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LANGSTON UNIVERSITY

Institutional Review Board

Policies and Procedures Handbook

Approved
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Langston University Institutional Review Board Policies and Procedures

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Introduction

A. Role and Scope

The Institutional Review Board (IRB) will ascertain the acceptability of all proposed human subject research at Langston University. The IRB will ascertain acceptability in terms of institutional commitments and regulations, applicable law, and professional conduct and practice standards. The IRB will be primarily concerned with the protection (level of risk) of human subjects in research. Research proposals involving human subjects and being submitted to external agencies for funding must be reviewed by the IRB prior to proceeding with the grant application. Copies of IRB Policies and Procedures will be made available to the Assessment and Accreditation Liaison Officer, Office of Institutional Advancement and Sponsored Programs, administration, faculty, and students.

B. Membership

- The IRB shall have at least ten (10) members with varying backgrounds based on: a) experience and expertise in professional and community affairs, and at least one scientist member, b) consideration of diversity, including race, ethnicity, gender, and cultural backgrounds, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- The IRB may not consist entirely of one gender or members of one profession.
- The IRB shall include at least one member whose primary concerns are in non-scientific areas (e.g., lawyer, ethicist, member of the clergy).
- The IRB shall include at least one student member.
- The IRB may not have a member who participates in the IRB's initial or continuing review of any project in which the member has a vested interest, except to provide the information requested by the IRB.
- The IRB may invite individuals with competence in particular areas to assist in the review of complex issues that require expertise beyond that available by members of the IRB. That invited individual may not vote.
- The Chairperson and all IRB members will be appointed using the University's procedure for committee assignment.
- The Chairperson will be appointed for three consecutive years.
- Four members will be appointed for three consecutive years.
- Three members will be appointed for two consecutive years.
- Two members will be appointed for a one-year term.
- An individual with a two- or one-year term may be appointed to a three-year term when the opening becomes available.
- New members appointed to the IRB should be recruited to meet the professional qualifications, areas of expertise, and gender similarities of members vacating positions on the IRB to maintain the necessary composition of the IRB.

C. Meetings

The IRB will meet one time per month, on the first Thursday of the month or on a date selected by a 2/3 majority of committee members. Researchers who wish or need to make a presentation in support of their proposal review request will be notified at least five (5) working days prior to the meeting. If a conflict exists with the scheduled meeting, IRB members must respond in writing and are encouraged to offer comments on any proposal(s) to be discussed at the meeting. Such correspondence from members shall become part of the documentation of the project review. In addition, minutes for the meetings will be recorded and shared with the IRB.

For emergency purposes only, a second meeting, scheduled by the IRB, may be called to review proposals received **after** the deadline for the scheduled monthly meeting.

D. Duties and Responsibilities

The IRB will review all proposals involving human subject research conducted at Langston University and/or in collaboration with other institutions. The IRB will approve, require modifications, or disapprove all research activities that involve human subjects.

The IRB will notify applicants of decisions made by the IRB concerning their proposed research. In addition, the IRB will conduct periodic reviews of ongoing research projects and maintain records of review proceedings, decisions, and activities, in accordance with Federal and University guidelines, for at least three (3) years following the termination of projects.

Definitions

Research

Research is any systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion conducted by Langston University faculty, staff, or students or that uses Langston University facilities, personnel or students is considered research and is subject to IRB approval. It does not matter whether the activity takes place within or as part of another activity (such as a demonstration or services program) or whether the research is the whole project.

When gathering data within the context of training, demonstration, or service projects, a project director may be asked several questions to determine if the work is research and requires IRB review:

- Will you seek out subjects, or settings that contain subjects, for your training, demonstration, or service project rather than the subjects seeking the service or training from you in their normal pursuit of professional services?
- Do you anticipate conducting the project in advance that you will analyze, interpret,

and disseminate the findings of your investigation?
- Is it possible that the knowledge you gain from your encounter with the subjects be applied beyond the service of the training project to a similar encounter to lead to a new procedure or process?
- If the project director answers "**yes**" to any of these questions, the training, demonstration, or service project has a research component.

1. **Instances of Non-Research**

   There are numerous forms of data gathering from human beings that do not constitute research, such as:

   - Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching.
   - Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. No dissemination of the information outside the unit or institution is foreseen or anticipated.
   - Evaluation data gathered for a contractor about a project or operation for which he/she is responsible if neither the researcher nor the contractor intends or anticipates the dissemination of the data.

   These three categories of data gathering fail to be research because there is no foreseeable dissemination of the data. Therefore, any record of the data remains private. If the researcher ever plans to disseminate data collected, he or she must request IRB approval.

2. **Theses and Dissertations**

   Theses and dissertations represent a special class of data record. By accepting a thesis or dissertation, the University disseminates its contents for use by others. Therefore, a thesis or dissertation involving human subjects at Langston University must always be submitted for review or certification of exemption from IRB review. In addition, theses and dissertations originating at another institution must have that institution's IRB approval or approval by an appropriate governing body, such as a thesis committee, prior to submission to the Langston University IRB for review.

Human Subjects

Definition of Human Subjects Research:
https://grants.nih.gov/policy/humansubjects/research.htm

According to 45 CFR 46, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private

information.

- **Intervention** generally includes both physical procedures by which one gathers data and manipulations of the subject performed for research purposes.
- **Interaction** includes communication or interpersonal contact (e.g., questionnaires, interviews, surveys) between the investigator and the subject.
- **Identifiable** means that the subject's identity is or may be readily ascertained by the investigator or associated with the information.
- **Private information** includes behavioral information within a context in which the individual can reasonably.
- Expect that no observation or recording is taking place. Thus, the individual will have provided information for specific purposes and can reasonably expect that information associated with his or her identity will not be made public.
- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Informed Consent

Informed consent is a primary ethical requirement underpinning human subject research. Therefore, the need for informed consent and the development of a legally effective consent document is vital in the design of research involving human subjects.

Informed consent is an ongoing process and the basis for meaningful exchange between the investigator and the research volunteer(s). No investigator may involve an individual in a research study until the investigator has obtained the legally effective written informed consent of the individual or the individual's legally authorized representative (e.g., parents; guardians). The consent form **must** be signed and dated by the subject (or his or her authorized representative) and the investigator, and it must be maintained in a secure location.

A. **Basic Elements** (Guidelines in **Appendix B**)

The basic elements to be included in a legally effective informed consent document are:

- A statement describing the study, its purpose(s), the duration of the subject's participation, a description of the procedures to be followed and the identification of any procedures that are experimental.
- A description of any foreseeable risks or discomforts to the subject and any benefits which may be reasonably expected.

- The possible alternative methods of treatment (if relevant).
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- A statement of whom to contact for answers to pertinent questions about the research subject's rights and whom to contact in the event of a research-related injury to the subject.
- An explanation of whether a subject is entitled to any compensation or will incur any costs from participation in the research.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is entitled. The subject may discontinue participation at any time without penalty or loss of benefits.
- A statement indicating that the participant has been provided written and verbal instructions identifying the process by which he or she may issue a complaint regarding conditions related to the research protocol and/or personnel involved in the research project.

B. Confidentiality

All information about the subject(s) participating in the research shall be handled in a confidential manner. Records shall not be used for any other purpose, nor shall they be shown to a third party, except as required by law. No subject's name or social security number shall be associated with any records; however, a subject may be assigned a study ID number. Study ID numbers shall be maintained in a locked file or a secure database accessible only to the Principal Investigator and/or Project Coordinator. No identifiable names shall be used in any publications of the research results.

C. Exceptions

The IRB may approve a consent procedure that does not include, or which modifies, some or all the elements of an informed consent document or may waive the requirement to obtain consent under the following conditions:

- The research cannot practicably be carried out without the waiver and either:

  1) It is a research demonstration project that is both a) directed or approved by the state, local, or tribal governments, and b) concerns only administrative-regulatory issues in service programs.
  2) It is research that involves no more than minimal risk and will give subjects pertinent information at the end (if appropriate). The waiver will not adversely affect subjects' rights or welfare.
     - The only record linking the subject and the research would be the informed consent document, and the principal risks would be potential harm resulting from a breach of confidentiality.
     - The research presents only minimal risk and involves no procedures

for which consent is normally required outside the research context.

- In cases where consent or documentation of consent is waived, the investigator may still be required to prepare a statement or information sheet containing the basic elements of the informed consent form which describe the project. A statement/information sheet would be distributed to the research subjects.

D. Specially Protected Individuals (See Appendix F)

Current government regulations recognize four groups of vulnerable subjects for whom additional guidelines have been prepared. These are:

- Children
- Pregnant women and fetuses/unborn children
- Prisoners
- Persons with mental disabilities

D. Health Insurance Portability and Accountability Act Authorization

Purpose:

To provide guidelines for researchers utilizing health information in human studies research at Langston University.

Definitions:

The following definitions are directly from NIH Publication Number 03-5388:

***Protected Health Information (PHI)*:** Individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act and employment records held by a covered entity in its role as employer.

***Covered Entity*:** a health plan, a health care clearinghouse, or a health care provider who transmits health information in the electronic form connected with a transaction for which HHS has adopted a standard.

***Authorization*:** An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose.

Overview:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule established a category of health information, Protected Health Information (PHI), which may only be used or disclosed in certain circumstances. Therefore, researchers wishing to utilize health information must ascertain whether the data

they want to collect falls within the HIPAA Privacy Rule.

Langston University is not a covered entity, and thus the preponderance of research conducted at Langston University will not be covered by the HIPAA Privacy Rule. However, those researchers planning to utilize health information in data collection must review the HIPAA Privacy rule guidelines.

Researchers will need to include an Authorization form with their IRB packet if:

a) the researcher intends to utilize a covered entity to recruit subjects

b) the researcher intends to collect PHI maintained by a covered entity as a data set in the research.
c) the researcher is a covered entity (a health care provider) and is including subjects in research protocol due to medical diagnosis and is utilizing PHI from a covered entity.
d) the researcher is a covered entity (health care provider) and is incorporating health care interventions for treatment in the research protocol and will be maintaining and transmitting PHI to the medical record set because of this intervention.

Self-reported health information is not considered PHI unless that information is added to a designated record set, i.e., records maintained by a covered entity to make health care decisions about the individual.

Those researchers seeking PHI in data collection or for subject recruitment must complete the “Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research” form and include this form with the IRB packet. This form is in addition to the required Informed Consent document. This form may be downloaded from the LU IRB website (**Appendix G**)

IV. Common Rule

Common Rule Update:

IRB Review and Informed Consent Under the Common Rule, research protocols must be approved by an Institutional Review Board (IRB) to ensure that the rights and welfare of the research subjects are protected. The regulations list several criteria for IRB approval, including the requirement that researchers obtain the informed consent of their research subjects. The informed consent process includes an explanation of the purpose of the research, a description of the research procedures, and a description of the risks and benefits of the research, among other things. An IRB may decide to waive the informed consent requirement if it determines that the research poses no more than minimal risk to the subjects. The waiver will not adversely affect their rights and welfare, and the research is not practicable without a waiver. The Common Rule defines human subject research to include studies that obtain data through direct intervention or interaction with

an individual and studies that acquire identifiable private information about an individual. Thus, the rule applies to non-interventional research on donated biospecimens and stored data provided the specimens and data are identifiable. The Common Rule states that information is identifiable if the researcher can readily ascertain the subject's identity. A biospecimen or genome sequence that has been stripped of any accompanying identifiers, such as name, address, social security number, or any other identifying number, image, or code, is not considered readily identifiable and is not subject to the Common Rule. The Common Rule permits the informed consent process to include corollary and secondary research. For example, researchers may wish to store information and specimens obtained during the primary research study for use in future studies. In such instances, an IRB may approve an informed consent document that asks research participants to allow future research on their identifiable information or specimens. However, the document must contain sufficient detail about the future research to allow for truly informed consent.
https://www.everycrsreport.com/files/2016-03-24_IF10380_04642f286e4fb7deefb13146b3051cda823b5f6e.pdf

Categories of Human Subject Research

There are several categories of human subject research, each requiring a different review procedure. The categories and their criteria are presented below:

Exempt (Form in Appendix C)

Research conducted at educational institutions or other organizations which utilizes routine educational practices with minimal adverse impact on students, specifically on their educational progress.

Research that does not require expedited or full review by the IRB may be certified as exempt by the IRB if such research only poses minimal risk to the participant(s). Exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of the subjects is protected, and the methods used to gain and provide information is appropriate.

Exemptions do not apply to research involving prisoners, fetuses/unborn children, pregnant women, or children, except for research involving observation of public behavior without interaction.

Criteria for exempt research are as follows:

- Research conducted in established or commonly accepted educational settings involving normal educational practices such as:
  1. Research on regular or special education instructional strategies.
  2. Research on the effectiveness of or the comparison(s) among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude,

achievement), surveys, questionnaires, interviews, or observational studies if information taken from these sources is recorded so that subjects cannot be identified directly or through identifiers (codes) linked to the subjects.

- Research involving the collection or study of existing data, documents, or records. To qualify for this exemption, these sources must be publicly available, or the investigator must record the information so that the human research subjects cannot be identified directly or through identifiers linked to the individuals.

No consent forms are required for research that qualifies for exempt status, and no IRB renewal is required. However, researchers must complete and submit the Initial Review Flow Sheet in **Appendix A** and the Exempt Review Form, found in **Appendix C**, to the Chairperson of the IRB.

Expedited (Forms in Appendix D)

If your research presents no more than minimal risk to human subjects, it can go through an expedited review process. Also, the expedited review process can be used if you are resubmitting a previously approved research that has no additional risk but has minor changes in the procedures.

Risk: Some research carries risk, or the probability of harm or injury, which could be physical, psychological, social, or economic because a subject participates in a research study. However, federal regulations define only “minimal risk.”

Minimal Risk: Minimal risk occurs where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those people encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, if a small amount of blood will be drawn during the study, the risk is no greater than the risk of doing so during a routine physical examination.

Risks in Social and Behavioral Research: In social and behavioral research, risks are more often psychological and social than physical, but for the subjects who experience them, the risks are real because they may engender powerful emotions that may result in both short and long-term effects. For example, if confidentiality is breached, a person may be stigmatized, become at risk of criminal or civil liability, or suffer serious and perhaps permanent damage regarding financial standing, employability, insurability, or reputation.

When the subjects and/or their responses would be identified and place them at risk of being criminally or civilly liable; or if their financial employability, insurability, and/or reputation standing would be damaged; or can be stigmatized or discriminated against, reasonable and appropriate protections must be implemented to ensure that their privacy and confidentiality are not breached and put them at greater than minimal risk.

If a study is planned carefully, many risks can be minimized. For example, where strong emotions are anticipated, the investigator should identify appropriate interventions beforehand and clearly state the application. Also, informed consent must spell out the

risks and how to mitigate them. For example, securing data (such as passwords and permitting access to data to the principal investigator) with sensitive personal data to avoid data breaches should be clearly spelled out.

- The following activities should not be considered to be of minimal risk just because they are part of the list. Inclusion simply means that the proposed activity is eligible for review through the expedited review process when it poses no more than minimal risk to human subjects:

    - Using the research materials (such as data, documents, records, or specimens) that have been collected already or will be collected solely for non-research purposes.

- Some of the research may qualify for exempt status:

    - Data from voice, video, digital, or image recordings made for research purposes.
    - Research conducted on individual or group characteristics or behavior, such as research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
    - Research that employs surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may qualify for exempt status.
    - Clinical studies of drugs and medical devices only when the following condition is met:

        - Research on drugs for an investigational new drug application (21 CFR Part 312) is unnecessary.
        - Research on medical devices for which an investigational device
        - exemption application (21 CFR Part 812) is not required;

            - or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

    - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (1) from healthy, non-pregnant adults weighing at least 110 pounds so long as the amounts drawn does not exceed 550 ml in an 8-week period and collection done no more than twice a week; or (2) from other adults and children (depending on the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected) the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection done no more twice per week.

    - Prospective collection of biological specimens for research purposes by noninvasive means.

- Collection of data through noninvasive procedures.
- Continuing review of research previously approved by the convened IRB as follows, where:

    1. the research is permanently closed to the enrollment of new subjects;
    2. all subjects have completed all research-related interventions;
    3. the research remains active only for long-term follow-up of subjects;
    4. where no subjects have been enrolled, and no additional risks have been identified; or
    5. where the remaining research activities are limited to data analysis

- Continuing review of research, not conducted under an investigational new drug application or investigational device exemptiondo not apply, but the IRB has determined and documented at a convened meeting that the research involves no more than minimal risk and not additional risks have been identified.

Expedited reviews are conducted by the IRB chairperson and one or more members of the IRB assigned according to expertise in the area of research to be reviewed. Under an expedited review procedure, these individuals may exercise the approval authority of the IRB, but they may approve the research.

For research that qualifies for expedited status, the following forms must be completed and submitted to the IRB Chairperson: 1) the Initial Review Flow Sheet (**Appendix A**), 2) consent form (**Appendix B**), 3) Expedited Review Form and Project Information Update (**Appendix D**).

Full Board (Forms in Appendix E)

All research that does not fit either exempt or expedited review criteria must be reviewed and approved by the entire IRB committee. Research initially submitted for an exemption or expedited review may be required to undergo Full Board Review. Researchers must submit the following to the IRB Chairperson: 1) consent form (**Appendix B**), 2) a copy of the full proposal, 3) the Initial Review Flow Sheet (**Appendix A),** and 3) Full Board Review Form and Project Information Update (**Appendix E**).

Review Process

All principal investigators proposing to conduct research involving human subjects must receive IRB approval prior to the initiation of research. A formal request to the IRB should be made by completing the appropriate forms and submitting those completed forms to the Chairperson of the IRB for consideration **at least two weeks prior to the next IRB meeting**. Regularly scheduled IRB committee meetings occur on the first Thursday of the month.

The principal investigator is responsible for preparing the Application for Review of Human

Subject Research and other required forms associated with the category of research under which the investigator is applying (See Initial Review Flowsheet in **Appendix A**). The complete application should be submitted to the IRB Chairperson.

All investigators must provide evidence of completion of a Human Participant Protections Certificate. An Institutional Review Board (IRB) Administration course funded by the National Institutes of Health (NIH) of the Office of Human Research Protection OHRP can be found at

https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html
or
Protecting Human Research Participants (PHRP) Online Training @ https://phrptraining.com/?utm_source=adwords&utm_medium

A completion certificate is available from the site upon completion of the program. A copy of this completion certificate should be included in the IRB packet. NIH no longer issues a certificate. You must use the one offered by the Collaborative Institutional Training Initiative (CITI) Program. See www.citiprogram.org.

Exempt Review

Applications for exempt research are reviewed by the IRB Chairperson or sent to one reviewer to certify exemption. This process takes **three to five working days,** depending on the reviewer's workload.

Expedited Review

Expedited research applications are reviewed by the IRB Chairperson and one or more IRB members. The selection of reviewers is based on expertise, with **review time requiring approximately two weeks.**

Full Board Review

Complete applications requiring Full Board Review are submitted to the IRB Chairperson, who will review the application for completeness and determine the need for additional information. Once a complete application has been submitted, the Chairperson will distribute the entire application to IRB committee members. In addition, the principal investigator or designee will be invited to attend the next regularly scheduled meeting to address any concerns or risk implications involved in the proposed research. After receipt of any requested information or changes, the application will be reviewed by the committee. Total review **time can range from two to six weeks**.

E. Review Criteria

In general, criteria for approval or disapproval of the proposal are the following:

1. **Risks**: Risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risks; and when appropriate, by using procedures consistent with evidenced-based best-practices on subjects for diagnostic and treatment purposes.

   Risks vs. Benefits: Risks to the individual subject must be acceptable to the IRB when measured against the possible benefit to him or her and the importance of the knowledge to be gained.

2. **Subject Selection**: Selection of subjects should be equitable.

3. **Informed Consent**: The method to obtain consent and the substance of the information upon which the subject bases his or her consent to participate in the research study must be adequate to assure informed consent.

4. **Safety and Confidentiality**: Appropriate safeguards must be provided to protect subjects' privacy and maintain the confidentiality of data gathered.

Review Results

The review committee may take one of the following four actions regarding applications for review:

1. **Approved**: The IRB may approve or certify exemption of the project as submitted.
2. **Approved with Provisions**: The IRB may approve a project contingent upon minor modification(s). However, the project may not proceed until final approval is received.
3. **Deferred for Provisions**: The IRB requires more information or modifications before the review can proceed.
4. **Disapproved**: When the IRB disapproves a project, the investigator may revise and resubmit the proposal.

   Written notification regarding decisions and actions of the IRB will be sent by the IRB Chairperson to individuals seeking application for review of human subject research at Langston University.

Periodic Review (See Project Information Update Form in Appendix E)

The next review date will be established and communicated to the principal investigator at the time of the initial review by the IRB. All studies will be reviewed within one year of initial approval. A review may be requested more frequently if the IRB identifies potential

risks to subjects warranting shorter review intervals.

The review will be made from the summary report by the principal investigator, to include:

- The number of subjects currently involved in the project,
- The number of subjects having completed the project,
- Reports on any harmful effects on subjects,
- Reports of any variances occurring in date record keeping,
- A summary of any change in the protocol since the last formal review,
- A request for continued approval when the date of expiration has been reached.

The IRB may approve or disapprove of the extension of the project's time based on the review. Approval must be by a majority vote of the IRB.

Suspension and/or Termination of Approval

The IRB shall have the authority to terminate or suspend approval of research when there is supporting evidence of:

- Failure of the investigator(s) to conduct research project according to IRB requirements.
- Unexpected harm to subjects associated with the research project.

Any suspension or termination of approval shall include a statement of the reason for the action. Written notification of suspension/termination of approval shall be promptly sent to the investigator(s) and appropriate institutional officials.

Maintaining IRB Records

Records to be maintained are:

- Copies of all research proposals reviewed, supporting documentation, progress reports, and injury reports.
- Summary form for the completed or terminated research upon completion of the research project.
- Minutes of IRB meetings include attendance, actions, voting records, bases for any required changes, and summaries of controversial issues and resolutions.
- Copies of correspondence between the IRB and investigators.
- A list of IRB members identified by earned degree, representative capacity, indications of experience (licenses, certifications, and current employment title).
- All records shall be retained for at least three (3) years after completion of the research.

- All records must be maintained in a secure space that guarantees privacy and confidentiality to the human subjects involved.
- All records shall be accessible for inspection by authorized personnel. The IRB must grant authorization.

Unexpected/Adverse Event Reporting

Purpose:

To define unexpected/adverse events involving subjects in human subject research and to prescribe reporting procedures for these events.

Overview:

Federal regulations (45CFR46.103 (b)(5)) require written procedures for Adverse events are those which cause unanticipated harm to the subjects or others. Unanticipated problems involve risks that are not explained in the consent process.
These events or unanticipated problems are categorized as (a) unforeseen; (b) caused harm or placed a person at increased risk of harm, and (c) were directly related to the research procedures.

Policy:

Prompt reporting is defined by the Langston University IRB as the requirement to report as soon as possible after the adverse event but absolutely no later than ten working days. One exception to the 10-day report period is the death of a research subject that was likely caused by the research procedure. A death must be reported within one working day.

The Principal Investigator will submit a written report of the above events using the Langston University IRB Unexpected/adverse Event Report Form. This form may be downloaded from the LU IRB website.

The IRB full board will review the report and determine if the event was

(a) unforeseen,

(b) caused harm or placed a person at increased risk of harm, and

(c) was directly related to the research procedures. Then, the IRB will take action, which may include but is not limited to:

- requiring a modification of the research protocol,
- requiring additional information on the informed consent, suspending or
- terminating the research.

References

ASPE. (n.d.). Health Insurance Portability and accountability act of 1996. https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996?%3F%3F%3Futm_source=FNN

Office of the Federal Register's Interim Final Rule (IFR): https://www.federalregister.gov/documents/2018/01/22/2018-00997/federal-policy-for-the-protection-of-human-subjects-delay-of-the-revisions-to-the-federal-policy-for.

US Department of Health and Human Services. Research. (2017). HIPAA Authorization for Research: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

Helpful Resources

Informed Consent: https://youtu.be/Y7uI3sM9wtc

Institutional Engagement in Human Subjects Research: https://youtu.be/7gmRz0dNUmI

Overview of Changes to Exemptions in the Revised Common Rule (Focusing on Exemptions 1, 2, 3, and 5): https://youtu.be/APRVsvKsPrM

Underlying reasons for institutional review boards (ethical violations)
https://youtu.be/PijojAe2KmM

https://youtu.be/FfX9pwYZ4YE

https://youtu.be/J3tQ93fQf8U

What is new in the Common Rule. IRB: https://youtu.be/U8fme1boEbE
https://youtu.be/zDsUUs9j3sQ

APPENDIX A

Langston University
Institutional Review Board

INITIAL REVIEW FLOW SHEET

Project Title:

_____
_____

Principal Investigators:

_____
_____
_____
_____

Date Submitted: _____

_____ Proposal (Project description and methodology section of research study attached.)
_____ Protocol and instruments attached
_____ Conditions of project site
_____ Anticipated duration
_____ IRB Application Form Completed
_____ IRB Research Form Completed (Exempt, Expedited, or Full Board Review)
_____ Human Subject Informed Consent Form (if applicable)

Note: Applicant should provide 12 sets of the entire IRB application packet to the chairperson for distribution to the board.

APPENDIX B

Langston University
Institutional Review Board
INFORMED CONSENT DOCUMENT FORMAT GUIDE

This guide is intended to be used as a model for consent forms for adults and parents or guardians of older children. Therefore, please present all information clearly and in lay language.

Project Title:

Investigators:

List all investigators and key personnel, including their degrees, responsible for obtaining informed consent or that will have contact with participants.

Purpose:

A brief general description of the purpose of the study that includes: a statement that study involves research; why they are being asked to participate; the type of information sought.

Purpose:

Clearly, and in layman's language, explain what the subjects will be asked to do, including: the topic areas of any instruments or tests; interviews; medical procedures; physical exercises; any other activities that the subjects will be asked to complete; audio or videotaping; identification of any procedures or products that are experimental; any possible discomforts or inconveniences that the subject might experience; expected duration of the subject's participation, including the number of individual interactions.

Risks of Participation:

Inform subjects about any expected risks: emotional, psychological, legal, pain, inconveniences.

Describe any procedures that will be made available to reduce risks (i.e., counseling services, CPR trained personnel, informational contacts, etc.) For research that involves physical activity, a liability statement may be needed.

Benefits:

Describe any benefits to the participants and others which may be reasonably expected from the research. (Do not include payments or other types of direct compensation.) Inform the subject if there is no expected benefit.

Confidentiality:

Provide a full explanation of confidentiality protections the investigator plans to use, including: where the data will be stored; who will have access to the stored data; how

long the data will be kept; how the data will be reported.

Describe any foreseeable risks to maintaining the confidentiality and how these will be minimized. For example, participants can skip parts of the research they are not comfortable with and can stop at any time.

Participant's names will not be linked to any material in reports, publications, or presentations.

Information Collected as part of the research will not be used or distributed for future research studies.

Researchers are not prevented from voluntarily disclosing certain information about research participants, such as evidence of child abuse or a participant's threatened violence to self or others. However, if a researcher intends to make such disclosures, it should be clearly indicated in the consent form.

Compensation:

Describe any compensation to be offered for participation, when given and any full or partial payment conditions. (It is considered coercive to make completion of the study the basis for compensation).

Appropriate alternatives to participating in the research must be clearly stated. This is particularly important when there is a dependent relationship where coercion could be perceived. (i.e., student/professor, prisoners, persons in mental hospitals or the military). If extra course credit is to be offered for participation, specific alternatives for earning extra credit must also be stated.

Contacts:

Provide subjects with information about whom to contact with questions about both the research and the subject's rights. The points of contact should include, at a minimum, the investigator's name and phone number and the following statement for the IRB contact:

"If you have questions about the research and your rights as a research volunteer, you may contact Dr. Teressa Hunter, IRB Chair, 212 Allied Health Building, Langston University, Langston OK 73050, 405-466-32742 or **teressa.hunter@langston.edu**."

Participant Rights:

Include a statement emphasizing that participation is voluntary and that subjects can discontinue the research activity at any time without reprisal or penalty. Any risks to subjects that might occur due to withdrawal must be made clear. Explain any reason the subject's participation may be terminated.

Signatures:

Preface the signature lines with the following statement (expand if appropriate):

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy of this form has been given to me.

____

---------- ----------__

Signature of Participant Date

I certify that I have personally explained this document before requesting that the participant sign it.

_____ _____

Signature of Researcher Date

Use the following signature block only if the consent form is for an older child and parental/guardian permission is required.

Parental Signature for Minor:

I have read and fully understand the consent form. As parent or guardian, I authorize _____ (print name) to participate in the described research.

_____ _____
Parent/Guardian Name (printed) Date

_____ _____
Signature of Parent/Guardian Date

I certify that I have personally explained this document before requesting that the participant sign it.

_____ _____
Signature of Researcher Date

APPENDIX C

Forms for Exempt Review
Langston University
Institutional Review Board

EXEMPT REVIEW
Application for Review of Human Subjects Research

Title of Project (pleasetype)

_____

_____

Attach a Copy of Project Thesis, Summary or Dissertation Proposal

I agree to provide proper surveillance of this project to ensure that the rights and welfare of human subjects are properly protected. Additions to or changes in procedures affecting the subjects after the project has been approved will be submitted to the Institutional Review Board Committee for review.

Principal Investigator(s): (if student, list adviser's name first)

_____	_____
Typed Name	Signature
_____	_____
Email Address	Date
_____	_____
Typed Name	Signature
_____	_____
Typed Name	Signature
_____	
Institution	
_____	_____
Department	School
_____	_____
Campus Address	Campus Phone

Briefly describe the background and purpose of the research:

_____
_____
_____
_____
_____

Who will be the subjects in this study, and how will they be solicited?

_____
_____
_____
_____
_____
_____

APPENDIX D

Langston University
Institutional Review Board
EXPEDITED REVIEW

Title of Project (Pleasetype)

_____

_____

_____

Attach a Copy of Project Thesis, Summary, or Dissertation Proposal

I agree to provide proper surveillance of this project to ensure that the rights and welfare of human subjects are properly protected. Additions to or changes in procedures affecting the subjects after the project has been approved will be submitted to the Institutional Review Board Committee for review.

Principal Investigator(s): (if student, list adviser's name first)

_____	_____
Typed Name	Signature
_____	_____
Email Address	Date
_____	_____
Typed Name	Signature
_____	_____
Typed Name	Signature
_____	
Institution	
_____	_____
Department	School
_____	_____
Campus Address	Campus Phone

Briefly describe the background and purpose of the research:

_____
_____
_____
_____
_____

Who will be the subjects in this study, and how will they be solicited?

_____
_____
_____
_____
_____
_____

EXPEDITED REVIEW FORM

Langston University
Institutional Review Board
PLANNING REVIEW FORM

1. Will this project use DNA or RNA molecules, viruses, bacteria, cells, or organisms constructed with Recombinant DNA methodology or techniques? ☐ **Yes** ☐ **No**

   (If yes, a Memorandum of Understanding and Agreement must be submitted to the IRB)

2. Will this project involve the field release of genetically modified organisms? ☐ **Yes** ☐ **No**

3. Are there any potential health or safety risks to project personnel arising from activities conducted overseas? (If Yes, the principal investigator must consult with the IRB.) ☐ **Yes** ☐ **No**

4. Will live vertebrate animals be used? (If Yes, please submit an animal protocol form to the Institutional Animal Care Board/Committee in the Research and Extension Department.) ☐ **Yes** ☐ **No**

5. Is there any planned or potential use of hazardous agents (e.g., infectious agents, toxins, mutagens, carcinogens, or explosive chemicals? (If Yes, provide the Office of Sponsored Programs with an additional copy of the proposal.) ☐ **Yes** ☐ **No**

6. Is there any planned or potential use of the following: ionizing radiation device (e.g., accelerators, x-ray machines; diagnostic, therapy microscope, CHESS; an electron reactor of fusion device. Specify type: non-ionizing radiation device (e.g., laser, infrared, ultraviolet, microwave, radio frequency, or ultrasonic) Specify type: _____ ☐ **Yes** ☐ **No**

7. Is there any planned or potential use of radioactive materials? ☐ **Yes** ☐ **No**

   (If Yes, you must be a permit holder or authorized under a current permit).
   Radioisotope Permit Number: _____
   Issued to: _____

8. Source of Cost-Sharing: ☐ Dept ☐ School ☐ University ☐ NA

9. Source of external matching funds, if applicable: _____

10. If the project will require any of the following, please identify the resources needed, their estimated costs, and explain below your plans to cover these costs.

_____ Renovation, construction, or rental space.
_____ Expanded utility or network services to support proposed additional equipment(e.g., computers, fume hoods, air conditioning).
_____ Additional personnel or space that will require support beyond that provided by the proposal.
_____ Use of additional test plots, agriculture lands, or ponds not currently assigned to Principal Investigator.
Explain:
_____
_____
_____

11. Do either you or other key personnel on this project have any financial interests or managerial responsibilities with the proposed project that could create a conflict of interest? (If yes, attach an explanation.) ☐ **Yes** ☐ **No**

12: Have you or any key personnel completed the Animal Disclosure Statement of External Interests and Time Commitments? ☐ **Yes** ☐ **No**

13. Will this project involve faculty leave or release teaching time? ☐ **Yes** ☐ **No**

14. Will this project involve waiver of any indirect costs? ☐ **Yes** ☐ **No**

Suppose you responded YES to Questions 10, 12, 13, or 14. In that case, the proposal should be discussed in advance with the appropriate Dean of the School, and his or her signature should be obtained on this form before it is forwarded to the Institutional Review Board.

_____---------- ----------__
Dean's Signature Date

_____

School

EXPEDITED RESEARCH

Langston University
Institutional Review Board
PROJECT INFORMATION UPDATE

Title of Project:

_____

_____

Principal Investigator(s): (if student, list adviser's name first)

_____	_____
Typed Name	Signature
_____	_____
Email Address	Date
_____	_____
Typed Name	Signature
_____	_____
Typed Name	Signature
_____	
Institution	
_____	_____
Department	School
_____	_____
Campus Address	Campus Phone

Is the research project terminated? ☐ **Yes** ☐ **No**

Date completed: _____

Provide a brief description of the outcome of the research activity:

_____

_____

_____

_____

_____

_____

_____	_____
Signature	**Date**

APPENDIX E

Langston University
Institutional Review Board
APPLICATION FOR REVIEW OF HUMAN SUBJECTS RESEARCH

Title of Project:

_____

_____

Attach a Copy of Project Thesis, Summary, or Dissertation Proposal

I agree to provide proper surveillance of this project to ensure that the rights and welfare of human subjects are properly protected. Additions to or changes in procedures affecting the subjects after the project has been approved will be submitted to the Institutional Review Board committee for review.

Principal Investigator(s): (if student, list adviser's name first)

Typed Name	Signature
Email Address	Date
Typed Name	Signature
Typed Name	Signature
Institution	
Department	School
Campus Address	Campus Phone

Briefly describe the background and purpose of the research:

_____
_____
_____
_____
_____

Who will be the subjects in this study, and how will they be solicited?

FULL BOARD REVIEW

Langston University
Institutional Review Board
PLANNING REVIEW FORM

1. Will this project use DNA or RNA molecules, viruses, bacteria, cells, or organisms constructed with Recombinant DNA methodology or techniques? ☐ **Yes** ☐ **No**

   If "Yes," a memorandum of Understanding and Agreement must be submitted to the IRB.

2. Will this project involve the field release of genetically modified organisms? ☐ **Yes** ☐ **No**

3. Are there any potential health or safety risks to project personnel arising from activities conducted overseas? ☐ **Yes** ☐ **No**

   If "Yes," the Principal Investigator must consult with the IRB.

4. Will live vertebrate animals be used? ☐ **Yes** ☐ **No**

   If "Yes," please submit an animal protocol form to the Institutional Animal Care Board/Committee in the Research and Extension Department. ☐ **Yes** ☐ **No**

5. Is there any planned or potential use of hazardous agents (e.g., infectious agents, toxins, mutagens, carcinogens, or explosive chemicals)? ☐ **Yes** ☐ **No**

   If "Yes," provide the Office of Sponsored Programs with an additional copy of the proposal.

6. Is there any planned or potential use of the following: ionizing radiation device (e.g., accelerators, x-ray machines; diagnostic, therapy microscope, CHESS; an electron reactor of fusion device)? ☐ **Yes** ☐ **No**

   If "Yes," please specify: _____

   Non-ionizing radiation device (e.g., laser, infrared, ultraviolet, microwave, radio frequency, or ultrasonic)? ☐ **Yes** ☐ **No**

   If "Yes," please specify: _____

7. Is there any planned or potential use of radioactive materials? ☐ **Yes** ☐ **No**

   If "Yes," you must be a permit holder or authorized under a current permit. Radioisotope Permit Number: _____ Issued to: _____

8. Source of cost-sharing: ☐ Dept ☐ School ☐ University ☐ Not Applicable

9. Source of external matching funds, if applicable: _____

10. If the project will require any of the following, please identify the resources needed, their estimated costs, and explain below your plans to cover the costs.

_____ Renovation, construction, or rental of space
_____ Expanded utility or network services to support proposed additional equipment (computers, fume hoods, air conditioning).
_____ Additional personnel or space that will require support beyond that provided by the proposal.
_____ Use of additional test plots, agriculture lands, or ponds not currently assigned to Principal Investigator.

Explain:

_____
_____
_____
_____

11. Do either you or other key personnel on this project have any financial interests or managerial responsibilities with the proposed project that could create a conflict of interest? ☐ **Yes** ☐ **No**

If "Yes," attach an explanation.

12. Have you or any key personnel completed the "Animal commitments? ☐ **Yes** ☐ **No**

13. Will this project involve faculty leave or release time? ☐ Yes ☐ No

14. Will this project involve a waiver of any indirect costs? ☐ Yes ☐ No

15. Disclosure statement of external interest and time.

Suppose you responded "YES" to Questions 10, 12, 13, or 14. In that case, the proposal should be discussed in advance with the appropriate Desn of School, and his or her signature should be obtained on this form before it is forwarded to the Institutional Review Board.

_____ _____
Signature of Dean of the School Date

_____
School

PROJECT INFORMATION UPDATE

FULL BOARD REVIEW
Langston University
Institutional Review Board

Title of Project:

_____
_____

Principal Investigator(s): (if student, list adviser's name first)

_____ Typed Name	_____ Signature
_____ Email Address	_____ Date
_____ Typed Name	_____ Signature
_____ Typed Name	_____ Signature
_____ Institution	
_____ Department	_____ School
_____ Campus Address	_____ Campus Phone

Is the research terminated? ☐ **Yes** ☐ **No** _____ **Date Completed**

Provide a brief description of the outcome of the research activity.

_____
_____
_____
_____
_____
_____

_____ Signature	_____ Date

APPENDIX F

Langston University
Institutional Review Board
VULNERABLE SUBJECTS GUIDELINES

The general requirements for obtaining informed consent, the elements to be included, and the provisions for waivers all apply to research involving vulnerable subjects, including children, pregnant women and fetuses/unborn children, prisoners, and individuals with impaired decision-making capacity. The process of obtaining informed consent for vulnerable populations is complicated by issues such as age, ability to understand, and relationships with parents or guardians.

Researchers may need assent for children of various ages. For example, a child who is 17 years and younger are generally considered not competent to make informed consent decisions and may never have the experience of signing an informed consent.

For research involving children 17 years and younger, investigators must obtain written consent from at least one parent or guardian for each child's participation in the project. If the project involves more than minimal risk, signatures of both custodial parents and guardians will be required.

Expedited proposals that involve children require two reviewers and will essentially need a longer review time frame. An assent form is necessary, along with the parental consent form. When research is conducted with schools, the research may require school administration approval and knowledge of Family Educational Rights and Privacy Act (FERPA) regulations.

APPENDIX G

Langston University
Institutional Review Board
AUTHORIZATION (PERMISSION) TO USE OR DISCLOSE (RELEASE) IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

Project Title

_____

_____

Principal Investigator: _____

What is the purpose of this form?
Researchers would like to use your health information for research. This information includes data that identifies you. If you sign this document, you give permission to ***[Name (or class of persons or organizations) who may use or disclose health information for the study {covered entity}.]*** to use or disclose (release) your health information that identifies you for the research study described below:

[Provide a description of the research study, such as the title and purpose of the research.]

What personal health information be used or disclosed?
The health information that may be used or disclosed for the research includes:

[Describe the information to be used or disclosed for the research project. This may include, for example, all information in your medical record, results of physical examinations, medical history, lab tests, or specific health information indicating or relating to a particular condition.].

Who can receive my health information for this purpose?
The health information listed above may be used and/or disclosed (released) to: ***[List ALL names or other identification, or All classes of persons who will have access to the PHI (e.g., research collaborators, sponsors, data coordination center, and oversight agencies, IRBs)]***

How will information about me be kept private?

[Covered entity] is required by law to protect your health information. By signing this document, you authorize ***[covered entity]*** to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by federal privacy laws (such as the

Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

What happens if I do not sign this permission form?
Please note that ***[covered entity]*** may not condition (withhold or refuse) treating you on whether you sign the Authorization.

What happens if I change my mind?
Please note that you may change your mind and revoke (take back) this Authorization at any time, except to the extent that it has already been acted upon. Even if you revoke this Authorization, health information already obtained about you may be used or disclosed as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact ***[insert contact name and information to include both phone number and mailing address]***.

How long will this permission last?
This Authorization ***[insert expiration date or event, such as "end of the research study."]***

_____ _____
Signature of Participant or Participants Personal Representative Date

_____
Printed name of Participant or Participants Personal Representative

If applicable, description of the personal representative's authority to sign for the participant.

APPENDIX H

Langston University
Institutional Review Board
UNEXPECTED/ADVERSE EVENT REPORT

Send one (1) copy of this form and one (1) copy of the consent form the subject signed to the IRB Office. Keep one (1) copy of this form for your files.

_____ _____
Investigator's Name Position on Grant/Research

_____ _____ _____
Department Address Phone Number

_____
Email Address

Current IRB Approval Number: _____

Project Title:
_____
_____

Did this event occur to a subject enrolled in your study? ☐ **Yes** ☐ **No**

Was the event attributable to a study procedure? ☐ **Yes** ☐ No

Was the event unexpected or more serious than expected? ☐ **Yes** ☐ **No**

Is this kind of adverse event described in the currently approved consent form? ☐ **Yes** ☐ **No**

Will the event require changes in the consent form or in the research procedures? ☐ **Yes** ☐ **No**

If "Yes," attach a copy of the revised consent form with the changes highlighted.

Have you reported this event to the study sponsor? ☐ **Yes** ☐ **No** ☐ **Not Applicable**

Has this kind of event happened before in connection with this study? ☐ **Yes** ☐ **No**

If "Yes," explain below.

_____
_____
_____
_____
_____

Who is financially responsible for the management of this adverse event?
_____ Sponsor: _____
_____ Subject/Subject's Insurer: _____
_____ Other (Please specify): _____

Estimate of cost for management. $_____ ☐ **Not Applicable**

If medical care was provided, location of care: _____ ☐ **Not Applicable**

Address: _____

Location of event: _____

Time and dates of occurrence: _____

Description of adverse effects and action(s) taken (use additional pages, if necessary)
_____
_____
_____
_____

*If any relationship between the event and the study can be ruled out, do not submit this form.

_____ _____
Signature of Investigator Date

_____ _____
Signature of IRB Chair Date