The FDA or OHRP Inspection

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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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