

IRB Policy #:	300
Policy Title:	<i>Noncompliance</i>
Date Approved:	
Date Reviewed:	

Purpose: Describe actions to be taken to review issues of noncompliance.

Policy:

The IRB shall be responsible for reviewing and determining all issues of serious or continuing noncompliance with 45 CFR 46.103(b)(5) or IRB requirements. Any serious or continuing noncompliance shall be reported to the Office of Research Compliance and the IRB chair, who together shall investigate all credible reports of alleged noncompliance and inappropriate involvement of human subjects in research.

Types of noncompliance (protocol deviations) include: Conducting research without IRB review, consent not obtained; wrong consent form used, failure to report serious adverse events or other problems, failure to maintain adequate records, failure to follow approved protocol, changing protocol without IRB approval, inadequate supervision, or inadequate training.

Sources include: Reports of noncompliance may come from IRB members, investigators, subjects and their families, University personnel, anonymous sources, the media or the public.

Noncompliance issues may arise if the investigator fails to adhere to the IRB-approved protocol, to submit an amendment for review and approval before instituting the change(s), to report unanticipated problems involving risks to subjects, or to adhere to the ethical management and documentation required by the IRB.

When a report of alleged noncompliance is received by the Office of Research Compliance and/or IRB chair, a preliminary investigation will be undertaken and a determination will be made as to whether subjects are at risk or can be allowed to continue in the research while the investigation progresses. A preliminary *administrative hold* shall be put on the research if the IRB suspects or determines subjects are at risk.

The PI and advisor shall be required to meet with a subcommittee of the IRB (in such number to make a fair and justifiable decision) and the Office of Research Compliance (ORC) to discuss the noncompliance issue and develop action plans to prevent recurrence and promote future compliance. The time and location shall be set by ORC. Based on the severity of the noncompliance or the policies of the funding source, as applicable, the infraction may fall under the jurisdiction of the OHRP. Programs and findings and recommendations from this meeting

shall be recorded and duly reported to the Vice Chancellor for Research.

The IRB shall send a letter to the PI citing the alleged areas of noncompliance, the associated federal regulations, and the corrective action plan. The PI will be asked to respond to the allegation and provide their specific plans to implement the proposed corrective action plan including a specified timeframe.

An audit may be conducted 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).

Actions the IRB may take:

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

The IRB may decide that the PI found in noncompliance should not be allowed to process new protocols or renew current projects until all concerns have been addressed.

The IRB 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,
- increasing monitoring of the research via data safety monitor or board and intervening as necessary through steps such as visits to the activity site and continuing evaluation to determine if any unanticipated risks to subjects or others have arisen,
- requesting a directed audit that target areas of concern,
- requesting a status report after subjects receive intervention,
- decreasing the continuing review cycle, or
- requesting additional PI/staff education focused on human subjects protection.

The IRB 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 committee's

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. These cases should be promptly reported in writing to the IRB chair and ORC. 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 for cause.

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 action.

The ORC shall facilitate and maintain documentation of all communication between the PI and the IRB. The ORC shall notify the IRB chair, Vice-Chancellor for Research, and school director within 1 working day of any determination of noncompliance. The ORC shall maintain and update the IRB database with current study information.

The Vice Chancellor for Research shall make the final determination regarding scientific or faculty misconduct and any penalty/sanction that may be appropriate, as well as whether or not any collected data may be used and under what conditions, according to institutional policies and procedures. The Vice Chancellor for Research shall notify the ORC. The ORC shall, in turn, notify the full IRB. The Vice Chancellor for Research shall notify OHRP of any determinations of noncompliance.