**Purpose:**

This guide describes the process to be followed when the principal investigator (PI) is notified by a federal regulatory agency (e.g. FDA, OHRP, DOD, NIH) that an inspection or an audit will occur. It is important to notify University offices as soon as you are aware to ensure availability of personnel and time to assist with a pre-audit review, if needed.

**Procedures:**

1. **PI must notify the IRB in writing about inspections/audits being conducted by a federal regulatory agency, as soon as possible.** This notice is emailed to HSPPO@louisville.edu. This notice should include:
   - IRB number
   - Protocol
   - Date and location of planned inspection
   - Name of agency conducting the inspection
   - Type of audit: random or for cause

2. In addition, the PI should notify the Institutional Compliance Officer and their Department Chair.

3. The PI should notify the HSPPO Director or Assistant Director as soon as the exit interview is scheduled. The HSPPO will send at least one representative to be involved in the exit interview.

4. If time allows, the Compliance Monitor will conduct a comprehensive review of the IRB file, research subject records, and regulatory files in advance of the inspection to ensure compliance with IRB policies and federal regulations.

5. Any report issued by the federal regulatory agency as a result of the inspection/audit must be submitted to the IRB for formal review. This report **MUST be submitted** within 72 hours of receipt.

6. The PI must notify the IRB immediately by phone and writing, if any federal agency suspends a study or requests a clinical hold on the study.

7. 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 federal agency.

8. Once the final letter from the federal agency it **must be submitted** to the IRB, through the electronic submission process within 5 working days.