

## **POLICIES AND PROCEDURES**

SECTION: Research and Compliance			NUMBER: CLN-39.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/12/2009	REV. B: 9/1/2010	REV. C:
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### **1. PURPOSE**

To outline the process of an FDA inspection at a clinical research site and describe activities that should be done to facilitate the inspection.

### **2. SCOPE**

Applies to Principal Investigator (PI), and when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

### **3. RESPONSIBILITIES**

The PI is responsible for maintaining accurate study documentation, and must be prepared to be audited by the U.S. Food and Drug Administration (FDA).

### **4. BACKGROUND**

FDA audits/inspections are typically conducted at clinical sites to determine compliance with federal regulations and adherence to FDA guidance, to verify the validity and integrity of clinical data submitted in applications for approval, and to ensure that the rights and welfare of subjects participating in clinical studies have been protected.

### **5. PROCEDURE**

- 5.1. Upon request of an FDA investigator, the PI should have readily available all requested trial-related records.
- 5.2. Upon notification of an impending FDA audit, the clinical research personnel who first received notification will inform the PI, Research and Compliance, and the study sponsor.
- 5.3. The PI must be available during the FDA inspection. If the proposed date of the audit is inconvenient for the PI, he/she or designee may contact the FDA investigator to request rescheduling at a mutually convenient time.
- 5.4. The PI should encourage the study personnel to cooperate with the FDA investigator(s). Designated personnel should be available to answer questions.
- 5.5. In preparation for the audit, the SC will obtain all study-related records, to include Case Report Forms (CRFs), source documents, and Investigator regulatory files.
- 5.6. The SC will organize all study-related files, arrange logistics, and prepare for the audit according to the FDA investigator's request.

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- 5.7. The PI will designate a liaison to facilitate the audit. This designated liaison will communicate directly with the FDA investigator prior to the audit, if possible, to make certain that all required records are obtained and necessary meetings are scheduled.
- 5.8. During the audit, the designated liaison will:
  - 5.8.1. Greet the FDA investigator(s) and verify identification/credentials
  - 5.8.2. Provide requested records
  - 5.8.3. Accompany FDA investigator(s) during tours and interviews
  - 5.8.4. Assist the FDA investigator(s) as needed
  - 5.8.5. Arrange for follow-up if required
- 5.9. The PI will meet with the FDA investigator(s) at the conclusion of the audit to discuss any questions or findings.
- 5.10. If the PI receives a Form FDA 483 (report of observations) after the audit, he/she should consult the sponsor on how to respond.
- 5.11. The PI or designee should send a copy of the Form FDA 483 to the sponsor's project manager, Research and Compliance, and the Institutional Review Board (IRB).
- 5.12. The PI should prepare a written response to any observations noted in the Form FDA 483 and send the response to the FDA within approximately 10 days of receiving the report. The written response should:
  - 5.12.1. Address each observation and explain what steps have been or are being taken to remedy the observation
  - 5.12.2. Be factual, professional, and cooperative
- 5.13. The PI or designee should send a copy of the written response to the Form FDA 483 to Research and Compliance and the IRB.
- 5.14. The PI or designee should attempt to obtain a copy of the official FDA investigator's field audit report (Establishment Inspection Report [EIR]) and the Form FDA 483 and other pertinent information (copies of inspection reports are usually available three to six months after inspection through the Freedom of Information (FOI) Office at FDA headquarters).

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### **6. TERMS & ABBREVIATIONS**

<b>CRF</b>	Case Report Form
<b>EIR</b>	Establishment Inspection Report
<b>FDA</b>	Food and Drug Administration
<b>FOI</b>	Freedom of Information (Act)
<b>IRB</b>	Institutional Review Board
<b>PI</b>	Principal Investigator
<b>SC</b>	Study Coordinator

### **7. REFERENCES**

- 7.1. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- 7.2. Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
- 7.3. ICH GCP Consolidated Guideline - Part 4.9 Records and Reports
- 7.4. ICH GCP Consolidated Guideline - Part 5.15 Record Access
- 7.5. FDA Compliance Program Guidance Manuals 7348.811 - Investigators

### **8. ATTACHMENTS**

None