FREQUENTLY ASKED QUESTIONS REGARDING HUMAN SUBJECT RESEARCH AT LOUISIANA TECH UNIVERSITY

(Last update January 18, 2022)

All proposed research involving human Subjects at Louisiana Tech University or performed by Louisiana Tech students, faculty and staff or using Tech facilities must be submitted for approval to the Human Use Committee which functions as Louisiana Tech's Institutional Review Board (IRB) Approval must occur BEFORE data is collected. Without prior IRB approval, investigators may not involve human participants in any research activity, including the recruitment of subjects. Informed consent is required for all research unless a specific waiver is obtained from the Human Subjects (IRB) Committee. The University does not accept the use of data obtained without IRB approval to satisfy dissertation, thesis or faculty research requirements, or the use of records, personnel or facilities of the university for unapproved research.
(http://www.latech.edu/tech/administration/policies-and-procedures/7108.html displays the university's policy)

The following are responses to frequently asked questions that you may find useful concerning Human Subjects research at Louisiana Tech University.

What is a human subject?
***"Human subject** means a living individual about whom an investigator (whether professional or student)conducting research: (i) obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information of biospecimens; or (ii)Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."* §_.102(e)(1)
*"**Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information."* §_.102(e)(5).

***"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 that has been provided for specific purposes by an individual and that can reasonably expect will not be made public (e.g., a medical record.".* § .102(e)(4)

Human Subjects Research is any research that involves human beings. More inclusive than just research where humans are directly employed as participants, Human Subjects Research also includes research using private information not specifically collected for research such as student records or medical records, or bodily materials (blood, hair etc., even if not collected by the researcher), and research using humans to test devices, as well as research involving the manipulation of individual's environments. Therefore, whether research involves people or files, blood or human products, tests or records of individuals, the research needs to be reviewed by the Human Subjects Committee IRB. Some research such as simple observation of public behavior where there is no expectation of privacy is exempt from regulation, but such exemption must be determined by the IRB, so submission is still required.

What does Louisiana Tech and the IRB and OHRP regulations consider research?
"Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purposes of this part, the following activities are deemed not to be research:
(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions." §___.102(l)

Basically, if you are gathering data on, produced by or about individuals and plan to disseminate it to others through activities such as publication or presentation you are performing research that needs IRB approval. Under this definition a classroom test or in-class educational activity solely for educational purposes is not research. Anything that you may plan to publish is research. Institutional reports may or may not be research depending on what sort of dissemination is involved. When in doubt, the wise thing is to submit your research protocol or to contact the Office of Research (Mrs. Barbara Talbot ext. 5075 < btalbot@latech.edu>) or the IRB for guidance.

Why must researchers submit their research for review?
"Protections for human subjects of research are required under Department of Health and Human Services (HHS) regulations at **45 CFR 46.** Subpart A of the HHS regulations constitutes the **Federal Policy (Common Rule) for the Protection of Human Subjects**, which has been adopted by an additional 16 Executive Branch Departments and Agencies." (**http://www.hhs.gov/ohrp/**)

Following these OHRP Federal guidelines provides important protection for the people who serve as participants in research, insures the research performed at or by Louisiana Tech is ethical and provides adequate protection for participants. Continuation of some university funding, particularly all Federal funding, is contingent on conscientious observation of the regulations. Most research granting agencies require IRB approval.

Health and Human Service regulations require that the IRB review the actual application or proposal for HHS support. The IRB's review should ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

Who is responsible for submitting the proposal?
Only faculty members are responsible both for submission and to ensure that appropriate guidelines are followed. The PI is required to immediately report any "adverse events" they may have affected the participants in the ongoing study. A student may deliver the proposal along with the note of approval from the faculty. Any changes required by the Human Use Committee also needs faculty approval before submission. While some schools charge for IRB review of some proposals, review is free at Louisiana Tech.

Can research start once IRB documents are submitted?
No. Research cannot begin until the Human Use committee examines and approves the study's description and documents related to the study. Examples of such documents include: informed consent forms, surveys, questionnaires or other study instruments, materials and advertisements used for recruiting subjects, and any related grant materials. A request for continued approval must be filed annually for continued approval of ongoing research.

Is it necessary to define acronyms or abbreviations?

Yes, all acronyms and abbreviations must be defined.

What is the Institutional Review Board (IRB) or Human Use Committee?
Office of Human Research Protections, a division of U.S. Department of Health and Human Services requires that educational institutions have a committee to review research involving human subjects. The Human Use Committee serves as Tech's IRB under the Office of Research and Partnerships and Executive Associate Vice President, Sumeet Dua. Representatives from every college and members from the community are appointed by President Guice and serve on Tech's Human Use Committee.

Is Tech's IRB the only approval I need?
Prior to submitting your proposal other approvals may be required (see form attached). The Office of University Research can offer guidance. The researcher should also take care to be cognizant of and observe other relevant regulations such as HIPPA (medical privacy) and FERPA (student privacy). Louisiana Tech researchers are required to have a form signed by their unit head indicating that the administrator is aware of the study (see Department Head Approval Form in the Human Use Approval Packet provided in section "D" of this link http://research.latech.edu/about/compliance_review_boards/human_use_committee. This is only an indication of awareness and not an approval.

Where may I find the guidelines to do research in medical facilities?
The DHH IRB Guidelines may be accessed at: http://dev2.dhh.state.la.us/OMF/research/IRBDOC.pdf

What if I collect some data in the course of instruction or other activity and later wish to publish or disseminate it? What if I change something in a previously approved study?
The PI is responsible for submitting a proposal to the IRB prior to attempting publication or dissemination. Approval will depend on the nature of the data how it was obtained, the reasonable expectations of privacy of those involved. It is always better to seek approval prior to the collection of data if there is any chance of publication. If a previously approved study is to be changed the IRB must be notified and the change must be approved prior to implementation. If it is clear the researcher is trying to circumvent the process approval may be denied in either case.

If my research is performed at another institution such as a school or hospital can I get that institution's IRB approval and forward that to Tech or use Tech's approval there?
Each institution is responsible to the Federal government through an Assurance signed by that institution. You must get the approval of both institutions' IRBs. There is usually some variation between IRBs. An IRB policy may be stricter than the regulations but not more lenient.

What is expedited review?
If the research involves only "minimal risk" the researcher may apply for expedited review. If the review is expedited the approval may occur prior to a meeting. For some proposals a meeting is necessary and expedited reviews can result in approval, requests for revisions or information or a referral to the full IRB. The expedited reviewer alone cannot disapprove a study, but refers it to the larger IRB. Expedited review does not eliminate the need for informed consent or other protections. Some proposals are required by regulation (e.g. children, protected groups, etc.) to receive a committee review, others are referred by the expeditor. The criteria is the same only the number of reviewers is changed. Expedited review occurs when IRB reviewer or reviewers examine the proposal in place of the full committee. Expedited review "may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects, their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented." (More information can be found at

http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm). The speed of expedited reviews depends on the complexity of the study and whether the research conforms to the guidelines or requiresrevision. It is recommended that studies be submitted a month in advance to allow for revision if necessary.

What is the IRBs authority? If I disagree with the IRB's decision can I appeal it to a universityofficial?
According to Federal guidelines, the IRB can monitor and approve research to determine if it follows University policies concerning Human Subjects and OHRP guidelines. It may approve or disapprove research, require changes in research protocols as a condition of continuation, impose restrictions, monitor research, require progress reports, or terminate/suspend a study. The guidelines prohibit university administrators, and faculty from reversing IRB decisions involving disapproval, suspending orstopping a research study. However, a researcher may offer further explanations or defense of proceduresto the IRB.

How do I submit a study?
Effective January 18, 2022, forms should be routed to the Office of Associate Vice President for Research and Partnerships (16th Floor Wyly Tower, Rm 1642) to expedite approval. The Committee encourages submission at least two weeks before the research begins and annually hereafter. Contact Arlene Hill at (318) 257-2838 toanswer any questions you may have regarding the review process. Forms are available from the Office ofSponsored Projects, or on line at **http://research.latech.edu/about/research_compliance/human_use_committee**

What if investigators from an organization outside of Louisiana Tech University wish to participatein La Tech-sponsored/La Tech University IRB – approved research:
Instructions for the approval of non-La Tech employees to participate in this type of project are specified by OHRP at: http://www.hhs.gov/ohrp/policy/guidancealternativetofwa.html. In essence these instructions direct the investigator/institution to enter into an "Individual Investigator Agreement". Pleasesee: http://www.hhs.gov/ohrp/policy/unaflsup.rtf.

Who can answer further questions regarding research with human subjects at Louisiana TechUniversity.
Human Use Committee Chair: Dr. Walter Buboltz, Psychology and Behavioral Sciences,
E-mail: buboltz@latech.edu) Phone: (318) 257-4039
Executive Administrative Assistant – Arlene Hill (ahill@latech.edu), Phone: (318) 257-2838

Where can I find more information?
The main source of information on Human Subjects Regulation is available from Office of HumanResearch Protections, <**http://www.hhs.gov/ohrp/**>

Online training is available at:
<**http://ohrp-ed.od.nih.gov/CBTs/Assurance/default.asp**> and
<**http://www.hrsa.gov/humansubjects**>

What if my study involves subjects who reside in a separate facility or are employed byanother organization?
The Louisiana Tech investigators who are conducting the study must present the study protocol(using approved Louisiana Tech forms and procedures) to the external organization. Written

documentation from the chief administrator (or designee) is required indicating that the facility IRB for that organization has approved the study and that the Louisiana Tech investigators may complete the study with the subjects at the facility.

Please see the sample letter attached below for organizations who will allow Louisiana Tech University investigators to conduct studies involving human subjects within their facility.

On Organization Letter Head (e.g. Ruston Residential Therapy Center)

Date

Dear Dr. Investigator (insert name of the faculty member who is responsible for the study),

The “Institutional Review Board”(insert name of the committee with relevant responsibility) of the “Ruston Residential Therapy Center” has reviewed the study entitled "Survey of People" (insert full title of the study) submitted by Dr. Smith and Dr. Jones (insert names of all investigators) of Louisiana Tech University. We are aware that the study will utilize the following instruments (insert bulleted list of the survey or other instruments used to gather data):

- Alpha Survey
- Beta Questionnaire
- Gamma Instrument

Responses from 100 People at our Facility will be collected by Dr. Smith and two graduate students (insert full names) during the period 1/1/14 to 5/1/14 (insert projected start and end dates for the data collection). HHS Guidelines for confidentiality, de-identification, and security of data will be followed as indicated by the Office of Human Research Protections. On DATE (insert date when the facility IRB or chief administrator approved the study), the Facility IRB approved the study as presented (minutes attached).

Signed,

Facility IRB Chair of Chief Administrator