

# Policy and Procedure for Responding to Allegations of Research Non-Compliance Office of Research Integrity & Safety Policy 1

## **PURPOSE**

To describe the policies and procedures the units of the Office of Research Integrity & Safety (ORIS) follow in responding to allegations of research non-compliance.

## **GENERAL DESCRIPTION**

The primary responsibilities of the ORIS are to ensure the protection and safety of animal and human subjects in research; the safe and secure use of biohazards, chemicals, radiation, and other potentially hazardous materials and equipment in research; appropriate laboratory environments; and responsible conduct of research. One component of these responsibilities is that the ORIS will follow these procedures while addressing allegations of non-compliance with institutional policy and state or federal regulations governing the conduct of research.

This policy provides general guidance; however, specific state or federal regulations or guidance requiring more stringent action will take precedence.

## **DEFINITIONS**

*Non-compliance* is defined as conducting research that disregards or violates federal and/or state regulations or institutional policies and procedures applicable to research. Three categories of non-compliance are noted:

1. *Minor non-compliance* includes minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose an immediate risk to subjects, the environment, or researchers, and/or violate research subject's rights and/or welfare (except for continuing non-compliance, see below).
2. *Serious non-compliance* is a failure to adhere to the laws, regulations, or policies governing research that may reasonably be determined to:
  - a. Involve substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human or animal research subjects, research staff, or others.
  - b. Result from deliberate disregard for the laws, regulations, or policies governing research that substantively compromise the effectiveness of the institution's research oversight program.
3. *Continuing non-compliance* is a persistent failure to adhere to the laws, regulations, or policies governing research and can represent either minor or serious non-compliance.

## **RESPONSIBILITY**

Execution of SOP: ORIS Staff; ORIS Directors for animal care and use, biosafety, research safety, human subjects, conflicts of interest, animal resources, research security and export control, support services (ORIS Director); compliance committees (IRB, IACUC, RSC, RadSC, UCOIC) Chairs (Chair(s)); Principal Investigator (PI)/Study Personnel.

## **PROCEDURES**

### **Submission and Screening of Allegations of Non-compliance**

1. Anyone may submit allegations of research non-compliance to ORIS Staff or the Chair(s) verbally or in writing. ORIS Staff and Chair(s) will protect the confidentiality of the person submitting the allegation (complainant) to the fullest extent possible.
2. The ORIS Director will conduct a preliminary review investigating whether the allegation involves a currently approved study, a sponsored study, or research that involves other research oversight committees/units. Initial findings will be communicated to the appropriate Chair(s).
  - a. Allegations that overlap two or more compliance areas require the collaboration of the appropriate Directors and Chairs to review concerns in their specific domains and coordinate findings and remediation.
3. If the Chair, Director, or their designees, believe there is a potential of an immediate risk to subjects, safety, or the environment, the Chair/Director may immediately require temporary cessation of a research protocol, in part or its entirety, and the sequestration of research records including raw data during the investigation.
  - a. ORIS Staff must immediately contact the appropriate Director, Chair, or the Associate Vice President for Research Integrity & Safety if they encounter a situation where there is the potential for immediate risk to subjects, safety, or the environment or, in their estimation, would require reporting to federal or state oversight agencies.
4. The ORIS Director(s) and Chair(s) will review the initial findings to determine whether to conduct further inquiry. Findings and determinations are reported to the respective compliance committee(s) at a convened meeting and reported to the respondent and complainant (if any).
5. If an allegation involves Serious Non-Compliance, the Chair/Director should inform the committee of the allegation and initial findings within seven business days.
6. The convened committee reviews the allegations during the meeting and may:
  - a. Request an investigation into the allegation (described below)
  - b. Determine that the initial inquiry is complete and approve remediation
  - c. Dismiss the allegation as unjustified and decide to take no action
7. The Chair/Director communicates the committee's decisions to the complainant if known and to the PI against whom the allegation was raised (respondent).

### **Initiating an Investigation into an Allegation**

1. The committee may decide to initiate an investigation based on the seriousness and/or the frequency of violations and/or disregard for the regulations or the institutional policies and procedures applicable to research.
2. Consideration of immediate (before completion of the investigation) suspension requires a meeting of the convened committee. This meeting should take place as soon as possible. A research protocol may be partially suspended or suspended in its entirety at the committee's discretion.
3. The Chair may appoint one or more voting committee members to conduct the investigation as a subcommittee. The Director/Staff assists the subcommittee member(s) in conducting the

investigation. The seriousness or complexity of the matter will dictate the size of the investigative subcommittee at the Chair's discretion. Ad hoc assistance may be utilized by the subcommittee to provide expertise.

- a. If two or more committees are charged, the committees' activities will be coordinated by the Associate Vice President for Research or his designee.
4. The Chair/Director notifies the PI when an investigation is initiated to determine the validity of the allegations. If the allegation involves a co-investigator or a research assistant, the Chair/Director also contacts that individual.

### **Conduct of the Investigation**

1. Information on the nature of the allegation, procedures approved in the research protocol, and procedures followed in the conduct of the study are collected and reviewed. The member(s) conducting the review may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; the applicable approved protocol; and any other pertinent information.
2. Separate interviews with the complainant (if any) and respondent are conducted. In cases where the complainant requests anonymity, the individual who received the original allegation interviews the complainant, if possible. The respondent is allowed to comment on the allegation and provide information. The interviewer(s) prepares the interview summaries and allows the interviewees to comment on the written summary. The respondent may submit a written rebuttal to the complaint.
3. Depending on the nature of the allegation and the information collected during the interviews, the subcommittee or its representative(s) may interview other individuals.
4. When appropriate, the subcommittee member(s) conducting the investigation prepares a summary report for the convened committee with the assistance of an assigned ORIS staff member, which may include a summary of the allegations, interview summaries, and copies of pertinent information or correspondence.

### **Review Procedures**

1. The ORIS Director advises the committee on the applicable University policies/procedures, sponsor reporting requirements, and federal regulations. ORIS staff document the investigation, answer questions about the review process, maintain the records required by state and federal laws, and serve as liaisons with the funding agency or agencies.
2. At a convened meeting, the appropriate compliance committee reviews the investigation results, including the summary report, the protocol, applicable documents, and any history of non-compliance.
3. The convened committee determines whether the investigation is complete.
4. The committee may give the opportunity or compel the respondent to meet with the convened committee before taking final action.

### **Investigation Outcomes**

1. The convened committee determines whether the allegation is substantiated and, if so, whether the non-compliance is minor, serious, or continuing based on the materials compiled during the

investigation

2. Depending on the outcome of the review, the convened committee may take a variety of actions, including, but not limited to, the following:
  - a. Approve continuation of research without changes
  - b. Request formal educational intervention
  - c. Request minor or major changes in the research procedures and /or consent documents
  - d. Submit a formal letter of concern, warning, or reprimand to the respondent with escalating copies to institutional officials, depending on the nature of the non-compliance.
  - e. Modify the continuing review schedule.
  - f. Require monitoring of research.
  - g. Require monitoring of the consent process.
  - h. Suspend or terminate approval/disapprove continuation of the study.
  - i. Require post-approval monitoring of other active protocols of the investigator.
  - j. Suspend the investigator's privilege to use animal or human subjects, biohazards, radioactive material, ancestral remains, or other regulated items.
  - k. Disqualify the investigator from conducting research with animal or human subjects, biohazards, radioactive materials, ancestral remains, or other regulated materials at the University.
  - l. Recommend to the Institutional Official that the investigator may not use the data collected for publication.
  - m. Require that the investigator contact subjects previously enrolled in the study, provide them with additional information, and/or re-consent them.
  - n. Request that the investigator inform publishers and editors of committee determinations if they have submitted or published manuscripts emanating from the research.
  - o. Suspend access to assigned laboratory space(s) or animal facilities.
  - p. Suspend extramural or intramural funding for non-complaint activities.
3. Depending upon the outcome of the review, the Chair informs the appropriate parties of the allegation, the review process, and the findings of the review: the Respondent, Institutional Official, Complainant, the Department Chair, Dean or Unit director, federal oversight agencies, if required, Sponsor, if appropriate, and other university personnel as appropriate.

### **Right to Appeal**

1. The PI can appeal to the committee to reconsider its determinations by responding in writing within ten business days of the date the committee issues the final decision. Appeals must describe the nature of any claimed procedural error in the review of new or clarified information that would potentially alter the outcome of the investigation (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect).
2. Appeals for reconsideration are communicated to the committee at their next convened regular meeting to determine whether to re-open the inquiry or reject the appeal.
3. The Chair informs the PI of the committee's determination.

### **Duty to Report**

While investigating or evaluating alleged non-compliance, ORIS Staff or one of the compliance committees may receive or discover information or evidence which indicates a violation of policies or laws under the purview of other UGA units, federal or state agencies, or law enforcement. In these cases, the Director of the applicable ORIS unit will inform the Associate Vice President for Research Integrity & Safety, who will escalate the matter to the appropriate organizational entity for further evaluation.

**END OF POLICY**