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

2 PREVIOUS VERSION
2.1 Revised from previous version dated 09/03/2020.

3 POLICY
3.1 In this procedure, CAPA plans are received by the IRB Office via a Reportable New Information (RNI) application.
3.2 CAPA plans are assessed in order to ensure appropriate adherence to and the effectiveness of the corrective and preventive actions to be implemented.

4 RESPONSIBILITIES
4.1 CAPA assessments may be requested by a convened Board 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 their observations and recommendations for next steps based on the available materials, interviews, or information obtained during the assessment.
4.4 The IRB Compliance Team will document their observations in writing in the form of an observations letter and provide 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 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 For a directed review, the process begins when the IRB Compliance Team receives instruction from an IRB Chair, convened panel, Executive IRB 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+.
   5.2.1 The IRB Compliance Analyst selects a CAPA plan considering the severity of the event reported, the quality of the plan, feasibility of review, observed patterns of non-compliance, and input from IRB Managers.
   5.2.2 The IRB Compliance Analyst will make an effort to not 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
Directed Review Notification template (HRP-1814) or the Routine CAPA Assessment Notification template (HRP-1816).

5.3.1 The PI will have to 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 at 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 The IRB Compliance Team will document their observations in writing and provide it to the PI and other individuals listed in 4.4 above within two weeks of the visit.

5.8 For randomly chosen CAPA Assessments, the primary IRB Compliance Analyst will do the following:
   5.8.1 Review the PI’s response to the observations and send queries to the PI as necessary.
   5.8.2 Send the PI a Close-Out email when the visit is complete, PI response is satisfactory, and all queries are resolved.
   5.8.3 Record the CAPA Assessment activity in the Compliance Tracker and report the activity at the IRB Chairs’ Meeting.

5.9 For CAPA Assessments requested by a convened Board, the PI will submit a formal response to the findings via an RNI application. The response will be routed to the convened panel that initially deliberated the CAPA.
   5.9.1 The convened Board will determine if any additional action is needed.
   5.9.2 Once the convened Board determines the PI response is satisfactory, an RNI Acknowledgement Letter will be issued to close out the activity.
   5.9.3 The primary IRB Compliance Analyst will record the CAPA Assessment activity in the Compliance Tracker and report the activity at the IRB Chairs’ Meeting.

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 Notification (HRP-1816)
6.6  TEMPLATE: Routine CAPA Assessment Observations (HRP-1817)

7  REFERENCES

None