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# Research: Research That Must be Reviewed by the IRB- AD.0162



## PURPOSE

The purpose of this policy is to provide guidance on the types of research activities that are subject to review and approval by the Lakeland Regional Health (LRH) Institutional Review Board (IRB). 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 explains the applicability of these terms to activities overseen and conducted by LRH employees, LRH Medical Staff Members, and all students, clinical residents, or other individuals performing research at an LRH location or using LRH information.

## POLICY

I. Human-subjects research conducted by LRH employees, LRH Medical Staff Members, and all students, clinical residents, or other individuals performing research at an LRH location or using LRH information, must be reviewed and approved by the LRH IRB.

II. Activities that 1) meet the United States Department of Health and Human Services (DHHS) definition of **research** and involve a **human subject** as defined by DHHS; or 2) meet the FDA definition of clinical investigation and involve a human subject or subjects as defined by the FDA are subject to IRB review and approval.

III. Activities included in the DHHS and FDA definitions of research:

   A. Many different types of research activities are encompassed by the DHHS and FDA definitions of research. For example, research objectives may range from understanding normal and/or abnormal physiological or psychological functions or social phenomena, to evaluating diagnostic, therapeutic or preventive **interventions** and variations in services and practices.

   B. The activities or procedures involved in research may be invasive or noninvasive, and

include removal of body tissues or fluids; administration or application of chemical substances or forms of energy; surgical interventions; modification of diet, daily routine or service delivery; alteration of environment; observation; administration of questionnaires or tests; randomization of subjects; review of records, and so forth.

C. Research activities may also be conducted or supported within a program or activity that otherwise may not be considered research, such as some demonstration and service programs. As such, the research aspect of the program falls under the jurisdiction of the LRH IRB.

D. Examples of human subject research studies that must be reviewed and approved by the LRH IRB:

    1. Thesis or Dissertation: Educational work which involves research on human subjects or a clinical investigation and results in a thesis or dissertation.
    2. Pilot studies: Pilot studies involving human subjects are considered human subject research and require IRB review.
    3. Clinical research: Involves research to increase scientific understanding about normal or abnormal physiology, disease states or development and research to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention. Vaccine trials, medical device or drug studies and cancer research are all types of clinical research.
    4. Behavioral and Social Sciences Research: Focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.
    5. Epidemiological research: Focuses on health outcomes, interventions, disease states and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. This research may be conducted through surveillance, observation monitoring, and reporting programs. Other methods are retrospective review of medical, public health and/or other records.
    6. Human genetic research: Includes studies such as pedigree studies, positional cloning studies, gene transfer research, longitudinal studies to associate genetic conditions with health, health care or social outcomes and gene frequency studies.
    7. Repository or Bank: Includes collecting or storing human biospecimens or data for future use in research.

E. Examples of activities that do not meet the definition of research:

    1. Scholarly and journalistic activities: Includes the collection and use of information, that focus directly on the specific individuals about whom the information is collected (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship). Research involving a single individual is not **generalizable** knowledge (see Case Reports).
    2. Health surveillance: Includes 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. Quality improvement activities: That implement established/accepted standards and that do not use research methodologies to answer a question or test a hypothesis. Includes **systematic**, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. Quality improvement involves deliberate actions to improve care, guided by data reflecting the effects of local care.
4. Medical quality assurance: This refers to activities particular to an institution's Quality Assurance (QA) program, such as those activities protected from disclosure as part of its confidential medical quality assurance program or other equivalent programs.
5. Program evaluation: This refers to assessments of the success of established programs in achieving objectives when the assessments are for the use of program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. [Note: Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge about a disease or condition.]
6. Customer satisfaction surveys: This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation. The purpose of these surveys is to improve a specific service or program or develop new services or programs under the control of the individual/organization obtaining the information and not to conduct research.
7. Case reports: Includes the use of medical information collected from a clinical activity rather than a research activity and presented on typically no more than two (2) patients. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI (a HIPAA Authorization or waiver may be required).
8. Community outreach: The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research community outreach activity is to prevent or control disease or injury and improve health, or to improve an ongoing community outreach program or service. Knowledge may be gained in any community outreach endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit patients participating in an outreach health program or a population by controlling a health problem in the population from which the information is gathered.
9. Publicly available data: Research involving publicly available information (e.g.,

census data, labor statistics) does not constitute human research.

10. Criminal Investigations: 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.
11. Official Activities: Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
12. Off-label use of drugs or biologics as part of usual clinical care;
13. Work preparatory to research that complies with the HIPAA Privacy Rule at 45 CFR § 164.512 (i)(1)(ii).

F. The following research is generally considered **non-human subjects research** and does not need IRB approval, however it is recommended to consult with the LRH IRB to ascertain determination:

1. Repository research, tissue banking, and databases: Research limited to obtaining de-identified stored data or biospecimens from a repository only if the investigator cannot readily ascertain the identity of the subject from whom the data or materials originated.
2. Anonymous pre-existing data sets or specimens: Anonymous pre-existing data or biospecimens (anonymous materials are those with no personally identifiable information contained in either the original data or attached to the original specimen).



# PROCEDURE

I. Determination of Human Subjects Research

A. When an investigator submits a new application; the IRB Chair or designee will review the application and determine if the study meets the criteria for human subjects research.

1. If the submission meets the criteria of human subjects research the application will be reviewed accordingly.
2. If the submission does not meet the criteria of human subjects research, the investigator will be notified.

II. Review and Approval of Human Subjects Research

A. All research conducted at LRH that meets the definition of human subjects research regardless of sponsorship, must be reviewed and approved, or determined to be exempt by an IRB. The LRH IRB may designate another IRB to serve as the Reviewing IRB according to the applicable SOPs. An IRB must review all human subjects research if one (1) or more of the following apply:

1. The research is funded by LRH;
2. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of LRH in connection with his/her institutional responsibilities, without regard to the location of research;
3. The research is conducted by or under the direction of any employee or agent of LRH using any of its property or facilities;

4. LRH receives a direct award and or contract to conduct human subjects research by the federal government, even where all activities involving human subjects are carried out by a subcontractor or collaborator; and/or
5. The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (**OHRP**) in which the LRH IRB is designated as the IRB of record through an established IRB Authorization Agreement.

B. No research involving human subjects, including intervention, **interaction**, collection of **identifiable private information**, administration of **test articles**, advertising, recruitment, or screening, may begin until the LRH IRB has reviewed and approved the research, issued an exempt determination, or accepted the oversight of an external IRB of Record.

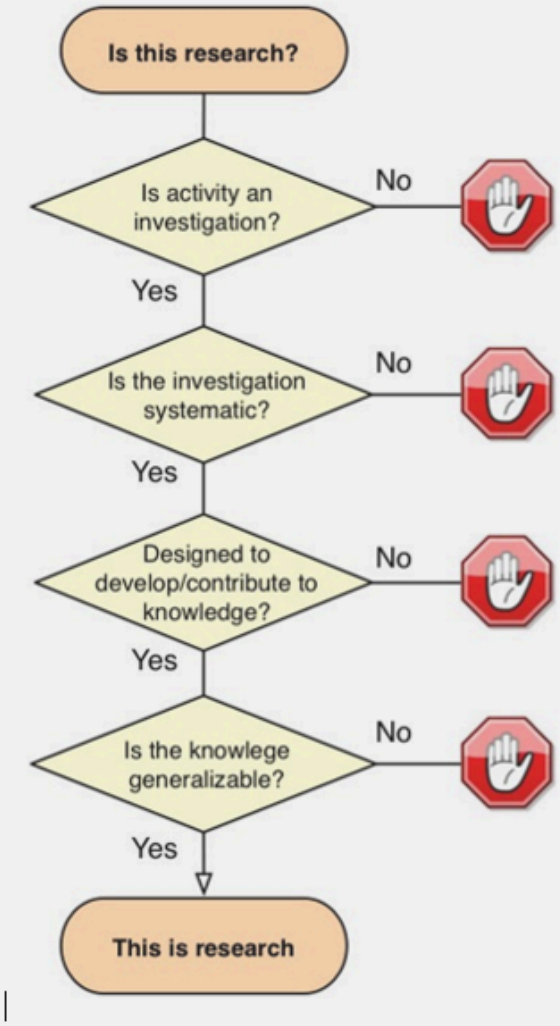
III. Failure to Submit Human Subjects Research for IRB Review

A. Failure to obtain IRB approval or an exempt determination from the IRB is considered non-compliance, which may result in a revocation of permission to conduct research at LRH.

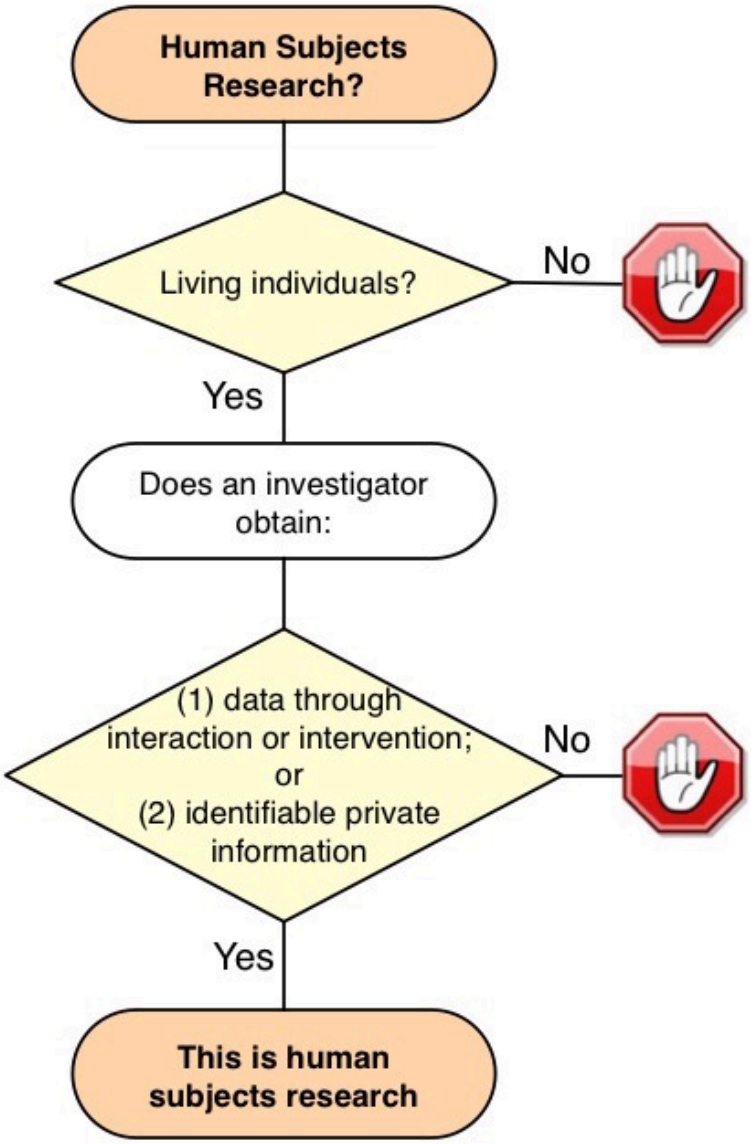
B. The IRB will not grant post-hoc approval for research conducted without prior IRB review and approval.

C. The IRB will not grant post-hoc exempt or **non-human subjects research** determinations for research already conducted at the time of the determination request.

# Appendix A


Is this research?
Is activity an investigation?
No
Yes
Is the investigation systematic?
No
Yes
Designed to develop/contribute to knowledge?
No
Yes
Is the knowlege generalizable?
No
Yes
This is research

# Appendix B




# DEFINITIONS

**Generalizable**: Externally applicable.

**Human Subject (DHHS)***: A **living individual** about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**.

**Human Subject (FDA)***: An individual who is or becomes a participant in research, either as a recipient of the

test article or as a control and/or an individual on whose specimen a device is used. A human subject may also include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research.

> *The difference between these definitions relate to the FDA's role in regulating investigational test articles (drugs, biologics or devices). If a person receives an investigational test article, then they are a human subject, regardless of the study design. Therefore, treatment with an investigational agent in a protocol designed to treat a single individual is enough to suffice that individual is a human subject even though generalizable knowledge will not result.

**Identifiable biospecimen***:* A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Identifiable private information***:* Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Interaction***:* Includes communication or interpersonal contact between investigator and subject.

**Intervention**: A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

**Living Individual/Decedent**: Research that includes both living individuals and decedents must be reviewed by the IRB. Human subjects research involving decedents is not covered under the Common Rule. However, decedents are still covered by HIPAA's Privacy Rule. If the research only pertains to decedents then the investigator does not need IRB approval, but must submit a HIPAA authorization to the IRB prior to conducting the research.

**Non-Human Subjects Research**: Activities that do not meet the definition of human subjects research.

**Private Information**: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party.

**Research (DHHS)**: A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge under 45 CFR §46.102(l).

**Research (FDA)**: Defines the term clinical investigation or research to mean any experiment that involves a test article and one or more human subjects where the test article is regulated by the FDA. The FDA considers the term clinical investigation as being synonymous with the following: research, clinical research, clinical study, study and clinical investigation under 21 CFR §56.102. FDA regulations govern clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. This includes any new or unapproved item regulated by the FDA and

the application of approved items to new populations or indications. Research from the FDA's perspective, hinges on whether or not an investigational **test article**, which could be a drug, a biologic or a device is used. This definition is different from the DHHS definition.

**Systematic**: Means that the activity follows a written plan and adheres to scientifically accepted principles for research design.

**Test article**: As defined by the FDA means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. §262 and 263b-263n); 21 CFR §50.3(j).

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

# REFERENCES


I. 2018 Requirements (2018 Common Rule) | HHS.gov
II. eCFR :: 21 CFR Part 50 -- Protection of Human Subjects
III. eCFR :: 21 CFR Part 56 -- Institutional Review Boards
IV. eCFR :: 21 CFR Part 312 -- Investigational New Drug Application
V. eCFR :: 21 CFR Part 812 -- Investigational Device Exemptions
VI. 42 U.S. Code § 262 - Regulation of biological products | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)
VII. TOPN: Public Health Service Act | US Law | LII / Legal Information Institute (cornell.edu)




## Approval Signatures

| Step Description | Approver | Date |
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| | Danielle Drummond: 0001 President & Chief Executive Officer - LRHS | 03/2024 |
| | Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou | 03/2024 |
| | Renee Reed: 4064 Senior Attorney | 03/2024 |
| | Michael Spake: 0057 SVP - External Affairs/Chief Compliance | 03/2024 |
| | Deana Nelson: 4080 SVP - Administration and Corporate Initiative | 03/2024 |

| | |
|---|---|
| Georgia Ann Keriazes: 0729 QI/ Due Pharmacist | 03/2024 |
| Andrew Bugajski: 4387 AVP - Research and Sponsored Studies | 11/2023 |