

**Policy and Procedures
For
Submission of Research
To
The Institutional Review Board
At
Louisiana State University Alexandria**
(September 11, 2009)

Introductory Statement

The policies and procedures included in this document are subject to revision, when deemed necessary, by the Louisiana State University at Alexandria (LSUA) Institutional Review Board (IRB). The IRB is being established to insure the ethical treatment of human participants in research conducted by members of the administration, faculty, staff, and student body at LSUA. The IRB will also be responsible for reviewing and approving any research proposed or conducted by any other individual or group that wishes to conduct research in association with LSUA or use LSUA employees or students as participants.

Purpose and Goals

The charge of the IRB is to review all research proposed by Louisiana State University at Alexandria administration, faculty, staff, students or outside entities to insure the ethical treatment of the human participants. The IRB has been established and will follow the guidelines for the ethical treatment of human participants published by the United States Department of Health and Human Services (HHS). The HHS policies for protection of human subjects are published under Title 45, (Public Welfare) Part 46 (Protection of Human Subjects) which became effective on June 23, 2005. The IRB will adjust its policies and practices, as needed, to maintain compliance with the HHS guidelines whenever they are revised. The IRB also plans to pursue becoming a Registered Institutional Review Board with the Department of Health and Human Services by January 1, 2010, and gaining the status of Federal Wide Assurance for the IRB the following year (2010-2011). Completing these goals would insure that LSUA administration, faculty, staff, and students would be able to apply for federal grants and

receive funding without the presence of the IRB approval being a concern of the granting agency

Make-up of Committee

The IRB is a Chancellors Committee, thus the Chancellor appoints its members. The LSUA IRB consists of five members. Four of these members are LSUA faculty and one is an outside member from the community. The outside or community member can have no other relationship to the university other than being a member of the IRB. Currently members can rotate on and off the committee but in the future members will need to have certification for the university to maintain Federal Wide Assurance to serve as a member of the IRB.

Procedures

The Institutional Review Board at LSUA has established the processes and procedures that anyone proposing to do research while at LSUA or using LSUA students or employees as participants must follow. Any member of the administration, faculty, staff, or student body who proposes to conduct research, anyone working on research in conjunction with anyone associated with LSUA, or anyone who is proposing to use LSUA students as participants in their research, must follow the procedures explained below before they will be allowed to collect data for their research. The procedures will include 3 possible levels of evaluation based on the type of project proposed and the perceived risk (possible risk) to the human participants involved in the research. The levels of review are “exempt”, “slight (minimal) risk,” and “greater than minimal risk.”

General Instructions

All research proposed by LSUA administration, faculty, staff, or student body, or anyone else associated with LSUA or wishing to collect data from LSUA students or employees must complete an IRB Request Form and submit the completed form and a research proposal to the IRB committee or its representative. The IRB Request forms are available by request from IRB committee members and will be available on the LSUA web-site (lsua.edu). When the IRB Request Form is completed the form and a copy of the applicant's research proposal should be sent to the Chairperson of the IRB Committee. The Chairpersons address is found on the IRB Request Form. Specific instructions for the submission process are explained below. The level of review will be determined by the Chairperson of the IRB.

Recommendation of Exempt

If a recommendation of exempt is decided, the IRB Request Form will be filed as exempt and the process will stop with the research approved to be conducted.

Recommendation of Slight (Minimal) Risk

If the recommendation is slight (minimal) risk, the IRB Request Form and a copy of the research proposal will be forwarded to the entire IRB committee for review. Three members of the IRB committee will be required to review the research, discuss the proposal and make a recommendation to the entire IRB committee. Then the entire IRB committee will vote (e-mail voting is acceptable when there are no outstanding issues) for approval the proposed research. The individual requesting the approval of the research, or their representative, is welcome to attend the IRB meeting where their proposal is considered if a meeting is convened. The Committee might ask the applicant

to appear before the committee to answer questions that are of concern to the IRB committee members.

Recommendation of Greater than Minimal Risk

When a research proposal is evaluated as having greater than minimal risk, the IRB Request Form and proposal will be forwarded to the entire IRB committee for review. In this case all five members of the IRB committee will evaluate the proposal and make recommendations. The entire committee meets and votes on the proposed research. The Committee will request the applicant to appear before the committee to answer questions that are of concern to the IRB committee members.

Proposals that are Not Approved

When a proposal is not approved, the committee will explain the threats to the human participants and make recommendations on how the proposal can be modified to gain approval by the IRB committee. Any time a researcher has questions about the use of human participants in research, the question should be directed to the Chairperson of the IRB and the Chairperson or another member of the committee will respond within 2 business days.

Special Consideration for Required Classroom Student Projects

It has been decided by the IRB committee that classroom projects that conducted by students as a requirement of a specific course will be exempt from IRB review unless the instructor of the class thinks it may involves “greater than minimal risk.” If the proposed research possibly involves “greater than minimal risk” is must pass through the normal IRB request process described above. The course instructor of the class will make the evaluations of the student proposals. The students will be required to complete an

IRB Request form and turn it in to the teacher as a part of the project. The faculty member will then retain the IRB Request Form and related information (copies of informed consent forms, debriefing statements, etc.) for 2 years. If the instructor has any questions about ethical considerations or the welfare of the human subjects, the faculty member should contact a member of the IRB committee. The IRB member will answer any questions and if needed will evaluate the proposed student research.

Independent Studies and Directed Research Projects

Individual student projects, student/faculty projects, and group projects conducted under independent or individual study course titles (Independent Studies or Directed Research) will be treated like all other class requirement proposals. That is, first an IRB Request Form and a proposal must be submitted to their instructor for approval and then sent on from there, if needed, as described earlier.

When the Committee Will Meet

The full committee will meet once each semester and any other time when it is necessary. Most submissions to the IRB can and will be handled without requiring a meeting of the entire committee (through electronic communications). The dates of the IRB meetings will be widely distributed across the LSUA campus to insure individuals with submissions before the committee can attend.