RESEARCH PARTICIPANT CONCERNS/COMPLAINTS

SOP #:	**413**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**05/1/09**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:		**ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB**					
RESPONSIBILITY FOR EXECUTING POLICY:		**IRB CHAIRPERSON, IRB COORDINATOR, IRB MEMBERS**					
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**ORIGINAL**		
APPROVAL AUTHORITY:		**Associate Vice President for Research and Economic Development**					
APPROVED BY:						**DATE:**	**04/29/09**

1. POLICY

The purpose of this policy is to establish procedures for handling concerns/complaints received by the Institutional Review Board regarding research involving human subjects. The right of research participants to lodge a concern/complaint and to be assured that the concern/complaint is taken seriously and resolved in a timely manner is of prime importance. The IRB Coordinator is responsible for investigating all concerns/complaints from subjects and any improprieties involving investigators or their staff. Concerns/complaints are handled in a timely manner, assuring protection of human subjects and holding 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 about a research project by telephone, in writing, or in person to the IRB Coordinator.

2. SPECIFIC POLICY

1. A research participant or anyone with a concern/complaint regarding a research study involving human subjects may raise the concern/complaint with the Research Development and Compliance (RDC) office. Upon receipt of a concern/complaint or allegation, the IRB Coordinator gathers the following information from the complainant:
   - Subject's (or complainant's) name, address, and phone number (This information is not mandatory, and a caller may report an incident anonymously; however, the IRB Coordinator advises the caller that a thorough review may not be possible, and that, without this information, follow-up responses to the subject are not feasible.);
   - Study protocol title (or acronym) and the name of the principal investigator;
   - Date(s) of the incident;
   - An explanation of the concern/complaint.

2. The subject is assured than an inquiry into the circumstances will be undertaken and that the IRB/RDC will take appropriate measures to address the issue. The subject is informed that a response will be forthcoming as rapidly as possible provided that contact information is given (e.g., if possible, within 2 to 3 weeks of the complaint). The limits to confidentiality are also explained to the subject at the time the issue is reported.

3. Concerns/complaints are handled in a confidential manner to the extent allowed by law. The RDC limits access to information concerning the complaint to employees with responsibilities that require knowledge of the concern/complaint.

4. The IRB Coordinator conveys the information regarding the concern/complaint to the PI of the study at issue, the Associate Vice President for Research and Economic Development, and the IRB Chairperson in a timely manner.

5. The IRB Coordinator promptly investigates the concern/complaint, 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 IRB Coordinator notifies the IRB for immediate action pending formal inquiry**.** The IRB Coordinator reports concerns/complaints involving serious issues immediately to the IRB Chairperson, the Associate Vice President for Research and Economic Development, the Vice President for Research and Economic Development, and, if appropriate, Legal Counsel.

7. The IRB Coordinator 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 Chairperson, in collaboration with the IRB Coordinator, ensures appropriate response to each complaint and reports the action(s) taken to the IRB. If the complaint or concern is of a minor nature such as a payment issue, the IRB Chairperson may resolve the issue without bringing it forth for an IRB committee vote. The IRB Chairperson refers major issues such as failure to acquire signed informed consent forms from potential subjects (if required), to the IRB and any actions by the IRB are voted on. All actions taken are at the institutional level and appropriate for the circumstances, and the final course of action is entirely dependent on the nature, severity, and degree of seriousness of the findings.

9. Depending on the nature of the event or circumstances, actions that may be taken include but are not limited to:
   - Further inquiry;
   - Administrative action;
   - Details and recommendations forwarded to the appropriate committee Chairs (e.g., IRB, Conflict of Interest/Scientific Misconduct Committee) for consideration in their committees;
   - Details and recommendations forwarded to the appropriate department Chairperson for action as appropriate;
   - Details and recommendations forwarded to the VPR, 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;
   - Other actions as deemed appropriate.

10. The RDC and IRB monitor any concerns/complaints that are received for issues of non-compliance. The IRB Coordinator brings issues involving noncompliance to the attention of the IRB Chairperson, the IRB, and the Associate Vice President for Research Economic Development. (See SOP 408: Non-compliance with IRB Policies and Procedures.)

3. RESPONSIBILITY

The IRB Coordinator is responsible for investigating all concerns/complaints related to human subject research received by IRB/RDC.

IRB Members are responsible for the review of reports of investigation of concerns/complaints and determination of actions needed to be taken by the IRB and Principal Investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

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

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Secretary, IRB Chairperson, IRB Members	Upon receipt of report of concerns/complaints, immediately notify the IRB Coordinator.
IRB Coordinator, IRB Chairperson	Conduct investigation into alleged concern/complaint. Notify the Chairperson requesting a written response.
IRB Coordinator, IRB Chairperson	Keep IRB notified as appropriate. Upon completion of the investigation, present the facts and findings to the IRB.
IRB Chairperson, IRB Members	Review the information at a convened meeting of the Full Board and make a determination as to appropriate action.
IRB Coordinator, IRB Secretary	Notify the Principal Investigator of the IRB's determination and any corrective action. Notify all appropriate parties of the allegation and outcome.
IRB Coordinator, IRB Secretary	Prepare related correspondence and maintain documentation of the investigation and outcome as required by regulatory requirements and/or institutional policy.