

The Dreaded IRB: How to Make It Easy!

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The definition of human studies research, by federal regulation and University policy is: "A systematic investigation designed to contribute to generalizable knowledge, in which an investigator obtains data through interaction with an individual or by using identifiable private information."

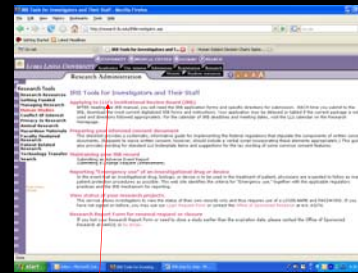
1. Start with this page: <http://research.lu.edu/Default.asp>



2. On the left hand side, click on: human studies



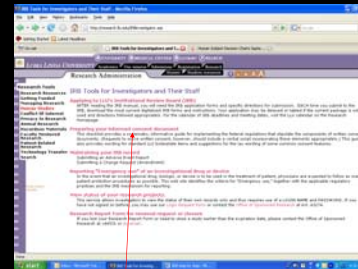
3. Click on: IRB tools for investigators and their staff.



4. There are lots of useful links in this area. The first one to check is: Applying to the LLU's IRB.



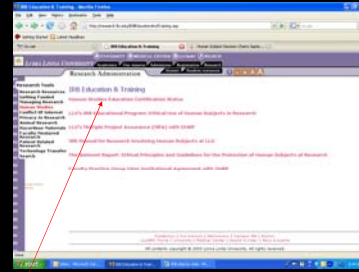
5. Use this link to:
- ✓ check the guidelines
 - ✓ check whether your study is eligible for "expedited" review
 - ✓ download the IRB application form
 - ✓ download the abstract form
 - ✓ download your "checklist" for review



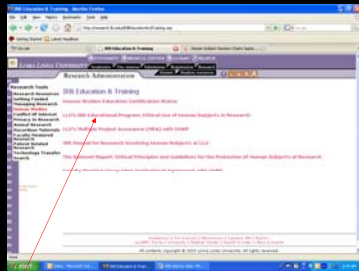
6. Use the previous page (IRB tools for investigators and their staff) to help you prepare the informed consent (if needed).



7. Make sure the Human Studies Education Certification Status is current (for all the researchers involved, including **YOU** and **YOUR MENTOR**). You can check this by going back once from the previous page and scrolling down to the bottom of the page. Click on: IRB Education and Training.



8. Check your mentor's status by clicking on the first link (Human Studies Education Certification Status)



9. Use the second link ([LLU's IRB Educational Program: Ethical Use of Human Subjects in Research](#)) if any of the researchers needs to update, renew or certify for first time.

Important Things to Know

Principal Investigator. For the purpose of IRB records, all student projects must list an LLU faculty member (usually the faculty advisor) as Principal Investigator to re-inforce the role of the faculty and to assure that a long-term contact person will be available for follow-up review by the IRB. This does not preclude the eventual possibility of a student being credited in publications and reports as the principal investigator.

Academic quality. The role of the IRB is not primarily a research review process but is intended to assure that the involvement of human subjects is conducted in an ethical manner, their rights are preserved, and their involvement is appropriate. Inherent in such a review is the need for a well designed, well organized, thoughtfully presented protocol. Signature of the faculty advisor on the application indicates not just awareness of the application but the academic department's assurance that the protocol meets its standards of academic excellence.

Important Things to Know

- **Human subject research.** LLU adheres to federal guidelines which define a human subject as a *living individual about whom an investigator (whether professional or student) conducting research obtains*
 - data through *intervention or interaction with the individual, or identifiable private information.*
- Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.
- Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- *Is it or isn't it?* Any question as to whether a project involves human subject should be directed to the IRB, which is authorized by LLU to make the final determination about such questions.

Checklist for Student IRB Applications (LLU IRB)

- The application packet must use the most current version of the IRB application form and adhere to the current IRB guidelines and University policies.
- A faculty member shall be listed as principal investigator.
- Every item on the application shall be answered, including required signatures. If appropriate, "Not Applicable" may be written in. If unclear whether an item on the application applies, call the IRB for resolution prior to submitting.
- All items listed in the [LLU Guidelines for Informed Consent](#) must be intelligently incorporated in either the formal consent form, an informational letter, or a verbal script, unless a memo is included with the IRB application justifying why the requirement for informed consent should be waived or any element of the routine elements omitted.

Checklist for Student IRB Applications (LLU IRB)

- All pages of the **protocol** should be numbered. All pages of the **consent form** must be numbered as directed, i.e., page 1 of 3.
- Protocol or supplemental pages must provide an explicit description of the recruitment of subjects: how (ads? posters? word of mouth? letter? phone?), where (location and environment), under what conditions (stressful? awkward or embarrassing? privacy?), by whom (relationship to subject – stranger? professional or lay? caregiver? teacher? clergy? family?), deception (as needed by research design). The application materials must demonstrate that the implications of this recruitment process have been carefully planned and address any risk to privacy, social relationships, personal well-being. How such concerns will be resolved should be describe in the materials.
- Exclusion criteria should NOT state the obvious, that is, the opposite of inclusion criteria. In preparing this section, list all inclusion criteria first. Then, assuming the subject meets these criteria, ask yourself if any additional factors would warrant exclusion from the study. If not, just state "none."

Checklist for Student IRB Applications (LLU IRB)

- Students as subjects are considered a protected, limited population. Specific groups of students may be targeted if the research topic pertains to that population. Otherwise, if fellow students are recruited to serve as normal healthy subjects, the recruitment methods must reflect creative effort to recruit from the broadest possible pool of potential subjects in order to avoid any inherent coercion or undue pressure of assisting a fellow student or pleasing a faculty member.
- The submission to the IRB must be complete, including a copy of surveys, questionnaires, data collection instruments, recruitment materials, letters to subjects or non-LLU sites, consent forms, etc. If a published, validated survey instrument is used, it may be described (including publication reference) without including it in the packet.

Checklist for Student IRB Applications (LLU IRB)

- Items which may be submitted concurrent to or even following initial IRB review include: permission letters from non-LLU sites or collaborating departments, recruitment ads, child's assent form. Such materials not available for inclusion with the IRB application at the time of IRB review should be described, stipulating the intent to submit at a future date. This is needed to demonstrate awareness of what is required to maintain a complete IRB file. If such items are so mentioned, IRB review will NOT be delayed. However, approval may be granted on a conditional basis pending receipt of stipulated items. Such items will still be subject to review as an amendment, for IRB approval either administratively or, on rare occasion, by full board.
- When making multiple copies for full IRB review: the protocol MAY be copied double-sided, but not the IRB application or consent form. The IRB application should NOT be copied on green paper. Only the original should be on green in order to differentiate the original from copies.

Checklist for Student IRB Applications (LLU IRB)

- All materials submitted with the IRB application should be stapled together into a single packet, if at all possible, avoiding the use of paper clips. The following sequence is preferred: IRB application, consent form, protocol, appendix materials (questionnaires, recruitment material, data collecting instrument, etc.)
- If there is a question whether a study qualifies for full IRB review rather than expedited or exempt, consult with IRB staff for a determination prior to making copies as needed for full IRB review.
- If the study involves interaction with patients, the California Experimental Subjects' Bill of Rights is required. This should be given to prospective subjects prior to recruiting them for the study. To illustrate that the investigator is aware of this sequence, a copy of the Bill of Rights should be inserted in the packet just prior to the consent document. (If desired, it can be numbered as page 1 of the consent.)

- Person doing the IRB application:
 - ✓The faculty Mentor
- Person responsible for the content of the IRB application
 - ✓The faculty Mentor
- Who goes to jail?

- Be prepared!
- Read the LLU Research Website!
- Discuss everything with the mentor.
- If you need help with research design:
 - ✓Go to the mentor.
- If you have any questions regarding IRB application:
 - ✓Mentor
 - ✓Office of sponsored research
 - ✓Me



THANK YOU!

