The FDA conducts inspections to determine if clinical studies are being conducted in compliance with applicable statutory and regulatory requirements. Clinical investigators who conduct FDA-regulated clinical investigations are required to permit FDA investigators to access, copy, and verify any records or reports made by the clinical investigator. This document is intended to provide a step-by-step overview of what to expect before, during and after FDA Inspections.

Contents

[*Initial Notification of Inspection* 1](#_Toc411435002)

[*Notify Relevant Weill Cornell Medical College Personnel* 2](#_Toc411435003)

[*Reserve a Space for the Inspection* 3](#_Toc411435004)

[*Equipment Review* 3](#_Toc411435005)

[*Regulatory Review* 4](#_Toc411435006)

[*Clinical Review* 7](#_Toc411435007)

[*Day of Inspection* 8](#_Toc411435008)

[*After Inspection* 9](#_Toc411435009)

[*Additional Resources* 9](#_Toc411435010)

# *Step 1: Initial Notification of Inspection*

The FDA can conduct both announced and unannounced inspections of clinical investigator sites. It is important to always be prepared for unannounced visits by following good clinical practices; however, in the event that announced visit is conducted, generally a telephone call is made to the site to schedule a visit. During the telephone conversation, it is highly encouraged to collect all of the information outlined in the table below.

|  |  |
| --- | --- |
| **Information to Obtain**  | **Notes/Comments** |
| **Date FDA Contacted Site** |  |
| **FDA Inspectors Information** | Name: |
| Title: |
| Email: Phone:  |
| **Name of PI Being Inspected** |  |
| **Name and Protocol # of Protocol(s) Being Inspected** |  |
| **Reason for Inspection (routine, random, high/low enrolling, for cause, etc.)** |  |
| **Personnel to be Made Available for Inspection** |  |
| **Specific Documents to be Made Available for Inspection** |  |
| **List Any Documents to be Sent to FDA Prior to Inspection**  | Documents: |
| Address/Email to Send Documents:  |
| **Date, Time and Duration of Inspection** | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Duration:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**\*Note: All communication between site staff and FDA should be documented and filed in the relevant study binder.**

# *Step 2: Notify Relevant Weill Cornell Medical College Personnel*

At Weill Cornell Medical College the following entities and study personnel must be notified of any FDA inspection.

|  |  |  |  |
| --- | --- | --- | --- |
| **Contact**  | **Date Notified** | **Confirmed Availability to Attend Inspection** | **Comments/Action Items** |
| **Joint Clinical Trials Office (JCTO)**JCTOoperations@med.cornell.ed**u** |  | \_\_YES \_\_NO \_\_N/A |  |
| **Quality Assurance Unit (QAU)** ngc2002@med.cornell.edu  |  | \_\_YES \_\_NO \_\_N/A |  |
| **Institutional Review Board (IRB)**IRB@med.cornell.edu  |  | \_\_YES \_\_NO \_\_N/A |  |
| **Study Sponsor (if applicable)** |  | \_\_YES \_\_NO \_\_N/A |  |
| **Study Team:*** Principal Investigator
* Sub-Investigator(s)
* Study Coordinator(s)
* Pharmacist
* Data Manager
* Laboratory Staff
* All Other Personnel Listed on Delegation Log
* All Other Personnel Listed on FDA From 1572
 |  | \_\_YES \_\_NO \_\_N/A |  |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
|  | \_\_YES \_\_NO \_\_N/A |
| **List Any Additional Staff Invited to Attend Inspection:** |  | \_\_YES \_\_NO \_\_N/A |  |

# *Step 3: Reserve a Space for the Inspection*

Reserving the proper location for your FDA inspection is important. The reserved location should be close to a copy machine and should not contain any records/files unrelated to the study. Staff member assigned to guide FDA Inspector should remain available for the Inspector during the entire visit.

|  |  |
| --- | --- |
| **Reserved Location:** |  |
| **Identify Personnel to Guide Inspector and Serve as Point of Contact** | Name/Title: |
| Contact Information: |

# *Step 4: Equipment Review*

If applicable, ensure all of the following clinic equipment have been properly calibrated and provide up-to-date calibration records. Where applicable, confirm temperature logs are complete and current.

|  |  |  |
| --- | --- | --- |
| **Equipment Type** | **Date Reviewed** | **Comments/Action Items** |
| **Refrigerators** |  | Double-Locked: \_\_\_ Yes \_\_\_ No \_\_\_N/A |
| **Freezers** |  | Double-Locked: \_\_\_ Yes \_\_\_ No \_\_\_N/A |
| **Study Agent Storage Area/Cabinets** |  | Double-Locked: \_\_\_ Yes \_\_\_ No \_\_\_N/A |
| **Study Binder/Material Storage Area** |  | Double-Locked: \_\_\_ Yes \_\_\_ No \_\_\_N/A |
| **Electronic Scales** |  |  |
| **Electronic Blood Pressure Cuff** |  |  |
| **List All Study-Related Laboratory Equipment:** |  |  |

# *Step 5: Regulatory Review*

Locate, compile, organize, and review the documents listed below for accuracy and completeness. Please contact the JCTO Quality Assurance Unit if you have any questions regarding the documents listed below (ngc2002@med.cornell.edu).

|  |  |  |
| --- | --- | --- |
| **Document** | **Confirm/Complete** | **Comments/Action Items** |
| **Principal Investigator CV** (including list of all active protocols) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Principal Investigator Medical License** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Principal Investigator Good Clinical Practice/Human Subjects Protection Training Documentation** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Principal Investigator Financial Disclosure Form** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Sub-Investigator(s) CV** (including list of all active protocols) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Sub-Investigator(s) Medical License** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Sub-Investigator(s) Good Clinical Practice/Human Subjects Protection Training Documentation** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Sub-Investigator(s) Financial Disclosure Form** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Staff CVs** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Staff Relevant Licensure** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Staff Good Clinical Practice/Human Subjects Protection Training Documentation** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Staff Financial Disclosure Forms** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Staff Protocol Training Log(s)** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Delegation Log/Signature Log** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Complete Subject Log** (list of all subjects including name, contact information, enrollment and completion dates) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Screening Log** (names of all participants screened including enrollment date and reason for screen failure if applicable; ensure log is current and legible) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Enrollment/Randomization Logs** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All IRB-Approved Protocol Versions** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All IRB-Approved Protocol Amendments, Clarifications, Amendments, and Study-Related Correspondence** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB-Approved Informed Consent** (all versions) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Investigators Brochures/Package Inserts** (all versions) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Initial Protocol Submission/Approval Letter** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Amendment Submission/Approval Letter**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Continuing Review Submission/Approval Letter**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Approval Letter for Informed Consent** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Approval Letter for Recruitment Materials** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **IRB Correspondence Related to AE/SAE** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Correspondence Related to Any Protocol Deviations** (to/from IRB/Sponsor) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **DSMB Reports** (including submission to IRB) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Documentation of Protocol Registration, Submission, Activation, and Deregistration** (if applicable) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Other IRB Correspondence**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Sponsor Correspondence**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Study Team Correspondence**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **FDA Form 1572** (all versions) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Monitoring Letters** (Site Qualification Letter, Study Initiation Letter, Routine Monitoring Visit Letter, Study Termination Letter) | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Monitoring Visit Log**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Recruitment Plan** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Relevant Standard Operating Procedures** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |

# *Step 6: Clinical Review*

Ensure the following documentation is accurate and complete for each study participant. Additionally, be prepared to review and provide support for all source documents. Please contact the JCTO Quality Assurance Unit if you have any questions regarding the items listed below (ngc2002@med.cornell.edu).

|  |  |  |
| --- | --- | --- |
| **Item/Documentation** | **Confirm/Complete** | **Comments/Action Items** |
| **Source Documents/Medical Records** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Relevant SOPs**  |  |  |
| **Signed/Dated Informed Consents** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Completed Case Report Forms** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Confirmed Subject Eligibility**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Protocol Tests/Evaluations Documented** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **AE/SAE Communication with Subject** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **All Data Entry is Current** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Laboratory Tests and Results are Graded and Signed** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Laboratory Normal Ranges** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Laboratory Certificates**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Specimen Logs** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Copies of Any Laboratory Audits** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Documented Premature Study Discontinuation**  | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Concomitant/Prohibited medications Documented and Reported** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Drug Accountability Log** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Documentation of Study Drug Transfers, Returns, and Destruction** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |
| **Study Drug Ordering/Shipping Documentation** | \_\_\_ Yes \_\_\_ No \_\_\_N/A |  |

# *Step 7: Day of Inspection*

When the FDA inspector arrives at the site, he/she will provide official identification/ID badge and present a Notice of Inspection form (FDA Form 482). The table below provides some insight on what to expect during the audit.

|  |  |
| --- | --- |
| **What to Expect** | **Notes/Comments/Questions** |
| **Principal Investigator and Study Team Meet with FDA Inspector** |  |
| **Principal Investigator Signs FDA Form 482 (if not presented with a 482, ask for 482)** |  |
| **Provide a Tour of the Facility** |  |
| **FDA Inspector will Request to Review Files** (Only provide requested files and be prepared to make copies of any requested information. The inspection may take several days, and at the end of each day, the inspector will review relevant findings with the study team which should be communicated with the study sponsor.) |  |
| **FDA Inspector Holds Exit Interview and Reviews Findings** (a representative of the Quality Assurance Unit should be present during the exit interview) |  |
| **FDA Inspector Issues FDA Form 483 (Inspectional Observations) for Any Deficiencies** |  |

# *Step 8: After Inspection*

Upon completion of the FDA Inspection please complete the below listed actions.

|  |  |  |
| --- | --- | --- |
| **Actions** | **Date Completed** | **Notes/Comments** |
| **Immediately Notify JCTO, IRB, and Sponsor of All Findings**  |  |  |
| **Draft Written Response to FDA Form 483** (if applicable)  |  |  |
| **Send Draft Response to FDA Form 483 to the JCTO Quality Assurance Unit for Review/Approval** (if applicable) |  |  |
| **JCTO Quality Assurance Unit will Review/Approve Response to FDA Form 483** (if applicable) |  |  |
| **File All FDA Correspondence from Inspection** |  |  |

**\*Note: Please copy the JCTO Quality Assurance Unit on all correspondence with the FDA following the Inspection. The Quality Assurance Unit can assist with preparing the response to the FDA Form 483 and must review/approve the response prior to submission to the FDA.**

# *Additional Resources*

* **FDA Inspection Guidance Document:** <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf>
* **FDA Information on Running Clinical Trials:** <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>
* **FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors:** <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>
* **FDA Clinical Investigator Training Course:** <http://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM337271.pdf>
* **CFR - Code of Federal Regulations Title 21:** <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68>
* **FDA Form 483 Frequently Asked Questions:** <http://www.fda.gov/ICECI/Inspections/ucm256377.htm>