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Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
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Research: Investigator, Research Personnel, IRB Member, IRB Administrator, and Institutional Official Training- AD.0161

PURPOSE

The purpose of this policy is to provide guidelines for the training and education of **investigators**, **research personnel**, **IRB** members, the IRB administrator, and the Institutional Official. It is intended that this research training and education policy be consistent with Health and Human Services (HHS) 45 CFR PART 46 Subpart A, Food and Drug Administration (FDA) federal regulations and good clinical practice. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in **research**.

POLICY

I. Overview

A. LRH has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of human subject research participants.

B. All individuals who are **engaged in human subjects research** are required to obtain LRH IRB-approved human subjects research protection education prior to receiving **Institutional Review Board (IRB)** approval for new and continuing research. This policy extends to anyone involved in the conduct of human subjects research.

C. It is the responsibility of investigators and their research personnel to maintain current certification in human research protection education while engaged in human subjects

research. All individuals engaged in human subjects research are required to obtain initial certification through the Collaborative Institutional Training Initiative (CITI) and refresher course(s) as applicable. Recertification must take place every three (3) years from the date of initial certification. Certain funding agencies and affiliates may have additional requirements for individuals conducting human subjects research.

D. The LRH IRB has the authority to suspend or withhold approval of projects that involve investigators and research personnel who fail to meet the education/training requirements as outlined in this policy.

E. Investigators engaged in human subject research whom are from R1 Universities/institutions can submit their CITI certificate from those institutions, and would satisfy the CITI training requirement--the submitted non-LRH CITI trainings must be comparable with the type of research as outlined below (i.e. Non-LRH CITI Biomedical). This applies to non-LRH agents conducting research at LRH, as well as LRH agents who are newly employed at LRH.

    1. LRH agents who choose to transfer qualifying CITI training(s) from their previous institutions, must use the LRH trainings as outlined below upon renewal of their CITI trainings and certification.

F. Compliance with initial and continuing educational requirements are monitored by the IRB Administrator.

II. Roles & Responsibilities

A. Investigators & Research Personnel

1. It is the responsibility of the **Principal Investigator (PI)** to ensure all research personnel have completed all necessary training before engaging in research activities. The following personnel engaged in human subject research must complete training:
    i. PIs and Investigators;
    ii. **Sub-Investigators**; and
    iii. Research (study) personnel.

B. IRB Members

1. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
2. The IRB shall prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time

employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

PROCEDURE

I. Required Training for Investigators and Research Personnel

A. Training is required for all investigators and research personnel every three (3) years. Once the CITI training has been initially completed, there is a recertification option for maintenance of certification. You may be required to complete one or both of the following training(s) depending on the type of research—please complete those courses which are most relevant to you.

1. For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/existing data review, specimen collection studies, or research involving patients ,please complete the CITI Biomedical Research (Stage 1 - Basic Course);
2. For study team members involved in research not involving patients' (i.e. staff or community members) survey data, questionnaires, participant observation, or non-invasive physical measurements to study human attitudes, beliefs, or behaviors; please complete the CITI Social and Behavioral Research (Stage 1 - Basic Course).
3. Although not required, it is highly recommended that all Principal Investigators take the Responsible Conduct of Research (RCR) course, which overviews research misconduct and questionable research practices; data management – i.e., data acquisition, record-keeping, retention, ownership, analysis, interpretation, and sharing; scientific rigor and reproducibility;
responsible authorship and publication; peer review; conflicts of interest in research; mentor/mentee responsibilities and relationships; collaborative science; civility issues in research environments, including but not limited to, harassment, bullying, and inappropriate behavior; policies regarding laboratory safety, biosafety, and human and animal research subjects; views about scientists as responsible members of society; social and environmental impacts of research; and contemporary ethical issues in biomedical research.

B. If the research is sponsored (funded from entities such as pharmaceutical companies, NIH, NSF, or PCORI) the investigator and research personnel must complete two or three of the following in addition to the CITI Biomedical and/or Social and Behavioral courses above:

1. All study team members involved in sponsored research of any kind must take the Responsible Conduct of Research (RCR) course.
2. For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/e reviews or specimen collection studies, complete the GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) and ;
3. For study team members involved in research not involving patients' (i.e. staff or community members) survey data, questionnaires, participant observation, or non-invasive physical measurements to study human attitudes, beliefs, or behaviors,

complete the GCP – Social and Behavioral Research Best Practices for Clinical Research.

C. For research involving populations or circumstances that are not adequately covered by the Biomedical Course, the IRB may request additional training on a specialized topic.
    1. For clinical use of a Humanitarian Use Device (HUD) – only the CITI HUD module is required.
    2. For investigational use of a Humanitarian Use Device (HUD) – The CITI HUD module is required, in addition to other relevant required training listed in this policy.

II. Required Training for IRB Members

A. The IRB Members will complete the following training within sixty (60) days of being officially appointed to the IRB:
    1. IRB Members Basic Course (contains a conflict of interest module).

B. The IRB will provide orientation to new IRB members regarding committee operations and expectations within thirty (30) days of appointment to the IRB.

C. The IRB Chair and Vice Chair will complete the following CITI training:
    1. IRB Members Basic Course (contains a conflict of interest module).
    2. IRB Chair Course.
    3. The following are largely covered in the two (2) trainings noted above, however it is recommended that the IRB Chair and Vice Chair also complete the following:
        i. CITI Biomedical Research (Stage 1 - Basic Course);
        ii. CITI Social and Behavioral Research (Stage 1 - Basic Course);
        iii. CITI training for GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus); and
        iv. GCP – Social and Behavioral Research Best Practices for Clinical Research.

D. Ongoing continuing education will be provided at IRB meetings.

III. Required Training for the IRB Administrator

A. The IRB Administrator will complete the following training:
    1. IRB Administrator Basic Course (contains a conflict of interest module).
    2. CITI Biomedical Research (Stage 1 - Basic Course); and
    3. CITI training for Good Clinical Practice (GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)).

IV. Required Training for the Institutional/Signatory Official

A. The Institutional/Signatory Official will complete the following CITI modules:
    1. Institutional/Signatory Official: Human Subject Research module;
    2. CITI Biomedical Research (Stage 1 - Basic Course); and

3. CITI training for (GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)).

V. Evaluation of IRB Members

A. In order to protect research participants, IRB members need to understand and be able to apply several areas of knowledge, including ethical principles, professional standards, organizational policies and procedures, laws, regulations, codes, and guidance.

B. IRB Members are assessed annually using the IRB member evaluation process.

VI. When education requirements are not fulfilled, the IRB Chair will recommend corrective action to maintain good standing with the IRB, which may result in inability to submit research to the IRB, or perform duties if sitting on the IRB.

DEFINITIONS

Engaged in Human Subjects Research: All personnel engaged in human subjects research must be listed as research personnel if they: intervene with subjects to collect biospecimens or data about them by performing research procedures, or by manipulating the environment for research purposes; conduct the informed consent process; collect or create identifiable, private information about subjects; or have access to **identifiable private information** about research subjects.

FDA: Food and Drug Administration.

Human Subject as defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies or analyzes the information or biospecimens; or (2) uses, studies, analyzes or generates identifiable private information or **identifiable biospecimens**. For the purpose of this definition:

1. **Intervention**: 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.
2. **Interaction**: Communication or interpersonal contact between investigator and subject.
3. **Private Information**: 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).
4. **Identifiable Private Information**: Information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.
5. **Identifiable Biospecimen**: A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

Human Subject as defined by the FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

IRB: Institutional Review Board.

Principal Investigator: Individual who conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in an investigation conducted by a team, the responsible leader of that team. (21 CFR § 56.102)

Research as defined by the DHHS: A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1. Systematic Investigation means an activity that involves a prospective plan to obtain data and conduct an analysis to answer a question. Research often includes interventions and interactions with human participants. Data can also be obtained by reviewing documents or other materials.
2. Knowledge is "generalizable" when the conclusions drawn from the data analysis can be applied to populations outside of the specific study population. In other words, if the results of the systematic investigation are externally applicable they are expected to be generalized to a larger population beyond the site of data collection and replicated in other settings.

Research (i.e., clinical investigation) as defined by the FDA: Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

1. Any use of a drug other than the use of an approved drug in the course of medical practice;
2. Any activity that evaluates the safety or effectiveness of a device; OR
3. Any activity the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Research (Study) Personnel: Refers to all individuals designing research, directing research, serving as a PI or **sub-investigator**, enrolling research subjects (including obtaining subjects' informed consent or screening potential subjects), or making decisions related to eligibility to participate in research, analyzing or reporting research data, analyzing or reporting adverse events, or submitting manuscripts concerning the research publication.

Sub-Investigator: In the event an investigation is conducted by a team of individuals, the Principal Investigator is the responsible leader of the team. Sub-investigator includes any other individual member of that team. (See 21 CFR § 312.3.). The National Institute of health defines the sub-investigator as an individual involved with the protocol director/principal investigator in the scientific development or execution of a project.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

https://about.citiprogram.org/en/homepage/

https://admin.aahrpp.org/Website%20Documents/AAHRPP%20Evaluation%20Instrument%20(2018-05-31)%20published.pdf

https://www.fda.gov/files/about%20fda/published/Institutional-Review-Board-%28IRB%29-Written-

Procedures---Draft-Guidance-for-Institutions-and-IRBs---Printer-friendly.pdf

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	03/2024
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	03/2024
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	03/2024
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