



SOP: Handling Complaints and Allegations of Non-Compliance

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1 PURPOSE

- 1.1 This policy establishes the process by which the Institutional Review Board (IRB) Office receives and handles complaints and allegations of non-compliance.
- 1.2 The process begins when a member of the IRB Office is informed of a complaint or an allegation of non-compliance.
- 1.3 The process ends when the complaint or allegation has been fully resolved or rescinded by the individual or when the investigation of an allegation of non-compliance has been completed.

2 PREVIOUS VERSION

- 2.1 Revised from version dated 01/31/2024.

3 POLICY

- 3.1 Federal regulations require each institution to have "...written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) ... any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval."
- 3.2 Complaints or allegations of non-compliance may be made by participants or their representatives, faculty, staff, or others engaged in research or responsible for related University oversight activities.
- 3.3 The IRB Office may receive complaints from participants or allegations through the following channels that include but are not limited to:
 - 3.3.1 Phone call
 - 3.3.2 Email
 - 3.3.3 In person
 - 3.3.4 EthicsPoint website
- 3.4 Complaints or allegations of non-compliance may be handled internally within the office or directed to an IRB panel, executive director, Institutional Official (IO), or other university department(s).
- 3.5 The IRB Office will route complaints that do not involve human participant research to the appropriate department(s).
- 3.6 The IRB Office will not engage with complainants who use profane or abusive language in their communication and may inform the appropriate university department(s).

4 RESPONSIBILITIES

- 4.1 Complaints may be received by any IRB Office staff member.
- 4.2 The IRB Office Compliance Team carries out the activities related to handling complaints and allegations of non-compliance.
- 4.3 The IRB Office Compliance Team reports the activities at the IRB Chairs Meeting.

5 PROCEDURE

- 5.1 Reporting complaints or an allegation of non-compliance:
 - 5.1.1 Investigators are required to report promptly to the IRB, using the Reportable New Information form, all findings and allegations of apparent serious or continuing non-compliance, researcher error, participant complaints that the research team cannot resolve, and unreviewed changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects.
 - 5.1.2 Non-compliance may be uncovered by the IRB or the IRB Compliance Team member (e.g., during ongoing review or monitoring of research or through audits or other



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- quality assurance activities). These findings are handled internally and then routed for IRB review, if appropriate.
- 5.1.3 Members of the research team, faculty, staff, administrators, sponsors, study participants, participating organizations, or other knowledgeable parties may also report allegations of non-compliance.
 - 5.1.4 Complaints or allegations of non-compliance received directly by the IO or Human Protection Administrator (HPA) are referred to the IRB Office.
- 5.2 When a complaint or allegation of non-compliance is received or sent to the IRB Compliance Team, the procedure is as follows:
- 5.2.1 Obtain detailed information from the complainant, such as the nature of the complaint/allegation, any study identifiers (if available), Principal Investigator (PI) or study contact name, their contact information (if available), and if necessary, the IRB Compliance Team may share identifying information about them and details of their complaint with other parties to aid in the investigation and resolution, including with the PI and members of the research team. If the complainant requests confidentiality (i.e., that the IRB Compliance Team not share their information), the IRB Compliance Team member will inform them that the IRB Compliance Team's ability to investigate and come to resolution may be impaired.
 - 5.2.1.1 An IRB Compliance Team member completes the CHECKLIST: Complaints and Allegations of Non-Compliance (HRP-1402) with all relevant information regarding the complaint or allegation.
 - 5.2.1.2 The IRB Compliance Team member saves all related documentation to the unit's shared drive.
 - 5.2.1.3 The IRB Compliance Team member will investigate whether the complaint or allegation is related to an approved research study and if a corresponding IRB application exists.
 - 5.2.1.4 The IRB Compliance Team member will contact the PI or individual listed as the study contact to discuss the complaint and determine the next steps or follow-up actions.
 - 5.2.1.4.1 A high-level summary of this discussion may be shared with the complainant to ensure the matter has been resolved.
 - 5.2.1.5 The IRB Compliance Team member may consult with the IRB Compliance Manager to determine if the allegation has a basis in fact or if the complaint is a minor administrative issue that is easily resolved. No further action is taken if the incident does not represent non-compliance (e.g., isolated subject payment complaint).
 - 5.2.2 If the nature of the complaint/allegation requires escalation and the research in question has a corresponding IRB application, the following actions will be taken:
 - 5.2.2.1 The IRB Compliance Team member may determine that the complaint/allegation represents potential non-compliance and compile any collected information for subsequent review by the Chair (or designee) or IRB Panel.
 - 5.2.2.2 If the IRB Compliance Team member determines the complaint/allegation involves an incidental disclosure of PHI or PII, they will notify the appropriate parties via email of the incident and the PI's planned corrective and preventive actions and consult on the required next steps in the Guidance on Evaluating Reports of Data Incidents. If the PI is asked to respond to the complaint or allegation, this information is included with the material provided to the Chair (or designee) or IRB Panel.



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- 5.2.2.3 The IRB Compliance Team member may instruct the research team to submit a Reportable New Information (RNI) application to formally document the event or submit an RNI on behalf of the PI.
- 5.2.2.4 The submission will undergo review in a manner consistent with procedures outlined in SOP: Reportable New Information (HRP-024).
- 5.2.3 If the nature of the complaint or allegation requires escalation and the research in question does not have a corresponding IRB application, the following actions will be taken:
 - 5.2.3.1 The IRB Compliance Team member may determine that the complaint or allegation represents potential non-compliance and compile any collected information for subsequent review by the Chair (or designee) or IRB Panel.
 - 5.2.3.2 If the PI is asked to provide a response to the complaint or allegation, this information is included with the material provided to the Chair (or designee) or IRB Panel.
 - 5.2.3.3 If an IRB Panel will review the complaint or allegation, the IRB Compliance Team member will provide consultation and clarification as needed. The complaint or allegation will be added to an IRB Panel meeting agenda by the IRB Analyst assigned to the Panel.
 - 5.2.3.4 The complaint or allegation will undergo review by the IRB Panel that may require subsequent action or further reporting to the Chair (or designee).
- 5.2.4 If the complainant uses profane or abusive language in their communication, the IRB Compliance Team member will:
 - 5.2.4.1 Not engage with the complainant
 - 5.2.4.2 Notify the IRB Compliance Manager
 - 5.2.4.3 Alert the PI to the communication if the Compliance Team member is able to identify the study
 - 5.2.4.4 May inform the appropriate department(s)
 - 5.2.4.5 End the response process
- 5.2.5 In instances where the complainant provides insufficient information to identify the study, PI, or study contact after multiple attempts by the IRB Compliance Team member to obtain this information, the response process ends.
- 5.2.6 All complaints and allegations received, including minor administrative issues resolved internally, are entered into the appropriate compliance tracking mechanism. A compilation of these complaints is provided to the IRB Chairpersons, Institutional Officials, and IRB Office staff at the monthly IRB Chairs' Meeting. The information is presented to inform them of issues or recurring concerns that may require new or revised policies and procedures.

6 MATERIALS

- 6.1 CHECKLIST: Complaints and Allegations of Non-Compliance (HRP-1402)
- 6.2 SOP: Reportable New Information (HRP-024)
- 6.3 GUIDANCE DOCUMENT: Evaluating Reports of Data Incidents (HRP-1908)

7 REFERENCES

- 7.1 45 CFR 46.103(b)(5)(i)
- 7.2 45 CFR 46.116(b)(5)
- 7.3 21 CFR 50.25(b)(5)
- 7.4 21 CFR 56.108(b)(2)