

Standard Operating Procedures for Clinical Research at USF Health CRC		
	FDA AUDITS	
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PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to outline the process of a FDA inspection at the research site and describe activities that should be done to facilitate the inspection.

SCOPE: Applies to all personnel involved in the implementation and coordination of clinical investigations

RESPONSIBILITY: Principal Investigator (PI) /Co-investigator(s) (Co-I) and, when delegated by the PI, sub-investigator(s) (Sub-I), and clinical research coordinators.

DEFINITIONS:

Corrective and Preventive Actions (CAPA): A system for implementing corrective actions and preventative actions resulting from the investigation of complaints, product rejection, non-conformance, recalls, deviations, audits, regulatory inspections and findings, and trends from process and product quality monitoring.

Establishment Inspection Report (EIR): A report generated after all FDA inspections and prepared by FDA's investigator immediately after the inspection.

Food and Drug Administration (FDA): The FDA is a federal agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation; and that these products are honestly, accurately and informatively represented to the public.

Freedom of Information Act (FOIA): This act provides for the disclosure of information held by administrative agencies to the public, unless the documents requested fall into one of the specific exemptions set forth in the statute. FOIA was implemented to prevent federal agencies from abusing their discretionary powers by forcing them to make certain information about their work available to the public.

Inspection: The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the research.

Inspection Observation (FDA form 483): Official FDA inspection form, completed by FDA investigators which note deviations, if any, and presented to the most responsible person at the inspected site at the end of the inspection.

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DEFINITIONS (cont.):

Notice of Inspection (FDA form 482): Official FDA inspection form completed by FDA Investigators and presented to the most responsible person (such as the principal investigator) at the site being inspected at the start of any inspection type.

PROCEDURE:

1. The PI and designated study staff will refer to a checklist for guidance to prepare for the audit (See *Appendix II: FDA Audit Checklist*).
2. Study personnel are strongly encouraged to review the *FDA Compliance Program Guidance Manual 7348.811 Bioresearch Monitoring: Clinical Investigators*. This reference provides a list of information that will be requested during every inspection.
3. During the audit, the research designee in authority will:
 - 3.1. Greet the FDA investigator(s) appropriately, verify identification/credentials and grant prompt access to the facility and the right people. This should be the Principal Investigator. The FDA will provide the PI with the FDA 482 (Notice of Inspection). FDA regulations require the FDA Investigator to give the FDA 482 to the most responsible individual.
 - 3.2. Provide requested records.
 - 3.3. Assist in assuring that each question is answered by person(s) knowledgeable about the issue. Be truthful and professional in interactions with FDA.
 - 3.4. Accompany FDA investigator(s) during tours and interviews
 - 3.5. Assist the FDA investigator(s) as needed. Communicate clearly.
 - 3.6. Arrange for follow-up communication, if required, to any unanswered questions or unfulfilled document reports.
 - 3.7. Take notes concerning the progress of the audit. These notes shall include those described in items 10-12 and 14. A form may be used to assist in this task, with spaces for the Investigator's name (if a team inspection), document requested, date and time of request, date and time delivered.
 - 3.8. Pass along requests to the document person who will obtain requested records and make photocopies for the FDA and clinical site.
 - 3.9. Pass along requests from FDA to interview research personnel to the documents person who will arrange such meetings.
 - 3.10. Document any line of questioning pursued by the Investigator(s) should be summarized, including significant information provided in response.

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PROCEDURE (cont.):

4. If possible, the principal investigator will meet with the FDA Investigator(s) at the conclusion of the audit to discuss any questions or findings.
5. After the audit, if the principal investigator receives a Form FDA 483 (Inspectional Observations), he/she should consult the sponsor and the USF Division of Research Integrity and Compliance (DRIC) on how to respond.
6. The principal investigator or designee should send a copy of the Form FDA 483 to the sponsor representative and to USF DRIC on how to respond.
7. The PI will prepare a written response to any observations noted in the Form FDA 483 and send the response to the FDA within approximately ten days of receiving the report. The written response should:
 - 7.1. Address each observation and explain the corrective action plan that have been or are being taken to remedy the observation and prevent future occurrences of similar observations.
8. The principal investigator or designee should request a copy of the official FDA investigator's field audit report, *Establishment Inspection Report (EIR)*, under the Freedom of Information Act (FOIA).

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REFERENCES:	21 CFR 312.62; 21 CFR 812.140; ICH GCP Consolidated Guideline - Part 4.9 Records and Reports; ICH GCP Consolidated Guideline- Part 5.15 Record Access; FDA Compliance Program Guidance Manuals 7348.811	
RELATED POLICIES:	USF HRPP Policies and Procedure Manual	
APPENDICES:	Appendix II: FDA Audit Checklist	
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01/01/2015	01/01/2015	06/01/2016