
- f. Be cooperative

IV. Preparation

- a. If an audit by the FDA is forthcoming, the following documents should be readily available to the FDA inspector. Having these documents available will facilitate and expedite the procedure
 - i. Approved copy of required protocol including amendments or extension protocols
 - ii. Completed, accurately filled out, signed FDA 1572 for each study
 - iii. Affirmative letter from the IRB approving the conduct of the study

- iv. Current CV for primary investigator and all sub investigators listed on the 1572
- v. Copy of the Investigator's Drug Brochure for the compound being tested
- vi. Properly executed, witnessed, and signed informed consent for each study patient
- vii. Completed, legible copies of all case report forms
- viii. Copies of all laboratory test results from both local and central laboratories
- ix. All drug shipment invoices
- x. Complete, up to date investigational drug dispensing record for each study
- xi. Copy of the study closure notification to the IRB if applicable
- xii. Complete patient list (including names and addresses) assigned to each study number

V. The Audit

- a. When the FDA arrives
 - i. Request identification
 - ii. Request FDA 482 (Notice of Inspection)
 - iii. Notify nurse research manager
- b. During the audit
 - i. Each day the nurse research manager will request a summary session at the end of the day
 - ii. Staff will respond to the auditors accordingly
 - 1. Answer only what is asked
 - 2. Clarify all misunderstandings
 - 3. Implement corrective action
 - 4. Be honest, complete, and up front. Say "I don't know" when applicable
 - 5. Make copies as requested (make additional copies of all requested items for site and for sponsor)
 - 6. Escort the inspector at all times
 - 7. Keep daily contact with the sponsor
 - 8. Sponsor personnel cannot be present during the inspection, but may be available by phone

c. Exit Interview

- i. The inspector will discuss audit findings with the PI, nurse research manager, regulatory coordinator, and study coordinator
- ii. Clarify any misunderstandings at this time
- iii. Inspector to issue Form 483
- iv. Inspector will then file a formal report to FDA headquarters who will assign site status. If further action is required from the site, an official letter will be sent to the site requesting corrective action. A response to this letter is required within 30 days.

Training