Long Island University
Institutional Review Board

Requirements for Informed Consent

Be sure to provide the prospective subjects with sufficient opportunity to consider whether or not to participate. Do not coerce or use undue influence that would affect a subject's decision to participate. No subject may be involved in research unless the subject's prior written consent has been obtained. The consent form should be in language that subjects can easily understand (8th grade level). Review the instructions below before preparing the consent form. Be sure to submit an original copy of the consent form as an attachment to the IRB application.

A well-written consent form should include the following:

1. statement identifying the researcher as LIU faculty or LIU student fulfilling degree requirements;

2. statement that the study involves research;

3. statement of the purpose(s) of the research;

4. time required for the subject's participation;

5. description of the procedures to be followed and identification of any that are experimental;

6. description of any reasonably foreseeable risks or discomforts to the subjects;

7. description of any benefits to the subject or to others that may reasonably be expected from the research;

8. disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;

9. statement describing the extent to which confidentiality of records identifying the subject will be maintained;

10. for research involving more than minimal risk, an explanation as to whether there will be any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

11. an explanation of whom to contact for answers to pertinent questions about the research and subjects' rights;

12. the name of the person to contact in the event of a research-related injury to the subject; and

13. statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; withdrawal will not effect subject's relationship with LIU or with any other organization or institution.

When appropriate, one or more of the following elements of information should also be provided to each subject:

14. statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

15. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

16. any additional costs to the subject that may result from participation in the research;

17. consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

18. statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

19. approximate number of subjects involved in the study.

Questions can be directed to Dr. Lacey Sischo, IRB Administrator via email (lacey.sischo@liu.edu) or phone (516-299-3591).