

IRB Procedures for Reports of Noncompliance

Purpose

The Institutional Review Board at Northern Illinois University is responsible for reviewing all reports of noncompliance that involve research in which human participants are involved. This policy is intended to clarify how the board receives, reviews, and makes determinations regarding concerns of noncompliance.

Policy Narrative

Noncompliance is any action or activity associated with the conduct or oversight of research involving human participants that fails to comply with either the research plan as approved by a designated Institutional Review Board (IRB) or with federal regulations or institutional policies governing human subject research. Noncompliance includes failure to have protocols reviewed by the IRB prior to beginning research with human subjects or deviations from the protocols approved by the IRB.

Complaints or reports of noncompliance from someone other than the Principal Investigator (PI) or study team personnel are handled as allegations of noncompliance until such time that the report is validated or found to be invalidated or dismissed.

Minor Noncompliance: Any behavior, action or omission in the conduct or oversight of research involving human participants that deviates from the approved research plan, federal regulations, or institutional policies but, because of its nature, the research project, or subject population, does or did not:

1. harm or pose an increased risk of substantive harm to a research participant.
2. result in a detrimental change to a participant's clinical or emotional condition or status
3. have a substantive effect on the value of the data collected; and
4. result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Serious Noncompliance:

Any behavior, action or omission in the conduct or oversight of human research that, in the judgment of a convened IRB, has been determined to:

1. adversely affect the rights and welfare of participants

2. harm or pose an increased risk of substantive harm to a research participant
3. result in a detrimental change to a participant's clinical or emotional condition or status
4. compromise the integrity or validity of the research; or
5. result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Continuing Noncompliance: A pattern of noncompliance that, in the judgement of a convened IRB:

1. Indicates a lack of understanding or a disregard for the regulations or institutional requirements that protect the rights and welfare of participants
2. Suggests a likelihood that noncompliance will continue without intervention
3. Involves frequent instances of minor noncompliance, such as repetitive protocol deviations

REPORTING NONCOMPLIANCE

Noncompliance by research personnel

Incidences of serious noncompliance should be reported to the Office of Research Compliance, Integrity and Safety within five business days of becoming aware that it has occurred. Such reports may be submitted via email or in writing to the IRB administrator. They may also be presented verbally to the IRB.

The report should include as much of the following information as is available to the person who is reporting the incident:

1. Study title, protocol number, and name of the Principal Investigator
2. A description of the incident and/or the events that led to the incident
3. An assessment of whether the incident adversely affected the rights or welfare of the research participants and/or resulted in either actual harm or increased risk of harm to the participants.
4. A description of any changes to the protocol that will be made as a result of the incident
5. A description of any corrective actions that can be or have been taken to ensure that similar events do not happen again

6. The name of the individual reporting the incident. This information will be kept confidential by the IRB to the fullest extent possible.

IRB ACTIONS IN RESPONSE TO REPORTS OF NONCOMPLIANCE

Initial Review of Reports of Noncompliance

The IRB Chair, IRB administrator, or other experienced designee will promptly undertake the initial fact-finding and inquiry of the allegation(s) or investigator report after an allegation has been reported to the IRB. The purpose of the inquiry is fact-finding and may involve examination of study records and discussion with the research team, other personnel, research participants, witnesses, the complainant (if not anonymous), and others as appropriate. If

the allegation is made by someone other than the Principal Investigator (PI), the PI will be notified in writing of the allegation and have an opportunity to respond to the allegation(s) during this initial inquiry. The results of the inquiry will be shared with the PI and others as described below.

If the initial inquiry results in a determination that the complaint may potentially violate other University policies, such as research misconduct or financial mismanagement, the IRB will share with or refer the complaint to the appropriate University authorities for resolution. The IRB will cooperate and coordinate its reviews with other University officials.

Dismissal of the Allegation or Complaint as Unjustified

If the allegation or report of noncompliance is found to be unjustified following the initial inquiry, the findings will be noted in the IRB records and written notice will be provided to the PI.

Findings of Minor Noncompliance

Issues of minor noncompliance may be resolved between any combination of the IRB Chair or his designee, the IRB administrator, the PI, and the PI's Department Chair. Possible actions may include resolution through corrective and/or preventative actions or educational measures as appropriate. The PI must provide written documentation of completion of such measures to the IRB within 30 days of being notified. The IRB

administrator will provide a written confirmation that the corrective action is sufficient and will document all information regarding the incident in the IRB records.

Findings of Serious and/or Continuing Noncompliance

If the initial inquiry indicates that the incident may constitute serious or continuing noncompliance, then the matter will be referred to the fully convened IRB. The IRB Chair or IRB administrator will notify the PI and the Institutional Signatory Official of the incident and may also provide preliminary notice to any applicable federal agency, such as the Office of Human Research Protections and/or the Food and Drug Administration, as appropriate.

If the research participants are at immediate risk of harm or have the potential to be placed at further risk prior to the outcome of the IRB meeting, then the IRB Chair may suspend any or all aspects of the study pending the decision of the full IRB.

The fully convened IRB will review the incident and make its own determination. The PI will be notified that he/she is welcome to attend the meeting to discuss the concerns and clarify the information from the initial review. The IRB may make the following determinations:

1. The incident does not meet the criteria for serious or continuing noncompliance, and it may be handled as minor non-compliance
2. More information is required, and the determination on the incident will be tabled until further information is gathered resulting in a review of the new information at a second convened meeting. The IRB may appoint either the IRB administrator or a subcommittee of two or more IRB members with suitable expertise along with the IRB administrator to gather the necessary information and provide the fully convened IRB with a written report. The researcher under investigation will be given the opportunity to submit written comments, and, if requested, to meet with the investigator(s).
3. The incident constitutes serious and/or continuing noncompliance.

If the IRB determines that the incident constitutes serious and/or continuing noncompliance, it may take any action it deems necessary to protect the rights and/or welfare of the research participants involved, including, but not limited to:

1. Remediation or educational measures required of the research team.
2. Monitoring of research activities by appropriate person(s).
3. Monitoring of the informed consent process by appropriate person(s).

4. Notification of past or current research participants.
5. Re-consenting of participants.
6. Modification of the research protocol.
7. Increased reporting by the PI of his/her human participants research activities to the IRB.
8. More frequent continuing review (renewal of approval) schedule.
9. Periodic audits by the IRB administrator or appointed member of the IRB.
10. Restrictions to the PI's research practice, such as limiting the privilege to minimal risk or supervised projects.
11. Suspension of approval for one or more of the PI's studies.
12. Termination of approval for one or more of the PI's studies.
13. Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

For all incidents determined by the fully convened IRB to be serious or continuing noncompliance, the IRB will notify the following individuals within seven (7) days of such determination: the PI and Faculty Advisor, where applicable, the PI's Department Chair, and the Institutional Signatory Official. Where applicable, the IRB will also notify within 30 days of such determination, NIU Sponsored Programs Administration; OHRP; FDA; the funding agency and, for any other institutions participating in the research, the IRB administrators of those institutions.

The IRB's determination will be communicated to the PI in writing. If the IRB requires any remediation or corrective actions on the part of the PI, this will also be communicated in writing. The PI must provide the IRB with written documentation that the remediation or corrective actions have been completed in the time frame designated by the IRB. Once the PI has satisfied the IRB's requirements, the matter will be considered resolved. A final written communication indicating resolution will be provided to the PI and others as appropriate. A copy of all correspondence regarding the issue will be maintained in the IRB records.

If a study is suspended or terminated, no new participants may be enrolled, and no study procedures may take place unless the IRB or IRB Chair determines that continuation of study procedures is in the best interest of the currently enrolled participants.

NONCOMPLIANCE BY IRBs, IRB MEMBERS, OR IRB staff

Noncompliance by the IRB, any member of the IRB, or IRB staff should be reported to the Vice President for Research and Innovation Partnerships (VPRIPS). This report should include a description of the incident and/or the events that led to the incident, the names of the persons involved, and the name of the person reporting the incident. The name of the person reporting the incident will be kept confidential to the extent possible.

RESEARCH CONDUCTED WITHOUT PRIOR IRB APPROVAL

No mechanism exists under 45 CFR 46 or NIU policy for retroactive IRB approval (or disapproval) of a project. Therefore, if the IRB becomes aware of research that has already been conducted without prospective IRB review and approval, the full IRB will investigate the project and report its findings and recommendations to the Vice President for Research and Innovation Partnerships who would then consider the IRB's recommendations in determining what action will be taken. In considering the project the IRB:

- **will** determine what level of risk and category of review (Administrative, Subcommittee, or Full) would have been assigned to the project had the application been submitted and processed in the proper sequence (i.e., prior to data collection).
- **will** determine whether the subjects were harmed in any way or if their rights and/or welfare were infringed.
- **may** make a recommendation to the VPRIPS as to whether or not the investigators should be allowed to make use of the data.
- **may** make a recommendation to the VPRIPS that notification be provided to the funding agency and/or the appropriate publication outlet (journal or organization to which a manuscript or abstract has been submitted, thesis/dissertation office, etc.) that the data were collected without IRB approval. If the data were collected for a thesis or dissertation, the researcher **may** be asked to include a statement that the data were collected without IRB approval in the methods section.

APPEAL OF IRB DECISIONS

Appeals of IRB decisions should be made in writing to the IRB, via the Office of Research Compliance, Integrity and Safety. The IRB will review the appeal at the next regularly convened meeting. Should a researcher wish, the appeal may be made in person.

Procedural History of the Policy

Approved by the convened Institutional Review Board and the VP for Research in January 2021.

