GUIDELINES FOR HUMAN SUBJECTS RESEARCH

AND

CONDUCT OF THE INSTITUTIONAL REVIEW BOARD

LOUISIANA TECH UNIVERSITY

Revised January 8, 2019

PREFACE

Louisiana Tech is strongly committed to ethical research and to following Federal regulations. The university does not accept the use of human research subjects data obtained without Institutional Review Board (IRB) approval. This includes research to satisfy dissertation, thesis or faculty research requirements, or the use of records, personnel or facilities of the university. Continuation of some university funding, particularly all Federal funding (research, scholarships etc.), is contingent on conscientious observation of the regulations. The Federal government and Louisiana Tech regard the regulations as a floor not a ceiling in the conscientious protection of subjects. The following site may be referenced for the university's general policy: https://www.latech.edu/about/administration/policies/p-7108/.

Faculty and student researchers are required to submit documentation of continuing education in the protection of human research subjects. Documentation must be submitted with all IRB human research proposals. This demonstration of continuing education is a part of Louisiana Tech's commitment to ethical research.

This handbook assists researchers at Louisiana Tech in understanding and complying with federal and university policies which protect human subjects.

In conclusion, all proposed research involving human subjects at Louisiana Tech University or performed by Louisiana students, faculty and staff or using Tech facilities must be submitted for approval to the Human Use Committee (HUC) which functions as Louisiana Tech's IRB for Human Subjects. Approval must occur before data is collected or subjects are recruited. Whether research involves people, files, blood or human products, tests or records of individuals, the research needs to be reviewed. Informed consent is required for all human subjects' research unless a specific waiver is obtained. Some research such as simple observation of public behavior is exempt, but such exemption must be determined by the IRB, so submission is still required.

Thank you for helping Louisiana Tech continue to fulfill its' research mission and maintain its commitment to ethical research and human subject protection.

Researchers with specific questions may contact:

Barbara Talbot
btalbot@latech.edu
(318) 257-5075

Richard Kordal, Co-Chair
rkordal@latech.edu
(318) 257-2484

Davy Norris, CI&R
dnorris@latech.edu
(318) 257-3798

Gary Stokley, Co-Chair
garystokley@gmail.com
(318) 278-3124

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1.0 Introduction

The primary goal of the Institutional Review Board (IRB) is to ensure the safety and welfare of human subjects in research and scholarly projects.

The IRB (also called the Human Use Committee) is responsible for ensuring compliance with the exacting federal requirements that govern ALL research with human subjects (whether funded externally, or not), unless they meet specific criteria for exemption.

It is the IRB's goal to assist faculty to conduct safe, successful studies with human subjects, by helping researchers meet the criteria for IRB approval. The IRB also seeks to limit liability for Tech as a by-product of protecting subjects.

All research projects involving human subjects or samples or data/records obtained from living subjects must be submitted to the IRB Office in University Research for review or exemption (with a copy of the grant proposal if external funding is sought), using standard forms and guidelines. These are available on request and are posted on Louisiana Tech's University Research web site. In no event may a project with human subjects begin data collection before written exemption, or written IRB approval is received. To assist researchers in determining whether their activities require IRB review the university has developed a checklist.

Non-exempt projects must be reviewed and approved at a convened meeting of the IRB, except for certain minimal risk projects that qualify for an expedited review performed by one or more IRB members which may occasionally be in conjunction with IRB designated external expert's advice.

Major alterations of existing protocols previously approved at full IRB review also require full review.

Except for projects that have undergone expedited review, all other projects must be re-reviewed by the IRB no more than 365 days after approval even if the start date of the research is postponed. The IRB office will issue requests for a progress report in advance of the review date; continued approval will be contingent on an adequate response.

All substantive inquiries for the IRB should be directed to either Gary Stokley, Co-Chair (garystokley@gmail.com) or Dr. Richard Kordal, Co-Chair (rkordal@latech.edu). Inquiries regarding access to forms, IRB meeting dates, and access to training should be addressed to Barbara Talbot (btalbot@latech.edu) in Sponsored Projects.

1.1 Statement of Principles

The principles upon which the Federal OHRP and University regulations governing human research are founded are embodied in the Belmont Report (http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/). Louisiana Tech regards these principles as the foundation for its program to protect the welfare of human subjects in research. The Louisiana Tech University Human Use Committee strives toward the highest protection of human research participants and to cultivate

through education an atmosphere of such protection throughout the entire University research community. We will continue to promote the highest ethical standards for the conduct of human subjects' research, and we will make ongoing efforts to identify and implement best practices for those efforts. The IRB/HUC endeavors to be a cohesive team to provide effective and efficient service to the University research community, and to do so in a supportive and pleasant environment.

1.2 Purpose of IRB

The primary purpose of the IRB is to protect the interests of human research subjects at Louisiana Tech or participating in Louisiana Tech researchers' projects. This includes ensuring that physical, psychological and social risks to participants are minimized, and when risks are present, risks are justified by the importance of the research and subjects are adequately informed of risks and consent without coercion.

Secondarily, through the approval process, the IRB seeks to protect both the university and the investigator(s) from possible adverse consequences of research with human subjects. The IRB and Sponsored Projects serve as a resource of information to assist researchers in engaging in ethical human subjects' research that conforms to Federal regulations and University policies.

The IRB seeks to assist the investigator to design or modify his/her research and projects so that they are in compliance with federal and university requirements, so that they can be approved and conducted.

1.3 Scope

All systematically planned research/projects using living humans as subjects, or samples or data/records obtained from living subjects, directly or indirectly, with or without their consent, must be approved in advance by the Louisiana Tech Human Use Committee. University regulations require that projects be submitted to determine if projects meet the criteria for exemption from IRB oversight and are formally exempted. Tech projects include projects in which Tech personnel and students participate, whether conducted on campus or elsewhere, and projects that use Tech funds or facilities even if not conducted by Tech personnel. Review and approval by another IRB does not negate the requirement for review and approval by the Tech IRB (if another IRB shares jurisdiction over a project, the Tech IRB requires a copy of that IRB's determination).

The Tech IRB reviews all non-exempt projects that use human subjects as objects of discovery, and does not limit its activities to the narrow definition of research used by DHHS in 45 CFR 46.

Authority

The Department of Health and Human Services (DHHS) regulations that define the authority of the IRB are found in 45 Code of Federal Regulations 46. Additional requirements are imposed by the Food and Drug Administration when Investigational New Drugs and Medical Devices are used in research. In addition, Tech has filed an

Assurance with DHHS describing the standards and procedures to which the University will adhere in overseeing research with human subjects. It is intended that the policies and procedures in this Guide be consistent with the referenced documents.

Scientific Practice

Research using human subjects should utilize best scientific practice to be considered ethical. The scientific practice of proposed human subjects' research will be evaluated as follows:

1. Studies for which the principal investigator is a student – the faculty advisor will evaluate the scientific practice of the study, and will indicate approval via signature on the Investigator's Assurance document.

2. Studies for which the principal investigator is faculty or staff - the department or unit head of the principal investigator (or the department or unit head's designee) is responsible for evaluating whether the scientific approach conforms to accepted practices for scientific investigation. If the department head wishes to allow someone other than him/herself to conduct the review, a written statement from the department/unit head must be on file in the HUC office indicating such and identifying the individual(s).

3. Studies for which the principal investigator is in an administrative position – the supervising administrator is responsible for evaluating whether the scientific approach conforms to accepted practices for scientific investigation. The results of the review will be communicated to the IRB on the Scientific or Scholarly Review Form.

4. In the event that the faculty advisor, department or unit head (or designee), or supervising administrator or the college research director declines to evaluate the research for accepted scientific practice in the area then the HUC will locate an expert in the proposed area to conduct the review.

2.0 Definitions of Research and Human Subjects

Definitions

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 the purposes of this policy, whether or not they are conducted or supported under a program which 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 (§46.102(l)):

(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.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research (§46.102(e)(1):

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

> * Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. † Interaction includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

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.

In order for obtaining private information to constitute human subjects research, it must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

All activities that meet the federal definition of research and involve "human subjects" must receive HUC/IRB review and approval prior to initiation of the research. Investigators seeking guidance on the question of whether their research project meets the requirement for being exempt from review may contact the Chair of the IRB or the Chief Research and Innovation Officer.

To distinguish research from non-research activities, the following criteria will be applied to the purpose/aim of the project, which must be clearly stated. If any of the following criteria are met, the project will undergo further IRB review:

1) The design of the project involves randomization (i.e., randomly assigning subjects to different treatment groups).

2) The intent of the project is to draw general conclusions that can be applied beyond a particular program or population.

3) The project will impose risks or burdens beyond the standard of practice to make the results generalizable.

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. If you change or modify a practice for the purpose of making generalizable conclusions, it is research. Anything that you may potentially plan to publish is likely research. It would be wise to seek guidance from the IRB/HUC or request exemption. Institutional reports may or may not be research depending on what sort of dissemination is involved.

See OHRP Decision Chart #1: Is an Activity Research Involving Human Subjects Covered by 45 CFR Part 46? (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1).

Dissemination of Results

Publication of results does not absolutely define an activity as research. Publication or presentation of results is clearly the goal of all research activity, but there are some situations in which academic forums are used to share the results of a non-research activity with interested colleagues in the hope that they will benefit from this information. Education, not research, is the most accurate term for these kinds of activities. Some demonstration and service programs may include research activities (45 CFR 46). It is important to remember that submitting a project for exemption by the IRB is a researcher's safest course when there is any doubt of whether a project is research.

To classify projects accurately as either research or non-research, one critical factor is the extent to which the project is being conducted to benefit people other than those who will participate directly in the activity.

The following question will be used as needed to further clarify whether a project is likely to generate generalizable knowledge and be classified as research:

> Would this project be conducted as proposed if the principal investigator knew that he or she would never receive any form of academic recognition for the project, including publication of results in a journal or presentation of the project at an academic meeting?

In other words, is academic recognition a motive for the conduct of this project. If yes, then the project is most likely research.

Quality Improvement

An activity that is initiated with a goal of improving the performance of an institutional practice in relationship to an established practice is called Quality Improvement (QI). In general, QI projects are aimed at improving local systems of care and are non-generalizable. A project is originally initiated as a local QI project but the findings are of interest to a large population and the principal investigator chooses to expand the findings into a research study, IRB review is required at that time. The principal investigator should clearly indicate to the IRB that the data were originally collected as part of a QI project. Often investigators find that proactively submitting QI projects which have potential for generalizable results is the preferable course of action. See http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html for further clarification. There OHRP cautions "Outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research"

Any dissemination activity describing a project as "research" must have received prior IRB review and approval. Therefore, projects determined to be QI initiatives should not be published as "research." Projects considered QI must also maintain the highest integrity and confidentiality possible. Characterizing a project as QI does not necessarily negate the need for informed consent or other protection of participants. Note: Other Louisiana Tech policies and Federal regulations beyond those pertaining to research may also apply (HIPPA, FDA, ADA, FERPA etc.).

Case Report

The first step to determine if a case report meets the definition of research is to determine whether the project contains both of the elements from the regulatory definition of research. It is typically reasonable to assume that the organization of information for a case report does not constitute a systematic investigation to the extent that would be expected of a research project.

Care should be taken, however, to distinguish a case report from an "N-of-1" research study in which there is a systematic manipulation of an intervention to produce generalizable results.

Oral History

Most oral history interviewing projects do not meet federal regulatory definitions of research primarily on the grounds that oral history interviews, in general, are not designed to contribute to "generalizable knowledge" and therefore can be excluded from IRB oversight. While historians do reach for meaning that goes beyond the specific

subject of their inquiry, unlike researchers in the biomedical and behavioral sciences, they do not seek to create models that predict and explain specific outcomes in all situations, nor do they seek to identify underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians' principal methodological aim is to explain a particular past, rather than to predict the future.

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the manner in which an individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of interviews offer up not similar "generalizable" information but a variety of particular perspectives on the topic.

To make distinctions between what does and what does not conform to the federal regulatory definition of research with regards to oral historical research, the following guidelines will be applied. If ALL of the following criteria are met, the project will not be required to undergo IRB/HUC review:

1) Those interviewed are not anonymous individuals selected as part of a random sample for the purposes of a survey;
2) Those interviewed are not asked to respond to a standard questionnaire administered to a broad swath of the population;
3) The interviews focus primarily on past events;
4) The interviews are conducted to understand or explain a particular past or unique event in history; and
5) The historian may make informed speculation about the future but does not try to predict it.

Those oral history projects that DO NOT meet <u>all</u> of these criteria would need to undergo IRB review. While not subject to IRB review the interviewer or collector of oral history should take care in following the ethical standards of their profession.

Student Projects / Classroom Activities

Louisiana Tech's HUC/IRB requires that all student research activities are supervised by a faculty member; however, some types of student research activities may not require IRB review. Louisiana Tech supports a wide range of both undergraduate and graduate student research projects using human subjects – from course-related research exercises to dissertation studies.

The transferring of information from one group of people to another is a common activity in all aspects of society. It is important to recognize that the goal of most educational activities is to spread or generalize knowledge. The fact that an activity is undertaken for the specific purpose of teaching somebody something does not mean that the activity involves research.

Student projects designed for the purpose of teaching research techniques that do not extend beyond the classroom typically do not require IRB approval. In general, student projects involving the interview or survey of other classmates, have minimal or no risk, are not considered a contribution to general knowledge and the results of the activity are not reported beyond the classroom. However, if there is a possibility that if results of the activity are impressive or generalizable, the professor or the students will want to publish or present the findings as research, it would be wise to seek approval before collecting data.

The following policy and procedures relate to student and classroom research projects.

A. Independent Research Projects

Independent research projects are those that employ systematic data collection with the intent of contributing to generalizable knowledge. Theses, dissertations, and honors research projects involving human subjects are considered research as defined by 45 CFR and will always require review by the IRB. Investigations designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

While such research is often disseminated through scholarly publication or presentation of the data, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to “generalizable (scholarly) knowledge” makes an experiment or data collection research, regardless of publication.

B. Research Methods Training / Curriculum

Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research do not meet the federal definition of research and are therefore not generally subject to IRB review/approval.

To distinguish research from educational activities in the classroom, the following criteria will be applied to the purpose/aim of the project, which must be clearly stated. If ALL of the following criteria are met, the project will not be required to undergo HUC/IRB review:

1) The project involves no more than minimal risk (i.e. “the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during a routine physical or psychological examination or test”). Examples of student research projects that fit the categories below are generally considered minimal risk.
    a. Research conducted in an educational setting involving normal education practices, such as research that examines or compares regular and special education curriculum including but not limited to instructional strategies/techniques, curricula, or classroom management methods.
    b. Research involving the use of educational tests, survey procedures, and interview procedures.

c. Observation of public behavior, without intervention, if confidentiality or anonymity is maintained.
d. Research with subjects who are elected or appointed public officials or candidates for public office, regardless of whether the subjects may be identified or the information is sensitive.
e. Research on individual/group characteristics or behavior in such areas as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior, etc. provided that confidentiality or anonymity is maintained.
f. Research employing focus group or human factors methodologies.
g. Collection of data from voice, video, digital, or image recordings for research purposes.
h. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if one of the following is true: the sources are publicly available or the information is recorded by the investigator in a way that subjects cannot be directly or indirectly identified.

2) The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed. Any interview, survey or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but limited to, any of the following sensitive topics requires IRB approval:
   a. Sexual orientation, incest, rape, sexual molestation, deviant sexual behavior or attitudes regarding sexual conduct (pedophilia, bestiality, etc.) practices of contraception, abortion and / or pregnancy
   b. Substance use and / or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained
   c. Questions regarding mental health (e.g., suicide, depression, obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.)
   d. Traumatic experiences of an individual, including war or combat experiences of veterans.

3) The project does <u>not</u> involve persons from vulnerable populations (for the purposes of classroom research). Vulnerable populations may include pregnant women, fetuses, children (with the exception of observational studies), prisoners, persons at high risk of incarceration or deportation, or who are cognitively impaired. Projects involving such subjects require IRB review prior to beginning the research. Projects must comply with the regulations set forth in the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupils Rights Amendment (PPRA).

4) The project must involve the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher. (This would include for example: participation as a research subject being required for a

grade or research participation required for athletic team membership or playing time)

5) The results of student projects can never be distributed outside the classroom and/or institutional setting or used for publication, although the results may be presented to instructors or peers in the class for educational purposes or as part of a class assignment.

Note: If a project is originally initiated as a class assignment but the findings are of interest and the faculty member or the student changes their intention for the use of the data for research purposes, IRB review is required (e.g., prior to the submission of a journal or conference paper or presentation). The principal investigator should clearly indicate to the IRB in their application that the data were originally collected as part of an educational activity by providing the course name and a copy of the syllabus. If there is any likelihood of use of class assignment data for research purposes submission prior to collection is strongly recommended.

Principal investigators must be aware that when disseminating educational results (typically within the classroom but not always), the word research cannot be contained within the publication or used in the presentation as this type project does not meet the systematic investigation criteria in the federal definition of research. However, if after receiving approval for existing data as described above in the note, research can be used in any dissemination efforts.

Professors desiring IRB/HUC approval for research in a classroom are cautioned to submit proposals as soon as possible preferably the quarter before. These proposals are required to be as specific as other IRB proposals (e.g. should include actual questionnaires or descriptions of specific procedures)

Responsibility for Oversight of Student Projects / Classroom Activities
Each faculty and department has the responsibility for: (1) assessing whether student projects / classroom activities involving human participants meet eligibility for review or exclusion from IRB/HUC review; (2) overseeing these activities; and (3) assuring that ethical principles are adhered to in the conduct of those activities. If there is doubt, the IRB/HUC chair may be consulted for advice.

With regard to classroom projects, faculty instructors are to be fully familiar with each student's project(s) and attests to this when signing the assurance portion of the application. It is also important that faculty who teach research methods courses educate students regarding the relevant ethical issues surrounding the use of human subjects in research including best practices such as informed consent.

Any uncertainties pertaining to educational research activities should be verified with the HUC/IRB office. The HUC/IRB reserves the right to review educational research activities that involve research with human subjects.

3.0 Responsibilities

3.1 University/Institutional Official

The Institutional Official (IO) is the University point of contact with DHHS' Office for Human Research Protections (OHRP), and he bears ultimate responsibility for ensuring University compliance with the federal requirements. At Tech, the Institutional Official is the President (Dr. Leslie K. Guice). The Institutional Official appoints the IRB members.

The Chief Research and Innovation Officer is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members and to recommend candidates to the President for appointment.

The institution attributes to the IRB those powers required by 45 CFR 46, and may not overrule disapprovals of projects or conditions of approval set by the IRB. However, the institution may disapprove studies which had been approved by the IRB.

The IRB may disapprove, discontinue, suspend or limit approved activities at any time it is deemed in the interest of protecting the rights and welfare of human subjects. Funds for studies may be withheld at the discretion of the University administration.

The Institution will notify OHRP of serious or continuing non-compliance with the terms of its Assurance or 45 CFR 46.

3.2 Chair, IRB

The daily responsibility for the management and operation of the Board and the IRB is vested in the Chair. The Chair is selected and appointed by the President of Louisiana Tech University. This selection is based upon the knowledge of the individual concerning human subjects protections and policies, regulations and processes related to the IRB. The President retains the sole authority to remove the Chair. The Director of the Office of Sponsored Projects is responsible for examining all grant applications to determine if necessary IRB review has been instituted. Staffing and support for the IRB is maintained in the Office of Sponsored Projects. The Chair may appoint a co-chair or a member to act in his/her absence.

Excerpt from OHRP IRB Guidebook 1-4 through 1-5, “One of the most important actions to be taken in establishing an IRB is selecting the individual who will function as Chair. The IRB Chair should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of this individual. The IRB must be, and must be perceived to be, fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.”

The IRB Chair shall be appointed for a three-year term. A Chair may be reappointed for additional three-year terms. The IRB Chair shall be evaluated on an annual basis by the Institutional Official. The Institutional Official will seek input from IRB members and members of the Human Research Protection Program in a formal manner. Evaluation will include consideration of effort, quality of work, and reappointment as appropriate.

If the IRB Chair must be absent, or must recuse him/herself from review of a research study, or for any reason is unable to fulfill the duties of the Chair, the Vice-Chair or an experienced IRB member may fulfill the Chair's duties.

The Chair shall receive a stipend of $2,000 annually that may be spent on any item or service that contributes to the Chair's professional development.

Responsibilities

The IRB Chair has primary responsibility for the following:

1. Providing leadership to the IRB to help ensure the rights and welfare of human subjects participating in research reviewed by the IRB
2. Conducting convened meetings, and reviewing and approving the minutes documenting IRB discussions and findings
3. Leading discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct. At the chairs invitation the Chief Research and Innovation Officer may be asked to be involved in helping with these discussions.
4. Managing conflicts of interest by ensuring that IRB members with conflicts are not present for review of research for which a conflict may exist
5. Maintaining confidentiality of IRB-related information
6. Participating in the development of meeting agendas, policies, procedures, and educational efforts to support the human research protection program
7. Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects
8. Assisting with investigations and review of alleged noncompliance with human subjects protections requirements.
9. Informing the Chief Research and Innovation Officer of serious and/or continuing non-compliance problems
10. Participating in the development of policies, procedures, and institutional efforts to promote a culture of shared responsibility for the safety and welfare of research participants.
11. Voting as a member of the IRB
12. Approving minor modifications to ongoing protocols with possible agreement by another Board member(s), for modifications that do not significantly affect the risk to the subject
13. Conducting an expedited review procedure and exercise all of the authority of the IRB except disapproval
14. Assisting the HUC Staff in assigning reviewers for Convened IRB and Expedited reviews

The IRB Vice-Chair

In the event of absence or conflicting interest, the IRB Vice Chair will fulfill the responsibilities of the Chair. The Vice Chair is appointed by the IO. In the event both the Chair and Vice Chair are absent or have a conflict, the Chief Research and Innovation Officer may designate an Acting Chair to preside over the meeting or the relevant portion thereof.

3.3 IRB Members

Voting members are appointed by the Institutional Official (IO) and are listed in the IRB Assurance with OHRP. Named alternate members may vote if the person to whom they are an alternate is absent or cannot vote by reason of conflict of interest.

The IRB is charged with the duty of making certain that all activities involving human subjects conform to the following guidelines and policies identified in this manual. The IRB conducts a critical evaluation of the possibility of risk or harm (physical, physiological, sociological or others, including invasion of privacy) as the consequence of this activity. The rights and welfare of the subject must be adequately protected, based on the above evaluation. The activity must have sufficient scientific merit in the field of research.

The Composition of the IRB

In order to promote complete and adequate review of research and research-related activities the IRB is comprised of 12 primary, voting members with diverse backgrounds and experiences. IRB members represent a variety of professions and disciplines to assure appropriate expertise is available to evaluate applications. Ex Officio members are appointed by virtue of their administrative position of the university and include the Chief Research and Innovation Officer, the Director of Environmental Health and Safety (or designee), and the Chair of the Animal Use Committee. Ex Officio members of the IRB are voting members.

All members are appointed by the President of Louisiana Tech University. The Board is comprised of both males and females and at least one member whose primary expertise is in a non-scientific area. There is at least one member whose primary concerns are in scientific areas. At least one member is not an employee or an immediate family member of a person affiliated with the institution. Membership is reviewed at the end of each academic year, although continual monitoring of membership is conducted to maintain needed diversity. Members are apprised of the membership reviews, changes in membership of the Board, and of other issues, such as individual requests for augmented meeting attendance or other suggestions during the next convened meeting.

Qualifications

IRB Members who represent various fields of scientific research are expected to have relevant experience in research with human subjects (e.g. recent studies), to be engaged in and knowledgeable of current issues in research with human subjects, and to be conscientious and responsible.

Appointment Term

Members shall be appointed for up to a three year term. Reappointments are made by the president. There is no limit to the number of terms an individual may serve, but it is suggested that a member serve two terms and then rotate terms with other individuals. If a member wishes to continue service, a recommendation is made to the IO for reappointment. Term of appointment begins or renews on July 1.

The president may remove a member from the IRB before the end of his/her appointed term. The IRB chair in consultation with the Chief Research and Innovation Officer may submit a request for removal to the president based on the member's failure to carry out the responsibilities of an IRB member (e.g. failure to attend meetings regularly, failure to comply with regulations and policies). The president makes the final decision on removals. If removed, prompt notification will be provided to the member. IRB members may request to be removed from the IRB without providing a reason (e.g. time commitment, personal reasons) and will be removed with notification to the president.

Duties of IRB Members
IRB members shall:

1. Uphold federal, state, and local regulations, university policies and procedures, and ethical standards for the protection of human research subjects.
2. Attend and contribute to discussion at IRB meetings, and enter into a process of discovery and discussion concerning the issues inherent in each proposal.
3. Review IRB meeting materials prior to the IRB meeting.
4. Act as lead reviewer on full review studies as assigned, including:
    a. Present motions for consideration (e.g. motion to approve, modify, or disapprove a study)
    b. Review application materials based on federal regulations, state law, and university policies.
5. Provide timely written or electronic feedback on all application materials assigned. Timeliness is based upon the deadline provided as part of the particular review assignment.
6. Disclose conflict(s) of interest
7. Communicate with researchers as needed (while making it clear they do not speak for the entire IRB)
8. Participate in review, improvement, and communication of HUC policies to improve the integrity and adequacy of human protection;
9. Participate in activities to enhance development as an IRB member, such as continuing education on human research activities.
10. Inform the Chair of noncompliance problems of which they become aware.

A current roster of all IRB members shall be maintained in the Office of Sponsored Projects and be made available on the IRB's website.

IRB members who are Tech faculty shall have their IRB service recognized for purposes of reappointment and tenure. The Chief Research and Innovation Officer shall provide an annual summary of IRB activities to the direct supervisor of each IRB member.

3.4 Investigators

An investigator is any individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent, intervening or interacting with subjects, interpreting or analyzing identifiable private information or data for research purposes and communicating with the IRB. A Principal Investigator is one

who performs the same tasks as investigators but also have overall responsibilities for the study. Studies wherein students are designated as the principal investigator, the responsibilities are shared equally with the advisor.

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. Research investigators who intend to involve human research subjects and who believe their studies qualify for exemption from IRB oversight under the terms of 45 CFR 46 must apply for exemption through the procedure established by the IRB Chair. It should be noted that " even when research is exempt from regulatory requirements under the Common Rule, institutions and investigators still have a responsibility to adhere to the underlying ethical principles for research involving human subjects" (http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter/).

Along with meeting the specific requirements of a particular research study, responsibilities of the investigator include those specified in the Assurance with OHRP. Research investigators must:

1. Acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of federal regulations, University policies, and IRB procedures for human subjects research;
2. Be familiar with the Belmont Report, the Louisiana Tech GUIDELINES FOR HUMAN SUBJECTS RESEARCH AND CONDUCT OF THE INSTITUTIONAL REVIEW BOARD, and to federal Office of Human Research Policy regulations;
3. Complete required training for investigators in the Use of human Subjects;
4. Provide a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained by the investigator for at least 3 years after the end of the study;
5. Promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects;
6. Report progress of approved research to the IRB as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year;
7. Promptly report to the IRB and IRB/HUC staff any injuries or other unanticipated problems involving risks to subjects and others. While this report may be initiated verbally there should be a written follow up;
8. Assure that all named researchers in the study have been given a copy of the protocol, have acknowledged an understanding of the procedures outlined in the application, and have received training in human subjects research;
9. Assure that all experiments and procedures involving human subjects will be performed under a qualified professional listed on this protocol and that there are

adequate resources (investigator time, equipment, and space) to protect participants before the study begins;
10. Promptly provide the IRB with any information requested relative to the project; including but not limited to consent forms, and/or collected data;
11. Maintain research records for 3 years after the study has closed regardless of the level of review; and
12. Provide all Human Subjects participants a copy of the consent form unless consent is waived.

Projects under the jurisdiction of the IRB must be directed by a TECH employee. The IRB may, at its discretion, make exceptions to this policy, for instance in the case of unpaid adjunct appointees, or in instances where projects originating externally use TECH resources, but TECH employees do not help to direct the project. Students must arrange for a TECH employee (usually their major professor or instructor) to act as project director or principal investigator and take full responsibility for the project and welfare of the subjects.

Although studies are required to be submitted by faculty members, we recommend that students be included in the preparation and training for the study, prior to submitting the study for approval by the appropriate compliance committee. This is especially important for doctoral students and thesis-based masters students.

3.5 Consultants to HUC

The purpose of this policy and procedure is to outline the HUC's and/or IRB's use of consultation when the IRB does not have the appropriate scientific or scholarly expertise to understand and conduct an in-depth review of a protocol, or does not have representation with knowledge about or experience with categories of participants vulnerable to coercion or undue influence.

The HUC and/or IRB will, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. Consultants do not vote with the IRB members.

When the determination is made by the IRB Chair or designated reviewer that the membership of the IRB does not have the appropriate expertise for the review of a particular protocol, the HUC will seek a qualified consultant willing to assist the IRB in the review of the protocol. When possible, the consultant will be identified from individuals from the University or local community with recommendations accepted from the IRB, HUC staff, the Chief Research and Innovation Officer, and/or the investigator submitting the protocol in question.

Once identified, prospective consultants will be contacted by the IRB Chair, designee or Chief Research and Innovation Officer regarding consultation activities. Designees include other members of the IRB. If willing to serve, the prospective consultant will be sent a copy of the Policy on IRB Member or Consultant Conflict of Interest, along with a confidentiality agreement and Conflict of Interest disclosure form to complete and return to the HUC Staff. Upon receipt of the confidentiality agreement and disclosure of no

conflicts, the protocol and relevant attachments will be forwarded to the consultant. The consultant will be asked to conduct an in-depth review of the protocol and provide written comments on his/her review.

If the protocol requires review by the convened IRB, the consultant will be asked to attend the meeting to present the review of the protocol to the Board and to answer any questions. However, if unable to attend the meeting, the consultant will provide his/her written review of the protocol for distribution to the Board prior to the meeting. The consultant may be available via phone to answer questions raised by the Board.

An IRB member has the latitude in determining when informal consultation of colleagues rises to the level of requiring written documentation.

3.6 Training

All investigators who wish to conduct human subjects' research at Louisiana Tech University must receive training in the protection of human research participants. All key personnel, originally listed or later added to a project through a modification, must comply with this mandate.

This training requirement shall be fulfilled through the online CITI course, and may be augmented by attendance at a live training session conducted by staff. Refresher training is required every three years and may be completed through the online CITI course. This training is available at www.citiprogram.org. Log in (register as new user) and select Louisiana Tech University Courses. Choose appropriate IRB (or other research integrity courses) and complete the modules (and print the certificate).

Documentation of completion of all requisite modules is required. At the end of the training a certificate of completion is available and should be printed out and submitted with each proposal. Researchers would be well served to print out several copies or save copies on their computer for future submissions. (Additional online training is also available at: https://www.hhs.gov/ohrp/education-and-outreach/index.html.)

Alternate training may be accepted but only at the discretion of the HUC Staff, or Chief Research and Innovation Officer.

All IRB members, alternates, and HUC staff receive human subjects protections education related to federal regulations and guidance, HUC policies and procedures, and IRB review processes. Minimally, initial training in human subjects protection, with continuing education every three years is required (e.g., completion of Collaborative Institutional Training Initiative modules). IRB members and HUC staff also receive additional education/new information via newsletters, email announcements, website postings, and in-person training sessions.

New IRB Members

The HUC Staff is notified by way of copied correspondence when the Institutional Official appoints a new member to the IRB. The HUC Office will contact the new

member to schedule an orientation meeting with the HUC staff. The orientation will cover the following topics:

a. IRB Member attendance
b. IRB meeting packets
c. Confidentiality
d. Office contact information
e. IRB Review process & reviewer sheets

The new IRB member will receive an electronic copy of a Member Handbook that contains at a minimum the following materials:

a. The Belmont Report
   http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/
b. The Nuremberg Code
   https://history.nih.gov/research/downloads/nuremberg.pdf
c. Louisiana Tech Policy on Use of Human Subjects in Research
   https://www.latech.edu/about/administration/policies/p-7108/.
d. Title 45, Code of Federal Regulations, Part 46, "Protection of Human Subjects"
   http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/
e. TITLE 21--FOOD AND DRUGS, CFR, FDA, Part 50, "Protection of Human Subjects"
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

All IRB members

At the discretion of the IRB Chair or Chief Research and Innovation Officer, a brief education session will be held at the beginning of or during a scheduled convened IRB meeting. Educational information may be sent to the IRB members. These sessions and the information presented will be documented in the minutes of the IRB meeting when presented or by correspondence if the information was mailed.

IRB Members must take the mandatory training for investigators before voting privileges will be allowed. The training must be completed at the same intervals as investigators.

4.0 IRB Meetings and Records

Quorum and Meetings

A quorum of the Board is defined as a majority of the membership. Alternate members attending the meeting in a non-voting capacity do not count toward the quorum. No member may participate in the initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the Board. Members with conflicting interests will leave the meeting room during the deliberations and voting on said project and may not be counted towards the quorum for that vote. These recusals are documented in the minutes of each convened meeting, as is the attendance.

The Chair, or presiding designee, determines establishment of quorum; this is recorded in the meeting minutes. At least one member whose primary concerns are in a non-scientific area must be present. When research involves categories of participants vulnerable to coercion or undue influence, at least one member who is knowledgeable about or experienced in working with such participants must be present.

Comments from members unable to attend a meeting that have been provided in advance (e.g., by fax or e-mail) may be considered by the attending IRB members, but may not be counted as votes or toward the quorum for convened meetings (§46.108(b)). Any member may participate by teleconference or videoconference, provided he/she has received all materials before the meeting and can actively and equally participate in the discussion. (http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-minutes-2015/#_Toc431480882)

If quorum is not met, then IRB voting cannot take place; and the items on the agenda will be tabled until the next convened IRB meeting. If quorum is lost during a convened meeting (e.g., due to a member leaving the meeting), then no further voting can take place; and the remaining items on the agenda will be tabled until quorum is restored or the next convened IRB meeting. HUC staff attending IRB meetings are responsible for recording the attendance of members as they enter and leave the room. If quorum is lost, HUC staff will notify the IRB Chair that no further actions can be taken until/unless quorum is restored.

IRB members with potential conflicts of interest must leave the room before discussion of the research, except to provide information requested by the IRB. Members with potential conflicts of interest may not be present for the vote and are not counted toward quorum for review of the research for which the potential conflict exists.

Meetings will be convened by the Chair at least three times per year; a regular schedule will be announced to satisfy the requirements of timely review. An emergency meeting may be called as necessary at 24 hours' notice. A meeting will be convened if requested by any two voting IRB members to consider a specified topic that cannot await a scheduled meeting.

While some human subjects studies may qualify for IRB expedited review and receive approval more rapidly, researchers are urged to allow adequate time for review. For studies that are received by November 1, February 1, and May 1, the HUC will respond with ‘approval’, ‘declined’, or ‘additional questions’ prior to the start of the following academic quarter. For studies that are projected to begin at the beginning of the summer or fall quarter, it is recommended that the approval documentation be submitted no later than May 1.

IRB Records

In accord with §46.115 IRB Records, Tech shall prepare and maintain adequate documentation of IRB activities, including the following:

(a) Copies of all reviewed research proposals as specified in §46.115 (a)(1)

(b) Minutes (§46.115 (a)(2)) of IRB meetings, in sufficient detail to show:

(i) attendance at meeting
(ii) actions taken by IRB
(iii) votes on these actions including votes for, against,, and abstaining
(iv) basis for requiring changes in or disapproving research
(v) written summary of the discussions of controverted issues and their resolution

(c) Records of continuing review activities (§46.115 (a)(3)), including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).

(d) Copies of all correspondence between IRB and the investigators.

(e) A list of IRB members in the same detail as described in §46.108(a)(2).

(f) Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

(g) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

(h) The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

(i) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

(j) The records required by this policy shall be retained in accord with §46.115(b).

Draft minutes will be forwarded for review and approval by the Convened IRB in the meeting packet for the next meeting after which they are prepared. The approved minutes (with any changes requested by the IRB) will be signed by the Chair, and/or Acting Chair presiding over the meeting for which the minutes were recorded, and maintained by the HUC staff along with a copy of the meeting packet materials and any relevant documents distributed during the meeting in an electronic file.

Confidentiality of records maintained by the HUC Staff and/or IRB means that detailed information regarding the study can only be shared with investigators listed on the project or appropriate institutional officials. HUC Staff and/or IRB may confirm or provide status of IRB approval, study number and/or study title in addition to providing additional information to participants to clarify concerns, procedures, etc. All other requests for information regarding the study must either be obtained directly from the PI /Co-PI or with written permission from the PI/Co-PI for the HUC Staff and/or IRB to share. Please note that these records are held by a state entity and therefore are subject to protection

and disclosure if required by law. Research information may be shared with the Tech IRB/HUC.

5.0 Conflicts of Interest

5.1 Conflicts of Interest for IRB Members and Consultants

As stated in §46.107(d), ”No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.”

Definition
Conflicting interest may include cases where the member is involved in an independent and potentially competing research program, cases where access to funding or intellectual information may provide an unfair competitive advantage, or cases where the member's personal biases (including personal relationships) may interfere with his or her impartial judgment. Conflicts of Significant Financial Interest, is defined by Tech in Policy 7114 (https://www.latech.edu/about/administration/policies/p-7114/).

Procedure

1. No IRB member may participate in the review of a protocol in which the member has an actual conflicting interest or the appearance of a conflict exists, except to provide information requested by the HUC.
2. In order to avoid real or perceived conflicts of interest, (i) no participating IRB member may hold an equity interest (e.g., partnership, stock, or profit-sharing) in the organization requesting HUC review; (ii) no participating IRB member may be paid more than reasonable compensation or receive more than reasonable benefits for IRB-related activities; and (iii) no IRB member may receive compensation or benefits under arrangements that could impede or discourage objective decision-making on behalf of human subjects.
3. It is the responsibility of each IRB member to reveal any potential conflict of interest to the IRB chair as soon as it is recognized. Reviewer comment forms for both expedited and Convened IRB reviews will request confirmation that no real or perceived conflict of interest exists for the designated reviewers.
4. IRB members should leave the meeting room before deliberation and voting on research in which they have a conflicting interest. The minutes will reflect the member as being absent with an indication that a conflicting interest was the reason for the absence.
5. If the investigator submitting a protocol feels that an IRB member has a potential conflict, the investigator should be encouraged to write the IRB Chair requesting that the member be excluded. At the investigator’s request and at the Chair’s discretion, the member should not have access to the protocol and should leave the room during deliberation and voting on the protocol.
6. If the IRB Chair indicates a conflict of interest, then the matter will revert to the IRB Vice-Chair. In the event that the IRB Vice-Chair also has a conflict of interest, then the HUC will assign an IRB member to chair the matter.
7. IRB members and consultants with a conflict of interest:

a. Are excluded from discussion except to provide information requested by the IRB.
b. Are excluded from voting except to provide information requested by the IRB.
c. Are not counted towards quorum.

Consultants with a conflicting interest can provide information requested by the IRB as long as their conflict of interest is disclosed.

5.2 Conflicts of Interest for the Institution, Researchers, and Research Staff

The purpose of this Standard Operating Procedure (SOP) is to establish the process to evaluate a report of a significant financial interest by a researcher or research staff involved in the design, conduct, or reporting of human subjects research or an institutional financial interest that is related to human subjects research.

Definitions

- "Immediate Family" means spouse and dependent children.
- "Financial Interest Related to the Research" means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:
    - Ownership interest of any value including, but not limited to stocks and options exclusive of interests in publicly-traded, diversified mutual funds.
    - Compensation of any amount including, but not limited to salary, honoraria, paid authorship, consultant fees, royalties, or other income.
    - Proprietary interest of any value including, but not limited to, patents, trademarks, copyrights, and licensing agreements.
    - Board or executive relationship, regardless of compensation.
    - The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the individual and not reimbursed to the individual so the exact monetary value may not be readily available) related to the institutional responsibilities. This does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

• "Institutional Conflict of Interest" is defined as a situation in which the financial investments or holdings of Louisiana Tech University or the personal financial interests or holdings of institutional leaders (those with direct authority over the allocation of institutional resources) might affect or reasonably appear to affect the design, conduct, reporting, review or oversight of human subjects research.

Procedure

In addition to the requirements outlined in this policy, human subjects research that is sponsored by external sources must comply with the Tech Policy 7119 on "Authorizing Contracts Between the University and a Member of the Faculty, Research Staff, or

Coaching Staff or a Company in Which the Employee had an Interest Under Specified Circumstances" (https://www.latech.edu/about/administration/policies/p-7119/).

Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Management Plans may include (but are not limited to) partial or complete divestment, limiting involvement of the conflicted individual, or additional oversight or disclosure. Disclosure alone cannot be used to manage conflicts of interests that might affect the protection of participants. Researchers and research staff will be required to submit an annual report describing his or her compliance with their Management Plan. Annual reports will be reviewed by the IRB Chair.

Institutional Conflict of Interest Related to Licensing

When Louisiana Tech University licenses technology or other intellectual property, it may receive equity in a company as a result of that license and/or a royalty or other fee as compensation for the use of that intellectual property. An institutional conflict of interest of interest is created if a researcher undertakes to do human subjects research on a drug, device, biologic, or other item on which Tech has a patent, has licensed the intellectual property, or receives royalties or other fees.

To identify institutional conflict of interest related to licensing, the HUC requires all new human subjects research protocols to indicate source(s) of all funding to be used in supporting the research. This information will be compared to a report provided by the Office of Intellectual Property and Commercialization listing all active university start-up companies that have been approved by the Louisiana Tech Research Corporation.

Major Gifts to Louisiana Tech University Foundation

The Louisiana Tech University Foundation receives, invests, and administers private support for Louisiana Tech University consistent with Tech's priorities and mission. An institutional conflict of interest is created if a Major Donor (> $10,000) undertakes to sponsor human subjects' research at Louisiana Tech University.

To identify institutional conflicts of interest related to major gifts, the HUC requires all new human subjects' research protocols to indicate source(s) of funding to be used in supporting the research. This information will be compared to a report provided by the Tech Foundation. Research involving a possible institutional conflict of interest related to major gifts will be reviewed by an external IRB per the Memorandum of Understanding executed between the two institutions.

6.0 Project Review

In order to submit an application for human subjects research to the Louisiana Tech IRB, the necessary information may be submitted through standard format, available on forms are available from the Office of Sponsored Projects (Keeney Hall), or on-line at **https://www.latech.edu/research-enterprise/research-compliance/.** Proposals will be reviewed in terms of the criteria which the IRB is required by 45 CFR 46 to consider; these are incorporated into questions in the IRB application. Contact. Richard Kordal

(318-257-2484), Gary Stokley (318-278-3124), Davy Norris (318-257-3798), or Ms. Barbara Talbot (318-257-5075) to answer any questions regarding the review process.

The following information provides guidance on human subject research that is exempt from IRB review, on submitting projects for expedited review, and on submitting projects that require convened IRB review.

6.1 Exempt Review of Applications

The purpose of this policy is to define the roles and responsibilities associated with exempt review of IRB applications. The criteria for determining whether research involving human subjects meets the criteria for exemption is made in accordance with §46.104(d)(1-8). See OHRP Decision Chart #2: Is the Research Involving Human Subjects Eligible for Exemption? https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. The determination that a research activity meets one or more of the 8 specific exempt categories identified in 45 CFR §46.104(d)(1-8) or 21 CFR §56.104 and is eligible for exempt review, must be documented and include a citation of the specific category or categories justifying the exemption. Exemption is granted by the IRB/HUC chair, or IRB/HUC designated reviewer or IRB/HUC.

The decision to approve, or any modifications or clarifications required as a condition for approval, will be promptly conveyed in writing by the HUC Office to the investigator and to other institutional offices as appropriate. The investigator must receive written notification of approval prior to initiation of any human subject research activities.

Any proposed or anticipated changes in the study must be submitted to the HUC Office for review and approval. The investigator must receive written notification of approval prior to implementation of any modifications. Changes may require the research to be referred for expedited or for full board review.

Annual continuing review is not required for exempt research and the project ending period will serve as the exempt expiration date. However, if the investigator determines that the study will exceed the approved expiration date, the investigator must submit for approval a continuation. An approved study may only be approved for a total period of 5 years after which a new IRB application must be submitted. IRB records of exempt research are purged after 5 years.

6.2 Expedited Review

If the research involves only “minimal risk” and fits a certain category of research specified in §46.110(a), or for minor changes in approved research, the researcher may apply for expedited review. If the review is expedited the approval may occur prior to a meeting. An expedited review is a procedure to review research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB. This type of review does not require a full board meeting.

The use of expedited review by the IRB is limited to protocols that present no more than minimal risk and meet specified criteria listed in the Federal Register. In accord with §46.110(b)(ii) and (iii) the expedited review procedure may also be used when there are only minor changes in previously approved research during the period for which approval is authorized, or for exempted research under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). For reference see OHRP Decision Chart 8 and Chart 9: May the IRB Review Be Done by Expedited Procedures? https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c8, and May the IRB Continuing Review be done by Expedited Procedures? https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c9.

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 are 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.

The speed of expedited reviews depends on the complexity of the study and whether the research conforms to the guidelines or requires revision. It is recommended that studies be submitted at least a month in advance to allow for revision if necessary or referral to full review if needed.

Special consideration will be given to full review when members of vulnerable groups are in the study population. Research involving prisoners is not eligible for expedited review and must be reviewed by the convened IRB. 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."

A list of projects approved by Expedited Review will be provided to each IRB member at each regular convened meeting, or by e-mail, and the IRB will be given an opportunity to discuss each project that was approved via expedited review.

Experienced Reviewers

The regulations state that only "experienced reviewers designated by the chairperson from among members of the IRB" may conduct expedited reviews. 45 CFR §46.110(b)(2), 21 CFR 56.110(b). The IRB chair will determine whether the member is experienced or if further experience is needed. To be considered experienced, an IRB member should have:

- attended and participated in at least 6 IRB meetings,
- completed new member orientation and OHRP new member training modules,
- served as a secondary reviewer on a full board application or conducted one expedited review under the guidance of the IRB Chair or HUC Staff,
- have previously submitted human subject research studies which were approved by an IRB, or

- had previous experience deemed to be sufficient by the IRB chair.

The IRB Chair or HUC staff assigns the protocol to an expedited reviewer with relevant expertise and knowledge of the area of investigation. Full copies of the IRB protocol including any attachments, relevant correspondence, or notes will be copied and sent to the reviewer by the HUC staff. The review process will include an in-depth review of all pertinent documentation. The IRB Chair or Chief Research and Innovation Officer may supplement an expedited review by adding conditions for approval.

When the research involves categories of participants vulnerable to coercion or undue influence, the expedited reviewer should be knowledgeable of the area of investigation. If the IRB does not have the appropriate scientific or scholarly expertise, consultation may be obtained in accordance with the SOP on Consultants. It should be noted however, that an official expedited review approval can only be made by an IRB/HUC member.

In reviewing the research, the expedited reviewer has the option of communicating directly with the investigator and HUC staff to convey necessary revisions or clarifications. The expedited reviewer may approve the protocol or require modifications or clarifications as a condition for approval or refer the protocol to the full board; the reviewer may not disapprove the research. The regulatory requirements for approval by the expedited procedure are otherwise identical to approval by the full board procedure.

Results of the review will be promptly conveyed in writing by the HUC office to the principal investigator, advisor (if applicable), and to other appropriate institutional offices.

6.3 Full Review (Convened Review)

1. Applications for full review must be received at least 2 weeks before the meeting (unless the Chair grants a reduction of this interval). The IRB members may refuse to consider an application if they have not had sufficient time to consider it.
2. If time permits, applications will be sent to each IRB member in advance of a meeting with a checklist of evaluation criteria. Applications consist of: Tech IRB application, proposed consent and assent forms, copies of all instruments and questionnaires, any related grant proposals and subject recruitment material.
3. The Chair or designate will contact the PI concerning any questions or additional information required if time permits, and present this information at the convened meeting where the project is reviewed.
4. During the meeting other comments and questions will be encouraged. After all the issues raised have been explored, the Chair will accept a motion to approve, approve conditionally, table, or disapprove a project. A vote will be held and a majority of a quorum will be required to approve. (The numerical vote including abstentions will be recorded, but those making and seconding the motion will not be recorded).
5. Normally, the Chair or members designated at the meeting by the HUC/IRB will be responsible for ensuring any contingencies/changes required by the

committee are met before issuing the formal approval document to the Project Director/Principal Investigator (PI).

6. The IRB may require or invite the PI or a representative to attend. Alternatively the IRB may require or invite the PI or a representative to be available for questions by phone.
7. Investigators associated with a project, spectators, and members having a conflict of interest will leave the room when requested to do so by the Chair, to facilitate uninhibited discussion, and may not be present for the vote.

If there are visitors or spectators present, final discussion and the vote on all projects up for review may be postponed until a convenient time during the meeting when the IRB will go into executive session.

6.4 Appeal of an IRB Decision

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 or stopping a research study. However, a researcher may offer further explanations or defense of procedures to the IRB.

Request for further consideration of an IRB decision must be made to the Chief Research and Innovation Officer in writing. Once a request for appeal has been received, the Chief Research and Innovation Officer will schedule a meeting of the IRB for the appeal. If the person making the appeal wishes to speak directly to the IRB, he or she may attend and do so at a scheduled time and date.

6.5 Renewal of Approved Applications

Projects are approved for a term not to exceed 12 months from the date of IRB approval. If projects appear to present unusually great or undefinable risks, the IRB may set the approval interval at less than 12 months. The IRB may consider whether involvement of vulnerable populations merits more frequent review. In addition, if a project has a number of project-related adverse events which cause concern, or if there are compliance or other problems associated with the project, the approval interval may be reduced so that re-review frequency is increased. If the faculty member associated with the project leaves university employment the IRB/HUC should be notified and a new university faculty /staff member identified as responsible for the project.

At a suitable interval before the expiration of a regular approval, HUC staff will send a notice reminding the PI that he/she must request continuation, or report termination of the project, and submit a short report detailing any non-compliance, unreported adverse events, new knowledge that might affect informed consent, project status and progress. There is no grace period for the conduct of research beyond the approval period specified by the IRB. The expiration date is the last date that the protocol is approved

and the last day that data may be collected and research may be conducted unless re-approval is granted. Continuing review and re-approval of research must occur on or before the date when IRB approval expires. When continuing review of a protocol does not occur prior to the end of the approval period, IRB approval expires automatically and the research must stop unless the IRB or the IRB Chair finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur under any circumstances after the expiration of IRB approval.

The IRB staff will review the reports, and prepare them for full or expedited review according to the original method of approval. The IRB staff will prepare and present a summary of any circumstances that require special attention by the reviewers. The IRB will vote to approve/disapprove continuation in the usual manner.

If deemed necessary, the IRB may appoint one or more members to directly review a project, work with its subjects, or review the data or informed consent process on an intermittent or continuous basis. This might be done in the case of very high-risk projects, or when there are concerns about the conduct of the study.

Any serious non-compliance or study-related adverse event(s) will be reported to the Institutional Official.

In accord with §46.109(e), the IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as prescribed in §46.109(f). Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

1. if the research is eligible for expedited review in accordance with §46.110

2. if the research has been determined to be exempt research as described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8).

3. if the research has progressed to the point that it involved only one or both of the following, which are part of the IRB-approved study:
(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

For protocols reviewed by the IRB at a convened meeting, the date of the meeting at which IRB approval occurs will be the approval date and continuing review must occur within the specified renewal time period, usually one year.

Continuing review must be conducted 30 days prior to the expiration date in order to retain the anniversary date as the next expiration date. Materials to be submitted by the researcher for continuing review include:

1. a complete Renewal Request form

2. a copy of the previously approved current consent document and any newly proposed consent document, if applicable or a clean copy of the consent form for approval
3. any relevant information not previously submitted, especially information about risks associated with the research

For continuing review by the convened IRB, the above materials and any previously approved modifications will be provided to the primary and secondary reviewers. At least one IRB member will be provided with and will review the complete protocol including any protocol modifications previously approved by the IRB. The above materials will be included in the meeting packet that is provided to all members. Renewal review must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. These criteria, at a minimum, include determinations that:

1. the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits particularly if any new information has emerged;
2. the selection of participants continues to be reasonable in relation to anticipated benefits;
3. informed consent continues to be appropriately documented (if required);
4. there are provisions for safety monitoring of the data;
5. there are protections to ensure the privacy of subjects and confidentiality of data;
6. there are appropriate safeguards for vulnerable populations;
7. the consent document is still accurate and complete; and
8. any significant new findings that may relate to the subject's willingness to participate are provided to the subject.

In accord with §46.110(b)(ii) an IRB may use expedited review procedure for minor changes in previously approved research during the period for which approval is authorized.

As specified in §46.109(f)(1) part (iii) unless an IRB determines otherwise, continuing review of research is not required if it has progressed to the point that it involves one of both of the following, which are part of the IRB-approved study:

(A) Data analysis, including the analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

6.6 Approval Process

All federal funding agencies require IRB approval prior to funding of an awarded federal research grant or contract involving human subjects within the period of support (§46.101). Sometimes as indicated in §46.118 initial results are needed before definite plans for the human subjects' can be set forth (e.g., projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies or purification of compounds). Other times, research is undertaken without the intention of

involving human subjects, but it is later proposed to involve subjects in research (§46.119). Therefore, in accordance with §46.104 no human subjects may be involved in any project until the project has been reviewed and approved by the IRB, Accordingly, the following procedure shall be used:

Procedure:

1. When a project plans to use human subjects in research, the human subjects' field of the Proposal Routing Form should be checked. The Office of Sponsored Projects notifies the Principal Investigator (PI) when the grant proposal is processed alerting them to the need for IRB approval before a fund may be established.
2. An Application for IRB Review of Human Subjects Research should be submitted with all relevant information known at that time. A timeline for development of instruments and procedures should be provided.
3. The application will be assigned a study number. When necessary, the Director, Sponsored Projects will notify the IRB Chair that an Application for IRB Review of Human Subjects Research has been received.
4. The file will then be placed in PENDING status. It will not be reviewed or approved. When instruments and procedures have been developed, they should be submitted. At that time, an IRB review will occur.
5. No human subjects may be used until IRB approval has been granted. Like all pending files, a pending notice will be sent on a quarterly basis reminding the PI that the IRB approval has not been obtained and additional items are needed for review.

An IRB application or exemption must be sought prior to or concurrent with submittal of the application for funding. Failure to do so, or to correct the omission in a timely manner, will result in withholding the funding application, withdrawal of it by the University, or declining to accept an award until the project has IRB approval. Researchers must follow all requirements of the sponsoring agency.

When multiple applications are submitted to sponsors, it must be made clear to the IRB whether they are parallel submissions for the IDENTICAL scope of work, or if the scope of work differs. In the latter case the IRB will require separate applications, unless at its discretion, it determines that a single IRB application is appropriate. Subsequent applications to the same or other sponsors will require a new IRB application because the scope of work is usually altered to a lesser or greater degree. The IRB does not have the resources to compare two grant applications to determine if they are the same, and therefore usually considers each on its merits. In a new application the applicant is encouraged to explain the relationship to a previous proposal, but may not incorporate material from it by reference. The IRB reserves the right to approve a new application as a modification to a previous IRB approval if the relative scopes of work and procedures lend themselves to this solution.

6.7 Notification of Review Results

Investigators will be notified in writing of approvals and disapprovals by the IRB office. Any contingencies required to receive approval must be met before the approval document is issued.

6.8 Suspension or Termination of IRB Approval of Research

All projects not formally reviewed and renewed beyond the final date of the initial approval are considered terminated. A project is not considered terminated until the data collection is complete, at least a preliminary analysis of the data is complete, and remaining data has been de-identified in such a way that it is no longer able to be associated with an individual participant.

As provided in §46.113, the IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be promptly reported to the investigator, appropriate institutional officials and the department or agency head.

7.0 Informed Consent and Assent

It is the policy of the Louisiana Tech University Human Use Committee that all human subjects' research shall be consistent with the ethical principles of the Belmont Report . Informed consent is to be sought from all participants unless specifically waived by the IRB and the requirements of §46.116(e)(3) are met. Informed consent is viewed as a PROCESS. It includes a thorough briefing of each potential subject, including all the elements of informed consent in §46.116, especially a discussion of any risks and potential loss of privacy; an effort to ensure the subject has fully understood what he/she will agree to and has had all questions answered; and signature of a consent form which documents that the subject has participated in the process of informed consent and has agreed to participate. Care should be taken in presentation format that all pertinent information is included in an understandable fashion and that elements salient to the participant not be buried in less relevant verbiage. Also care should be taken to insure that language and information is presented in a manner appropriate to the participants' educational level, and is understandable by participants. Signature of a consent form does not by itself constitute informed consent.

The Application for IRB Review of Human Subjects Research will be used to solicit necessary information from the investigator regarding the circumstances surrounding the consent process in order that the IRB may evaluate whether the consent process meets the relevant regulatory and ethical obligations. The IRB is allowed to waive the requirement for written documentation of the consent process by determining that the criteria for waivers are met. The IRB reviewer(s) will review submitted protocols for the inclusion of certain vulnerable populations, in order to ensure these obligations are met and document the review including the findings which justify the waiver or alteration.

In addition to parental permission, assent is to be sought from minors of sufficient age to be able to grant it (usually 6 and older), and a minor may not be entered into a study without assent. If the child is too young to sign the assent form, a witness to the assent process will sign the form. The IRB recognizes foster parents and legal guardians as having the authority to enter children in their care into studies. Note from: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/

> "Under §408(b) the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is conducted under §46.406 or §46.407, permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Although the regulations state that children are unable to provide legally effective informed consent to participate in research, some might be able to give their assent. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (§46.402(b))."

Exempt projects

Even when a project is exempt from the regulations governing human subjects research in accordance with 45 CFR §46.104 or 21 CFR §56.104, there may be an ethical obligation to obtain the participants' consent (or parental/guardian permission and child assent for research involving children) or at least provide them with information regarding the research. For exempt research, there must be a mechanism of disclosure to participants that the project involves research, the procedures associated with the study, contact information for the researcher, and a statement that participation is voluntary. If such disclosure is not practicable, the researcher must provide justification for a waiver in that regard.

Expedited and Convened IRB reviewed projects

Projects requiring expedited or convened IRB review must comply with §46.116 and §46.117 in regard to required elements and documentation of consent. Research regulated by the FDA must also meet the criteria of 21 CFR §50 Subpart B. Additionally, research involving children must comply with requirements for parental permission and child assent in accordance with 45 CFR §46.408. In order to request a waiver of any of these requirements, an investigator must provide project specific justification for the request. Any such waiver will only be approved by the IRB if the project is not regulated by the FDA and the waiver meets the requirements of §46.116(e)(3) and/or §46.408 in regard to a waiver of parental permission and/or child assent. See OHRP Decision Chart 10: Can Informed Consent Be Waived or Consent Elements Altered? http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/#c10. And Decision Chart 11: Can Documentation of Informed Consent Be Waived? http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/#c11.

General Requirements for Informed Consent

As specified in §46.116(a)(1)-(6), the general requirements for informed consent are as follows:

1. Informed consent must be obtained prior to conducting the study.
2. The subjects must be given sufficient opportunity to discuss and consider whether to participate in the study with minimal possibility of coercion or undue influence.

3. Information given to the Subject shall be given in language that is understandable to them.
4. The information provided should be sufficient to make an informed decision.
5. Except for broad consent: (i) the informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding why one might or might not want to participate in the research, and (ii) present sufficient detail to facilitate the subject's understanding why one might or might not want to participate.
6. May not include any exculpatory language.

Basic Elements of Informed Consent

In accordance with §46.116(b)(1)-(9), the basic elements of informed consent shall include the following information.

- **Purpose of the Study**: an explanation of the purposes of the research and expected duration of the subject's participation. A description of procedures to be followed and identification of any procedures that are experimental.
- **Potential Risks:** a description of any reasonably foreseeable risks or discomforts to the subject.
- **Potential Benefits:** a description of any benefits to the subject or to others that may be reasonably expected from the research.
- **Alternative Procedures:** a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- **Confidentiality:** a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- **Compensation:** for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs.
- **Contact Information:** an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- **Right to Refuse:** a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- **Identifiable Private Information or Identifiable Biospecimens:** For research that involves either or both of the above, one of the following statements:
    - A statement that identifiers may be removed and that, after such removal, the information or biospecimens could be used in future research studies or distributed to another investigator for future research studies without additional informed consent, if this might be a possibility.
    - A statement that the subject's information or biospecimens collected as part of research, even if identifiers are removed, will not be used or distributed for future research studies.
- **Signature**

Additional Elements of Informed Consent

As provided in §46.116(c)(1)-(9), in addition to the above, when appropriate one or more of the following additional elements of information shall also be provided to each subject or the legally authorized representative:

- **Pregnancy Risks:** A 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.
- **Investigator Termination:** anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.
- **Additional Costs:** any additional costs to the subject that may result from participation in the research.
- **Subject's withdrawal:** the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- **Continued Participation in Light of Significant New Findings:** a statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
- **Number of Participants:** the approximate number of subjects involved in the study.
- **Commercialization of Biospecimens:** a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- **Disclosure of Clinically Relevant Results:** a statement regarding whether clinically relevant research results, will be disclosed to subjects, and if so, under what conditions.
- **Genetic Analysis:** for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

Waivers or alteration of consent

The IRB may waive the requirement to obtain informed consent for research or approve the alteration of some or all of the elements of informed consent if it determines that the regulatory criteria specified in §46.116(e)(3) are met. When the IRB considers altering or waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants. When granting changes or waivers of the requirement to obtain written document of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research.

Documentation of Informed Consent

As provided in §46.117(a), informed consent shall be documented by the use of a written consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. Frequently in survey research, the consent is the only document linking the Subject to the research and the principal risk would be potential harm from a breach of confidentiality §46.117(c)(1)(i). In such cases documentation may be waived if all the requirements of §46.117(c)(1)(i),(ii) and (iii) are met. In cases in which the documentation requirements is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research §46.117(c)(2).

Observation of the Informed Consent Process

The IRB has the authority to observe or have a third party observe the consent process and the research, §46.109(g). The IRB will consider whether the consent process should be observed by someone outside the research team when the study includes participants with diminished decision-making capacity or individuals particularly vulnerable to coercion (such as children or individuals in a subordinate position to the researcher), or when other circumstances warrant as judged by the IRB. When the IRB determines the consent process should be observed, the reviewer(s) (primary and secondary for CIRB or the expedited reviewer) will determine whether the observer will be a member of the HUC staff, an IRB member, or another individual as determined by the IRB.

Payments to Subjects

The IRB may permit payments to research subjects in return for participation, providing that such payments are not coercive in the context of the project environment

When Following Department of Education Regulations

When complying with Family Educational Rights and Privacy Act (FERPA):

1. Researchers indicate on the application whether educational records will be accessed.
2. The reviewer will ensure that procedures and consents outlined are in compliance.
3. Permission will be obtained from the schools where research is to be conducted.
4. An educational agency or institution may disclose personally identifiable information from an education record of a study without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
    - Develop, validate, or administer predictive tests.
    - Administer student aid programs.
    - Improve instruction.

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the organization or researcher conducting the research that specifies:

- The determination of the exception.
- The purpose, scope, and duration of the study.
- The information to be disclosed.
- That the information from educational records may only be used to meet the purposes of the study state in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representative of the organization with legitimate interests.
- That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- The time period during which the organization must either destroy or return the information.

Educational records may be released without consent under FERPA if all personally identifiable information has been removed including:

- Student's name and other direct personal identifiers, such as the student's social security number or student number.
- Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

  The IRB/HUC may request an individual with FERPA expertise to assist in evaluating projects with FERPA considerations.

7.1 VULNERABLE PARTICIPANTS

CHILDREN

All research involving children will be reviewed in accordance with the ethical and regulatory considerations applicable to children under 45 CFR §46 Subpart D or 21 CFR Part §50 Subpart D. Research involving children may only be approved if the special protections outlined in the regulations and this SOP are provided. Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations. 21 CFR §56.103(c)

In order to be approved by the HUC, research involving children must fall into one of four categories outlined in Subpart D. The four categories are based on degree of risk and benefit to individual subjects.

Categories of Research Involving Children:

1. Research Not Involving Greater than Minimal Risk to Children (45 CFR §46.404)
2. Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Child (45 CFR §46.405)
3. Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to the Individual Child, but Likely to Yield Generalizable Knowledge about the Child's Disorder or Condition. (45 CFR §46.406)
4. Research Not Otherwise Approvable, which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children (45 CFR §46.407)

The HUC must determine if assent of the child participants must be solicited based on the ages, maturity, and psychological state of the children involved. In general, age 6 is the recommended age to begin seeking assent, but it may be appropriate for younger children depending on their aptitude. If assent is solicited, the HUC must determine that the language used to explain the procedures is appropriate.

Assent is a process in which the research is adequately explained, questions fully answered, and agreement to participate, if granted, is documented. In obtaining a minor's assent, at a minimum, the subject must have explained to him or her orally in age-appropriate terms what will happen to the individual, why it is being done (e.g., "to find out..."), any risks or discomfort expected, and any benefits to the individual or to others. Refusal to assent must be honored, no matter how irrational it may appear to be. Mere absence of dissent may not be regarded as assent.

The HUC must determine whether and how assent should be documented. If a waiver of assent is requested by the investigator, the HUC must determine that at least one of the necessary conditions outlined in 45 CFR §46.408(a) is met. A sample assent form is provided in the appendix.

The permission of each child's parents or legally authorized representative must be solicited unless the HUC determines that the conditions outlined in §46.408(c) are met. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

If a waiver of documentation of permission is requested by the investigator, the HUC must determine that the requirements outlined in §46.117 are met.

When permission is sought from only one parent, the HUC must determine that at least one of the conditions outlined in §46.408(b) is met.

When child participants are wards of the state or any other agency, the HUC must determine that all of the conditions outlined in §46.409 are met.

When child participants have a legally authorized representative or are wards of the state or any other agency, written documentation of the judicial appointment must be provided to the researcher at the time of consent, and a copy maintained by the researcher with the consent/assent documents.

The HUC must assure that it possesses the expertise necessary to review research involving children as participants or seek the expertise of a consultant in accordance with the Tech HUC guidelines.

COGNITIVELY IMPAIRED

Cognitive impairment means having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional function to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent upon drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

All research involving cognitively impaired participants will be reviewed and approved in accordance with special considerations as determined by the Belmont Report, Federal and State regulations, and as outlined in this SOP.

Research in which cognitively impaired individuals will be considered as participants may be reviewed at the administrative, expedited or convened IRB level. Research involving cognitively impaired participants may not be approved by the IRB when all of the following conditions apply:

1. There is no advance directive (completed before cognitive impairment) which provides evidence of willingness to participate in the research;
2. Subjects are too intellectually impaired to give consent;
3. The research involves greater than minimal risk; and
4. Offers no prospect of direct benefit to the individual subject.

For participants who lack decision-making capacity, the permission of the individual’s legally authorized representative is required and assent should be obtained from the participant. When participants who lack decision-making capacity have a legally authorized representative, written documentation of the appointment must be provided to the researcher at the time of consent, and a copy maintained by the researcher with the consent/assent documents. In research situations where there is the potential for direct benefit to the participant, the HUC/ IRB may waive the requirement to obtain

assent; however, permission from the legally authorized representative must be obtained, unless the criteria are met to approve a waiver of informed consent.

When reviewing research (i.e., initial review, continuing review, protocol amendments, and reports of adverse events or unanticipated problems) involving cognitively impaired participants, the convened IRB will include into its composition one or more individuals who are knowledgeable about and experienced in working with the cognitively impaired. When reviewing said research at the expedited level, the reviewer(s) will be knowledgeable about and experienced in working with the cognitively impaired.

PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES

Additional health concerns during pregnancy and the need to avoid unnecessary risk to the fetus warrant special consideration from the IRB of research involving women who are or may become pregnant. All research involving pregnant women, human fetuses, and neonates of uncertain viability or nonviable neonates will be reviewed and approved in accordance with 45 CFR 46 Subpart B and/or 21 CFR 56. All research involving the transplantation of fetal tissue will be reviewed and approved in accordance with Public Law 103-43.

Research involving pregnant women, human fetuses, and neonates may be approved at the administrative, expedited or convened IRB level. When it is appropriate, any research project that includes women of childbearing potential as possible participants must include a 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) as part of the informed consent process. Each participant will be advised to notify the investigator immediately should she become pregnant. The IRB should determine if the risk is great enough to exclude pregnant women from the research project or to study them separately. (All conditions must be met as required in 46.204). For non-exempt research, subjects should be informed if there is foreseeable risk to pregnant women, fetuses, or neonates. If no reasonably foreseeable impact of the non-exempt research on a fetus or neonate is present, the consent form should include a statement to that effect when women of childbearing potential are possible participants.

PRISONERS

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, additional safeguards are provided for the protection of prisoners who may be asked to participate in research as human subjects.

A Prisoner is any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

The majority of the HUC/IRB must have no association with a prison in which prisoners are asked to become human subjects in a study. In addition, at least one member of the Board must be a prisoner or a representative with appropriate background and experience to assist the board in a determination.

When considering research studies which involve prisoners as subjects, the HUC/IRB must approve such research only if it finds that

(1) The research under review represents one of the categories of research permissible under §46.306(a)(2);
(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
(3) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
(5) The information is presented in language which is understandable to the subject population;
(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

The Board shall carry out such other duties as may be assigned by the Secretary of DHHS. The institution shall certify to the Secretary, in such form and manner as the Secretary DHHS may require, that the duties of the Board under this section have been fulfilled.

Permitted research involving prisoners.

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and
(2) In the judgment of the Secretary the proposed research involves solely the following:
    (i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    (ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    (iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
    (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

STUDENTS AND EMPLOYEES

Louisiana Tech students and/or employees will be considered vulnerable participants in Tech research due to their potential subordinate position within the institution. Research involving Tech students and/or employees must be reviewed at the expedited or convened IRB level. The university administration's permission may be required.
The following conditions must exist for research involving TECH students and/or staff to be approved by the HUC:

1. Participation in the research must not bestow any competitive academic, athletic, scholarship, or occupational advantage over other TECH students or staff who do not participate, and the researchers must not impose any penalty on those participants who choose not to participate.
2. Participants who are TECH students and staff must not be systematically treated differently from participants that are not TECH students and/or staff.
3. Any student research offering extra credit to participating students must provide alternative opportunities to earn extra credit to students declining to participate in research.

The HUC may make exception to any or all of the above conditions provided the inclusion of these participants in the research provides direct benefit to the subject. The investigator should provide documentation supporting the exception request.

8.0 Confidentiality/Anonymity

The purpose of this policy is to outline the responsibilities of individuals (faculty, staff and/or students) in the protection of research data in order to protect the confidentiality, integrity, and availability of data from unauthorized generation, access, modification, disclosure, transmission, or destruction.

Proposed changes to 45 CFR 46 includes the establishment of mandatory data security and information protection standards for all studies by creating levels of security based on the HIPAA Privacy Rule. This would in essence cover all research data that is collected, stored, and/or analyzed including biospecimens, survey data, and research using administrative records, etc.

Definitions
Protected Health Information (PHI): All "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral is deemed "protected health information" (PHI) under HIPAA federal law.

Personal Identifying Information (PII): The state of Louisiana defines “personal information” specifically in Louisiana code §51:2007; as an individual's first name or first initial and last name in combination with any one or more of the following data elements, credit or debit card numbers or other financial account numbers; password or personal identification number required to access an identified financial account other than a password, personal identification number, or other identification number transmitted by an authorized user to the issuer of the account or its agent; Social Security number.

De-identification and Re-identification of Protected Health Information Policy
It is the policy of Louisiana Tech University to encourage the use and/or disclosure of de-identified health information whenever feasible. Louisiana Tech University will not use codes to re-identify data that are created as a derivation of protected health information and could possibly be used to identify individuals by persons using the de-identified data. If a code is used to re-identify the data it will be kept in a safe and secure location, and will not be shared with those using the de-identified data. Re-identification will require the same protection as individually identifiable data.

“Safe Harbor” Provision
"Safe Harbor" De-identification of health information as required by the Privacy Rule 45 CFR §164.514(a) states each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de-identified:

1. Names

2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:
    a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
    b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people changes to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers; license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

De-identified data <u>may</u> contain:

- Age with dates limited to the year
- Ages over 90 must be aggregated to 90+
- Aggregated zip codes in the form of initial 3 digit zip codes to include at least 20,000 people
- Gender
- Race
- Ethnicity
- Marital status

Statistical Method Provision

A person with appropriate knowledge and expertise:

- Applies generally accepted statistical and scientific principles and methods for rendering information not individually identifiable
- Makes a determination the risk is very small that the information could be used by itself or in

- combination with other available information by the anticipated recipients
- Document the analysis and results in making determination

Procedures

1. Complete de-identification certification and assurances, when study is approved.
2. Create de-identified reports using the Safe Harbor Method, or the Statistical Method.
3. Review data before designating it as de-identified.
4. Secure any code developed to re-identify the data.

Electronic Data Storage and Security

The increasing use of electronic data collection and storage must be addressed in current research protocols. Traditionally the researcher was able to discuss locked rooms, locked filing cabinets and proper paper handling procedures. These physical security precautions must be complemented by electronic security protections to include data encryption, firewalls, and user identity management to ensure the protection of electronic data sets used in IRB protected research.

The easy use of portable devices, the availability of web-based survey tools, and an awareness of Internet security require researchers to be able to evaluate confidentiality and data security when electronic data are collected and stored as part of IRB protected research.

The guidelines below apply to all studies involving electronic data where the participant is identifiable and data of a personal or health nature are involved.

Electronic data must be stored on devices that have appropriate security controls installed, such as password protection, firewall protection, anti-virus protection, automatic system patching and system backup. Users who are not involved in an approved specific research project or are no longer working on particular protocols must be removed from access to research data. For example, a folder common to an entire department is not an acceptable storage location for protected research data. Access to the research directory must be restricted to only the researchers listed on a protocol.

Researchers feel a strong sense of ownership of their data, and the security of that data is an ongoing responsibility. Many research protocols contain a longitudinal component where electronic data are maintained for several years. Protocols that contain a cross-walk table with PII to a random identifier are a particular concern. The crosswalk table file is required to be encrypted. De-identified data do not require encryption.

Laptop, jump drives, CD/DVD and other portable devices are required to have disk encryption when used to store PHI, PII, FERPA or IRB protected research data of any type. All websites (typically web surveys) that accept PII of research participants must be protected by SSL encryption, and all file transfers of data collected must be done by secure protocols such as HTTPS or SFTP.

Researchers who manage their own systems and servers must thoroughly understand the implications and protections required. Departmental IT staff should be consulted about assistance with data security controls and for assistance in application of data security. Departments vary in the breadth and scope of their local resources and may have specific security procedures.

UNIVERSAL CONFIDENTIALITY STATEMENT

Students and faculty members are sometimes assigned to a clinical agency via contractual agreement or Memorandum of Understanding between the Louisiana Tech University and the agency. In this case, the Tech representative may be allowed access to the records of clients, employees, research subjects or operational business information (specific to the agency and/or its affiliated third parties, and licensed products or processes). Information specific to clients, employees or subjects from any source in any form, including, but not limited to, paper records, oral communication, audio recording, electronic display, and research data files is strictly confidential. Access to confidential clients/subjects information is permitted only on a need-to-know basis and limited to the minimum amount of confidential information necessary to accomplish the intended purpose of the use, discloser or request. Information obtained for research purposes much be de-identified according to "safe harbor," statistical de-identification, and limited data set provisions, as described above.

It is the policy of Louisiana Tech University that students, faculty, and staff shall respect and preserve privacy and confidentiality of clients/subjects information, regardless of the agency to which the student or faculty is assigned.

Violations of this policy include, but are not limited to:

- accessing confidential information that is not within the scope of your assignment;
- misusing, disclosing without proper authorization, or altering confidential information;
- disclosing to another person your sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
- using another person's sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
- intentional or negligent mishandling or destruction of confidential information;
- leaving a secured application unattended while signed on;
- attempting to access a secured application or restricted area without proper authorization or for purposes other than official business
- failing to take proper precautions for preventing unintentional disclosure of confidential information; or
- failing to properly secure research data files.

Violation of this policy by students, faculty or staff assigned to any agency with which Louisiana Tech University has a Contractual Agreement or Memorandum of Understanding, may constitute grounds for corrective action, up to and including, loss of agency privileges, academic or employment suspension, or termination in accordance

with applicable agency or University procedures. Violation of this policy by any member of the University's body, faculty, or staff may constitute grounds for termination of the contractual relationship or other terms of affiliation between the University and the agency. Unauthorized release of confidential information may also subject the violator to personal, civil, and/or criminal liability and legal penalties.

INFORMATION SECURITY POLICY

Scope

The scope of information security is protection of information that is written, spoken, recorded electronically or printed, from accidental or intentional misuse, modification, mishandling, destruction or disclosure. Information will be protected throughout its life cycle (origination, entry, processing, distribution, storage and disposal).

Policy

Information, as hereinafter defined, in all its forms and throughout its life cycle will be protected in a manner consistent with its sensitivity and value to any agency to which a student, staff or faculty member is assigned via contractual agreement or Memorandum of Understanding between Louisiana Tech University and the agency. This protection includes an appropriate level of security over the equipment and software used to process, store, and transmit information.

This policy applies to all information which includes clinical information generated in the context of patient care, course requirements or clinical research, including, for example, laboratory data, x-ray results, results of other tests and procedures, dictated and written notes detailing patient histories and physical exam findings, personnel records and operational information. Such client/employee/subject-related data may be available electronically, or in written form in standard medical records, patient charts, employee files and/or business documents. It may be available for individual or groups of clients/employees/subjects. Such information may reside in large central computer databases, such as those maintained by large hospitals and academic health centers where it can be made available electronically to peripheral workstations, such as clinical workstations or peripheral clinical or personnel databases maintained by individual agency personnel. It may also reside in databases that are separate from the centrally maintained databases, such as the clinical, operation, personnel or research databases that have been developed by certain agency personnel members.

9.0 Protocol Changes or Problems

9.1 Protocol Modification / Amendment

Approval for any modification or change to a protocol instrument or consent document under IRB jurisdiction must be approved by the IRB (except for minor items such as correction of grammatical and typographical errors). Modification requests will be reviewed in the same way as the original proposal.

Minor changes in previously approved research during the period for which approval is authorized by may be reviewed through an expedited review procedure, § .110(b)(ii).

9.2 Adverse Event Reporting

An adverse event is any unanticipated reaction or event related to human subject research which has a harmful effect on the subject. It may be physical, psychological or social.

Adverse events should be immediately reported whether or not the investigator believes them to be caused by the study. The investigator should report any measures taken for the benefit of the subject and to mitigate the potential of recurrences.

PI's are required to report adverse events as promptly as possible after they occur. The IRB requires an immediate report of the problem, and one or more follow-up reports detailing how it was resolved, and what steps were taken to prevent its recurrence. The Chair will evaluate each adverse event report and determine whether it needs further action beyond that taken by the investigator. The Chair will inform the Vice President of Research of any adverse events reported.

Options include seeking further information, temporarily suspending the study, discussing the matter at an emergency or regular meeting of the IRB, and there determining what further action to take, up to permanent suspension of the project. It may be appropriate to require modification of the consent form if the adverse event represents a previously unrecognized risk to participants.

9.4 Notification of Non-compliance

Any serious or continuing noncompliance with TECH's Assurance or 45 CFR 46 of which the IRB becomes aware shall be reported by the IRB to the Institutional Official, and if required, thence to OHRP.

Adverse events that are determined by the IRB to be study-related and which result in serious harm (physical, psychological or social) to a subject shall be reported to the Institutional Official, who shall determine if a report to OHRP is required or advisable; he will also determine what reporting within the University administration is required.

10.0 Collaborative Research and Performance Sites

It is the policy of the Tech HUC that all non-exempt human subjects research (HSR) in which Tech is engaged and/or which is conducted at a Tech location must be approved by the IRB.

10.1 Louisiana Tech investigators collaborating with non-Tech investigators or sites

<u>Tech Investigator collaborating with an Unaffiliated Investigator (UI) to conduct HSR at a Tech or non-Tech location</u>

When a Tech investigator proposes to collaborate with an UI to conduct human subjects research, the Tech investigator must describe activities of the UI in the IRB application so that the Tech HUC staff may make a determination as to whether the UI is engaged in human subjects research.

When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party. When the researcher is the lead researcher of a multi-site study, applications include information about the management of information that is relevant to the protection of participants, such as:

- Unanticipated problems involving risks to participants or others.
- Interim results.
- Protocol modifications.

When the researcher is the lead researcher of a multi-site study, the IRB evaluates whether the management of information that is relevant to the protection of participants is adequate.

a. Unaffiliated Investigator not engaged in HSR

If the Tech HUC determines the UI is not engaged in human subjects research, HUC approval will not be required of the UI. However, if the UI is associated with an institution with its own IRB, the Tech HUC may suggest or require the UI to confer with the IRB of that institution, and may require documentation of that decision.

b. Unaffiliated Investigator engaged in HSR

If the Tech HUC determines the UI is engaged in human subjects research, the UI must have the project approved or determined to be exempt by an IRB. In cases of federally-funded, non-exempt human subjects research, the research must be reviewed and approved by an IRB designated on an FWA (Federal Wide Assurance).

i. If the UI belongs to an institution with an FWA, it will be expected that the covered institution will provide IRB review of the project by an IRB designated on its FWA. However, other arrangements may be made for IRB review, including petition of the TECH HUC to serve as IRB of Record for the UI as described below.
ii. If the UI belongs to an institution with an IRB but lacks an FWA, the Tech HUC will request the approval of that institution's IRB but may require other arrangements for HUC review of the project, such as the Tech HUC serving as IRB of Record.
iii. If the UI does not belong to an institution with either an FWA or an IRB, or is acting as an independent consultant apart from any such affiliation, other arrangements must be made for IRB review, such as the Tech HUC serving as IRB of Record.

In instances where an UI is acting as an independent consultant or otherwise separate from an institution with which he or she normally has an affiliation, the Tech HUC must

receive documentation on that institution's letterhead from the IRB or other appropriate office that the individual is in fact unaffiliated with said institution for the given project.

Whenever the Tech HUC is petitioned to serve as the IRB of Record for an UI, such an arrangement will be made at the discretion of the appropriate officials as described below.

In instances in which an UI is affiliated with a FWA-holding institution, but officials of both institutions agree for the Tech HUC to serve as IRB of Record, an IRB Authorization Agreement must be executed. For non-exempt research, the arrangement must be approved by a subcommittee of the Convened IRB and the Tech Institutional Official. The subcommittee will consist of the Chair, Vice Chair, and another member of the IRB named by the Chair. All three members of the subcommittee must participate to conduct business.

In instances in which an UI is not affiliated with a FWA-holding institution, an Individual Investigator Agreement (IIA) must be executed for the Tech HUC to serve as IRB of Record. Use of the Individual Investigator Agreement must comply with OHRP Guidance titled "Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement."

In any case, when the Tech HUC is to serve as IRB of Record, unaffiliated investigators must satisfy the requirements for human subjects protections training or the equivalent as determined by chair or designated IRB/HUC member .

In addition to those circumstances described above, the Tech IRB/HUC will in certain circumstances agree to defer to another IRB designated on an FWA in regard to the activities of a Tech Investigator engaged in HSR. Such an arrangement may be considered, for example, when the project is conducted primarily by investigators at the other institution with minimal involvement of the Tech Investigator. In such a case, the agreement to defer to another IRB may be made with the approval of the IRB Chair and the Tech Institutional Official, with a subsequent report made to the Convened IRB for informational purposes.

However, the IRB Chair may defer the decision to the Convened IRB. Prior to entering into an IRB Authorization Agreement allowing another institution to serve as the Tech IRB of Record, the Tech HUC will seek to ensure that the designated institution has AAHUC accreditation. Whether or not the designated institution has AAHUC accreditation, the IRB Authorization Agreement or MOU must describe how the responsibilities are divided between Tech and the other institution's IRB and will ensure that the Tech HUC will receive documentation pertaining to the study including but not limited to IRB minutes, investigator education, reports such as problems, noncompliance, and closing reports.

<u>Tech Investigator engaged in HSR at a non-Tech location</u>

Whenever a Tech Investigator conducts HSR at a non-Tech location, the Tech Investigator must include with the HUC application information necessary to ensure the protection of human research participants and required communication between the

Tech HUC and other sites. Additionally, the form must be accompanied by a letter or email of permission from an appropriate entity (IRB or Research Review Committee) addressing the items outlined in the application form. If the site has an IRB, this permission must come from the IRB. If the institution is engaged in research, the non-Tech IRB approval letter will suffice as the permission letter.

These requirements only apply if the research is to be physically conducted on site at the non-Tech location. For example, an organization providing information to prospective research participants does not necessitate a written permission letter if that is the extent of their involvement.

If a school is to be involved, the permission letter must come from an administrator at the Principal or Vice/Assistant-Principal level, or from the school district's Superintendent in accordance with the school's policies. The Tech HUC will accept the letter or email of permission as indication of compliance with the school's policies.

For research not funded by the US Department of Education:

The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a parent.
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect study privacy that are provided by the agency in the event of the administration or distribution of a survey to a study containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
    - Political affiliations or beliefs of the student or the student's parent.
    - Mental or psychological problems of the student or the student's family.
    - Sex behaviors or attitudes.
    - Illegal, anti-social, self-incriminating, or demeaning behavior.
    - Critical appraisals of other individuals with whom respondents have close family relationships.
    - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
    - Religious practices, affiliations, or beliefs of the student or the student's parent.
    - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program.
- The right of a parent of a student to inspect, upon the request of the parent, any instructional materials used as part of the educational curriculum for the student.

- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to a student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangement to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
- The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

Tech investigator engaged in HSR as part of outside employment or practice of profession (including consulting)

When a Tech affiliate engages in outside employment to conduct HSR, such an arrangement will not engage Tech in research. In accordance with Tech Policy 1416 - Outside/Dual Employment & Dual Office Holding, employees desiring to engage in outside employment must submit the Disclosure of Outside Employment form.

When engaging in outside employment to conduct HSR, the Tech employee must disclose this arrangement to the Tech HUC. The disclosure Form, signed by all applicable parties, must be submitted to the Tech HUC to document such an arrangement so that Tech HUC approval is not required. Tech employees engaging in outside employment will not ordinarily be covered by the Tech HUC for associated HSR activities and will have to make other arrangements for IRB approval of their activities. The Tech employee may petition the Tech HUC to cover those activities, but such an arrangement will be made only with the approval of the Convened IRB and the Tech Institutional Official.

Tech Investigator proposing to conduct human subjects research internationally, or domestically with non-English speaking subjects and/or subjects from a foreign culture

In addition to other requirements of this policy regarding UIs and non-Tech locations for HSR, when HSR is to be conducted internationally, or conducted domestically with non-English speaking participants and/or participants from a foreign culture (to include American Indian reservations), the HUC must have knowledge of the local research context in accordance with OHRP Guidance titled “IRB Knowledge of Local Research Context.”

The HUC must either have members with the appropriate knowledge or obtain consultation from individuals with appropriate knowledge of the local research context. The appropriate individual must have personal knowledge of the local research context,

such knowledge having been obtained through extended, direct experience with the research institution, its subject populations, and/or its surrounding community.

It is preferable to obtain a local context review from an IRB listed on an FWA at an institution located geographically near the site of the research. However, if this is not a possibility, the review may be conducted by a consultant to the HUC.

During the initial review, the International Compilation of Human Research Standards will be referenced for additional safeguards for research conducted with international populations. For Convened IRB Review, if the local context review is provided in writing, it must be included in the meeting packet for IRB members in advance of the meeting.

10.2 Unaffiliated Investigator (UI) proposing to conduct human subjects research (HSR) at a Tech location without collaboration of a Tech Investigator

When an Unaffiliated Investigator proposes to conduct HSR at a Tech location, the UI must contact the HUC for a determination as to whether Tech is engaged in the HSR. An unaffiliated investigator is one who does not have an official association with Tech. This determination is required if Tech will release prospective subjects' information to the non-Tech investigator, or provide prospective subjects with information regarding the research. Such a determination is not required for researchers who will directly contact Tech-affiliated individuals regarding the availability of research without physically visiting a Tech location (e.g., contact by phone, mail, or e-mail only).

a. Tech not engaged in HSR

If it is determined by the HUC staff chair that Tech is not engaged in HSR, the activity will be allowed to commence after the approval of the appropriate Tech Dean, Director, or Department Head (D/D/D). The UI may be required to submit documentation of IRB and D/D/D approval to the Tech HUC. The Tech HUC reserves the right to review any materials associated with the research to ensure compliance with this policy. However, the Tech HUC will not serve as IRB of record for research in which Tech is not engaged.

In general, an institution is considered to be engaged in human subject research when its employees or agents:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (§46.102(e)(1)(i) and (ii)).

Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

In general, an institution is considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution. In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects' permission for investigators to contact them are not considered engagement in research. However, obtaining informed consent from a research participant is considered engagement in research.

(For more details, please see OHRP guidance on this topic
at: http://www.hhs.gov/ohrp/policy/engage08.html, specifically, Section (B) (4))

b. Tech engaged in HSR

If it is determined by the HUC that Tech is engaged in HSR, the UI will be required to have a Tech faculty or staff member who agrees to serve as Principal Investigator at Tech to oversee the research conducted at the Tech location. The UI must have IRB approval from an IRB listed on an OHRP-approved Federalwide Assurance (FWA). The activities of the Tech Investigator will be reviewed via normal procedures of the Tech HUC.

10.3 Other Circumstances

Any other circumstances regarding TECH affiliates and/or TECH locations associated with the conduct of human subjects research not described here-in will be considered on their own merits by the IRB Chair and/or VP-Research and action taken as deemed appropriate. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

Membership of the Institutional Review Board and Human Use Committee

Member Name	Degree or Other Credentials	Position or Title (if any)	Affiliation with Institution (If none, state)
Abbott, Dena	Ph.D. (S)	Asst. Professor Counseling Psychology & Behavioral Sciences	Louisiana Tech University dabbott@latech.edu
Colvin, Lauren	MBA (N)	Asst. Professor Health Informatics & Information Management	Louisiana Tech University lcolvin@latech.edu
Dickerson, Marcia	Ph.D. (S)	College of Business	Louisiana Tech University marcia@latech.edu
Griswold, Ed	Ph.D. (S)	Environmental Safety	Louisiana Tech University egris@latech.edu
Hohlt, Rick	Mr. (N)	Retired-Ruston Daily Leader	600 Hummingbird Lane rickhohlt@suddenlink.net
Holly, Kevin	Ph.D. (S)	Director, Laboratory Animal Facilities	Louisiana Tech University kholly@latech.edu
Kordal, Richard	Ph.D. (S)	Director of Intellectual Properties	Louisiana Tech University rkordal@latech.edu
Norris, Davy	Ph.D. (S)	Chief Research & Innovation Officer	Louisiana Tech University dnorris@latech.edu
O'Neal, Patrick	Ph.D (S)	Biomedical Engineering	Louisiana Tech University poneal@latech.edu
Pierce, Latoya	Ph.D. (S)	Psychology & Behavioral Science	Louisiana Tech University lapierce@latech.edu
Postel, Doug	Provost/ Administrator (N)	La Delta Community College Campus Director	None dougpostel@ladelta.edu
Stokley, Gary	Ph.D. (S)	Keller Williams Realty	None garystokley@gmail.com
Yates, Amy	Ph.D. (S)	Human Ecology	Louisiana Tech University yates@latech.edu

S – Scientist, N – Non-Scientist

Barbara Talbot, IRB/Human Use Administrative Assistant (318)257-5075

Appendix: Forms and Samples

IRB PROPOSAL EXEMPT CHECK-OFF FORM- Studies involving vulnerable populations cannot be exempt

(For use by reviewer only)

Project #: _____

Title of Proposal: _____

Name of Principal Investigator (s): _____

Date of Submission: _____

Instructions: Please check the criterion used to exempt proposal

CRITERION

_____1. No specially protected subjects are involved (children, prisoners, pregnant women etc.).

_____2. Project conducted in an established educational setting involving normal educational practices, instructional strategies, effective educational techniques methods or curricula. (45 CFR 46.101b (1)

_____3. Project only uses de-identified educational tests, survey procedures, interview procedures, or observation of public behavior without intervention.

_____4. Project involves only collection of existing (prior to study) and/or study of de-identified data or Specimens (publicly available, de-identified by researcher).

_____5. Study only involves evaluation or examination, public benefit or service programs.

_____6. Study involves taste and food quality evaluation of wholesome food without additives or consumer acceptance studies.

RECOMMENDATIONS (LIST ACCEPTANCE OR ANY SUGGESTED ALTERATIONS TO STUDY)

Name of Reviewer: _____

Date of Review: _____

IRB PROPOSAL EXPEDITED REVIEW CHECK-OFF FORM- Studies involving vulnerable populations cannot be expedited

(For use by reviewer only)

Project #: _____

Title of Proposal: _____

Name of Principal Investigator (s): _____

Date of Submission: _____

Expedited review only applies to projects that present no more than minimal risk to human subjects and applied to one or more of the following categories. Subject consent is required:

Instructions: Please check the criterion used to expedite proposal (Source: 63 FR 60364-60367)

_____1. Research of drugs and medical devices for which an investigational new drug or device application is not required.

_____2. Research involving human blood or tissues collected from subjects that have given consent to do so.

_____3. Research involving data, documents, records or specimens that have been collected or will be collected solely for non-research purposes.

_____4. Collection of data from voice, video, digital, or image recording for research purposes.

_____5. Research on characteristics or behavior including perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior. This research can employ surveys, interviews, oral history, focus groups, program or human factor evaluation or quality assurance methodologies.

_____6. Continuing review of research previously approved by non-exempt or non-expedited IRB process which is closed to enrollment of new subjects, in which all subjects have completed research-related interventions, where no additional risk have been identified and where remaining activities are limited to data analysis

Name of Reviewer: _____

Date of Review: _____

IRB PROPOSAL FULL IRB COMMITTEE REVIEW CHECK-OFF FORM-

(For use by reviewer only)

Project #: _____

Title of Proposal: _____

Name of Principal Investigator (s): _____

Date of Submission: _____

Instructions: Please check the criterion used to identify proposals requiring full review

CRITERIA

_____1. Research involves participants in a protective class (specify class:_____).

_____2. Research involves Invasive physiological or medical research.

_____3. Research where there is a risk that confidentiality could be violated and if breached could result in potential criminal or civil liability or damage to a subject's financial standing, employability, or reputation.

_____4. Research involving deception of research subjects.

Name of Reviewer: _____

Date of Review: _____

HUMAN USE COMMITTEE REVIEW
APPROVALS FOR SUBMISSION

This page must be signed by the Principal Investigator, other investigators, and the Department Head or Dean of the Principal Investigator, when submitting a proposal to the Human Use Committee for expedited approval.

Signatures on this form indicate that each responsible party is aware of this proposal and/or survey being conducted, and that all aspects of the study comply with the appropriate University Policies and Procedures.

(Print or type below)

_____
Department

_____ _____
Faculty Member Serving as Principal Investigator (Signature) Date

_____ _____ _____
Student Researcher (If applicable) Academic Program Date

_____
Department Head Name (Print)

_____ _____
Department Head Date
(Actual Original Signature Required)

Checklist for definition of research:

Do you plan to publish this study?	□ **YES** □ NO
Will this study be published by a national organization?	□ **YES** □ NO
Are copyrighted materials involved?	□ **YES** □ NO
Do you have written permission to use copyrighted materials?	□ **YES** □ NO
Researchers must comply with all training requirements from their funding agency.	
COMMENTS:	

STUDY/PROJECT INFORMATION FOR HUMAN SUBJECTS COMMITTEE

Describe your study/project in detail for the Human Subjects Committee. Please include the following information.

TITLE:

PROJECT DIRECTOR(S):
Contact Information (Title, Department, E-mail, Phone)

PURPOSE OF STUDY/PROJECT:

SUBJECTS:

PROCEDURE:

BENEFITS/COMPENSATION:
If extra credit is offered to students participating in research, an alternative extra credit that requires a similar investment of time and energy will also be offered to those students who do not choose to volunteer as research subjects.

RISKS, DISCOMFORTS, ALTERNATIVE TREATMENTS:

SAFEGUARDS OF PHYSICAL AND EMOTIONAL WELL-BEING:

HUMAN SUBJECTS CONSENT FORM

Note: Use the Human Subjects Consent form to briefly summarize information about the study/project to participants and obtain their permission to participate. Assure that subjects in protected classes (e.g. prisoners, pregnant women or human fetuses or neonates, children) are provided complete information about the risks and benefits.

The following is a brief summary of the project in which you are asked to participate. Please read this information before signing the statement below. You must be of legal age or must be co-signed by parent or guardian to participate in this study.

TITLE OF PROJECT:

PURPOSE OF STUDY/PROJECT:

SUBJECTS:

PROCEDURE:

BENEFITS/COMPENSATION:

RISKS, DISCOMFORTS, ALTERNATIVE TREATMENTS: The participant understands that Louisiana Tech is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

The following disclosure applies to all participants using online survey tools: This server may collect information and your IP address indirectly and automatically via "cookies".

I, _____, attest with my signature that I have read and understood the following description of the study, "_____", and its purposes and methods. I understand that my participation in this research is strictly voluntary and my participation or refusal to participate in this study will not affect my relationship with Louisiana Tech University or my grades in any way. Further, I understand that I may withdraw at any time or refuse to answer any questions without penalty. Upon completion of the study, I understand that the results will be freely available to me upon request. I understand that the results of my survey will be confidential, accessible only to the principal investigators, myself, or a legally appointed representative. I have not been requested to waive nor do I waive any of my rights related to participating in this study.

_____ _____

Signature of Participant or Guardian Date

CONTACT INFORMATION: The principal experimenters listed below may be reached to answer questions about the research, subjects' rights, or related matters.

Principal Investigator: _____

Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenters:

Dr. Richard Kordal, Director of Intellectual Properties (318) 257-2484 rkordal@latech.edu

STUDY/PROJECT INFORMATION FOR HUMAN SUBJECTS COMMITTEE

Describe your study/project in detail for the Human Subjects Committee. Please include the following information.

TITLE: An exploration of personality characteristics and mood state.

PROJECT DIRECTOR(S): Professor XYZ
EMAIL: xxx
PHONE: xxx
DEPARTMENT(S): Behavioral Sciences

PURPOSE OF STUDY/PROJECT: To determine the relationship, if any, between socialized personality characteristics and mood state.

SUBJECTS: Louisiana Tech University students selected from psychology classes.

PROCEDURE: Approximately 200 students from introductory psychology classes will voluntarily complete a packet of self-report inventories, including a sex role questionnaire, a depression inventory, and a self-efficacy survey. Data will then be analyzed to determine the relationship among these variables.

INSTRUMENTS AND MEASURES TO INSURE PROTECTION OF CONFIDENTIALITY, ANONYMITY: The 21 items Beck Depression Inventory (BDI) developed by Aaron T. Beck will be used to assess mood. The Bem Sex-Role Inventory (BSRI), a 60 item inventory developed by Sandra Bem, will be utilized to assess sex-role. The 27 item Self-Efficacy Scale (SES) developed by Robert Tipton and Everett Worthington will be used to measure self-efficacy. Additionally, a brief self-report instrument developed by the researchers will be used to collect demographic information and additional characteristics. All collected information will be held confidential and only viewed by the researchers

RISKS/ALTERNATIVE TREATMENTS: The participant understands that Louisiana Tech is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

BENEFITS/COMPENSATION: None

SAFEGUARDS OF PHYSICAL AND EMOTIONAL WELL-BEING: This study involves no treatment or physical contact. All information collected from the survey will be held strictly confidential. No one will be allowed access to the survey other than the researchers.

Note: Use the Human Subjects Consent form to briefly summarize information about the study/project to participants and obtain their permission to participate.

Louisiana Tech University
Institutional Review Board
De-identification Certification Form

Principal Investigator: _____

Project Title: _____

In order to be exempt under privacy provisions, each of the following (safe harbor) identifiers of the research subjects or of their relatives, employers, or household members must be removed prior to disclosure.

Note: Scrambling of names and social security numbers is not considered de-identifying health information.

By completing this form, you are certifying that, as principal investigator of this study, and on behalf of the research team assisting you, neither you nor your research team will disclose the following subject identifiers from any health information obtained for use in a research study to which this form applies.

Review and verify that the following data elements will not be used and disclosed by checking each element.

1.	Names	
2.	All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code.	
3.	All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated in a single category of 90 or older.	
4.	Telephone Numbers	
5.	Fax Numbers	
6.	Electronic Mail Addresses	
7.	Social Security Numbers	
8.	Medical Record Numbers	
9.	Health Plan Beneficiary Numbers	
10.	Account Numbers	
11.	Certificate/license numbers	
12.	Vehicle Identifiers and Serial Numbers, including license plate numbers	
13.	Device Identifiers and serial Numbers	
14.	Web Universal Resource Locators (URLS)	
15.	Internet Protocol (IP) Address Numbers	
16.	Biometric Identifiers, Including Finger and Voice Prints	
17.	Full face Photographic Images and any Comparable Images	
18.	Any other unique identifying number, characteristic, or code	
19.	The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identity an individual who is a subject of the information.	

Investigator's Assurances

1. I certify protected health information (PHI) received or reviewed by research personnel for the research project referenced above does not include any of the identifiers listed above of the research subjects or their relatives, employers, or household members.

2. If I assign a code or other means of record identification, in order to allow information to be de-identified or re-identified:

    a. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and
    b. I will not use or disclose the code or other means of record identification for any purpose other than re-identification, and
    c. I will not disclose the mechanism (algorithm or other tool) for re-identification.

3. Before I allow a code to be used to re-identify this information,

    a. If the purpose of the re-identification is within the scope of the original research protocol, I will obtain approval of an amendment from the IRB and comply with the requirements of HIPAA: or
    b. If the purpose of the re-identification is outside the scope of the original protocol, I will submit a full new study proposal, obtain IRB approval and comply with the requirements of HIPAA.

4. I have completed and attached a data use agreement entered into with any individual and/or sponsor outside Louisiana Tech University covered entity to which statistically de-identified information will be used and/or disclosed.

5. I understand that the code or other means of record identification must not be disclosed to non Louisiana Tech entities.

_____

Principal Investigator/Responsible Investigator (if applicable) Date

Louisiana Tech University
Institutional Review Board
De-identification and Re-identification of Protected Health Information Policy

It is the policy of Louisiana Tech University to encourage the use and/or disclosure of de-identified health information when ever feasible. Louisiana Tech University will not use codes to re-identify data that are created as a derivation of protected health information and could possibly be used to identify individuals by persons using the de-identified data. If a code is used to re-identify the data it will be kept in a safe and secure location, and will not be shared with those using the de-identified data. Re-identification will require the same protection as individually identifiable data.

"Safe Harbor" Provision

"Safe Harbor" De-identification of health information as required by the Privacy Rule 45 CFR §164.514(a) states each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de-identified:

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:
    a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
    b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people changes to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers; license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

De-identified data may contain:

- Age with dates limited to the year
- Ages over 90 must be aggregated to 90+
- Aggregated zip codes in the form of initial 3 digit zip codes to include at least 20,000 people
- Gender
- Race
- Ethnicity
- Marital status

The covered entity does not have actual knowledge that information could be used alone or in combination with other information to identify an individual.

Statistical Method Provision

A person with appropriate knowledge and expertise:

- Applies generally accepted statistical and scientific principles and methods for rendering information not individually identifiable
- Makes a determination the risk is very small that the information could be used by itself or in
- combination with other available information by the anticipated recipients
- Document the analysis and results in making determination

Procedures

1. Complete de-identification certification and assurances, when study is approved:
2. Create de-identified reports using the Safe Harbor Method, or the Statistical Method.
3. Review data before designating it as de-identified.
4. Secure any code developed to re-identify the data.

UNIVERSAL CONFIDENTIALITY STATEMENT

As a student or faculty member assigned to a clinical agency via contractual agreement or Memorandum of Understanding between the Louisiana Tech University and the agency, you are allowed access to the records of clients, employees, research subjects or operational business information (specific to the agency and/or its affiliated third parties, and licensed products or processes). Information specific to clients, employees or subjects from any source in any form, including, but not limited to, paper records, oral communication, audio recording, electronic display, and research data files is strictly confidential. Access to confidential clients/subjects information is permitted only on a need-to-know basis and limited to the minimum amount of confidential information necessary to accomplish the intended purpose of the use, discloser or request. Information obtained for research purposes much be de-identified according to "safe harbor," statistical de-identification, and limited data set provisions.

It is the policy of Louisiana Tech University that students, faculty, and staff shall respect and preserve privacy and confidentiality of clients/subjects information, regardless of the agency to which the student or faculty is assigned. Violations of this policy include, but are not limited to:

- accessing confidential information that is not within the scope of your assignment;
- misusing, disclosing without proper authorization, or altering confidential information;
- disclosing to another person your sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
- using another person's sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
- intentional or negligent mishandling or destruction of confidential information;
- leaving a secured application unattended while signed on;
- attempting to access a secured application or restricted area without proper authorization or for purposes other than official business
- failing to take proper precautions for preventing unintentional disclosure of confidential information; or
- failing to properly secure research data files.

Violation of this policy by students, faculty or staff assigned to any agency with which Louisiana Tech University has a Contractual Agreement or Memorandum of Understanding, may constitute grounds for corrective action, up to and including, loss of agency privileges, academic or employment suspension, or termination in accordance with applicable agency or University procedures. Violation of this policy by any member of the University's body, faculty, or staff may constitute grounds for termination of the contractual relationship or other terms of affiliation between the University and the agency. Unauthorized release of confidential information may also subject the violator to personal, civil, and/or criminal liability and legal penalties.

I have read and agree to comply with the terms of the above statement and will read and comply with all agency and University policies and standards relative to confidentiality and information security. A copy of the Information Security Policy is attached.

Please check one ☐ Faculty ☐ Student ☐ Staff

_____ _____

Signature **Date**

Louisiana Tech University
Institutional Review Board

INFORMATION SECURITY POLICY

Policy

Information, as hereinafter defined, in all its forms and throughout its life cycle will be protected in a manner consistent with its sensitivity and value to any agency to which a student, staff or faculty member is assigned via contractual agreement or Memorandum of Understanding between Louisiana Tech University and the agency. This protection includes an appropriate level of security over the equipment and software used to process, store, and transmit information.

This policy applies to all information which includes clinical information generated in the context of patient care, course requirements or clinical research, including, for example, laboratory data, x-ray results, results of other tests and procedures, dictated and written notes detailing patient histories and physical exam findings, personnel records and operational information. Such client/employee/subject-related data may be available electronically, or in written form in standard medical records, patient charts, employee files and/or business documents. It may be available for individual or groups of clients/employees/subjects. Such information may reside in large central computer databases, such as those maintained by large hospitals and academic health centers where it can be made available electronically to peripheral workstations, such as clinical workstations or peripheral clinical or personnel databases maintained by individual agency personnel. It may also reside in databases that are separate from the centrally maintained databases, such as the clinical, operation, personnel or research databases that have been developed by certain agency personnel members.

Scope

The scope of information security is protection of information that is written, spoken, recorded electronically or printed, from accidental or intentional misuse, modification, mishandling, destruction or disclosure. Information will be protected throughout its life cycle (origination, entry, processing, distribution, storage and disposal).

EXAMPLES OF BREACHES OF CONFIDENTIALITY

Accessing information that is not within the scope of your job/role as student, staff or faculty member: • Unauthorized reading of client/employee/subject account information; • Unauthorized reading of a client's/subject's chart; • Unauthorized access of personnel file or business/operational information; • Accessing information that you do not "need-to-know" for proper execution of your job functions.	**Misusing, disclosing without proper authorization, or altering confidential information:** • Making unauthorized marks on a medical record; • Making unauthorized changes to a personnel file or research data files; • Sharing or reproducing information in a client's/subject's chart or personnel file with unauthorized personnel; • Discussing confidential information in a public area such as a waiting room or elevator
Disclosing to another person your sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas: • Telling a co-worker your password so that he or she can log in to your work; • Telling an unauthorized person the access codes for personnel files or patient accounts.	**Using another person's sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas:** • Using a co-worker's password to log in to the hospital's computer system; • Unauthorized use of a login code for access to personnel files or client/subject information, or restricted areas.
Intentional or negligent mishandling or destruction of confidential information: • Leaving confidential information in areas outside your work area, e.g. the cafeteria or your home; • Disposing of confidential information in a non-approved container, such as a trash can.	**Leaving a secured application unattended while signed on:** • Being away from the desk area while logged into an application; • Allowing another person to use your secured application for which he or she does not have access after you have logged in.
Attempting to access a secured application or restricted area without proper authorization or for purposes other than official business: • Trying passwords and login codes to again access to an unauthorized area of the computer system or restricted area; • Using a co-worker's application for which you do not have access after he or she is logged in.	**Unintentional disclosure of patient information:** • Failure to take necessary precautions to properly prevent unauthorized viewing of displayed confidential information in public areas; • Discussing confidential patient information in public areas; • Inappropriately removing documents containing confidential information from clinical areas.

The examples above are only a few types of mishandling of confidential information. If you have any questions about the proper handling, use or disclosure of confidential information, please contact your supervisor or supervising faculty member immediately.

SAMPLE MEMO FROM NON-TECH COLLABORATING INSTITUTION IRB

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

Sample Parental Permission Form

Project Title: Comparison of Strategies for Addressing Some Kind of Behavior

Performance Site: X Elementary School

Investigators: The following investigator is available for questions, M-F, 8:00 a.m.-4:30 p.m. Dr. Jane Doe Psychology Dept., LSU (504) 578-0000

Purpose of the Study: The purpose of this research project is to develop effective strategies for teachers to use with students in a certain category of behavior .

Inclusion Criteria: Children 6-9 years of age whose teachers have referred them for certain behavior. To participate in this study you must meet the requirements of both the inclusion and exclusion criteria.

Exclusion Criteria: Children who do not meet the age requirements or who have not been referred for disruptive behavior, or whose teachers do not use time-out in their classrooms.

Description of the Study: Over a period of one month, 2-3 days per week, the investigator, posing as a teacher's aide, will observe subjects' certain behavior, assign specific tasks to the subjects, and will use three intervention techniques with the subjects: describe each one …

Benefits: Subjects will have the opportunity to earn "awards" for performance of tasks assigned by the "teacher's aide." The study may identify new strategies which will help the subjects to …
Risks: There are no known risks.
Right to Refuse: Participation is voluntary, and a child will become part of the study only if both child and parent agree to the child's participation. At any time, either the subject may withdraw from the study or the subject's parent may withdraw the subject from the study without penalty or loss of any benefit to which they might otherwise be entitled.

Privacy: The school records of participants in this study may be reviewed by investigators. Results of the study may be published, but no names or identifying information will be included for publication. Subject identity will remain confidential unless disclosure is required by law.

Financial Information: There is no cost for participation in the study, nor is there any compensation to the subjects for participation.

Signatures: The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigator. If I have questions about subjects' rights or other concerns, I can contact Dr. L, IRB Chairman, at this number.

I will allow my child to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of this consent form.
Parent's Signature:_____ Date:_____

The parent/guardian has indicated to me that he/she is unable to read. I certify that I have read this consent from to the parent/guardian and explained that by completing the signature line above he/she has given permission for the child to participate in the study. Signature of Reader:_____ Date:_____

Sample Child Assent Form

I,_____, agree to be in a study to find ways to help children act better in school. I will have to do special school work for the teacher's aide in my classroom. Sometimes I will do math and reading. Other times I may get to play a game with another student. I have to follow all the classroom rules, even when I am working with the teacher's aide. I can decide to stop being in the study at any time without getting in trouble.

Child's Signature:_____

Age:_____ Date:_____

Witness* _____ Date:_____

* (N.B. Witness must be present for the assent process, not just the signature by the minor.)