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Approved By: ORI Director	Signature	Date	Date First Effective: 05-31-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 08-19-09

OBJECTIVE

To provide guidance in handling concerns, complaints, or questions received regarding a research study involving human subjects

GENERAL DESCRIPTION

The right of research subjects to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. The Research Compliance Officer (RCO) or designee in the Office of Research Integrity (ORI) is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. The RCO or designee handles these issues in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone, in writing, or in person to the RCO or designee. Each IRB approved informed consent document includes a toll free telephone number to reach the RCO or designee; the toll free telephone number is also listed on the ORI and University websites.

RESPONSIBILITY

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

PROCEDURES

Concerns/Complaints/Questions

1. A research subject or anyone with a concern, complaint, or question regarding a research study involving human subjects may raise the concern, complaint, or question with the ORI.

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Upon receipt of a concern (e.g., allegation), complaint, or question, the RCO or designee gathers the following information from the complainant as appropriate:

- Subject's (or complainant's) name, address, and phone number (This information is NOT MANDATORY, and an individual may report an incident anonymously; however, the RCO or designee advises the individual that a thorough review may not be possible, and that, without this information, follow-up responses to the individual are not feasible.);
- Study protocol title (or acronym) and the name of the PI;
- Date(s) of the incident, and;
- An explanation of the concern, complaint, or question.

2. The RCO or designee assures the individual (or complainant) that he/she will inquire into the circumstances and that the IRB/ORI will take appropriate measures to address the issue. Furthermore, the RCO or designee informs the individual that a response to him or her will be forthcoming as rapidly as possible provided that contact information is given (e.g., if possible, within 2 to 3 weeks if the issue is a complaint). The RCO or designee also explains to the individual the limits to confidentiality.
3. The RCO or designee handles the concern, complaint, or question in a confidential manner to the extent allowed by law. The ORI limits access to information concerning the contact to employees with responsibilities that require knowledge of the concern, complaint, or question.
4. The RCO or designee conveys the information regarding the concern, complaint, or question to the PI of the study at issue, the ORI Director, and the IRB Chair in a timely manner.
5. The RCO or designee promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issue(s) at the administrative level.
6. If the alleged impropriety involves potential harm to subjects or others, the RCO or designee notifies the IRB for immediate action pending formal inquiry. The RCO or designee reports concerns, complaints, or questions involving serious issues immediately to the IRB Chair, the ORI Director, the Vice President for Research (VPR), and, if appropriate, Legal Counsel.
7. The RCO or designee manages the inquiry, preparing related correspondence, and maintaining documentation of the review for up to six years from completion of the inquiry or close out of the IRB file, whichever is longer.
8. The IRB Chair or his/her designee, in collaboration with the RCO or designee, ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature such as a payment issue, the IRB Chair, the RCO, or designee may resolve the issue without bringing it forth for an IRB committee vote. The IRB Chair, the RCO, or designee refers major issues such

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as failure to obtain signed informed consent from potential subjects (if required) to the IRB committee, and the IRB votes on any actions the IRB takes. All actions taken are by the IRB, are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings.

9. Depending on the nature of the event or circumstances, the IRB may take the following actions but is not limited to:
 - Further inquiry;
 - Administrative action;
 - Details and recommendations forwarded to the appropriate committee chairs (e.g., IRB, Radiation and/or Safety Committees) for consideration in their committees;
 - Details and recommendations forwarded to the appropriate department chair for action as appropriate;
 - Details and recommendations forwarded to the VPR, Veterans Affairs Medical Center Research and Development Office/Committee, and/or University Legal Counsel for action;
 - Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable, and;
 - Other actions as deemed appropriate.

10. The ORI and IRB monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The RCO or designee brings issues involving noncompliance to the attention of the IRB Chair, the IRB, and the ORI Director. (See the Noncompliance SOP.)

REFERENCES

- 45 CFR 46.116(a)
- 21 CFR 50.25(a)