

FDA AUDIT PROCESS FOR WMED IRB

PROCESS FOR A SCHEDULED OR UNANNOUNCED FDA AUDIT:

1. Scheduling an Audit
 - a. An FDA inspector(s) contacts the IRB designee (usually the IRB Chairperson) by telephone or in writing to schedule a site visit, or the inspector(s) may come to a site without notice.
 - b. If there are extenuating circumstances (ie, IRB Chair or Vice Chair are not available) a short delay for the audit may be requested for a mutually convenient time. The FDA does not have to honor this request.
 - c. The WMed IRB designee who receives the initial notification of an FDA audit notifies the WMed HRPP Director or listed alternate.
 - d. The WMed HRPP Director, or listed alternate, facilitates communication and oversight of the FDA audit visit until its completion utilizing the WMed FDA Audit Response Plan.

2. Preparing for the Audit
 - a. The WMed HRPP Director, or alternate, works with appropriate IRB designee(s) to assign and facilitate the notification of the following staff with pertinent details, if applicable:
 - 1) IRB Chair, IRB Vice Chair, IRB Manager, IRB Staff, and Education-Quality Improvement Program Personnel
 - 2) WMed Assistant Dean for Research Compliance
 - 3) Assistant Dean for Clinical Research Operations
 - 4) Center for Clinical Research Director and employees
 - 5) WMed Dean (Institutional Official)
 - 6) WMed Associate Dean for Research
 - 7) WMed Associate Dean Administration and Finance (Compliance Officer)
 - 8) Legal Services
 - 9) If the audit will involve review of IRB records at Bronson contact:
President & CEO, Vice President and Chief Compliance Officer, Chief Quality Officer, Senior VP of Legal & Legislative Affairs (Institutional Official), Director of Quality & Safety and VP of IT and Medical Records Director
 - 10) If the audit will involve review of IRB records at Borgess, contact:
President & CEO, Chief Strategy Officer (Institutional Official), Borgess Legal Services, Accreditation & Regulation Consultant, IT and Medical Records
 - 11) WMed Department Chair, if applicable
 - 12) WMed IT (for electronic record access)
 - b. The IRB Manager or designee(s) ensure that all documentation (ie, study-related submission documentation, IRB communications, IRB approval documentation, HRPP and IRB Handbook, IRB minutes, IRB membership rosters, etc.) identified as the focus of the audit are accurate, complete, and available for review by the inspector(s).

FDA AUDIT PROCESS FOR WMED IRB

- c. The IRB Manager and/or designee(s) will work in conjunction with the HRPP Director and E-QIP Team to help ensure all documentation is in good order and available for FDA review.
3. Inspector(s) Arrival
 - a. Upon arrival, the FDA inspector(s) shows credentials and an FDA badge. Proper identification is required prior to review of records.
 - b. The inspector presents a "Notice of Inspection" (Form FDA 482).
 - c. The WMed HRPP Director or alternate, IRB Chair and appropriate IRB staff will be notified upon FDA inspector(s) arrival and will be asked to make time available for the duration of the audit.
 - d. The inspector(s) may request a short interview with the IRB Chair and/or appropriate designee(s) and obtain information about the IRB's policies and procedures before beginning the audit.
 - e. The WMed HRPP Director or alternate and IRB designee provides the inspector(s) with a quiet area, free from excessive interruptions in which to work. The inspector(s) may request that a telephone be available.
 4. During the Audit
 - a. The IRB designee provides orientation and access only to the IRB records and files that have been requested to be inspected. The IRB's procedures and membership rosters are examined to determine whether they conform to current FDA regulations (21 CFR Part 56, Subparts A-D) or other applicable research regulations. Usually, the IRB's performance is evaluated by tracking one or more studies that are subject to IRB review under FDA regulations. During the inspection, FDA inspector(s) typically reviews and copies:
 - i. Records of IRB membership
 - ii. IRB procedures and guidelines
 - iii. Minutes of IRB meetings for the past year
 - iv. Documents related to the studies given by the clinical investigator to the IRB
 - v. Documents related to the studies sent by the IRB to the clinical investigator
 - vi. Any other materials about these studies
 - b. As much as possible, all records and/or documents requested to be inspected by the FDA will be reviewed by the HRPP Director or alternate and/or IRB designee prior to providing them to the FDA Inspector(s). This review should not impede the inspection.
 - c. A designated research staff member is available at all times to bring requested materials to the inspector(s) and to make copies of requested documents. The HRPP Director or alternate and/or IRB designee(s) should be available as needed for any questions and/or clarifications related to documents to be reviewed and to facilitate electronic record access. The WMed IRB designee makes duplicate copies of any photocopied documents provided to the inspector(s). These copies are to be retained for WMed IRB records.
 - d. An individual is designated to take notes of the audit, including but not limited to items reviewed, questions asked, individuals interviewed, responses provided.

FDA AUDIT PROCESS FOR WMED IRB

5. Follow-up After the Audit
 - a. The HRPP Director or alternate, IRB Chair, IRB designee(s) and any other required staff members participate in the exit interview with the FDA inspector(s). At this interview, FDA inspector(s) who conducted the inspection will review and discuss the findings from the inspection, and if deficiencies are found, issue a written Form FDA 483 (Inspectional Observations, 483) to the IRB representative. The Form FDA 483 describes any inspectional observations that, in the opinion of the FDA personnel conducting the inspection, represent deviations from applicable statutes and regulations. The IRB may respond to the Form FDA 483 observations verbally during the exit interview and/or respond in writing.
 - b. If a Form FDA 483 is issued, the HRPP Director, IRB Chair and the Corporate Compliance Officer prepares and sends a response to the audit report to the FDA District Office listed in the upper left corner of the Form FDA 483 no later than 15 business days following receipt of report.
 - c. The HRPP Director or alternate and/or IRB designee develops and maintains a separate binder containing all documentation from the audit, including:
 - 1) Records of communication with the FDA
 - 2) Copy of records provided to the FDA
 - 3) FDA Form 483 (if applicable)
 - 4) Response to 483 (if applicable)
 - 5) Establishment Inspection Report (EIR)
 - d. If applicable, the HRPP Director in conjunction with the IRB Chair and E-QIP Team evaluates the audit report to identify areas for improvement and facilitates the development of a CAPA to improve quality.

REFERENCES:

1. 21 CFR Part 50 – Protection of Human Subjects
2. 21 CFR Part 56 – Institutional Review Boards
3. 21 CFR Part 312 – Investigational New Drug Application
4. 21 CFR Part 812 – Investigational Device Exemptions
5. Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Institutional Review Board Inspections, U.S. Department of Health and Human Services, Food and Drug Administration, January 2006
6. WMed Policy/Procedure Number HRP001, Human Research Protection Program
7. WMed Human Research Protection Program and Institutional Review Board Handbook

GEN01 Code of Professional Conduct

GEN04 Conflicts of Interest and Commitment

HRP01 Human Research Protection Program

WMed Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook

ATTACHMENTS:

None