

PRINCIPAL INVESTIGATORS AND INVESTIGATIVE STAFF

SOP #:	601	VERSION #:	1	EFFECTIVE DATE:	5/1/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB MEMBERS, IRB STAFF					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:		/ /

1. POLICY

It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The researcher and the research staff interact with subjects; therefore it is vital that open and frequent communication with the investigative team be maintained.

2. SPECIFIC POLICIES

2.1 Investigator Notifications

2.1.1 Initial Submissions (Exempt, Expedited, Full Board): The Investigator will be notified in writing of the IRB decision as soon as possible after the meeting. If the approval is withheld pending receipt and review of minor modifications from the Investigator or Sponsor, the Investigator must submit a response to the IRB within 90 days of the date of notification. This time period may be extended if the Investigator/Sponsor communicates a need for an extension.

2.1.2 Continuing Reviews and Protocol Changes: Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews or protocol changes.

Written notification of continued approval will be sent to the Principal Investigator. If the Principal Investigator is a student, a copy of the approval will be sent to the student’s adviser. If the Principal Investigator is a faculty member, a copy will be sent to the Department Chair.

2.1.3 Notification of Final Approval: Investigators will be notified in writing of the final IRB approval. The IRB approved consent form will be stamped with the approval and expiration date and submitted to the Investigator with the final approval document. Standard conditions for continued approval include, but are not necessarily limited to:

- Informed consent is obtained and documented.
- The IRB is notified of adverse events within appropriate time periods.
- The IRB is notified of unanticipated problems.
- Changes to the protocol, and deviations from the protocol are reported.
- Continuing review reports are submitted to the IRB.

- Documentation of FDA approval prior to study initiation (if required).

Written notification of approval will be sent to the Principal Investigator. If the Principal Investigator is a student, a copy of the approval will be sent to the student's adviser. If the Principal Investigator is a faculty member, a copy will be sent to the Department Chair.

2.1.4 Disapproval: Correspondence will provide the reason(s) for disapproval and instructions to the Investigator for appeal of this decision.

2.1.5 Tabling: Correspondence will provide reason(s) for tabling and instructions to the Investigator to respond to this decision.

2.1.6 Expiration: If the Investigator does not respond to continuation notices, the approval for the project will expire and a letter of expiration will be sent to the Investigator and appropriate institutional and/or regulatory officials. The IRB has the right to decline future research proposals from the Investigator or from students whom he or she serves as advisor until all submitted research is current.

2.2 Investigator Appeal of IRB Action

An Investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to the IRB. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal may be in writing or in person and must be reviewed by the Full IRB at a convened meeting. If the appeal is denied and the study disapproved, no one at the University can override the IRB's decision.

If an Investigator feels that his or her proposal has been disapproved by the IRB because of incorrect, unfair, or improper evaluation by the IRB, he or she may appeal to the IRB Chairperson or the Associate Vice President for Research and Economic Development, who may then request a reconsideration of the proposal by the Full Board. An avenue always open to the Investigator is to modify the protocol to conform to IRB and HHS/FDA guidelines. However, Investigators do not have the option to seek the reversal of an IRB decision by submitting the same protocol to another IRB.

At any point in time, Investigators (and research personnel) can direct questions, express concerns, and convey suggestions regarding the human research protection program to the Associate Vice President for Research and Economic Development and/or the Vice President for Research and Economic Development.

2.2.1 Noncompliance

Investigator noncompliance may often be the result of communication difficulties. Therefore, the IRB will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized. However, if it appears that an Investigator is intentionally in noncompliance, the IRB, through the Associate Vice President for Research and Economic Development, will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent to the individual's supervisor, Dean and Sponsor (if applicable).

Should noncompliance continue, appropriate action would be determined at a convened meeting. Action by the IRB can include, but is not limited to:

- Halting the research until the Investigator is compliant;
- Requiring the Investigator to complete a training program;
- Barring the Investigator from conducting further research;
- Any other action deemed appropriate by the IRB.

When unapproved research is discovered, the IRB and the University will act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the Investigator's fitness to conduct future human subject research.

The IRB's responsibility is to protect the rights and welfare of research subjects, which could be placed at risk if there is misconduct on the part of an Investigator or any member of the investigative team. It is, therefore, the duty of the IRB to be receptive to and act on good faith allegations of misconduct. Allegations of Misconduct in Science, as defined by University Policy, must be referred to the Vice President for Academic Affairs.

2.3 Investigator and IRB Communications

The Investigator and his or her staff can call or email the Research Development and Compliance office at any time with questions, concerns, or suggestions. The phone call or e-mail will be routed to the appropriate personnel. All attempts will be made to respond to messages or e-mails within 48 hours.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development is responsible for overseeing all IRB communications.

The IRB Secretary is responsible for generating appropriate correspondence in response to IRB meetings and decisions.

The IRB Secretary is responsible for distributing IRB correspondence to appropriate parties.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.113
45 CFR 46.109, 46.113

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>Associate Vice President for Research and Economic Development</i>	Ensure that all communications follow established procedures and format. Supervise staff to ensure that all communications with Investigators, regulatory bodies, and others as appropriate are accurate and timely.

<i>IRB Secretary</i>	<p>Ensure that the determinations and requirements of the IRB are communicated to the Investigator as soon as possible.</p> <p>Send a memo to the Investigator if a response is not received within 90 days to requests and revisions of initial review.</p> <p>Provide a copy of the approved IRB minutes to the IRB members and other appropriate individuals.</p>
<i>IRB Chairperson, IRB Vice Chairperson, IRB Members</i>	<p>Review and sign IRB decision communications.</p>
<i>IRB Secretary</i>	<p>Ensure that all communications are documented and retained in the study file.</p> <p>Ensure that the appropriate entities are copied on the documentation and notification of any IRB determinations and actions.</p> <p>Triage questions, concerns and/or suggestions as appropriate.</p> <p>Record and distribute correspondence as directed.</p>