**Human Subjects Research Noncompliance**

1. **GENERAL OVERVIEW**

Compliance with applicable policies, laws, and regulations is a shared responsibility that involves investigators, the Institutional Review Boards (IRB), Office of Research Compliance (ORC), supporting units, and the university. The federal regulations do not define non-compliance and this document establishes the IRB’s policy on the investigation and investigation outcome of suspected non-compliant activity.

All reports are subject to applicable law and administrative rules and regulations. Disclosure of the identity of the respondent and complainants in noncompliance investigation proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair investigation as allowed by law and regulation. Subject to applicable law, confidentiality shall be maintained for any records or evidence from which research subjects might be identified.

Changes in approved research are permitted without IRB review and approval to eliminate apparent, immediate hazards to subject. Any such changes must be promptly reported to the IRB.

Adverse events are different from non-compliant events; refer to the Human Subjects Research Adverse Events Policy for more information.

1. **DEFINITIONS**

**Adverse events:** any undesirable and unintended effect, whether anticipated or not, experienced by a research subject occurring as a result of participating in a research project.

**Continuing noncompliance:** is multiple or repeated instances of noncompliant activity, which may involve concerns that have or have not been previously reported to the IRB.

**Noncompliance:** is failure to comply with applicable policies, laws, regulations, protocols, or IRB requirements. Noncompliance may be intentional or unintentional. Noncompliance may be non-serious or serious. Examples of non-compliant activities include:

* Conducting non-exempt research without IRB approval
* Conducting research on an expired or unapproved protocol
* Failure to obtain consent or use of an inadequate consent process
* Inadequate Principal Investigator (PI) oversight of research activities or research personnel
* Initiating changes to non-exempt research without IRB approval unless the change is to eliminate apparent or immediate hazard to subject

**Non-serious noncompliance**: does not increase risk to research participants, compromise participants’ rights or welfare, or affect the integrity of the research/data or the human subjects research protection program.

**Serious noncompliance:** increases risk to research participants, compromises participants’ rights or welfare, or affects the integrity of the research/data or the human subjects research protection program.

1. **MANAGING ALLEGATIONS of NONCOMPLIANCE**

Allegations of noncompliance should be promptly reported to the ORC. ORC staff will process all potential noncompliant activities for the IRB Chair to make an initial review. Actions undertaken in response to an allegation or finding of noncompliance will be completed in a timely manner, based on the circumstances, seriousness, and complexity of the potential noncompliance.

The IRB and Institutional Official (IO) have the authority to suspend or terminate approval of research that is or may be found to be non-compliant.

# Investigation

1. The ORC will notify the IRB Chair of the potential of noncompliance.
2. The IRB Chair will conduct an initial investigation into the initial report. Based on the initial investigation, the IRB Chair may determine a claim to be unsubstantiated, form a subcommittee (other supporting units will be included if necessary), assign the investigation to the IRB, or conduct the investigation with ORC staff.
   1. The Institutional Official will be notified of all investigations.
   2. Any individual with a potential conflict of interest may not participate in an investigation.
   3. When an investigation is assigned to the IRB the potential non-compliant activity will be assigned to an agenda. The PI must attend the meeting to provide an overview of the concern and field questions from the Board. After addressing the Board’s requests, the PI will be excused so the Board can discuss the project and issue a determination.
3. The PI will be notified of the investigation and initial report of potential noncompliant activity. The PI will provide investigators with sufficient information to conduct the investigation. The ORC will make protocols available. The PI, research staff, or others may be interviewed and/or an audit of the project/lab may be conducted during the investigation. Access to relevant materials (including data) and laboratory space must be provided to the IRB.
   1. If the PI is not responsive or unavailable, the PI’s Department Chair or College Dean will provide investigators with the ability to conduct the investigation.
4. After completing the investigation, the IRB investigators will complete a Determination Report\* that is sent to the study PI, the IO, the IRB, and any other relevant parties.

\**Unsubstantiated claims or minor violations resulting in no further action may not result in a formal determination report. The IO, IRB, and PI will be advised accordingly.*

**Possible outcomes of the investigation as determined by the IRB investigation:**

* Dismissal of the allegation
* Referral to other appropriate university process
* No further action required
* Corrective action(s) required
* Suspension or termination of the project
* Report to external party when required by regulation, law, or policy

# Investigator requests for reconsideration

The study PI may request a reconsideration of the investigation outcome. All requests for reconsideration must be made in writing (email) within five business days of the date of the Determination Report.

**Reference material**

<https://www.hhs.gov/ohrp/compliance-and-reporting/types-of-determinations/index.html>

<https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>

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