



To: LTU Faculty and Staff

From: Maria Vaz, Provost

Subject: Research Support Services Committee, Institutional Review Board, and Policy on Research with Human Participants

Date: January 22, 2008

I am excited to announce a recent development in support of faculty research and scholarship: the establishment of the LTU Institutional Review Board (IRB).

As faculty and students begin to engage in scholarship that involves human participants, it is extremely important that we place the protection of individuals participating in research activities as one of our most important priorities at Lawrence Tech. The Research Support Services Committee (RSSC)¹ has responded to this need by establishing the LTU Institutional Review Board. LTU's IRB has been established in response to Federal requirements specified by the Department of Health and Human Services.

Chaired by Mark Brucki, Director of Technology Partnerships, and comprised of an interdisciplinary team of faculty and staff, the IRB is responsible for the regulation and monitoring of all University research on or involving human participants, including research development, testing and evaluation. Although there is a broad range of research activity with human participants that do not require review by the IRB (see below), the IRB must ensure that all federal and state regulatory requirements are met by the University.

The RSSC will present a "*Learn All About It*" luncheon on January 22 to inform the campus community about the IRB and the policy on research with human participants. In the mean time, I would like to bring to your attention the requirements of all faculty, staff, or students who wish to use human participants in their research at LTU. These regulations follow the standards set out in the Department of Health and Human Services' Code of Federal Regulations, 45 CFR 46².

- (1) All student and faculty projects that satisfy the criteria for research³ with human participants⁴ must be reviewed by LTU's IRB. This includes senior/honor's projects, master's theses or doctoral dissertations. IRB review requires completion of an easy to follow IRB application.
- (2) Several classroom projects and course laboratory sections may not be subject to IRB regulations, and therefore do not require IRB review⁵. In the case where a project is not subject for review, the instructor/faculty member is responsible to uphold all applicable ethical standards and guidelines in course-related research activities when it comes to the treatment of human participants. It is the responsibility of the supervising instructor/faculty member to determine whether projects are subject to review. It is always best to err on the safe side and seek

consultation from the IRB committee if a question arises regarding human participants, research and classroom activities. If you are not clear on whether your project is considered research with human participants contact IRB@ltu.edu for clarification.

- (3) Any research projects with human participants from which findings will be published or otherwise disseminated must have the approval of the IRB before submission for publication.
- (4) Potential participants need to be given sufficient information that is accurate and balanced in order to make an informed decision about their participation in a research study.
- (5) LTU's IRB requires completion of an online training course in the Protection of Human Participants for all faculty, staff, or students who request IRB approval for the research with human participants. This training and certification of its completion can be obtained through an IRB-approved on-line tutorial, found at:
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

In closing, please note that the IRB submission processes will be made available at the “*Learn All About It*” luncheon January 22, 2008. These forms and procedures will also be made available on the Provost's office website, http://www.ltu.edu/provosts_office/applied_support.asp.

Please direct any questions regarding IRB approval to Mark Brucki (mbrucki@ltu.edu), Matthew Cole (mcole@ltu.edu), or Steve Howell (howell@ltu.edu).

¹ The RSSC is co-chaired by Rob Fletcher, Associate Professor of Mechanical Engineering and Director, Alternative Energy Program, and Steve Howell, Interim Associate Provost and Interim Dean of Graduate Programs. RSSC committee members represent each of our four colleges, in addition to business services and university advancement. The purpose of the RSSC is to support Lawrence Tech faculty engaged in all types of scholarship, from basic and applied research, to research in the scholarship of teaching and learning, and creative and artistic work.

² <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

³ *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

⁴ *Human participant* means a living individual about whom an investigator conducting research (whether faculty, staff or student) obtains data through intervention or interaction with the individual, or through identifiable private information.

⁵ The following are not considered research with human participants and do not require IRB review:

- Data collected for internal departmental, school, or other LTU administrative purposes (e.g. teaching evaluations, course evaluations, quality assurance).
- Reviews and searches of existing literature and research involving a living individual, such as a biography, that is not generalizable beyond that individual.
- Public archival data (e.g. data from public libraries, newspapers) so long as the analysis of the data will not make the data individually identifiable.
- Class projects or term papers if all of the following are true:
 - a. The project is limited to surveys/questionnaires/interviews/observations of public behavior directly related to topics being studied in an official college course so long as the assessment tools

contain no sensitive personal questions or other personal information that could stigmatize an individual (e.g., questions about criminal activity, medical history, drug use, sexual behavior).

b. No identifying information is recorded to link a person with the data such that it could reasonably harm the individual's reputation, employability, financial standing, or place them at risk for criminal or civil liability.

c. The participants in the project are not from a vulnerable or special population (e.g., pregnant women, prisoners, children or adolescents under the age of 18, cognitively impaired individuals).

d. The collected data does not leave the classroom setting, or if the project involves collecting data on an organization, agency or company, the data are shared only with that entity.

e. No LTU employee or student is receiving financial compensation for collecting, organizing, analyzing, or reporting the data.

• Pilot projects/preliminary activities performed to determine if a study is feasible so long as vulnerable populations, methods with more than minimal risk, or sensitive personal questions will not be used.