SOP: Institutional Review Board Federal Inspections

1 PURPOSE

1.1 This procedure establishes the process to manage federal regulatory inspections of the IRB.

1.2 The process begins when the IRB is notified of an upcoming inspection.

1.3 The process ends when the regulatory agency notifies the IRB the inspection has concluded, based on the agency's procedures and the findings observed. E.g., the inspection process may conclude at the exit interview if no findings are observed, or additional determination letters/reports and further follow-up from the IRB may be required.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None - New SOP to support IRB inspections conducted by a federal agency.

3 POLICY

3.1 IRB records subject to oversight by the agency conducting the inspection are made accessible for inspection in accordance with HRP-072 - SOP - IRB Records Retention.

4 RESPONSIBILITIES

4.1 The Institutional Official/Organizational Official (IO/OO) is responsible for the acknowledgement and oversight of the IRB inspection. Additionally, is it the responsibility of the IO/OO to review any written response to findings raised during the inspection.

4.2 The IRB Manager or designee is responsible for carrying out these procedures.

5 PROCEDURE

5.1 If notification of the inspection is provided in advance, ask the inspector for the following details (if not provided):

5.1.1 Inspector's name and contact information.

5.1.2 Date and time the inspection will start.

5.1.3 Anticipated duration of the inspection.

5.1.4 In person or virtual.

5.1.5 Scope of the inspection and inspection type (i.e., surveillance/not-for-cause vs. directed/for-cause).

5.1.6 Any specific areas of concern, materials or files to have available for review, and/or individuals they will interview.

5.2 Notify the IO/OO, IRB chair(s), IRB members, IRB staff, and all other pertinent parties of the inspection.

5.2.1 If applicable, notify IT the inspector will need read-only access to applicable studies within the electronic system, based on the agency conducting the inspection.

5.2.2 Notify Huron Consulting Group of the inspection.

5.3 Communicate expectations and responsibilities of IO/OO, IRB chair(s) and IRB staff during, and in preparation of, the inspection.

5.3.1 The IO/OO, IRB chair(s), and IRB Manager should be available for interview (including the entrance and exit interviews) and/or consultation during the inspection.

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5.3.2 Designate at least one senior level staff member to be the inspector's point of contact, responsible for:
- 5.3.2.1 Participating in the entrance briefing.
- 5.3.2.2 Answering questions on behalf of the institution.
- 5.3.2.3 Always being available to the inspector during the inspection.
- 5.3.2.4 Locating all requested information and/or individuals the inspector requests interviews with.
- 5.3.2.5 Preparing documents.
- 5.3.2.6 Making copies.
- 5.3.2.7 Debriefing with the inspector.
- 5.3.2.8 When necessary, assigning additional staff members the responsibility of supporting the point of contact (e.g., in locating information, making copies, and/or providing IT expertise when inspections are conducted remotely).

5.4 Prepare to provide the following to the inspector:

5.4.1 HRPP Toolkit documents including all SOPs, general documents, forms, worksheets, and checklists.
- 5.4.1.1 Review HRP-105 - OHRP FDA Written Procedure Crosswalk to ensure all information is correct and includes up-to-date document versions.

5.4.2 Recent updates to the IRB registration and federalwide assurance (FWA) in accordance with HRP-080 - SOP - IRB Formation and Registration and HRP-081 - SOP - IRB Removal.

5.4.3 A list of active protocols subject to oversight by the agency conducting the inspection.
- 5.4.3.1 Include/identify any protocols meeting criteria specifically requested by the inspector (e.g. studies involving children).

5.4.4 IRB membership records, including HRP-601 - DATABASE - IRB Roster.

5.4.5 IRB meeting minutes.
- 5.4.5.1 Minutes that have not yet been finalized should be identified as drafts.

5.4.6 Organizational (or personnel) charts identifying:
- 5.4.6.1 The IRB office within the institutional reporting structure.
- 5.4.6.2 IRB staff within the IRB's reporting structure.

5.4.7 IRB records, as identified in HRP-070 - SOP - IRB Records.
- 5.4.7.1 If an electronic submission system is utilized, determine whether the inspector will be provided read-only access or hard copy files.

5.4.8 If the inspection is occurring on-site:
- 5.4.8.1 A private office or conference room for the inspector to work in that, when possible, is not located directly in the IRB office but in the vicinity and is spacious enough to accommodate meetings with multiple individuals.
- 5.4.8.2 Access to the building, as well as a copy machine and internet.

5.5 At the start of the inspection:

5.5.1 Ask the inspector to present their credentials (if not already provided). Ensure the individual conducting the inspection has the authority to do so.
- 5.5.1.1 Confirm the center (e.g., CDER, CDRH) that has requested the inspection.
- 5.5.1.2 Questions or concerns regarding the legitimacy of the credentials should be directed to the agency conducting the interview.

5.5.2 For inspections conducted by the Food & Drug Administration (FDA), ask the inspector for FDA Form 482 "Notice of Inspection" (if not provided).

5.5.3 If on-site, provide an orientation to the facility to the inspector and escort them to their workspace.

5.5.4 During the entrance briefing:
- 5.5.4.1 Provide the inspector with a copy of HRP-105 - OHRP FDA Written Procedure Crosswalk.

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5.5.4.2 Request a daily debrief at the end of each day. The inspector may not be required to provide this service, but if willing, provides an opportunity to clarify questions.

5.6 Document all activities that take place during the inspection to facilitate addressing any findings and/or responding to questions following the inspection. Documentation should replicate records the inspector maintains. This includes (but is not limited to) maintaining:

5.6.1 A list of all individuals who attend the entrance briefing, all debrief meetings, and the exit interview, as well as minutes of these meetings.

5.6.2 All documents provided by the inspector to the IRB.

5.6.3 A list of all materials provided to the inspector.

5.6.4 Questions asked by the inspector and corresponding responses.

5.6.5 A list of all staff interviewed by the inspector and notes on any post-interview debriefs.

5.6.6 A list of all attendees and notes on any convened board meetings the inspector observes.

5.6.6.1 IRB meeting minutes should document the presence of the inspector.

5.6.6.2 Questions should only be directed to the inspector at the start and/or close of the meeting; they should not participate in the review/discussion of materials on the agenda.

5.6.7 Copies of all documents the inspector copies.

5.7 During the exit interview, request clarification as necessary on the following:

5.7.1 Any discrepancies or findings identified, either verbally or in writing by the inspector and their rationale.

5.7.2 Next steps, including if and when a formal inspection report or evaluation will be provided to the IRB and how and when to respond to the report.

5.7.3 Any other anticipated actions that may be taken by the regulatory agency.

5.8 Following the inspection:

5.8.1 Debrief with the IO/OO and IRB chair(s) to review findings and determine appropriate corrective actions measures. Respond, in writing, as directed by the regulatory agency to all written reports/evaluations.

5.8.1.1 If the inspection was conducted by the FDA and a Form 483 “Inspectional Observations” was issued, respond within 15 business days.[i]

5.8.2 Ensure all corrective actions are specific, measurable, designed to address the root cause of the non-compliance, and include a timeline for implementation.

5.8.2.1 Following implementation, at an appropriate time based on the action, evaluate all corrective actions to confirm the non-compliance has been appropriately addressed.

5.8.3 Promptly implement all corrective actions and, if applicable, all actions required by the regulatory agency.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-070 - SOP - IRB Records

6.3 HRP-072 - SOP - IRB Records Retention

6.4 HRP-080 - SOP - IRB Formation and Registration

6.5 HRP-081 - SOP - IRB Removal

6.6 HRP-105 - OHRP FDA Written Procedure Crosswalk

6.7 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors “FDA Institutional Review Board Inspections”, January 2006.

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7.2 Office for Human Research Protection's Compliance Oversight Assessments, January 2024.
7.3 Public Responsibility in Medicine & Research (PRIM&R) & Bankert, E.A. (2005, 2021). *Institutional Review Board: Management and Function* (2nd & 3rd ed.). Jones & Bartlett Publishers.

[i] FDA Bioresearch Monitoring Program (BIMO) Compliance Program Manual – Institutional Review Boards