



SOP: Handling Complaints and Allegations of Non-Compliance

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1 PURPOSE

- 1.1 This policy establishes the process by which the IRB Office receives and handles complaints or allegations of non-compliance.
- 1.2 The process begins when a member of the IRB office is informed of a complaint or allegation of non-compliance.
- 1.3 The process ends when the complaint has been fully resolved or rescinded by the individual or when the investigation of an allegation of non-compliance has been completed.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 10/23/2019.

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 and/or directed to an IRB panel, executive director, Institutional Official (IO), or other university departments.
- 3.5 If the complaint does not involve human participant research, the issue is routed to the appropriate department.

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/or 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 quality assurance activities). These findings are handled internally then routed for IRB review, if appropriate.



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- 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.
- 5.2 When a complaint or allegation of non-compliance is received and/or sent to the IRB Compliance team, the procedure is as follows:
 - 5.2.1 Detailed information is obtained from the complainant, such as the nature of the complaint, any study identifiers (if available), PI or study contact name, and their contact information (if available).
 - 5.2.1.1 An IRB Compliance team member completes Research Participant Complaint Checklist (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 adds a summary of the event to the appropriate compliance tracking mechanism.
 - 5.2.1.4 The IRB Compliance team member will determine the study in question and if a corresponding IRB application exists.
 - 5.2.1.5 The IRB Compliance Analyst will contact the PI or individual listed as study contact to discuss the complaint and determine the next steps or follow-up actions.
 - 5.2.1.6 The IRB Compliance Analyst will consult with the IRB Compliance Manager to determine if the allegation has no basis in fact or that the complaint is a minor administrative issue that is easily resolved. If the incident does not represent non-compliance (e.g., isolated subject payment complaint), no further action is taken.
 - 5.2.2 If the nature of the complaint 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 Analyst may determine that the allegation represents potential non-compliance and compiles any collected information for subsequent review by the Chair (or designee) or IRB Panel.
 - 5.2.2.2 If the investigator 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.
 - 5.2.2.3 The IRB Compliance Analyst 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 HRP-024 Reportable New Information SOP.
 - 5.2.3 If the nature of the complaint 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 Analyst may determine that the allegation represents potential non-compliance and compiles any collected information for subsequent review by the Chair (or designee) or IRB Panel.
 - 5.2.3.2 If the investigator 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 the complaint or allegation will undergo IRB Panel review, the IRB Compliance Analyst will create a summary of the event and subsequent information. The complaint or allegation will be added to an IRB Panel meeting agenda by the IRB Analyst assigned to the Panel.



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- 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 Complaints or allegations of non-compliance received directly by the IO or HPA are referred to the IRB Office and handled as described above.
- 5.2.5 A summary of this discussion will be shared with the complainant to ensure the matter has been resolved.
- 5.2.6 All complaints and allegations, including minor administrative issues resolved internally, are entered into the appropriate compliance tracking mechanism. A compilation of these complaints is provided to the IRB Chairmen, Chairwomen, Institutional Officials, and IRB Office staff at the monthly IRB Chairs' Meeting. The information is presented to make them aware of issues and/or recurring concerns that may require new or revised policies and procedures.
- 5.2.7 In instances where insufficient information is provided, a summary of the incident is detailed within the compliance tracking mechanism.

6 MATERIALS

- 6.1 CHECKLIST: Research Participant Complaint (HRP-1402)
- 6.2 SOP: Reportable New Information (HRP-024)

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)