

Use of Human Subjects: Basic Requirements and Procedures

Strict federal regulations (45 CFR 46) and University policy govern the use of human subjects to protect their welfare, ensure their safety, and to ensure their documented informed consent is obtained (Except in rare instances where it may not be possible - see 45 CFR 46)

1. APPROVAL: All projects that use human subjects (including use of data or material from living individuals) in ALL research or experiments, OR as the object of projects or surveys, especially if they may result in publication in any form (including evaluative projects) must be approved or exempted in advance by the LSU Institutional Review Board (IRB).

2. IRB APPROVAL: Human subject welfare oversight is managed by IRB Chair Dennis Landin, 130 David Boyd Hall, irb@lsu.edu, 578-8692). An application form package is available to be downloaded from the website (www.lsu.edu/irb). Further guidance is available there.

The IRB is expected to meet at least every 2 months to ensure timely review of projects requiring full review. Some projects qualify for an expedited review (about 4 weeks). IRB approval is good for no longer than 365 days from the date of approval (NOT from the start of the study). Before this period expires, renewed approval must be sought from the IRB (the IRB will request a brief report).

3. EXEMPTION: Three intercollegiate screening committees have been appointed to help determine what projects meet the criteria for exemption from IRB oversight. Any one screening committee member or an IRB member may recommend exemption, based on a completed Exemption Application Form, a project summary, consent form and instruments. The Exemption Application Form is available on the IRB website for the Principal Investigator to make a preliminary assessment of the exemptability of a project, and to apply for exemption. A person not in one of the colleges represented by the screening committees may send an exemption request to a committee member in a related field, or to the IRB Office by email at irb@lsu.edu.

4. STUDENTS may only be Principle Investigator of exempt projects. A university employee must be the responsible Principle Investigator of all non-exempt projects.

5. CLASS PROJECTS present special problems, especially if the instructor intends to collect the data for his own research/publication use. It is best to seek advance exemption or IRB approval for the overall research/publication, or design such projects so that they are exempt. (Some projects otherwise exempt are not if some of the subjects are minors <18).

A single exemption may be sought for a group of standard projects to be conducted by a class. If projects are to be designed by class members, the students may read the Belmont Report (see below), complete an Exemption Application Form for each project and send it to one of the screening committee members or IRB Office. Non-exempt class projects must be approved in advance by the IRB in the usual way.

6. KNOWLEDGE OF REGULATIONS: Principle Investigators of IRB- approved projects are required to be familiar with the Belmont Report, the PHS regulations governing research with human subjects, and the University's Assurance with PHS regarding human subjects, particularly page 9, investigator responsibilities. Principle Investigators of exempt projects are also required to comply with the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report), including securing documented Informed Consent.

7. INFORMED CONSENT: Unless specifically waived by the IRB, consent forms must be used in obtaining informed consent. Documentation of informed consent is required to be kept on file by the investigator for 3 years after the end of the study. If the investigator leaves the University, the records should be turned over to the Department Head. IRB forms, the Belmont Report, the regulations governing research with humans, and other relevant materials are available on the IRB website at www.lsu.edu/irb or from the IRB Office.

Please contact a committee member or Dennis Landin (irb@lsu.edu, 578-8692) if you have questions.