FDA Inspections and Alerts

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FDA & OHRP Inspections

For routine inspections expect to receive an FDA pre-announced inspection phone call or letter from one to three days in advance of the visit. Please notify UCLA officials upon receiving the call or letter from the FDA to schedule the inspection. The following officials can provide support and guidance for your inspection: OHRPP Leadership (UCLA IRB), Terra Hughes (CTSI Office of Regulatory Affairs), Maggie Lindenbaum (JCCC Clinical Research Support Services) and the UCLA Office of Compliance. If the FDA will be inspecting a drug study(s), notify the UCLA Department of Pharmaceutical Services, Investigational Drug Section at 310-267-8522.

The following general guidelines are recommended during an FDA inspection from the time the FDA inspector is greeted to the time the exit interview is conducted and a response to the FDA's observations are made.

- Investigators are required to permit the FDA to inspect and copy any records pertaining to the investigation, including, in certain situations, those which identify subjects
- Designate a person to serve as escort who will oversee the inspection (usually the research coordinator for the study)
- The escort serves as an institutional monitor as well as guide and general study contact person
- The FDA inspector must not be permitted free access to areas where files are kept

Please see UCLA Clinical Research Advisory Notices for more information.

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Before the Site Inspection

- Complete the FDA Site Pre-Inspection Checklist and identify records the FDA is likely to audit.
- Identify all subjects
- Locate and print copies of the study enrollment/screening log
- Locate and have readily accessible ALL Informed Consents
- Locate and have readily accessible ALL Case Report Forms and all supportive source documentation

- Sequester these records and any reviews or prep work done in anticipation of the visit for easy access, but do not volunteer any of these records to the inspector unless directly asked. Always wait for a specific request to provide information.
- Expect to have an initial meeting with the inspector in a private room prior to the start of the inspection.
- Secure a private for the initial and exit meetings and a room for the inspection Depending on the space the initial and exit meetings can be conducted in the same space as the inspection.
- Upon notification of the inspection, the coordinator should review the Coordinator Checklist.

Inspector Arrival

Please also refer to your department policy for FDA site inspections.

- There may be times when persons outside the study team (e.g., department directors) should be notified that the FDA is conducting an inspection in the building.
- If the location where the initial meeting and inspection will occur require the use of a sign in log, and the inspector will not sign in, make a note in the sign in log of the name, date/time, purpose and escort name.
- The escort should walk the inspector to an appropriate meeting room. The inspector will present his/her credentials to verify that they are in order; do not expect the investigator to permit a copy to be made of the badge/credentials.
- The inspector will then present a Notice of Inspection (Form 482) to the Principal Investigator. This notice authorizes the inspection and its presentation officially begins the inspection.
- The inspector will explain the intended purpose and scope of the inspection, and then ask the PI to summarize the study.The PI should expect inquiries in any of the following areas during this initial meeting:
    - Experience as a Clinical Researcher
    - Oversight of the study
    - Oversight of the investigational product
    - Oversight of study personnel

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The FDA or OHRP Inspection

The escort should have made arrangements for a comfortable work area for the FDA inspector(s) for the duration of the inspection. The room must contain no confidential records, including clinical or research related. The inspector should be accompanied by the escort or designee at all times while in the presence of study related documents, samples, or other confidential information. If the inspector needs to make a phone call and requires some privacy, they should have access to a “sterile” room (no study related information is present) or public area where they can conduct their business. In general, while an inspector is here in an official capacity, they should not be left alone.

The inspector must never have access to any site records not specifically provided by the host. Standard procedure is for the inspector to request files for review, starting with the “general” study materials including the regulatory documents binders, then all signed informed consent forms, followed by a sampling of specific patient records. Study finances and personnel records are not included in the standard inspection. The Principal Investigator should set aside time each day to talk with the inspector, as well as being available for questions that may arise.

The escort’s role is to coordinate all FDA requests and see that the inspector’s questions are answered honestly and completely. Listen to the question; answer the question that was asked. Defer to others if you don't know; when possible use documents already provided for support of answers. Stop when the question is fully answered. There is nothing wrong with silence: when you have answered, wait for the next questions.

How to answer FDA Questions:

- Be concise; answer only the question that is asked
- Always be clear with the answers to questions
- Be positive and confident
- Take corrective actions if possible, commit only to what you can deliver
- DO NOT volunteer information.
- DO NOT guess or speculate
- DO NOT lie
- DO NOT argue
- DO NOT panic
- DO NOT sign affidavits

Please see the UCLA FDA guidance on Preparing for an FDA Clinical Investigator Inspection for additional information.

Inspection of Documents

- Escort the inspector to an information sterile room away from sources of casual conversation to review requested documents. Always sequester the reviewer in an isolated room and bring the requested documents to them.
- Only documents specifically requested by the inspector shall be provided for review. The escort may need to obtain patient records from the hospital or clinic records to supplement or corroborate the research records.
- Gather the documents requested for review. When documents are copied for inspectors, a copy is also made to retain or identify each copied document by maintaining an inspection record log. All copies provided should be stamped “Confidential”. Usually copies are provided without charge to the FDA; however, if the inspector requests an inordinate number of copies, notify the inspector that an invoice will be provided.
- Documents that the inspector is not entitled to review or copy: financial, personnel (except for training/qualification records), and internal audits (section 704(a) FDC Act).

Photographs

If the FDA inspector insists on taking photographs, take duplicates at the same time.

Samples

If the FDA inspector requests a reasonable quantity of samples, fill the request but pull identical samples to retain. Ask the FDA to issue a receipt for the samples (FDA Form 484). Depending on the nature of samples requested, advise the FDA that an invoice will be presented.

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After the Inspection

The Exit Interview

The FDA will usually hold an exit interview at the conclusion of the inspection. The escort, Principal Investigator, a representative from Institutional Compliance, and other individuals as appropriate should be notified of the time and place and expect to attend. During this exchange, if serious deficiencies have been found during the inspection, an Inspectional Observations (FDA Form 483) will follow from the regional office, listing the deficiencies. If no deficiencies are found, or the inspector has comments that she or he believes are not serious enough to warrant an FDA Form 483

, no form will be issued.

During the exit interview:

The Principal Investigator will seek to correct any errors in the findings. Both the FDA and Principal Investigator will make sure everything is clear and understood. Observations, comments, and commitments will be noted in the escort inspection notes.

After the Inspection

Responding to FDA Form 483:
The PI or designated representative shall draft a response to an FDA Form 483. The PI is responsible for sending the draft of the response to the institutional contacts listed below. The PI is also responsible for sending the written response to the FDA for review and comments prior to sending the final response to the FDA. The PI is responsible for sending the draft of the response to the institutional contacts listed below.

The written response should include specifics:

- Determine if a finding was an oversight/one-time occurrence; or systemic, where a change of procedure is indicated.
- Delineate corrective actions: including justification of why the proposed response will remediate the issue; and a realistic timeline for correction.
- If the PI disagrees with an observation: respond factually, providing clear and verifiable evidence.
- Address each particular observation or finding, point by point.
- The reply should be sent within 15 business days. Keep a copy of the final signed response in your office.

To Request an Establishment Inspection Report (EIR)

The FDA inspector will file an EIR within approximately 30 days. This report is subsequently available through the FOI. It may be requested from:

FOI, Freedom of Information Office
5600 Fisher
Rockville, MD 20857

Institutional Followup

Please provide a copy of the final establishment inspection report (EIR) and/or the Inspectional Observation Form 483 upon receipt to the IRB (Kristin Craun), Office of Regulatory Affairs (Terra Hughes) (for non-Oncology trials), JCCC Office of Regulatory Compliance (for Oncology Trials).

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FDA Alerts

See the following links for alerts, announcements, and safety recalls from the U.S. Food and Drug Administration.

MedWatch Safety Alerts for Human Medical Products
MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics.

FDA Drug Information

Index of FDA Approved Drugs

FDA Index to Specific Drug Information This Index does not include all FDA approved drugs. It only includes drugs that have been the subject of a Drug Safety Communication, Healthcare Professional Information sheet, Early Communication About an Ongoing Safety Review, or other important information. Please use Drugs@FDA to search for information on a drug not found in the Index.

Recalls, Market Withdrawals, & Safety Alerts
List of recalls, alerts, and warnings of foods, drugs, medical devices, and cosmetics.

FDA Drug Alerts and Statements
Information on drug safety and availability for consumers and health professionals, new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products.

Dietary Supplement Alerts and Safety Information Alerts
FDA alerts for consumers and healthcare professionals.

FDA Drug Alerts – Cancer
FDA notification of recent FDA approvals and other important FDA actions pertaining to therapies for cancer patients.

FDA Device Alerts
Problems with medical devices may be caused when devices malfunction. But problems also may arise when users--either health professionals or the general public--do not understand or follow proper use instructions. FDA issues alerts and warnings to explain why problems may be occurring and clarify proper procedures to ensure safe and effective use of devices.

Postmarket Drug Safety Information for Patients and Providers
Links to safety sheets with the latest risk information about particular drugs, related press announcements, and other fact sheets.

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Related Guidance, Tools & Templates

General Guidance for Site Inspections
Customizable template that outlines the process for an FDA/OHRP inspection, and describes activities that should be done to facilitate the inspection

FDA Site Pre-Inspection Checklist and Coordinator Checklist
Organizational tools to aid inspection preparation

FDA Inspection Information
Intake form for FDA/OHRP Inspection Requests

Preparing for an FDA Inspection Presentation for Coordinators to prepare for and participate in external audits and what comprises inpection readiness

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