UNIVERSITY OF LOUISIANA AT MONROE
POLICIES AND PROCEDURES MEMORANDUM

Title:	**HUMAN SUBJECTS PROTECTION POLICY**
Effective Date:	**10/13/2008**
Update Responsibility:	**Academic Affairs**
Update Date:	**NONE**
Cancellation Date:	**NONE**

1) PURPOSE/PREAMBLE

The University's Institutional Review Board (IRB) is charged with protecting the rights and welfare of human subjects engaged in research at the University of Louisiana at Monroe, and in research conducted elsewhere by faculty, students, staff or other representatives of the University. The University adheres to the 1991 Federal Policies for the Protection of Human Subjects (called the common rule) adopted by the Federal government and set forth in 45 CFR 46 (Code of Federal Regulations) and as revised August 1991. These guidelines apply to all research involving human subjects. The Office of Sponsored Programs and Research's (OSPR) website contains all the policies, procedures, and forms for human subject protection.

2) DEFINITIONS

a. Certification refers to the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.
b. Code of Federal Regulations (CFR) refers to the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.
c. Exempt refers to research activities that do meet the definition of research with human subjects but are not covered by the provisions of the Common Rule. Thus, they do not require review as described in the Rule. The Chair of the IRB must make this determination.
d. Expedited Review refers to research that must meet two criteria: Pose no more than minimal risk to subjects, and consist only of one or more research activities specified in the regulations.
e. Human Subject refers to a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.
f. IRB refers to an institutional review board established in accordance with and for the purposes expressed in the Code of Federal Regulations.
g. IRB approval refers to the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
h. Minimal risk refers to the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
i. Research refers to a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.
j. Principal Investigator refers to the ULM faculty or staff member designated by the University and recognized by the funding agency as the person directly responsible for the project or program supported by the award.

3) PROCEDURES

a. There is a federal mandatory training requirement for all individuals working in human research. You must take the training before you can do research projects with humans. For more information, see the OSPR Website.

b. All research using human subjects, including social, behavioral and educational research, must either be reviewed and approved by the University's IRB, or judged to be exempt from such review by the chair of the IRB.
c. The IRB looks at four principal issues when reviewing a proposal:
   i. are the rights of the human subjects safeguarded,
   ii. does the proposal assure that the University meets relevant Federal Guidelines,
   iii. do the procedures selected cause the least amount of risk necessary and
   iv. are the procedures and design sufficiently effective to justify the involvement of human subjects?
d. Each proposal must detail the measures taken to protect the confidentiality and privacy of the participant subjects. The depth to which proposals are examined depends on the nature of the research question, subjects, and/or methods. Work with individuals at special risk or unusually invasive procedures require more extensive justification.
e. The Federal Government recognizes three categories of research proposal review, Full Board Reviews, Expedited Reviews and Exempt Reviews (in this case, exempt means "exempt from Full Board Review").
   i. Exempt reviews are conducted by the IRB chair or one other specially appointed IRB member rather than by the full board.
   ii. Expedited reviews are conducted by a two-person subcommittee instead of the entire IRB.
   iii. If the research is not eligible for exempt or expedited review, the full IRB will review and determine if the protocol should receive IRB certification.
f. IRB approval is for one year only, unless the risk level, subject population or research protocol has changed. Any change in the risk level, subject population, or research protocol requires immediate IRB review. For any project in which the use of human subjects extends beyond one year, the investigator must apply for renewal one month before the expiration date.

4) RESPONSIBILITIES

a. Principal Investigator – must submit to OSPR the completed IRB application form, including all informed consent forms, questionnaires, tests, and other data collection tools to be used, and one (1) copy of the full research proposal, if appropriate.
b. OSPR – will log the protocol, and forward to the IRB chair for consideration. After the IRB makes a determination, OSPR will notify the Principal Investigator and maintain a copy of all associated documentation in adherence to record retention regulations.
c. IRB – will determine the required type of review, review the protocol, make an approval determination, and return to OSPR for final disposition of the protocol.

Policy References:

Research Administration and Management. [edited by] Elliott C. Kulakowski and Lynne U. Chronister. Jones and Bartlett Publishers. Sudbury, MA. 2006.

Title 45--Public Welfare, Subtitle A--Department Of Health And Human Services, Part 46--Protection Of Human Subjects (45 CFR 46) retrieved from: http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html

Review Process:

Academic Deans

Distribution:

Academic Deans