

IRB Policy on Noncompliance Investigation Procedures

Purpose

The following is the University of Alaska Anchorage (UAA) Institutional Review Board (IRB) policy on noncompliance investigation procedures, in accordance with the [Department of Health and Human Services](#) (HHS), [Office for Human Research Protections](#) (OHRP), the IRB's Federal Wide Assurance (FWA), and the [U.S. Food and Drug Administration](#). Noncompliance is a deficiency, either major or minor, in a research activity which is not in accordance with the policies and regulations previously cited. The committee is mandated to review allegations of researcher misconduct and research proposal noncompliance. In the event of an investigation, the Institutional Official works collaboratively with the IRB to ensure that applicable policies are being followed.

Policy Definitions

1. *Noncompliance*: The term “noncompliance” means the failure to comply with accepted standards and regulations set forth by institutional, local, state, and federal policies.
2. *Allegation*: The term “allegation” means a report that noncompliance may have occurred, and requires further investigation to determine whether noncompliance has in fact occurred.
3. *Investigation*: The term “investigation” means a formal evaluation of allegations of noncompliance to determine if noncompliance has occurred and if so, to determine the responsible person(s). Investigations must be described in a written report to OHRP, which determines whether regulatory action must be taken, based on the report.
4. *Suspension*: The term “suspension” means that all suspended research activities must be stopped immediately. Furthermore, research activities may not be resumed until the Investigator(s) is (are) informed in writing by the IRB. A suspension may be temporary or final, depending on the outcome of the investigation.
5. *Institutional Official*: The Institutional Official (IO) is the signatory authority on the Federal Wide Assurance (FWA) filed with OHRP to ensure compliance with human subjects regulations.
6. *Harm*: According to the OHRP, risk of harm as a result of participating in a study includes “physical, psychology, economic, or social harm.” Researchers must disclose any foreseeable risks upon proposal submission and the IRB must evaluate whether foreseeable risks are acceptable in light of the potential benefits of the study.

General Principles

1. *Lines of Authority*
Per HHS Policy (45 CFR 46.113), the IRB is authorized to suspend human participant research during a convened meeting with a quorum of voting members. Additionally, the Institutional Official may suspend a research project if, in his/her professional opinion unexpected serious harm to human participants or public safety exists, or if a principal investigator is not following approved procedures. If research activity is suspended, the Institutional Official does not have the authority to override sanctions imposed by the IRB and only the IRB can repeal a suspension.

2. *Confidentiality*

The IRB will ensure that confidentiality is maintained throughout an investigation. Under the Alaska Whistleblower Act (AS 39.90.100-150), any public employee(s), who submits the allegation, will *not* receive reprisals for submitting the allegation to the IRB. Under the Board of Regents Policy and Regulations (09.01.09), students are protected from reprisals for submitting the allegation to the IRB. Details regarding the progress of the investigation, including the allegation and the complainant, are considered confidential. The IRB acknowledges that false allegations can jeopardize the integrity of the institution, employees, and research.

3. *Reporting Timeline*

A person who wishes to report an allegation of noncompliance should notify any appropriate individual (see “Reporting Allegations of Noncompliance”) promptly. If the allegation rises to the level of possible noncompliance, the IRB Chair will convene an emergency meeting of the UAA IRB as soon as possible. The IRB will work to ensure a timely response to an allegation. The researcher against whom the allegation is made will be contacted. If the researcher does not respond to the IRB in a timely manner or does not acknowledge the IRB’s concerns, the committee may contact the researcher’s superiors (e.g., Department Chair, Director, or Dean) about the allegation and request their assistance to resolve the matter.

4. *Reporting Allegations of Noncompliance – Whistleblowing*

The general public, institutional employees or students should report allegations of noncompliance to any of the following individuals: IRB Chair, IRB Co-Chair, Institutional Official, or IRB member (see the IRB web site: <http://www.uaa.alaska.edu/research/ric/irb/membership.cfm>). Allegations can be reported verbally or in a written document. Whistleblowers are not required to be identified for an allegation to be submitted; however, it is the responsibility of the person(s) receiving the allegation to fully document all communication regarding the allegation to prevent miscommunication. Documentation should include the time and date of the allegation, description of the allegation (including time and date of any observations that raise concern), and why the allegation is being made.

Investigation Procedures

1. *Initial Evaluation and Action*

- A. Once the IRB is notified of alleged noncompliance, the IRB will hold a meeting to determine one of the following actions:
 - a) further investigation with immediate action (e.g. suspension);
 - b) further investigation but no immediate action (e.g. inquiry); or
 - c) no action.
- B. The IRB must report suspended activity to the Institutional Official, who may need to report the suspension to OHRP and if applicable, the FDA. HHS regulations require that any suspended human participant research that is conducted or supported by HHS be reported to OHRP immediately (HHS regulations, 45 CFR 46.103(a) and (b)(5)). The report to OHRP must include:

- a) the name of the institution;
- b) the research project title and/or grant proposal that was suspended;
- c) the name of the principal investigator of the protocol;
- d) the research project number assigned by the IRB;
- e) a detailed description of the suspension; and
- f) any corrective actions the institution is taking to address the suspension.

- C. If the IRB Chair has an actual or perceived conflict of interest, the Institutional Official will delegate the responsibility of the investigation to an IRB member who does not have a conflict of interest.
- D. The Institutional Official, legal counsel, complainant, and the person against whom the allegation is being made may be invited to participate in the investigation.

2. *Inquiry*

- A. The IRB Chair may serve as the primary contact to execute an inquiry. The Chair may also appoint a subcommittee to participate in the inquiry. While an inquiry may not result in a suspension of research activity, the IRB may determine:
 - a) corrective action is needed; and
 - b) recommend the form of corrective action.

3. *Suspension and Investigation*

- A. An emergency meeting may be held to:
 - a) discuss an allegation of noncompliance and/or serious adverse event; or
 - b) determine whether an activity should be suspended. The UAA IRB Chair may appoint a subcommittee to proceed with an investigation.
- B. If an investigation is warranted, the IRB may collect information through:
 - a) interviews with people affiliated with the allegation;
 - b) interviews with human participants or participating organizations; and
 - c) consent records, data records, and any other relevant documentation.

4. *Outcomes of an Investigation*

- A. It is the responsibility of the IRB Chair, in consultation with the Compliance Office, to compile a final report for the Institutional Official. The Institutional Official may need to submit the final report to OHRP. Similar to an initial report of suspension, the final report to OHRP must include:
 - a) the name of the institution;
 - b) the research project title and/or grant proposal that was originally suspended;
 - c) the name of the principal investigator of the protocol;
 - d) the research project number assigned by the IRB; and
 - e) any corrective actions the institution is taking to remediate the immediate problem and ensure that the incident will not happen again with that principal investigator or with other researchers.

- B. In the report, the IRB will determine one of the following actions:
 - a) There was no evidence to support the allegation.
 - b) The allegation was not supported; however, it may require additional action by administration.
 - c) The allegation was valid and requires additional action.
- C. HHS Policy requires that the Institutional Official report any serious or continuing noncompliance to OHRP.
- D. The Institutional Official will inform the whistleblower about the outcome of the investigation. If the allegation is found to be malicious, or have ill intent, the outcome will be shared with appropriate institutional authorities.