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. 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 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 i.

PROCEDURES

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 onthe 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

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 actions

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