LIU IRB OVERVIEW

Institutional Review Boards (IRBs) are committees charged by the federal government with protecting the rights and welfare of human subjects involved in research. LIU has two IRBs (one in Brooklyn and one in Post) which are comprised of LIU faculty, staff, and community representatives. The IRBs review research conducted by LIU faculty, staff, and students. If a project involves LIU personnel "engaged" in "research" involving "human subjects," IRB submission and review is required.

Once a determination has been made that IRB submission is required it is important to understand (a) awareness of time, (b) submission requirements, (c) IRB review process, (d) what to know once IRB approval has been granted, and (e) noncompliance.

TIMELINE

The time from IRB submission to approval varies depending upon the type of review conducted by the IRB. Below is a description of the three review types, their process, and expected duration. Final determination regarding level of review is made by the IRB.

1. **Exempt:** Under federal regulations, certain types of research may be exempt from further IRB review if the study involves no more than "minimal risk" and falls into one or more of six exempt categories. For example: surveys; questionnaires or interviews; benign behavioral interventions; research use of data protected by HIPAA; and research on teaching or instruction. The determination of exemption may not be made by the investigator. Once submitted, allow approximately 1 week for review. Either (a) approval of exemption, (b) request for revisions, or (c) notification that the project does not qualify for exemption, will be sent by e-mail. If the protocol does not qualify for exemption the applicant will be asked to complete an expedited or full board application.
2. **Expedited:** The IRB may use an expedited review procedure when the research involves no more than "minimal risk" to the subjects and where the only involvement of human subjects will be in one or more of the expedited categories. For example: blood draws; non-invasive specimen samples; data collected from running on a treadmill; sensitive identified interviews; and secondary data analysis from non-public sources. Once submitted, expect approximately 2 weeks for initial review by a designated member of the IRB. Either (a) determination of expedited approval, (b) request for revisions, or (c) notification that the project does not qualify for expedited review, will be sent by e-mail. If the protocol does not qualify for expedited status it will be processed for either exempt or full board review.
3. **Full Board:** Submissions that involve more than "minimal risk," do not qualify for exempt or expedited review, or fail to receive exempt or expedited approval, are sent to a convened IRB for review. For example: invasive clinical procedures; use of FDA regulated drugs or devices; maximal stress tests; and use of x-ray equipment. Submissions that include certain vulnerable populations (e.g., undocumented immigrants) may also be reviewed at a full board meeting. Investigators planning to submit a full review protocol should be aware of meeting dates and application deadlines that are posted on the IRB website. After review at a convened meeting either (a) determination of approval, (b) modifications required to secure approval, (c) deferral and re-review at a subsequent meeting, or (d) notification of disapproval will be issued by e-mail.

SUBMISSION REQUIREMENTS

LIU requires that anyone engaging in human subjects activities (e.g., recruiting, consenting, interacting, intervening, obtaining or accessing identifiable data must have appropriate training to assure that the rights, welfare, and safety of human participants involved are protected. Information on training requirements and instructions on how to access Collaborative Institutional Training Initiative (CITI) are on the IRB website. CITI

certificates must be included in the submission. Until the new online submission system IRBManager is implemented, studies are submitted to the IRB for review via email (irb-brooklyn@liu.edu or irb-post@liu.edu).

The submission should include the following. "*" Denotes required documents.

- *IRB application
- *CITI certificates for all study personnel listed on the application
- Consent/Assent forms
- Recruitment materials (e.g., flyers, advertisements, scripts, etc.)
- Data collection instruments (e.g., surveys, interview questions, secondary data sheets, etc.)
- Grant application if federally funded

IRB REVIEW PROCESS

Once submitted, the IRB Administrator will review submission for completeness (e.g., consent forms, questionnaires, recruitment materials, data collection instruments) and appropriate review type (exempt, expedited, full board). Expedited studies are sent to an available IRB member; when possible protocols are sent to the member whose expertise most closely matches the research topic. Exempt studies are reviewed by the IRB Administrator. Full board studies undergo a pre-review process allowing for revision prior to review at a convened board meeting. Notifications of approval or revisions will be communicated by e-mail.

AFTER IRB APPROVAL

Once approval has been granted by the IRB, the following require future submissions to the IRB:

- Continuation: Federal regulations require full board studies be reviewed no less than once per year.
- Amendments: Any modifications to the planned research must be reviewed and approved prior to implementation as they may affect the treatment of human subjects.
- Reportable Events: Events may include adverse events/reaction from subjects, subject complaints, protocol deviations, and incidences of non-compliance.
- Study Completions/Closeouts: A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary.

NONCOMPLIANCE WITH IRB POLICIES, PROCEDURES, OR DECISIONS

THE IRB CANNOT RETROSPECTIVELY APPROVE RESEARCH. DO NOT BEGIN RESEARCH WITHOUT IRB APPROVAL

Human subjects research that deviates from the policies, procedures, stipulations, or decisions of the IRB is subject to further inquiry by the IRB. Initially, the IRB may send the investigator(s) in question a notice requesting the suspension of all research activities while the issue of non-compliance is reviewed, consistent with Federal Mandate 45 CRF Part 46.113. This initial notice will also include a statement detailing the rationale for the IRB's action. Finally, IRB will investigate allegations of non-compliance.