

## **Non-Compliance with Human Subject Protection Regulations**

**Summary/Purpose:** This policy describes the process that the IRB follows to deal with allegations and findings of non-compliance with human subject protection regulations and guidelines.

### **Definitions:**

**Non-compliance:** Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal regulations or the requirements or determinations of the IRB. Non-compliance actions may range from minor to serious, be unintentional or willful, and may occur once or more than once. The degree of non-compliance is evaluated on a case-by-case basis and will take into account such considerations as to what degree subjects were harmed or placed at an increased risk and the willfulness of the noncompliance. Examples include, but are not limited to: Failure to obtain IRB approval; inadequate or non-existent procedures for the informed consent process; inadequate supervision; failure to follow instructions from the IRB; failure to report adverse events or protocol changes; or protocol deviations.

**Allegation of Non-compliance:** A disclosure of possible non-compliance with human subject protection regulations.

**Complainant:** Person reporting a non-compliance.

**Continuing Non-compliance:** A pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants, should have been seen as compromising the scientific integrity of a study (such that important conclusions could no longer be reached), suggests that non-compliance will continue without intervention, or consists of frequent instances of minor non-compliance. Continuing non-compliance also includes failure to respond to a request for information or for actions to resolve non-compliance with human subject protection regulations.

**Minor Non-compliance:** Non-compliance that is neither serious nor continuing. An example of minor non-compliance includes failure to comply with UM IRB administrative policies (for example, turning in a progress report late, using a consent form lacking the IRB approval stamp, or failing to submit an IRB application for a study later determined exempt).

**Serious Non-compliance:** An action or omission in the conduct or oversight of research that affects the rights and welfare of participants, increases risks to participants, decreases potential benefits, or compromises the integrity or validity of the research. Examples of serious non-compliance include, but are not limited to: Conducting non-exempt research without IRB approval; enrollment of subjects who fail to meet inclusion or exclusion criteria of a protocol that increases the risk to the subject; enrollment of research subjects while study approval has lapsed; or major protocol deviations that may place subjects at risk from the research.

### **Reporting Allegations of Non-compliance:**

Allegations of non-compliance may come to the attention of the IRB in several ways, including but not limited to:

- New applications or continuing reviews submitted to the IRB;
- Post-approval monitoring;
- Reports from collaborators, employees, participants, family members, community members;
- Complaints from anonymous sources.

Allegations of non-compliance should be reported to the Director of Research Integrity and Compliance or the IRB Chair. Allegations should include a detailed description of the non-compliance, the name of the Principal Investigator listed on the IRB protocol, and, if known, the title and number of the protocol. Complainants will be protected from repercussions as per University policy.

### **Process for Handling Allegations of Non-compliance:**

1. An allegation of non-compliance is reported to the Director of Research Integrity and Compliance or the IRB Chair, who performs the investigation along with the other members of the IRB Executive Committee
2. The Executive Committee determines whether the allegation has a basis in fact. If the allegation is serious, the Executive Committee may convene the IRB to consider suspending the research while investigating the allegation. If the allegation is serious, and the noncompliance is evident from the facts, the Executive Committee may suspend the research.

Investigation may include but is not limited to:

- a. Informing the Principal Investigator of the allegation and requesting a response (mandatory);
  - b. Interviewing members of the research team, complainant, and/or subjects;
  - c. Conducting an unannounced laboratory visit;
  - d. Reviewing research records.
3. If the allegation is determined to have a basis in fact, the Executive Committee classifies the non-compliance as serious, continuing, or neither serious nor continuing.
  4. If the non-compliance is determined to be neither serious nor continuing, the Executive Committee may decide what actions to take, and report the outcome to the full IRB at the next convened meeting.
  5. If the non-compliance is determined to be serious or continuing, or if the categorization is not clear, the finding is brought to the IRB at a convened meeting for consideration of actions to be taken. Findings of serious or continuing non-compliance are reported to OHRP, supporting agencies, and institutional officials as appropriate.

**Process for Handling Non-compliance Determined to be neither Serious nor Continuing:**

1. The Executive Committee discusses what actions will be taken, and reports these actions to the IRB at the next convened meeting. These actions may include but are not limited to:
  - a. Sending a letter of reprimand to the Principal Investigator (copied to department chair, dean, institute director, or center director);
  - b. Educating the investigator, department, institute, center, or staff.
2. If the Executive Committee cannot agree on actions to take, the non-compliance will be reviewed at the next convened meeting of the IRB.

**Process for Handling Non-compliance Determined to be Serious or Continuing:**

1. The Institutional Official is informed and consulted.
2. The non-compliance is reviewed at a convened meeting of the IRB.
3. The following information is distributed to the IRB:
  - a. Title and abstract of the research project and/or grant proposal in which the non-compliance occurred;
  - b. Name of the Principal Investigator on the protocol;
  - c. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement); and
  - d. A detailed description of the non-compliance.
4. The IRB discusses what actions will be taken. These actions may include but are not limited to:
  - a. Educating the investigator and/or all research staff;
  - b. Suspending the protocol;
  - c. Suspending all protocols of the investigator (temporarily or permanently);
  - d. Conducting random audits of the investigator and/or all research staff;
  - e. Modifying the protocol;
  - f. Obtaining information from other organizational entities (e.g., legal counsel, Institutional Official).
5. The Executive Committee reports a summary of the non-compliance and the action(s) taken or in progress to OHRP, supporting agencies, the IRB, and institutional officials as appropriate.