



SOP: Directed Review (For Cause) Audits

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1 PURPOSE

- 1.1 This procedure establishes the process to conduct for-cause Directed Reviews.
- 1.2 The process begins when a question relating to non-compliance (perceived or confirmed) is raised. A directed review may be required as a result of:
 - 1.2.1 Reportable new information. See SOP: Reportable New Information (HRP-024).
 - 1.2.2 Any review of submitted materials via eIRB+.
 - 1.2.3 Any allegation of non-compliance (perceived or confirmed).
 - 1.2.4 A suspension or termination of IRB approval (see HRP-026 and HRP-029).
 - 1.2.5 Request by an IRB Chair, convened panel, Executive IRB Director or IRB Manager.
- 1.3 The process ends when the Directed Review is complete and the Directed Review letter/report has been provided to the Institutional Review Board (IRB), Vice President for Research, Institutional Official or designee.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 04/02/2018.

3 POLICY

- 3.1 The IRB Office has the responsibility to: (1) Implement a Directed Reviewing program to monitor compliance and improve compliance in identified problem areas, and (2) Investigate and remediate identified systemic problem areas and, where necessary, request that the Vice President for Research remove individuals from involvement in the Human Subject Protection Program (Human Research Protection Program Plan (HRP-101)).
- 3.2 The IRB Office and IRB investigates allegations of non-compliance in Human Subject Research and imposing corrective actions as needed. In addition to Directed Reviews conducted by the IRB Office in response to reports of alleged noncompliance, the IRB Office also conducts routine post-approval monitoring of Human Subject Research studies in order to review and ensure compliance and in the conduct of Human Subject Research at the University. (Human Research Protection Program Compliance policy)

4 RESPONSIBILITIES

- 4.1 The IRB, Vice President for Research, Institutional Official or designee:
 - 4.1.1 Requests that the IRB Office Compliance Team review the Investigator and study materials as needed to answer the questions raised by the review of non-compliance or other eIRB+ submission.
 - 4.1.2 Charges the Compliance Team with the question(s) to be answered and the scope of the review.
- 4.2 The Compliance Team creates an investigational plan and carries out these procedures upon notification of directed review request.
- 4.3 The Compliance Team makes their findings and recommendations for next steps based on the available materials, interviews or information obtained during the Directed Review.
- 4.4 The Compliance Team will document their findings in writing in the form of an audit letter and provide it to the following individuals:
 - 4.4.1 Principal Investigator (PI)
 - 4.4.2 Primary contact
 - 4.4.3 With a copy to:
 - 4.4.3.1 Investigator's Department Chair or designee
 - 4.4.3.2 IRB Compliance Manager
 - 4.4.3.3 IRB Office Executive Director
 - 4.4.3.4 Other Institutional Officials as appropriate



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5 PROCEDURE

- 5.1 The Compliance Analyst will notify the investigator that a Directed Review is being conducted, the question to be answered and/or reason for the Directed Review, and the timeline for completion.
- 5.2 Determine what information to gather and what individuals to interview.
 - 5.2.1 The Compliance Analysts prepare and maintain the Directed Review file, which typically consists of the following elements (but may vary depending on the circumstances of a particular Directed Review):
 - 5.2.1.1 IRB Submission
 - 5.2.1.2 Consent Document
 - 5.2.1.3 Protocol
 - 5.2.1.4 Continuing Review (most recent)
 - 5.2.1.5 Post Approval Monitoring Checklists (HRP-430 or HRP-429)
 - 5.2.1.6 Report (official Directed Review report)
 - 5.2.1.7 IRB final Findings/Determinations (The response from the research team and the IRB Panel's determination)
- 5.3 Gather information and interview individuals.
 - 5.3.1 This might involve one or more of the following activities:
 - 5.3.1.1 Interviewing research staff
 - 5.3.1.2 Reviewing regulatory and all applicable documentation
 - 5.3.1.3 Reviewing a sample of the consent forms (e.g., 20% of consent forms depending on study enrollment and audit focus)
 - 5.3.1.4 Reviewing a sample of data or case report forms (e.g., 10% of participant files depending on study enrollment and audit focus)
 - 5.3.2 IRB Compliance Analysts complete HRP-429 for studies classified as biomedical research
 - 5.3.3 IRB Compliance Analysts complete HRP-430 for social-behavioral research studies
- 5.4 Conduct information gathering and interviews until sufficient information is obtained.
- 5.5 The Compliance Team will document their findings in writing and provide it to the Investigator and other individuals listed in 4.4.3 above.
 - 5.5.1 This documentation will include the following:
 - 5.5.1.1 Executive Summary
 - 5.5.1.2 Instructions for Investigator about how to submit a formal response
 - 5.5.1.3 A list of observations and corresponding corrective actions and/or best practice recommendation.
 - 5.5.2 The Investigator will submit the Audit Report and his or her response to the Institutional Review Board for review and acknowledgement through an RNI submission in eIRB+.

6 MATERIALS

- 6.1 SOP: Reportable New Information (HRP-024)
- 6.2 CHECKLIST: Post-Approval Monitoring: Social Behavioral Research (HRP-430)
- 6.3 CHECKLIST: Post-Approval Monitoring: Biomedical Research (HRP-429)
- 6.4 SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026)
- 6.5 SOP: Suspension or Termination of IRB Approval by Convened Panel (HRP-029)

7 REFERENCES

- 7.1 POLICY: Human Research Protection Program Compliance
- 7.2 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)



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