



<b>Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures</b>		
<b>SOP #7</b> <b>Revision #1</b>	<b>TITLE: Noncompliance</b>	Date Effective: 11/2/12 Revision Date:
Approved By: RP Director	Signature 	Date: 11/2/2012
Approved By: IRB Chair	Signature 	Date: 11/2/2012

## **PURPOSE**

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

## **GENERAL DESCRIPTION**

The primary responsibility of the IRB is to ensure the protection of the rights and welfare of human subjects in research. As part of this responsibility, the IRB follows these procedures to address allegations of noncompliance with IRB requirements and/or federal regulations governing the conduct of human research.

### *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.

*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 risk to subjects and/or violate subject's rights and welfare.

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

1. involve 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 compromise the effectiveness of a facility's human research protection or human research oversight programs.

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

## **RESPONSIBILITY**

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Execution of SOP: Research Protections (RP) Staff, Director of RP (RP Director), IRB Chair, Principal Investigator (PI)/Study Personnel.

**PROCEDURES**

*Submission and Screening of Allegations of Noncompliance*

1. Anyone may submit allegations of noncompliance involving human subject research to RP or the IRB Chairperson verbally or in writing. RP and the IRB Chair will protect the confidentiality of the person submitting the allegation (complainant) to the fullest extent possible.
2. The RP Director conducts a preliminary review to investigate whether the allegation involves a current IRB approved study, a sponsored study, or research that involves other research review committees/units (i.e., Institutional Biosafety Committee) and communicates initial findings to the IRB Chairperson.
3. If an allegation involves exempt research, the IRB Administrator and IRB Chair will review the initial findings to determine whether to conduct further inquiry. Findings and determinations are reported to the IRB at the next meeting and reported to the respondent and complainant (if any).
4. If an allegation involves non-exempt research, the IRB Chair informs the IRB of the allegation and initial findings. If the allegation involves increased risk to human subjects and initial findings indicate that the allegation may be justified, the IRB is informed within 7 days.
5. The convened IRB reviews allegations and may 1) request a formal inquiry into the allegation; 2) determine that the initial inquiry is complete and approve a review outcome (described below); or 3) dismiss the allegation as unjustified and decide to take no action. The IRB Chair communicates the IRB’s decisions to the complainant, if known, and to the investigator against whom the allegation was raised (respondent).

*Initiating an Inquiry into an Allegation*

1. The IRB may decide to initiate an inquiry based 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.
2. The IRB may appoint one or more voting members to conduct the inquiry. The RP Director assists the IRB representative in conducting the inquiry. In more serious cases, the convened IRB gathers the information as a group rather than delegating the responsibility to one or more voting members.

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3. If the IRB believes there is a potential immediate risk to subjects, the convened IRB may immediately suspend IRB approval and/or sequester research records including raw data during the inquiry.
4. The IRB Chair notifies the PI when an inquiry is initiated to determine the validity of the allegations. If the allegation involves a co-investigator or a research assistant, the IRB Chair also contacts that individual.

*Conduct of the Inquiry*

1. Information pertaining to the nature of the allegation, procedures approved in the IRB protocol, and procedures followed in the conduct of the study are collected and reviewed. The member conducting the review 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.
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. The respondent is given an opportunity to comment on the allegation and provide information. The interviewer 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 convened IRB or its representative may interview other individuals.
4. When appropriate, the IRB member(s) conducting the inquiry prepares, with the assistance of an assigned RP staff member, a summary report for the convened IRB which may include a summary of the allegations, interview summaries, and copies of pertinent information or correspondence.

*Review Procedures*

1. The RP Director advises the IRB on the applicable University policies/procedures; sponsor reporting requirements; and federal regulations. IRB Administrators document the inquiry, 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. The IRB reviews the results of the inquiry including, the summary report, the protocol, the informed consent document if applicable, and any history of noncompliance at a convened meeting.
3. The convened IRB determines whether the inquiry is complete.
4. The IRB may give the respondent the opportunity to meet with the convened IRB before taking final action.

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*Review Outcomes/IRB Actions*

1. The convened IRB determines whether the allegation is substantiated, and if so, whether the noncompliance is minor, serious, or continuing based on the materials compiled during the inquiry. If the noncompliance is serious or continuing and the research is sponsored, the incident(s) is reported to the applicable agency/sponsor.
2. Depending on the outcome of the review, the convened IRB may take a variety of actions, including, but not limited to, the following:
  - a. Approve continuation of research without changes;
  - b. Determine research to be exempt;
  - c. Request formal educational intervention;
  - d. Request minor or major changes in the research procedures and /or consent documents;
  - e. Modify the continuing review schedule;
  - f. Require monitoring of research;
  - g. Require monitoring of the consent process;
  - h. Suspend or terminate IRB approval/disapprove continuation of the study;
  - i. Require post approval monitoring of other active protocols of the investigator;
  - j. Suspend the investigator’s right to request initial IRB review of human subject research for a period of time;
  - k. Disqualify the investigator from conducting human subject research at the University;
  - l. Determine 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; and/or
  - n. Request that the investigator inform publishers and editors of IRB determinations if he/she has submitted or published manuscripts emanating from the research.
3. Depending upon the outcome of the review, the IRB 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, Office for Human Research Protections and/or the Food and Drug Administration, if required, Sponsor, if appropriate, and other university personnel as appropriate.

*Right to Appeal*

1. The PI can appeal the determinations of the IRB by responding in writing within 10 days of the date the IRB issues the final decision. Appeals must describe the nature of any claimed procedural error in the review (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect). Appeals are communicated to the IRB to determine whether to re-open the inquiry or reject the appeal.

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2. The IRB Chair informs the PI of the IRB determination.

**SUPPORT PROCESSES AND PROCEDURES**

IRB SOPs

**REFERENCES**

21 CFR 56.123, 45 CFR 46.112