Policy and Procedure for Responding to Allegations of Research Non-Compliance Office of Research Compliance Policy 1

PURPOSE

To describe the policies and procedures the units of the Office of Research Compliance (ORC) follow in responding to allegations of research noncompliance.

GENERAL DESCRIPTION

The primary responsibilities of the ORC 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 ORC will follow these procedures while addressing allegations of noncompliance with institutional policy, and state and/or federal regulations governing the conduct of research.

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

DEFINITIONS

Noncompliance is defined as conducting research in a manner that disregards or violates federal and/or state regulations or institutional policies and procedures applicable to research. Three categories of noncompliance are noted:

1. *Minor noncompliance* includes minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose immediate risk to subjects, the environment, or researchers, and/or violate research subject's rights and/or welfare (with exception of continuing non-compliance, see below).

2. *Serious noncompliance* 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 noncompliance* is a persistent failure to adhere to the laws, regulations, or policies governing research and can represent either minor or serious noncompliance.

RESPONSIBILITY

Execution of SOP: Office of Research Compliance (ORC) Staff; ORC Directors for animal care and use, biosafety, research safety, human subjects, animal resources (ORC Director); Compliance Committee

Chairs (Chair(s)); Principal Investigator (PI)/Study Personnel.

PROCEDURES

Submission and Screening of Allegations of Noncompliance

1. Anyone may submit allegations of research noncompliance to ORC Staff or the Chair(s) verbally or in writing. ORC Staff and Chair(s) will protect the confidentiality of the person submitting the allegation (complainant) to the fullest extent possible.
2. The ORC Director will conduct a preliminary review investigating whether the allegation involves a current 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 which overlap two or more compliance areas requires 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 in its entirety, and/or the sequestration of research records including raw data during the investigation.
    a. ORC Staff must immediately contact the appropriate Director, Chair, or the Associate Vice President for Research Compliance 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 ORC 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 7 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. In the event that two or more committees are charged, activities of the committees 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 pertaining to 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 given an opportunity to comment on the allegation and provide information. The interviewer(s) prepares summaries of the interview and gives the interviewees the opportunity 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, with the assistance of an assigned ORC staff member, a summary report for the convened committee which may include a summary of the allegations, interview summaries, and copies of pertinent information or correspondence.

Review Procedures

1. The ORC Director advises the committee on the applicable University policies/procedures; sponsor reporting requirements; and federal regulations. ORC staff document the investigation, answer questions about the review process, maintain the records as 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 results of the investigation including, the summary report, the protocol, applicable documents, and any history of noncompliance.
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 noncompliance 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 or biohazards
    k. Disqualify the investigator from conducting research with animal or human subjects, biohazards, or radioactive 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 and provide them with additional information and/or re-consent them
    n. Request that the investigator inform publishers and editors of committee determinations if he/she has submitted or published manuscripts emanating from the research.
    o. Suspend access to assigned laboratory space(s) or animal facilities.
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 10 business days of the date the committee issues the final decision. Appeals must describe the nature of any claimed procedural error in the review or 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 determination.