



SOP: Corrective Action and Preventive Action (CAPA) Plan Assessments

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1 PURPOSE

- 1.1 This policy establishes the process by which the Institutional Review Board (IRB) Office receives and assesses a corrective and preventive action (CAPA) plan.
- 1.2 The process begins when a CAPA assessment is requested by an IRB Chair, convened IRB Panel, Executive IRB Director, Associate Director, or IRB Manager, or is randomly chosen for a routine quality assurance assessment.
- 1.3 The process ends when the convened IRB Panel or IRB Compliance Team determines that adherence to and effectiveness of the CAPA plan is sufficient, and the IRB Compliance Team reports the activity to the Northwestern University Institutional Review Board at the IRB Chairs' Meeting.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 05/26/2021.

3 POLICY

- 3.1 In accordance with the regulations that govern human research, the IRB Office has the authority to observe or have a third party observe the consent process and the [conduct of] research (45 CFR [§46.109](#) (g) and 21 CFR [§56.109](#) (f)).
- 3.2 In this procedure, CAPA plans are received by the IRB Office via a Reportable New Information (RNI) application.
- 3.3 CAPA assessments are done to ensure appropriate adherence to and the effectiveness of the CAPA plans that were proposed and implemented.

4 RESPONSIBILITIES

- 4.1 CAPA assessments may be requested by a Panel or randomly chosen by the IRB Compliance Team for quality assurance purposes.
- 4.2 The IRB Compliance Team carries out the activities related to CAPA assessments.
- 4.3 The IRB Compliance Team makes observations and recommendations for the next steps based on the available materials, interviews, or information obtained during the assessment.
- 4.4 The IRB Compliance Team documents their observations in writing in the form of an observation letter and provides it to the following individuals:
 - 4.4.1 Principal Investigator (PI)
 - 4.4.2 RNI submission preparer
 - 4.4.3 Other Institutional Officials as appropriate
 - 4.4.4 Investigator's Department Chair, Division Chief, or supervisor (for directed review)
 - 4.4.5 IRB Compliance Manager (for directed review)
 - 4.4.6 Associate Director of Compliance and Reliance (for directed review)
 - 4.4.7 IRB Office Executive Director (for directed review)
- 4.5 The IRB Compliance Team reports routine and directed CAPA assessment activities at the IRB Chairs Meeting.

5 PROCEDURE

- 5.1 When selected for a directed review CAPA Assessment, the process begins when the IRB Compliance Team receives instruction from an IRB Chair, Panel, Executive IRB Director, Associate Director, or IRB Manager to assess an investigator's implementation of their CAPA plan.
- 5.2 When selected for routine monitoring, the process begins when the IRB Compliance Analyst selects a CAPA plan via a report from eIRB+.



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- 5.2.1 The IRB Compliance Analyst selects a CAPA plan considering the severity of the event reported, the quality of the plan, the feasibility of review, observed patterns of non-compliance, and input from IRB Office leadership.
- 5.2.2 The IRB Compliance Analyst will attempt not to select multiple CAPA plans from the same Principal Investigator within the same calendar year for routine review.
- 5.3 The primary IRB Compliance Analyst, who will serve as the point person for the review, will contact the PI and RNI submission preparer to schedule the CAPA assessment using the TEMPLATE: Directed Review Notification (HRP-1814), the TEMPLATE: Routine CAPA Assessment Visit Notification (HRP-1816), or the TEMPLATE: Routine CAPA Self-Assessment Notification (HRP-1824).
 - 5.3.1 The PI must provide all appropriate documentation regarding the CAPA plan. This includes but is not limited to:
 - 5.3.1.1 Regulatory binder or research record
 - 5.3.1.2 Participant files
 - 5.3.1.3 Internal policies or guidance documents
- 5.4 In preparation for the assessment, the primary IRB Compliance Analyst will create a CAPA Assessment Guide (HRP-1813) containing the following information:
 - 5.4.1 A summary of the event and subsequent IRB review
 - 5.4.2 A list of all CAPA plan action points
 - 5.4.3 Assignment of IRB Compliance Analysts to review specific sections of the CAPA plan (if necessary)
- 5.5 The primary IRB Compliance Analyst will disseminate the guide to the rest of the IRB Compliance Team for use during the visit (if necessary).
- 5.6 The IRB Compliance Analyst(s) will conduct a review that may involve one or more of the following activities:
 - 5.6.1 Interviewing research staff
 - 5.6.2 Reviewing regulatory and all applicable documentation
 - 5.6.3 Reviewing a sample of the consent forms (e.g., 40% of consent forms depending on study enrollment and audit focus)
 - 5.6.4 Reviewing a sample of data or case report forms (e.g., 20% of participant files depending on study enrollment and audit focus)
- 5.7 For routine CAPA Assessment visits, the IRB Compliance Analyst will do the following:
 - 5.7.1 Document their observations in writing using the Routine CAPA Assessment Observations Letter template (HRP-1817) and provide it to the PI and other individuals listed in 4.4 above within two weeks of the visit.
 - 5.7.2 Review the PI's response to the observations and send queries to the PI as necessary.
 - 5.7.3 Send the PI a closeout email when the visit is complete, the PI's response is satisfactory, and the PI resolves all queries.
 - 5.7.4 Record the CAPA Assessment activity in the appropriate compliance tracking mechanism and report the activity at the IRB Chairs' Meeting.
- 5.8 For routine CAPA Self-Assessments, the IRB Compliance Analyst will do the following:
 - 5.8.1 Review the PI's response and documentation regarding the implementation of the CAPA plan and send queries to the PI as necessary.
 - 5.8.2 Send the PI a closeout email when the visit is complete, the PI's response is satisfactory, and the PI resolves all queries.
 - 5.8.3 Record the CAPA Assessment activity in the appropriate compliance tracking mechanism and report the activity at the IRB Chairs' Meeting.



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- 5.9 For directed review CAPA Assessments, the IRB Compliance Team will document their observations in writing using the Directed Review Observations letter template (HRP-1815) and provide it to the PI and other individuals listed in 4.4 above within two weeks of the visit.
 - 5.9.1 PI will submit a formal response to the observations via an RNI application. The response will be routed to the Panel that initially deliberated the CAPA.
 - 5.9.2 The Panel will determine if any additional action is needed.
 - 5.9.3 Once the Panel determines the PI response is satisfactory, an RNI Acknowledgement Letter will be issued to close out the activity.
 - 5.9.4 The primary IRB Compliance Analyst will record the CAPA Assessment activity in the appropriate compliance tracking mechanism and report the activity at the IRB Chairs' Meeting.
- 5.10 The PI is responsible for maintaining documentation related to the CAPA Plan assessment and all correspondence with IRB Compliance Team members in their study files.
- 5.11 PI failure to engage in CAPA Plan assessment or complete the process for the selected CAPA will result in escalating notifications from the IRB Office Compliance Team, up to the appropriate level of school/department/institutional leadership.
 - 5.11.1 An initial reminder and subsequent follow-up notices will be sent to the PI regarding the status of the CAPA Assessment request or clarification response.
 - 5.11.2 If the PI or primary contact fail to respond, the follow-up query is sent to the PI's direct supervisor, the Executive Director, the Associate Director of Compliance and Reliance, and the Compliance Manager, followed by subsequent notices to their school's research dean, and culminating with a notice to the Institutional Official.
 - 5.11.3 Investigators who fail to engage or complete a CAPA Plan Assessment will be documented and reported at the IRB Chairs' Meeting.
 - 5.11.4 Continued failure to participate in monitoring activities may impact future submissions to the IRB and/or result in additional corrective actions imposed.

6 MATERIALS

- 6.1 SOP: Reportable New Information (HRP-024)
- 6.2 TEMPLATE: CAPA Assessment Guide (HRP-1813)
- 6.3 TEMPLATE: Directed Review Notification (HRP-1814)
- 6.4 TEMPLATE: Directed Review Observations (HRP-1815)
- 6.5 TEMPLATE: Routine CAPA Assessment Visit Notification (HRP-1816)
- 6.6 TEMPLATE: Routine CAPA Self-Assessment Notification (HRP-1824)
- 6.7 TEMPLATE: Routine CAPA Assessment Observations (HRP-1817)

7 REFERENCES

- 7.1 SOP: Ongoing HRPP Evaluations (HRP-061)
- 7.2 POLICY: Human Research Protection Program Compliance
- 7.3 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
- 7.4 GENERAL DOCUMENT: Investigator Manual (HRP-103)
- 7.5 45 CFR 46.109 (g)
- 7.6 21 CFR 56.109 (f)