

Audit and Inspection Guidelines

I. Purpose

Research is subject to audit and inspection by regulatory agencies, including the Food and Drug Administration (“FDA”) and Office for Human Research Protections (“OHRP”). Federal law allows an FDA investigator who provides written notice (Form 482) and shows appropriate credentials to enter a regulated establishment. FDA has broad authority to inspect equipment, materials, products, labeling and certain records.

An inspection can be comprehensive, focused on a specific issue or set of issues, or in response to a reported problem. Investigation techniques may include observing operations, examining equipment, reviewing documents, collecting product samples, and interviewing employees. Likewise, OHRP has broad audit and inspection powers to ensure protection of human subjects in research. Any external investigation, inspection or other external review and its outcome must be reported to the Einstein IRB Director.

II. Recommendations

A. Preparing for the inspection

1. When an inspector from a regulatory agency calls to schedule an inspection, ask the following :
 - a. Inspector name, agency and contact information
 - b. The name of the PI being inspected
 - c. What studies are being inspected
 - d. The reason for the inspection
 - e. Does the inspector want specific personnel available?
 - f. Does the inspector want specific documents available?
2. Document any telephone conversation(s) that occur between the inspector and the study staff.
3. Print any records specifically requested in advance by the inspector. The inspector is not authorized to review documents using MMC electronic medical Records systems. Hard copies should be provided.
4. As soon as you are notified of an impending inspection, notify the following parties. Include the study name, the IRB number, and the date of the inspection:
 - a. All study staff

- b. Department Chair
 - c. Sponsor (if applicable)
 - d. Einstein IRB Manager (in all cases)
 - e. BRANY IRB Manager (if applicable)
 - f. Montefiore Research Billing Compliance Analyst
 - g. The Department of Pharmacy (if applicable)
5. The inspector will usually request that the inspection take place within 10 days. This request should be accommodated.
 6. Reserve a room in a private area for the inspection. The room should contain no files or records. Make sure that there is a copy machine located close to the room.
 7. Identify a person who will serve as an escort and oversee the inspection. This person is usually a research coordinator familiar with the study. The escort will serve as a guide and general study contact person. The escort will need to accompany the inspector when touring the facility and be readily available to the inspector at all times but does not need to be always present in the room while the inspector is reviewing documents.
 8. Ensure that all study documentation, including informed consent forms, source documents, CRFs, regulatory documents, and sponsor correspondence are available for review by the inspector, if requested.
 9. Keep all study documents and records ready and accessible, but do not volunteer a list of them to the inspector. Always wait for a specific request to provide information.

B. During the Inspection

1. The Principal Investigator (PI) or his/her designee should meet the inspector and receive and, in the case of an FDA inspection, sign the FDA form 482 "Notice of Inspection." Request to see the inspector's identification if he/she does not present it to you.
2. The inspector may request a tour of the facility areas where the research took place. The escort should accompany the auditor at all times during the tour.
3. Provide the inspector only with files that have been requested.
4. The inspector may request copies of some documents. Remove subject identifiers from the copies given to the inspector. Make a copy for yourself of any documents that are requested by the inspector.
5. The PI should set aside time each day to talk with the inspector, as well as being available for any questions that may arise.

6. Answer all questions from the inspector honestly and completely. Listen carefully to the question and only answer what was asked. It is OK to defer to the PI or other study staff if you don't know the answer. Keep a log of questions asked by the auditor.
7. How to answer Questions:
 - a. Be concise; answer only the question that is asked
 - b. Always be clear and honest in your answers
 - c. Do not provide information that the inspector has not asked for. When answering questions, do not guess or speculate. If you don't know the answer, write down the question and refer it to the appropriate person (PI or other study staff.)

C. After the inspection

1. The inspector will hold an exit interview at the conclusion of the audit. At a minimum, the escort, PI, and a representative from the Einstein IRB should attend this interview. The purpose of this interview is to review the findings and deficiencies, if any.
2. Findings will be reviewed during the exit interview
 - a. The escort should document the conversation, specifically noting observations, recommendations, comments, and commitments.
 - b. If any deficiencies were found during an FDA inspection, they will be noted on the FDA Form 483. The PI should forward a copy to the Einstein IRB Director.
3. A corrective or preventative action plan, if indicated, should be submitted to the IRB in advance of submission to the Regulatory Agency.
4. All correspondence received from regulatory agencies before, during and after the inspection should be submitted to the IRB.

For questions, contact the Einstein IRB Director at 718.430.2237.