
The Food and Drug Administration—or FDA—conducts periodic, scheduled inspections to determine whether IRBs are operating in compliance with current FDA regulations and laws and are following their own written procedures.

FDA’s human subjects regulations appear in title 21 of the Code of Federal Regulations.

- Part 50 pertains to the protection of human subjects in research.
- Part 56 addresses FDA requirements for the membership and responsibilities of institutional review boards.
- Part 312 includes requirements for investigational new drug—or IND—applications.
- Part 812 includes requirements for investigational device exemptions, or IDEs.

The University of Michigan Human Research Protection Program’s Operations Manual outlines the policies according to which all nine of the institution’s IRBs function and on which they base their own standard operating procedures.

Before an inspection, the FDA District Office contacts the appropriate Institutional Official to schedule a site visit. After issuing a notice of inspection (called a Form FDA 482) and presenting their credentials to the Institutional Official, FDA personnel interview representatives from the IRB and the institution, in order to obtain information about the IRB’s policies and procedures. FDA usually evaluates the IRB’s performance by tracking one or more FDA-regulated studies subject to IRB review. Inspectors also examine the IRB’s procedures and membership rosters, to determine whether they conform to current FDA regulations.

During an inspection, FDA personnel typically review and copy

- records of IRB membership
- IRB procedures and guidelines
- minutes of IRB meetings over the past year
- study-related documents that researchers have submitted to the IRB
- study-related documents that the IRB has issued to researchers
- other materials about the studies that inspectors are tracking

At the end of the inspection, FDA personnel conduct an exit interview with institutional and IRB representatives. They discuss the outcome of the inspection and, if they have observed deficiencies, issue a Form FDA 483, enumerating those observations that FDA inspection personnel feel represent significant deviations from FDA regulations and applicable laws. The IRB may respond to the 483, both verbally during the exit interview and, if they choose, in writing within fifteen (15) days after the inspection to FDA’s District Office in Detroit. It is UM’s practice to respond in writing to any Form 483 observations. .

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FDA Inspections of IRBs

After an inspection, FDA personnel prepare and issue an Establishment Inspection Report, or EIR. The EIR, the 483 (if issued), and any IRB response then undergo further evaluation by FDA headquarters in Maryland. When FDA headquarters has completed its evaluation, FDA typically sends one of the following to the institutional official:

- a letter stating that FDA observed no significant deviations from FDA regulations. Sometimes, when no deviations have been observed, FDA chooses not to send a letter;
- an *informational* or *untitled letter* identifying deviations from FDA regulations and laws for which voluntary corrective action is sufficient. Sometimes, FDA requests that the IRB respond to this letter;
- a *Warning Letter* identifying serious deviations from FDA regulations and laws. A Warning Letter generally requests prompt correction by the IRB, as well as a formal written response to FDA.

FDA may require the IRB to respond to an inspection letter within a specified period and to present a corrective action plan. Based on this response, FDA may schedule a re-inspection to confirm the adequacy of corrective actions.

In addition to issuing these letters, FDA may take other administration actions against the IRB or institution. Until the IRB or institution takes appropriate corrective action, FDA may (for studies subject to FDA regulations)

- withhold approval of new studies conducted at the institution or reviewed by the IRB
- direct that no new subjects be added to ongoing studies
- terminate ongoing studies, provided that termination will not endanger subjects
- notify state, federal, and other regulatory agencies of the deficiencies found during the inspection, if noncompliance poses a significant threat to the rights and welfare of human subjects

If the IRB has refused or repeatedly failed to comply with FDA's IRB regulations, and the noncompliance adversely affects human subjects' rights or welfare, the FDA Commissioner may begin proceedings to disqualify the IRB or the institution from conducting human subjects research.

Contact the IRB for more information about FDA inspections.

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