SOUTHERN ILLINOIS UNIVERSITY CARBONDALE
Institutional Review Board

IRB Policy #	**300**
Policy Title	***Noncompliance***
Initial Approval	**November 12, 2021**
Last Reviewed	**May 09, 2025**
Target Audience	**Principal investigators and all study personnel conducting human subjects research, IRB committee members, and institutional officials involved in the review or oversight of such research.**

Policy Purpose

Federal regulations require institutions to have and follow "written procedures for ensuring prompt reporting to the Institutional Review Board (IRB), appropriate institutional officials, and the department or agency head" of any serious or continuing noncompliance (45 CFR 46; 21 CFR 56). This policy describes the responsibilities and procedures for reporting and investigating allegations of noncompliance, serious or continuing noncompliance, and, when necessary, initiating corrective action(s) and submitting findings to regulatory agencies, funding authorities, and other institutional entities.

Policy Definitions

Investigator means the principal investigator (PI), co-PI, faculty sponsor, and any individual listed on the key personnel table of the IRB application.

Noncompliance is any failure (intentional or unintentional) to follow (a) applicable federal regulations, state, and local laws or institutional policies governing human subject protections, or (b) the requirements or determinations of the IRB, including 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. Appendix A includes illustrated examples of noncompliance.

Serious Noncompliance is any noncompliance (intentional or unintentional) that increases the risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data and research. *Apparent serious noncompliance* describes an event that appears to constitute serious noncompliance, and so requires reporting to the IRB for consideration, but the IRB has not yet made a formal assessment of the event.

Continuing Noncompliance is a pattern of repeated noncompliance which continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable time. *Apparent continuing noncompliance* describes an event(s) that appears

to constitute continuing noncompliance, and so requires reporting to the IRB for consideration, but the IRB has not yet made a formal assessment of the event.

Allegation of Noncompliance is an unconfirmed report of noncompliance.

Finding of Noncompliance is a determination that an instance of noncompliance occurred.

Policy Statement

Noncompliance with IRB-approved protocols, including the failure to submit amendments for review and approval, neglecting to report unanticipated risks to subjects, or failing to adhere to IRB-required ethical management and documentation, can pose significant risks to subject safety and the integrity of research.

The SIUC IRB is committed to ensuring the ethical conduct of research involving human subjects. All SIUC faculty, staff, students, study personnel, and institutional officials are expected to support this commitment and promptly report any suspected noncompliance to the Office of Research Compliance (ORC) and/or IRB Chair, who together, or through their designee(s), shall investigate all credible reports of alleged noncompliance and inappropriate involvement of human subjects in research.

The IRB shall be responsible for reviewing investigative findings and determining all issues of serious or continuing noncompliance with human subjects research regulations or IRB requirements. Findings of noncompliance may result in corrective action plans, further IRB oversight, or in severe cases, suspension or termination of study approval. In certain instances, referral to other review committees, including disciplinary boards, may occur.

The IRB will work with the ORC and/or other appropriate institutional official(s) to report investigational activities and findings, when necessary, to applicable regulatory or oversight agencies, sponsors or contract research organizations, and other performance sites involved in research affected by the event. The ORC shall facilitate and maintain documentation of communications, findings, and reporting.

Note: some events may constitute noncompliance as well as unanticipated problems. For additional policy guidance on unanticipated problems, refer to IRB Policy 280: Adverse Events and Unanticipated Problems.

General Procedures

Reporting Suspected Noncompliance

All SIUC faculty, staff, students, study personnel, and institutional officials are responsible for supporting the ethical conduct of research; this includes prompt reporting, within seven calendar days, any instances or allegations of noncompliance. Individuals should report instances or allegations of noncompliance to the ORC and/or the IRB Chair.

Reports of noncompliance may come from IRB members, investigators, subjects and their families, University Personnel, anonymous sources, the media, or the public. The identity of complainants will be kept confidential to the extent possible. SIUC will not tolerate retaliation against individuals who report suspected noncompliance violations in good faith.

Reviewing Suspected Noncompliance

The IRB Chair, ORC Director, and/or IRB may seek input from individuals with relevant expertise during any assessment or investigation of noncompliance. No individual with a conflict of interest may participate in the review, investigation, or in the development of corrective actions related to suspected noncompliance events.

The IRB Chair and ORC Director, or their designee(s), shall conduct an initial assessment of any reported noncompliance within 14 calendar days. They will inform the IRB and appropriate institutional officials of their findings. Preliminary reports, either verbal or written, may serve as a mechanism to keep relevant officials informed. If the IRB Chair or other relevant institutional official(s) suspect or determine subjects are at risk, they shall place a preliminary *administrative hold* on the research while the report is under review.

The initial appraisal will consider if the report is credible (i.e., has a basis in facts) and falls within the scope of human subjects protections, and if so, whether the allegation meets the definition of noncompliance. If not, a report summarizing the findings will be recorded in the IRB records, and no further action taken.

If the initial investigation results in the finding of only minor noncompliance that is not serious or continuing noncompliance, the IRB Chair and/or ORC Director may resolve the issue without additional investigation or review through a direct meeting with the PI and/or advisor (for student projects). A report summarizing findings and recommendations for resolution will be recorded in the IRB records and provided to the PI in writing. Within 10 calendar days of receipt of the report or on a date agreed upon in writing by the IRB Chair and/or ORC Director, the PI must reply with a corrective management plan and timeline for addressing the recommendations in the report. If the PI fails to respond or fails to appropriately implement recommendations within the agreed timeframe, the IRB Chair and/or ORC Director will refer the matter to a convened meeting of the IRB with a quorum present.

If the initial investigation suggests a finding of greater than minor noncompliance that is either serious or continuing, the IRB Chair, in consultation with the ORC Director, shall appoint an IRB sub-committee (in such numbers to make a fair and justifiable decision) to meet and evaluate findings. The subcommittee may, at any time and at their discretion, refer the matter for further investigation or for review during a convened meeting of the IRB with quorum present.

The PI, and advisor (for student projects), shall be required to meet with the subcommittee and the ORC to discuss the noncompliance event and develop a corrective plan to prevent

recurrence and promote future compliance. The ORC shall, in consultation with the subcommittee members, set the meeting time and location. Should the PI fail to respond to meeting requests, the subcommittee will develop a corrective action plan without the PIs input.

A report summarizing the findings and recommendations for resolution will be recorded in the IRB records and provided, in writing, to the PI and other relevant institutional officials. Within 10 calendar days of receipt of the report (or other date agreed upon in writing with the subcommittee, IRB Chair, and/or ORC Director), the PI must reply with a corrective management plan and timeline for addressing the recommendations. If the PI fails to respond or fails to appropriately implement recommendations, the matter will be referred to a convened meeting of the IRB with quorum present. Repeated failure to respond to any investigative request or corrective action may result in referral to appropriate institutional disciplinary board(s).

The IRB or ORC may conduct an audit if the breadth of noncompliance (of an ongoing study or study placed on administrative hold) is not known. The audit may include only information requested from, and provided by, the PI or may require an onsite visit from an IRB subcommittee where original documentation is reviewed and/or observed. Any new areas of concern shall be reported in writing to the full IRB and placed on the IRB's agenda for consideration in determining additional action (e.g., administrative hold of other studies under the purview of the PI, audit of other studies).

Review Outcomes and Resolution

During any investigation into apparent noncompliance, a range of outcomes are possible. Potential review outcomes and/or corrective actions may include:

- The review may determine that the research study is in compliance with Federal regulations and IRB policy and no further action is necessary.

- The review may determine that the PI is in noncompliance and should not be allowed to submit new protocols or renew current projects until all concerns have been addressed.

- The review may determine the research study under review is substantially in compliance with federal regulations and IRB policy but may make specific recommendations to improve or enhance the protections for the study's human subjects or impose additional oversight such as:

    - Verifying subject selection is appropriate and observing the actual informed consent process,

    - Increased monitoring of the research via a study safety monitor and intervening as necessary through steps such as visits to the activity site and

continuing evaluation to determine if any new unanticipated risks to subjects or others have arisen,

- Requesting a directed audit targeting areas of concern,
- Requesting a status report after subjects receive intervention,
- Increasing the frequency of the continuing review cycle, or,
- Requesting additional PI/staff education focused on human subjects protection.

- The review may determine that the research study is not in compliance with federal regulations and/or IRB policy and/or that the PI's response is not adequate to satisfy the concern. However, the IRB may conclude that the incident appears to be isolated and, in essence, a miscommunication or misunderstanding of a nonserious and noncontinuing nature. The IRB may impose restrictions and/or require additional subject protection such as:
  - Special reporting to and rigorous oversight by the IRB specific to the areas of concern (e.g., shortened continuing review intervals, follow-up audits or monitoring),
  - Oversight or mentoring by a school director or more senior investigator,
  - Verifying that subject selection is appropriate and observing the actual informed consent process,
  - Monitoring the progress of the activity and intervening as necessary through such steps as site visits, continuing evaluation to determine if any unanticipated risks have arisen, and/or,
  - Requesting an ad hoc review from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern.
- The IRB may determine that the PI's failures to comply with federal regulations and/or IRB policy pose such significant risks to subjects that the IRB may suspend or terminate its approval of the study, including other studies for which the investigator serves as PI.

The investigator who believes the IRB has erred in its findings of noncompliance may submit a written request asking the IRB to reconsider. With the appeal and new information, the IRB may vote to confirm or modify its original findings and actions.

The IRB shall refer allegations of scientific or faculty misconduct to the Vice Chancellor of

Research for appropriate review, and any penalty/sanction will be determined through appropriate administrative processes, according to institutional policies and procedures.

Reporting to Regulatory and/or Grant Authorities

The University shall duly report any investigation, findings, or corrective action plans related to serious or continuing noncompliance, when required under federal regulations or sponsor terms, conditions, or agreements, to the HHS Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), sponsoring authorities, and/or other relevant agencies. The Office of Research Compliance shall submit such reports with the review, approval, and signature of SIUC's Institutional Official, the Vice Chancellor for Research (VCR). The IRB and/or IRB Chair are responsible for providing timely and comprehensive updates to the VCR and the Office of Research Compliance to ensure informed oversight and timely reporting.

Procedural Guidance for Multisite Studies

Unless otherwise specified in the reliance agreement, the SIUC IRB and ORC are responsible for reviewing reports and allegations of noncompliance in human subjects research for which the SIUC IRB is the Reviewing IRB, regardless of the study's status (open or closed). The SIUC IRB has final authority to determine if the noncompliance is serious and/or continuing, unless otherwise specified in the terms of the reliance agreement. The ORC shall facilitate communication between the SIUC IRB and the relying institution(s) to ensure timely review, reporting, and resolution of any reports or allegations of noncompliance. SIUC shall promptly report any investigations, findings, or corrective actions to the necessary regulatory authorities and/or sponsors, when required, unless otherwise specified in the terms of the reliance agreement. SIUC shall provide the relying institution(s) with draft copies of such reports a provide a minimum of 5 calendar days, when feasible, for review and comment prior to submission.

When SIUC is relying on an external reviewing IRB, any allegations of possible noncompliance received by the ORC or IRB that have not already been reported to the Reviewing IRB will be communicated to the Reviewing IRB based on the reliance agreement in place. The ORC will coordinate with the Reviewing IRB, with input from the SIUC IRB Chair and SIUC Vice Chancellor for Research. The Reviewing IRB has final authority to determine if the noncompliance is serious and/or continuing, unless otherwise specified in the terms of the reliance agreement. SIUC will work with the Reviewing IRB in developing corrective action as needed to assist with resolution of the problem. If the Reviewing IRB determines the noncompliance to be serious and/or continuing, it is responsible for reporting the findings to the appropriate regulatory agencies and/or sponsors, unless otherwise specified by the terms in the reliance agreement. The policies of Reviewing IRB will apply to the appeal of any determination unless otherwise specified by the terms of the reliance agreement. SIUC institutional officials may refer SIUC involved study personnel for additional disciplinary review, if warranted and those proceedings fall outside the scope and process of the Reviewing IRB.

References and Resources

FDA Policy for the Protection of Human Subjects, 21 C.F.R. 50. (1991). https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-policy-protection-human-subjects

HHS Protection of Human Subjects in Research, 45 C.F.R. 46. (2019). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Smart IRB (2019). Reportable events: Investigator-initiated multisite studies. *SMART IRB Harmonization Steering Committee*. https://smartirb.org/assets/files/Reportable_Events.pdf

Appendix A: Examples of Noncompliance Events

- Conducting non-exempt human subjects research without IRB approval.
- Conducting human subjects research without obtaining required informed consent.
- Implementing a significant modification to IRB-approved research without prior IRB approval (except to eliminate an immediate hazard).
- Failing to adhere to eligibility criteria, such that subjects were placed at increased risk of harm, or their rights or welfare were adversely affected.
- Failing to adhere to the ethical management and documentation required by the IRB.
- Failing to perform safety assessments within protocol-specific time frames, such that subjects were placed at increased risk of harm, or their rights or welfare were adversely affected.
- Failing to communicate new information to research subjects about study participation relevant to subject rights or welfare, such as new risks that could affect subjects' willingness to participate in the study.
- Violating any conditions of IRB approval that could adversely affect subject rights or welfare.
- An event leading to a finding, such as from an audit, inspection, or inquiry by an inspector, that subjects were placed at increased risk of harm or that subjects' rights or welfare were adversely affected.
- The PI or other member of the study team repeating the same mistakes on a specific protocol after the initial discovery, reporting, and/or implementation of a corrective action plan.

- The PI or other study team members making mistakes on multiple protocols after the initial discovery, reporting, and/or implementation of a corrective action plan.

Note: some events may constitute continuing noncompliance as well as unanticipated problems. For additional policy guidance on unanticipated problems, refer to IRB Policy 280: Adverse Events and Unanticipated Problems.