University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #10	**TITLE: Noncompliance**		**Page 1 of 6**
Approved By: ORI Director	Signature	Date	Date First Effective: 05-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 09/04/2014

OBJECTIVE

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

GENERAL DESCRIPTION

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their research staff, the participants who enroll in research, IRB members, and ORI staff. 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. ORI 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 SOP.)

Definitions

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their 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.

RESPONSIBILITY

Execution of SOP: Office of Research Integrity (ORI) Staff, IRB Chair, IRB Members, ORI Research Compliance Officer (RCO), ORI Director, Principal Investigator (PI)/Study Personnel

PROCEDURES

Submission and Screening of Allegations of Noncompliance

1. Anyone may submit allegations of noncompliance or continuing noncompliance involving human subjects research to the ORI verbally or in writing. ORI staff or the IRB may also identify concerns during the review process. The ORI/IRB maintains confidentiality regarding the identity of the person submitting the allegation to the extent possible.

2. The RCO or designee (e.g., ORI staff) screens the allegation/concern of noncompliance to determine whether the protocol(s) affected is supported by federal funds.

3. The RCO or designee also determines whether the protocol has issues pertinent to other research review committees, i.e., Institutional Biosafety Committee, Markey Cancer Center, Center on Aging, Radiation Safety Committee, Radioactive Drug Research Committee, Office of Sponsored Projects Administration, and Investigational Drug Service.

4. If the RCO or designee finds any issues pertinent to these research review committees, he/she coordinates with these units as outlined in the IRB/ORI coordination SOP, if appropriate.

Assessment of Allegations

1. The RCO or designee reviews allegations/concerns to determine whether the facts justify the allegation (i.e., there are supporting documents or statements).

2. If the RCO or designee deems an allegation/concern unsubstantiated (i.e., finds no supporting documents or statements), he/she consults with the IRB Chair or his/her designee and, if appropriate, the ORI Director. The IRB Chair, ORI Director, or designee may decide no additional action is needed, further inquiry is necessary, or the issue should be presented to a convened IRB.

3. If the RCO or designee determines that an allegation/concern is substantiated but the concerns are minor or administrative issues, the RCO or designee (e.g., ORI staff) manages the concern through communications with the PI or the complainant (e.g., timely reward payment). The RCO or designee reports the minor issue to the IRB Chair, designee, and/or ORI Director. The IRB Chair, ORI Director, or designee may determine that the noncompliance does not meet serious or continuing noncompliance and no additional action is needed, or determine further inquiry is necessary, or determine the issue should be presented to a convened IRB.

4. If the RCO or designee determines the allegation/concern may be substantiated and may involve an unanticipated problem or serious or continuing noncompliance, he/she forwards applicable materials to the IRB Chair or designee with a copy to the ORI Director as appropriate.

5. At the completion of the assessment, when appropriate, the RCO or designee communicates (by phone, email, or letter), the IRB Chair's or designee's decision to the complainant (if the identity of the person is known) and, if applicable, to the individual against whom the allegation/concern was raised (respondent).

Initiating an Inquiry into More Serious Violations

1. If the allegation/concern involves more serious issues than administrative or minor concerns, the convened IRB, 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 subjects research.

2. If the RCO (or designee), IRB Chair, or convened IRB determines that an allegation/concern is substantiated and suggests that subjects are at immediate risk, the IRB Chair, in consultation with the ORI Director or designee, considers whether to immediately suspend IRB approval in accord with the Termination and Suspension SOP.

3. If the convened IRB or the IRB Chair or designee decides to initiate an inquiry to determine the validity of the allegations/concerns, ORI staff notify the complainant or individual/IRB that identified the concern. If the allegation/issue involves a co-investigator or a research assistant, ORI staff may also contact that individual. The RCO or designee or the IRB Chair notify the PI via telephone and/or e-mail. RCO or designee or IRB Chair sends written follow-up correspondence.

4. The IRB may appoint one or more voting member(s) or RCO or designee (e.g., the IRB Chair or his/her representative) to gather information pertaining to the nature of the

allegation/concern, the procedures approved in the IRB protocol, and the procedures followed in conducting the study.

5. The IRB representative interviews the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation/concern interviews the complainant. In some cases, the complainant may have already submitted a written complaint. Either the IRB representative or the RCO or designee may request additional information from the complainant.

6. The convened IRB, the IRB Chair, or a designated IRB representative (e.g. RCO or designee) interviews the respondent and gives him/her the opportunity to comment on the allegation/concern and provide information. The respondent may submit a written rebuttal to the complaint. Either the IRB or the RCO may request additional information from the respondent.

7. Depending on the nature of the allegation/concern 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.

8. When appropriate, the IRB member(s) conducting the inquiry prepares, with the assistance of an assigned ORI staff member, a summary report for the convened IRB. The report may consist of a summary of the allegations/concerns, 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/issues, the interview summaries, and copies of pertinent information without an accompanying written report from the review team.)

Review Procedures for Potential Serious or Continuing Noncompliance

1. The ORI 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 and federal laws, and serves as a liaison with the funding agency or agencies.

2. 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.

Review Outcomes/IRB Actions

1. The convened IRB makes the determination whether the allegation/concern 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 or designee, reports the incident(s) to the applicable agency following procedures outlined in the Mandated Reporting to External Agencies SOP.

2. 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 inspections of other active protocols of the investigator (See Quality Improvement Program Directed On-Site Review SOP.);
   - 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, ORI Director, IRB Chair or designee communicates (phone call, email, or letter) the IRB decision to the person raising the allegation (if the identity of the person is known) and to the respondent.

3. The IRB informs the following individuals of the allegation/issue, 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;
- Vice President for Research;
- Office for Human Research Protections and/or the Food and Drug Administration (See Mandated Reporting to External Agencies SOP.);
- Sponsor, if appropriate;
- Other administrative personnel as appropriate (See applicable IRB/ORI coordination SOPs).

5. 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.

6. The IRB may resolve questions or concerns raised by a PI regarding the outcome of a specific IRB noncompliance review through direct communication with the PI. If not resolved, the convened IRB reviews the appeal in conjunction with a separate party (e.g., chair/vice chair from a different committee, consultant, etc.) to assist in adjudicating the appeal. The appeal determination final.

REFERENCES

21 CFR 56.123
45 CFR 46.112