

Audit by Federal Agency

Overview:

This guidance describes the process that must be followed when principal investigators are notified by federal regulatory agencies (e.g., FDA, NIH, DOD) that an inspection or an audit is being scheduled. It is important to notify relevant University offices as soon as possible to ensure availability of personnel and time to assist with a comprehensive review, if needed.

Description:

1. Principal investigators (PI) must notify the IRB in writing about inspections/audits being conducted by a regulatory agency, as soon as possible. This notice should include:
 - IRB protocol number
 - Date and location of the planned inspection
 - Name of the agency
 - If known, the name of the inspectors or auditors
 - Type of audit: random or for cause
2. The PI should make arrangements to ensure that the Authorized Institutional Official (or his designee) be included in the exit interview. The Authorized Institutional Official for the University of Pittsburgh is George A. Huber, JD, MSIE, MSSM, Interim Vice Provost, Research Conduct and Compliance.
3. If time permits, the Education and Compliance Office (ECO) will make arrangements to conduct a comprehensive review of the IRB file, research participant records, and regulatory files in advance of the inspection to ensure compliance with IRB policies, applicable federal regulations and Good Clinical Practices.
4. Any report issued as a result of a regulatory inspection/audit must be submitted to the IRB for formal review to determine whether any observations constitute serious or continuing non-compliance with the federal regulations governing human subjects research.
5. The PI must provide prompt notice to the IRB if any federal agency suspends a study or requests that a clinical hold be placed on the study.
6. **Within 10 working days** of receipt of the final agency report, the PI must submit any written response to the IRB for its review and approval **BEFORE** sending that final response to the agency.

7. Contacts:

- IRB: contact Jean Barone, Director of Regulatory Affairs, at 412-383-1480 or via email at baronej2@upmc.edu
- Education and Compliance Office: contact Kelly Dornin-Koss, Director, at 412-383-1711 or via email at dorninkl@upmc.edu

Definitions:

Random audit: As part of a general research oversight program, auditors will randomly choose studies to ensure they are being conducted properly. It is not uncommon for sponsors, federal agencies, and compliance monitors to routinely select, by chance, studies to audit or possibly by populations studied.

For Cause audit: The audit may be initiated due to a complaint, evidence of non-compliance, or concerns about the qualifications of investigators.

Form 483: A list of observations made by the FDA representative during an inspection.

Additional Information:

Food and Drug Administration (FDA)

- 5.1 – Inspection Information
<http://www.fda.gov/ICECI/Inspections/IOM/ucm151267.htm#5.1.1.3>
- FDA 483- Inspection Observations
<http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm>

University of Pittsburgh

- Education and Compliance Office
<http://www.ecohsr.pitt.edu/>