After the Inspection

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).

Last updated: 26 Aug 2022

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