

## SOP-R-005: TC IRB Standard Operation Procedures (SOP) on Noncompliance

### Purpose

This SOP provides definitions and procedures for the reporting and review of known or suspected noncompliance for research under the oversight of the Teachers College (TC) IRB. Research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements outlined in the IRB Reliance SOP.

In conducting its review of protocol deviations, unanticipated problems, subject complaints, and other reportable events, the IRB will also consider whether the event or issue was caused by, contributed to, or otherwise related to noncompliance.

### Definitions

1. **Noncompliance** is defined as any failure to follow:
  - a. Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
  - b. The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

2. **Serious Noncompliance** is defined as noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data or the research.
3. **Continuing Noncompliance** is defined as a pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.
4. **Apparent Noncompliance** describes an event that appears to constitute noncompliance, but the IRB has not yet made a formal assessment of the event.

### Reporting

Investigators and their study staff are required to report instances of possible noncompliance to the IRB within **7 working days** of discovery using the Event Report form in Mentor IRB. Additionally, anyone may report concerns of possible noncompliance to the HRPP or IRB verbally, by email, or other means. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and, unless reporting anonymously, cooperating with any subsequent fact-finding in relation to the report.

If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she may contact the Research Compliance Director or IRB Chair directly to discuss the situation informally.

### Procedures

1. Upon receipt of the Event Report, the IRB staff pre-reviews the submission and, if needed, contacts the investigator for corrections or additional information. If the report came from someone other than the investigator verbally, by email, or by other means, the IRB Director or assigned staff will develop a

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written report summarizing the available information and will upload the report into the IRB electronic system. If the information provided suggests that subjects may be at risk of harm without immediate intervention or that research misconduct may have occurred, the Research Compliance Director, IRB Chair, and, when appropriate, the IO or designee, will be notified so that they can take any necessary steps to ensure the safety of subjects or investigate the matter.

2. The IRB Chair or designated reviewer receives and reviews the report and makes an initial determination as to whether the event represents noncompliance, and, if so, if the noncompliance may be serious or continuing. If needed, the reviewer may request additional information from the investigator or others. When circumstances warrant, the Research Compliance Director or Research Compliance Manager may bypass this step and assign the report for convened board review.
3. If the reviewer determines that the event or issue is not noncompliance, or is noncompliance but not serious or continuing, they will review any proposed corrective and preventative action plans and determine if the plan is acceptable as proposed or if modifications to the plan or additional actions are required. As warranted, the reviewer may refer the matter to the convened IRB for review. The results of the review will be recorded in the electronic system and communicated to the investigator.
4. If the reviewer determines that the event or issue may be serious or continuing noncompliance, the report will be referred for review by the convened IRB. The convened IRB will determine whether the event is serious or continuing noncompliance. The IRB will review any proposed corrective and preventive action plan and determine if the plan is acceptable as proposed or if modifications to the plan or additional actions, such as those outlined below, are necessary to ensure the protection of human subjects. If needed, the IRB may request additional information from the investigator or others. The results of the review will be recorded in the IRB minutes and communicated to the investigator.
5. When the IRB determines that an event is serious or continuing noncompliance, the IRB may take any of the following actions, or others, to ensure the protection of human subjects:
  - a. Requiring modifications to the protocol or research plan
  - b. Revising the continuing review timetable
  - c. Modifying the consent process
  - d. Modifying the consent document
  - e. Providing additional information to current participants (e.g., whenever the information may relate to the subject's willingness to continue participation)
  - f. Providing additional information to past participants
  - g. Requiring additional training of the investigator and/or study staff
  - h. Requiring that current subjects re-consent to participation
  - i. Monitoring the research
  - j. Monitoring consent
  - k. Reporting or referral to appropriate parties (e.g., the IO, General Counsel, IT)
  - l. Suspending IRB approval

- m. Terminating IRB approval
  - n. Other actions as appropriate given the specific circumstances
6. When the IRB determines that an event is serious or continuing noncompliance, the IRB staff will follow the procedures for reporting to regulatory agencies, sponsors, and organizational officials in Reporting to Federal Agencies, Departments, and Organizational Officials. When appropriate, a preliminary report may be submitted while more information is obtained to inform the determination or actions.
7. Investigators may request that the IRB reconsider its determination by following the procedures in IRB Actions, Failure to Respond, Appeals.

### **Apparent IRB Noncompliance**

When there has been apparent serious or continuing noncompliance on the part of the IRB (e.g., repeated failure to make a required determination), the IRB Director will gather the relevant facts and report the matter, with any recommendations, to the IO. The IO may take actions as needed to further investigate the matter (e.g., a directed audit) prior to determining whether the apparent noncompliance is serious or continuing. The IO may also require corrective and preventive actions as warranted to remedy the matter and prevent recurrence. Serious or continuing noncompliance on the part of the IRB will be reported as necessary following the procedures outlined in Reporting to Federal Agencies, Departments, and Organizational Officials.