Florida Agricultural & Mechanical University
Board of Trustees Policy

Board of Trustees Policy Number:	Date of Adoption/Revision:
2008-12	October 8, 2008

Subject	**Institutional Review Board**
Authority	**HHS guidelines, 45 CFR 46, FDA Guidelines (21CFR-Part 56). §46.116 of the Code of Federal Regulations. §46.117 of the Code of Federal Regulations.**
Applicability	**Use of Human Subjects in Research**

I. Policy Statement and Purpose

The Institutional Review Board (IRB) will ascertain the acceptability of ALL proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will be primarily concerned with the protection (level or risk) of human subjects in research. The IRB will conduct its activities, according to and as required by FDA guidelines (21CFR-Part 56). In order to increase the effectiveness of the IRB, copies of the *IRB Manual* will be made available to the Office of Sponsored Programs, Deans, Department Chairs and active principal investigators. The *Manual* is available on the web at www.famu.edu/research.

II. Definitions:

Principal Investigator - Any full time tenure earning faculty at Florida A&M University.

III. Composition:

The Florida A&M University IRB includes members that have expertise in a wide range of medical and social research areas, familiarity with applicable regulations and laws and with relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations such as children, prisoners, pregnant women, and disabled persons. The committee strives for a balance of men and women with representation from minority populations.

The following criteria apply to the IRB:

1. The IRB board is composed of at least five members with varying backgrounds. Every nondiscriminatory effort is made to assure that the board is composed entirely of either men or women.
2. At least one member (the Community Representative) has no affiliation, other than IRB membership, with the University and is not an immediate family member of anyone affiliated with the University. Whenever the primary Community Representative is unable to attend an IRB meeting, every attempt is made to appoint an alternate Community Representative to serve.
3. Typically, at least one IRB board member has primary professional expertise in a scientific field relevant to the type of research reviewed, and at least one member has primary concerns in a nonscientific field.

IV. Appointment and Length of Service Terms

In the selection new members, the Director of the Animal Care and Research Compliance works with department heads and other University officials to seek candidates for nomination with consideration for maintaining the diversity and specialty requirements of the board. Each appointee outside of the community member must be a tenure track faculty at the University. When an appropriate candidate is found, an invitation letter is sent requesting confirmation of intention to serve. The formal appointment of new members is made by the designated Institutional Official for Human Subject Protection (Vice President for Research). Each member is appointed to a three-year renewable term.

V. Duties and Responsibilities

A member of the IRB has the primary duty of protection of the rights and welfare of individuals who serve as the subjects of research. The members are serving as a link between the investigator and the research subjects.

A. Regular Members

Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if an application adequately protects the rights and welfare of subjects.

B. Nonscientific Member

Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Example: Non scientific members who are lawyers should present legal views of specific areas that may be discussed.

C. Community Representative

Community representative are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

D. IRB Chairperson

In addition to the above duties, the chairperson is responsible for chairing the meetings. The IRB Chairperson performs, or delegates to appropriate voting IRB members authority to perform, expedited and exempt review when appropriate. The IRB chairperson is also empowered, pending IRB review to suspend the conduct of a study if he/she determines that an Investigator is not following IRB requirements. The IRB Chairperson may also delegate to the IRB Vice Chairperson to assist or act on behalf of the IRB Chairperson at IRB meetings.

E. Obtaining an IRB Review

All principal investigators proposing to conduct research involving human participants should seek an IRB review as soon as possible in the following manner:

1. Complete the Application for IRB Review and answer all questions in the manner in which the same information appears in the proposal.
2. Attach a copy of the Informed Consent to the IRB Review Form, when appropriate.
3. Submit one copy of the following to the IRB Administrative Office:
   a. Full proposal
   b. Informed Consent
   c. When appropriate, submit copy of all instruments to be administered and data collection sheets.
4. The IRB staff shall deliver copies of the application and Informed Consent to each member of the Board for review.
5. The project will be reviewed at the next scheduled meeting of the IRB. The principal investigator or a designee may attend the meeting to present the risk implications involved in the proposed research. If needed, principal investigators who are unable to attend the meeting should be available for a teleconference.
6. Faculty advisors to graduate students' research shall always be listed as the principal investigator.

F. Expedited Review Procedure

A less than formal IRB review, expedited, can be conducted for minimal risk and for minor changes in approved research. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The procedure for an expedited review is as follows:

1. May be carried out by the IRB chairperson or one or more experienced reviewers designated by the chairperson as authorized by Section 56.110 of the FDA regulations.
2. Chairperson or the IRB member(s) may exercise all of the authorities of the full Board except that the reviewer(s) may not disapprove the research. (A majority of the IRB members is needed to disapprove a research activity).
3. All IRB members must be apprised of an expedited review.
4. FDA may restrict the use of expedited reviews by an institution when the restriction is seen as needed to protect the rights of human participants.

G. Approval Notification

Written notification of approval will be sent by the IRB secretary to the principal investigator.

1. Notifications will include, as appropriate, approval of the:
   a. informed consent
   b. protocol
   c. investigators
   d. limitations imposed by the Board
   e. dates of approval for the protocol
2. Written notification will include the following responsibility by the investigators during the research period:
   a. promptly report to the Board any changes in research activities,
   b. no changes without Board review and approval unless "apparent immediate hazard to human participants" is being eliminated
   c. promptly report any unanticipated problems involving risks to the subjects or others

H. Modification of Projects

1. When modifications of pre-approved projects are necessary, the principal investigator will submit a memo to the IRB office.
2. The memo should contain:
   a. the original approval date
   b. the nature of the changes to the protocol
   c. rationale for the changes

I. Informed Consent

1. All research projects will include an Informed Consent which meets FDA guidelines 21CFR-Part 50. An Informed Consent shall provide the following information:
   a. A statement that the study involves research
   b. An explanation of the purpose of the research
   c. The expected duration of the participant's participation
   d. A description of the procedures to be followed
   e. Identification of any procedures which are experimental
2. A description of any reasonable foreseeable risks or discomforts to the participant.
3. A description of any benefits to the participant or to others, which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
6. For research involving more than minimal risk, an explanation of any compensation and an explanation of any medical treatments that are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to the participant is otherwise entitled.
9. When appropriate, one or more of the following elements of information shall also be provided in the consent.
10. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
11. Anticipated circumstances under which the participant's participation may be terminated by the investigator, without regard to the participant's consent.
12. Any costs to the subject that may result from participation in the research.
13. The consequence of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the participants.

14. A statement will be provided to the participant indicating findings developed during the course of the research which may be related to participant's willingness to continue participation.
15. The approximate number of participants involved in the study.
16. Documentation of informed consents:
    a. Written approval of the IRB must be on record.
    b. Copy shall be given to the persons signing the form.
    c. The **consent that will be read** to the participants or their legally authorized representatives or they shall have adequate opportunity to read the consent before it is signed.
    d. If consents are to be used with verbal explanations the Board will approve a written summary of what is said to the participant or the representative:
        i. only the form itself is signed by the participant/representative,
        ii. the witness shall sign the form and a copy of the summary (person actually obtaining the consent shall sign a copy of the summary), and
        iii. A copy of the summary shall be given to the participant or representative.

J. Exempted Research

Exemption from full IRB approval which involve human participants may be possible when the following conditions are met:

1. Research is for educational projects. The research can involve educational techniques, tests, classroom methods, and interview procedures.
2. Responses will be recorded in such a manner that the human subjects cannot be identified directly or through identifiers linked to the participants. The only exemption to non-identification will be participants which are elected or appointed public officials or candidates for public office.
3. If invasive procedures, pathological specimens or diagnostic specimens are necessary these sources must be collected through existing participant records.
4. Research involves adult participants. Studies of children require consent or involvement of parents.
5. Researchers will submit a written protocol for IRB approval. IRB members will review and vote for or disapproval of the exemption. Approval for the project exemption is achieved by a majority vote of the committee.
6. Studies must include approval from designated institutional site areas (i.e., hospitals, agents or clinics).

I. Research request from outside of University

Research that is requested from outside of the University must adhere to the following procedures:

1. Those requesting to perform research form outside of the university must first contact the IRB Administrative Office.
2. the Administrative office will pair the requestor with a principal investigator (see definition) at the university.
3. The faculty person at Florida A&M University will serve as the Pi for the project and the outside requestor the Co-PI.
4. The application will follow the current procedure noted above for presentation and approval from the IRB.