

	<b>DEFINITION OF HUMAN SUBJECTS RESEARCH</b>			
	<b>P &amp; P</b>	<b>VERSION DATE</b>	<b>REPLACES P &amp; P</b>	<b>PREVIOUS VERSION DATE</b>
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## I. INTRODUCTION

Any activity that meets either (A) the Department of Health and Human Services (DHHS) definition of both “research” and “human subjects” or (B) the Food and Drug Administration (FDA) definitions of both “clinical investigation” and “human subjects” requires review and approval by the LSUHSC-NO IRB.

The IRB reviews each study submission to ensure that research being conducted adheres to the highest ethical standards involving the use of humans as subjects in research, while complying with all university, state, federal, and agency requirements.

## II. DEFINITIONS

### A. Department of Health and Human Services (HHS)/Common Rule

**Research:** *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(I)]*

This leads to two further explanations:

- 1) **Systematic investigation:** An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. Often include surveys, interviews, data analyses, cognitive experiences, or medical chart reviews.
- 2) **Generalizable Knowledge:** Knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts:
  - i) Knowledge that contributes to a theoretical framework of an established body of knowledge;
  - ii) Primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study;
  - iii) Dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research)
  - iv) Results are expected to be generalized to a larger population beyond the site of data collection;
  - v) Results are intended to be replicated in other settings.

Activities that meet the criteria of both a systematic investigation **AND** generalizable knowledge are considered “research.”

**Human Subject:** a living individual **about whom** an investigator conducting research:

- 1) Obtains information or biospecimens through intervention or interaction with the individual, **AND** uses, studies, or analyzes the information or biospecimens; **OR**
- 2) Obtains, uses, studies, analyzes, or generates *identifiable private information or identifiable biospecimens.* [45 CFR 46.102(e)]

**Special Note:** *identifiable private information/identifiable biospecimens* is private information that is individually identifiable, including coded private information or biological specimens. Whether or not “coded private information/specimens” is classified as “human subjects” is determined by the following the source of the data (primary or secondary data) and ability or inability of the investigator to link data/ specimens to specific individuals either directly or indirectly through coding systems.

This leads to further explanations:

- **Living:** information or biospecimens obtained about/from individuals who are living. Research involving only information or biospecimens associated with individuals who are deceased (decedents) is not covered under the Common Rule but is still covered by HIPAA's Privacy Rule. If the project includes only information/specimens from cadavers, autopsy specimens or specimens/information from subjects, it is not considered Human Subjects.
- **About Whom:** the information or biospecimens received from/about the living individual must be about the person.
- **Intervention:** includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture, tissue samples etc) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction:** includes communication or interpersonal contact between investigator and subject.
- **Identifiable:** the identity of the subject is or may readily be ascertained by the investigator with the information obtained as part of the research.
- **Private information or biospecimens:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, academic records, personal journals). The opposite of this is public use data or information that is in the public domain (for example, available to the public without terms or conditions or signing an agreement or joining a membership).
- **Individually Identifiable:** The identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimens
- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- **Coded Private Information or Specimens:** identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code

exists, enabling linkage of the identifying information to the private information or specimens.

## **B. Food and Drug Administration (FDA)**

Food and Drug Administration (FDA), meanwhile, uses the term "clinical investigation" to define which FDA regulations apply to studies. For the purposes of FDA regulations, the terms research, clinical research, clinical study, study, and clinical investigation are synonymous.

If the activities involve use of an FDA regulated test article (i.e., drug, device, food substance, or biologic under the purview of the FDA), LSUHSC-NO IRB applies the FDA definitions of "human subjects."

Research - For the purposes of FDA regulations, the terms research, clinical research, clinical study, study, and clinical investigation are synonymous.

Clinical Investigation: Any experiment that involves the use of a *test article* (i.e., drug, device, food substance, or biologic), one or more human subjects, meets requirements for prior submission to the FDA (involves drugs or medical devices other than the use of FDA approved drugs or medical devices in the course of medical practice), or results are intended to be part of an application for research or a marketing permit. [ [21CFR56.102](#) ]

- **A test article** 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 Federal Food, Drug and Cosmetic Act. (21 CFR 50.3(j))

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral healthrelated outcomes. [ [45 CFR 46.102\(b\)](#) ]

Human Subject: The FDA regulations define "Human Subject" as 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 individual or a patient." [ [21 CFR 56.102\(e\)](#) ] (Drug, Food, Biologic).

If the research involves a Medical Device, individuals are considered a "subject" when they participate in the investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. [ [21 CFR 812.3\(p\)](#) ] NOTE: This definition includes the use of tissue specimens even if they are unidentified.

If the research involves any of the following, FDA regulations 21 CFR 50 & 56 apply and require IRB approval prior to implementation:

- Any use of a drug in research other than the use of an FDA approved drug in the course of medical practice;
- Any use of a medical device in studies where the purpose is to determine the safety or effectiveness of the device; or
- Data will be submitted to or held for inspection by FDA as part of a marketing permit.

## **C. Additional Agencies and Institutional Oversight**

In cases in which any other federal agency apply, institutional oversight of the activity follows the definitions for “research” and “human subjects” as defined by the relevant agency. In cases where the definition of “research” or “human subject” is different from above, LSUHSC-NO IRB applies institutional oversight based on the applicable sponsor or agency specific definitions.

For **Department of Defense-supported research**, institutional oversight of the activity follows the definitions of “*research*” and “*experimental subject*” as defined by Department of Defense regulations [DoD Directive 3216.02]: “An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects.”

### III. ACTIVITIES REQUIRING IRB REVIEW AND APPROVAL

- Gathering data about an individual that is identifiable (i.e., the identity of the individual is or may be readily ascertained or associated with the information provided) and is considered private information for research purposes
- Interacting (communication and/or interpersonal contact) with a human subject for the purposes of gathering data or information about that person for research purposes
- Performing an intervention that includes physical procedures by which data are gathered (e.g., taking blood or tissue samples, etc.) on an individual and/or that manipulate the individual’s environment for research purposes
- Any activity that is subject to FDA regulations as a clinical investigation must be reviewed and approved by the IRB. FDA regulations apply if:
  - Project involves the use of a drug, biologic, dietary supplement, or medical device that is not approved for use for any purpose in the United States;
  - Project involves the study of a drug, biologic, dietary supplement, or medical device for which some aspect of the administration is dictated by your research protocol (e.g., randomization, protocol dictates route or dose, etc.); OR
  - Study data will be reported to the FDA (e.g., comparison studies of marketed drugs, clinical trials of new or investigational drugs or devices, or studies of in vitro diagnostic devices).

### IV. ACTIVITIES NOT MEETING THE REGULATORY DEFINITION OF HUMAN SUBJECTS RESEARCH

Any activity that does not involve research as defined by the federal regulations, human subjects, or an FDA clinical investigation is considered a non-human subjects research project. Examples of non-human subjects research are:

- **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (Please note: For scholarly and journalistic activities to be considered to not meet the definition of research, they must be conducted solely for the primary intent of the activity in question. For example, an oral history project being done solely for the purpose of

collecting oral history interviews for archiving in a repository to be made available to the public for future use and historic preservation would not be considered research. However, a project that is designed to contribute to generalizable knowledge that happens to involve the use of oral histories and is being conducted for both purposes (i.e., contributing to generalizable knowledge and collecting oral history interviews), whether or not the interviews will be deposited into an archive, may still meet the definition of research and require IRB review.)

- **Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, 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 manmade disasters).
- **Criminal Justice Activities**: 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
- **Authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- **Quality improvement projects**, including program evaluation
- **Single patient case studies**
- **Projects where LSUHSC-NO is not considered engaged in research activities**
- **Research with deceased individuals**
- **Research accessing only a limited data set or deidentified data set**
- **Research on coded tissues or samples** for which the investigator does not hold the code linking samples to identifiable information

If your project is not human subject's research, no IRB application is needed. If documentation of this decision is required (e.g., by a sponsor or collaborator), the investigator can submit a "not human subjects" protocol request. View our website for a more detailed description of "not human subject's research activities."

## V. PROCEDURE

- It is the responsibility of each investigator to seek IRB review and approval prior to initiation of any research involving human subjects or before conducting any clinical investigation.
- The investigator is responsible for making a preliminary decision regarding whether his/her activities meet either (a) the U.S. Department of Health and Human Services (HHS) definitions of both "research" and "human subjects" and/or (b) the FDA definitions of both "clinical investigation" and "human subjects." Resources listing activities that are not

subjects to HSR regulations and how to determine the level of review are available on our website to guide investigator in making this decision.

- In cases where it is not clear whether the study requires IRB review, the IRB highly recommends the investigator to submit a protocol for an official determination request, and the IRB office will provide the decision to the submitter through the electronic system.
- If the project is not human subjects research and does not require IRB review and approval, documentation of this decision can be provided by the IRB Office by submitting a “not human subjects.”