

6.0 HANDLING ALLEGATIONS of NONCOMPLIANCE

6.1 OBJECTIVE

To describe the policies and procedures the Institutional Review Board (IRB) and the Office of Research Regulatory Compliance (ORRC) follow for handling allegations of noncompliance

6.2 GENERAL DESCRIPTION

The primary responsibility of the IRB is to ensure protection of the rights and welfare of research subjects. In performing that responsibility, the IRB addresses allegations of noncompliance with IRB requirements and/or federal regulations governing the conduct of human research. ORRC staff, IRB members, or IRB consultants do not participate in alleged noncompliance reviews if they have a conflict of interest (See the IRB Member and Consultant Conflict of Interest SOPP).

6.3 DEFINITIONS

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subject research. For the purpose of this SOPP, noncompliance does not include minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose risk to subjects and/or violate subject's rights and welfare.

Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

- (1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
- (2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

6.4 RESPONSIBILITY

Execution of SOPP: ORRC Staff, IRB Chair, IRB Members, Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel

6.5 PROCEDURES

6.5.1 Submission and Screening of Allegations of Noncompliance

- Anyone may submit allegations of noncompliance or continuing noncompliance involving human subject research to the ORRC verbally or

in writing. The ORRC/IRB maintains confidentiality regarding the identity of the person submitting the allegation to the extent possible.

- The RCO screens the allegation of noncompliance to determine whether the protocol(s) affected is supported by federal funds.
- The RCO also determines whether the protocol has issues pertinent to other research review committees, i.e., Institutional Biosafety Committee, Radiation Safety Committee, and Office of Sponsored Research Projects (formally known as Research Administrative Services).
- If the RCO finds any issues pertinent to these research review committees, he/she coordinates with these units as outlined in IRB/ORRC coordination SOPP, if appropriate.

6.5.2 Determination That an Allegation Is Justified or Unjustified

- The RCO reviews all allegations to determine whether the facts justify the allegation (i.e., there are supporting documents or statements).
- If the RCO deems an allegation unjustified (i.e., finds no supporting documents or statements), he/she forwards the allegation materials to the IRB Chair or designee for review.
- If the IRB Chair or designee deems the allegation unjustified, the appropriate convened IRB reviews the allegation. The convened IRB may dismiss the allegation as unjustified after review of the material(s) and decide to take no action.
- If the convened IRB finds the allegation is unjustified and takes no action, the RCO communicates (by email, or letter) the IRB's decision to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent).
- If the RCO determines that an allegation is justified and concerns administrative issues, the RCO or designee manages the concern through communications with the PI.
- If the complaint/concern is minor or administrative, the RCO may determine not to require a formal inquiry, interview, or summary with opportunity to comment.
- Upon resolution of the issue, the RCO provides an oral or written summary of the resolution to the applicable IRB at the next convened IRB meeting for review and approval.

6.5.3 Initiating an Inquiry into an Allegation

- If the allegation involves more serious issues than administrative or minor concerns, the convened IRB or the IRB Chair or designee decides whether to initiate an inquiry. The convened IRB or IRB Chair bases the decision on the seriousness and/or the frequency of violations and/or disregard for the federal regulations or the institutional policies and procedures applicable to human subject research.
- If the RCO, IRB Chair, or convened IRB determines that an allegation is justified and suggests that subjects are at immediate risk, the RCO or the IRB Chair informs the convened IRB. The convened IRB considers whether to immediately suspend IRB approval and to sequester research records including raw data. However, in most cases, upon receipt of the allegation, the convened IRB takes no formal action until it conducts an inquiry to collect additional information and concludes the review.
- If the convened IRB or the IRB Chair or designee decides to initiate an inquiry to determine the validity of the allegations, ORRC staff notifies the PI. If the allegation involves a co-investigator or a research assistant, ORRC staff also contact that individual. The RCO or the IRB Chair makes the initial notification via e-mail. The IRB Chair sends written follow-up correspondence.
- The IRB may designate one or more voting member(s) (e.g., the IRB Chair or his/her representative) to gather information pertaining to the nature of the allegation, the procedures approved in the IRB protocol, and the procedures followed in conducting the study. The RCO assists the IRB Chair or IRB representative in conducting the inquiry. Periodically, with allegations involving administrative or minor noncompliance, the IRB may request that the RCO gather the facts without involving an IRB member. In more serious cases, the convened IRB gathers the information as a group rather than delegating the responsibility.
- The IRB representative interviews the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation interviews the complainant. The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary. In some cases, the complainant may have already submitted a written complaint, which the IRB representative or RCO then verifies. Either the IRB representative or the RCO may request additional information from the complainant.
- The convened IRB, the IRB Chair, or a designated IRB member interviews the respondent and gives him/her the opportunity to comment on the allegation and provide information. The RCO or designee prepares a summary of the interview and gives the respondent the opportunity to comment on the summary. The respondent may submit a written rebuttal to

the complaint, which the RCO or designee verifies. Either the IRB representative or the RCO may request additional information from the respondent.

- Depending on the nature of the allegation and the information collected during the interviews, the convened IRB or its representative may interview other individuals. In addition, in conducting the review, the convened IRB or its representative may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; the applicable approved IRB protocol; and any other pertinent information.
- When appropriate, the IRB member(s) conducting the inquiry prepares, with the assistance of the RCO, a summary report for the convened IRB. The report may consist of a summary of the allegations, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action (In some cases, the IRB representative simply provides the IRB with a summary of the allegations, the interview summaries, and copies of pertinent information without an accompanying written report from the review team).

6.5.4 Review Procedures

- The ORRC advises the IRB regarding the applicable University and federal regulations, assists the IRB in documenting the review, answers questions about the review process, maintains the records as required by state, federal *and tribal laws*, and serves as a liaison with the funding agency or agencies.
- The IRB reviews the material presented by the review team at a convened meeting at which a quorum is present. The materials provided include the summary report of the noncompliance, the protocol if applicable and the informed consent document if applicable. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.

6.5.5 Review Outcomes/IRB Actions

- The convened IRB makes the determination whether the allegation is substantiated, and if so, whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. If the noncompliance is serious or continuing and the research federally funded, the IRB, with the assistance of the RCO, reports the incident(s) to the applicable agency following procedures outlined in the Mandated Reporting to External Agencies SOPP.

- The convened IRB may take a variety of actions, depending on the outcome of the review, including, but not limited to, the following:
 - Approve continuation of research without changes;
 - Request formal educational intervention;
 - Request minor or major changes in the research procedures and /or consent documents;
 - Modify the continuing review schedule;
 - Require monitoring of research;
 - Require monitoring of the consent process;
 - Suspend or terminate IRB approval/disapprove continuation of the study;
 - Require audits of other active protocols of the investigator
 - Disqualify the investigator from conducting research involving human subjects at the University;
 - Determine that the investigator may not use the data collected for publication;
 - Require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or re-consent them;
 - Request that the investigator inform publishers and editors if he/she has submitted or published manuscripts emanating from the research; and/or
 - The RCO communicates (email or letter) the IRB decision to the person raising the allegation (if the identity of the person is known) and to the respondent.

- The IRB informs the following individuals of the allegation, the review process, and the findings of the review, if appropriate, depending upon the outcome of the review, the external sponsor, or the requirements of the applicable regulatory agency:
 - Investigator;
 - Complainant;
 - The department chair;
 - Dean or unit director;
 - Associate Vice President for Regulatory Research Compliance;
 - Office for Human Research Protections and/or the Food and Drug Administration (See Mandated Reporting to External Agencies SOPP);
 - Sponsor, if appropriate;
 - Other administrative personnel as appropriate (See applicable IRB/ORRC coordination SOPPs).

- The IRB resolves questions or concerns raised by a PI regarding the outcome of a specific IRB noncompliance review through direct communication with the PI.

- The PI submits concerns in writing to the IRB within thirty days of the date the IRB issues the final decision. The IRB limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was

incorrect) or grievances against sanctions imposed as a result of a finding of noncompliance. The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.

- The record for the purpose of the concern raised shall be the record established during the protocol review.

6.6 REFERENCES

21 CFR 56.123

45 CFR 46.112