

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
<b>Revision #12</b>	<b>TITLE: Determination of Activities That Need IRB Review</b>		<b>Page 1 of 5</b>
Approved By: ORI Director	Signature	Date	Date First Effective: 05-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 02-15-19

## **OBJECTIVE**

To describe policies and procedures for determining the types of activities that qualify as human research or clinical investigations and therefore require prior Institutional Review Board (IRB) review and approval

## **GENERAL DESCRIPTION**

In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a University of Kentucky (UK) faculty, staff, or student conducts human research. The UK policy document entitled “When Do Activities Involving Human Subjects Need Institutional Review Board (IRB) Review and Approval?” outlines what types of activities are human subjects research or clinical investigations and therefore require IRB review and approval.

### *Definitions*

#### *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(l)]. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Also, if a study involves human subjects (in accordance with the human subject definition below) and is being done for the purpose of completing an academic degree program (e.g., thesis, capstone, dissertation, etc.), it is considered by the university to meet the definition of research, whether designed to contribute to generalizable knowledge or not.

*Human Subject* is a living individual about whom an investigator (whether professional or student) 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.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #12</b>	<b>TITLE: Determination of Activities That Need IRB Review</b>	<b>Page: 2 of 5</b>

*Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual will not be made public (e.g., a medical record).

*Food and Drug Administration (FDA)*

*Clinical investigation* involves 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.

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), UK applies the FDA definitions of "human subjects."

*Human subject (FDA)* is an individual who is or becomes a participant in research either as a recipient of a test article or as a control or as an individual on whose specimen a device is used. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)] (Drug, Food, Biologic).

*Human subject (FDA for medical devices)* is a human who participates in an 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)] (Medical Devices). 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.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #12</b>	<b>TITLE: Determination of Activities That Need IRB Review</b>	<b>Page: 3 of 5</b>

*University of Kentucky*

The definition of *human subject* typically means only “living individuals”; however, at UK, research involving fetal tissue requires IRB review. Other exceptions involving collection of human specimens in FDA regulated device research may apply.

In cases where the definition of “research” or “human subject” is different from above, UK IRB applies institutional oversight based on the applicable sponsor or agency specific definitions (e.g., See the Department of Defense/IRB/ORI Coordination SOP).

A *principal investigator* may be a UK employee, UK student, or in rare cases may be an employee at a site with which UK has signed an IRB Memorandum of Understanding, IRB Authorization or Individual Investigator Agreement.

For the purpose of evaluating whether an activity meets the definition of research, the following activities have been excluded:

- 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).
- 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

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #12</b>	<b>TITLE: Determination of Activities That Need IRB Review</b>	<b>Page: 4 of 5</b>

investigative purposes.

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

## **RESPONSIBILITY**

Execution of SOP: Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff, IRB Members, IRB Chairs.

## **PROCEDURES**

### *Human Subject Research Determinations*

1. 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.
2. 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.” The document titled “When Do Activities Involving Human Subjects Need Institutional Review Board (IRB) Review and Approval?” is available to guide the investigator in making this decision. However, only the IRB or its official designee(s) can make an official determination.
3. The investigator may contact ORI staff, the IRB Chair/Vice Chairs, or IRB members for advice on the applicability of the federal regulations and UK policy.
4. In cases where it is not clear whether the study requires IRB review and/or to receive an official determination, the ORI or IRB may ask the investigator to submit a Not Human Research (NHR) determination request form to the IRB/ORI detailing the proposed project/research. The Director or IRB Chair or their designees review the request and make the final determination whether the activities meet the federal definitions using, as a guide, such documents as (but not limited to), “When Do Activities Involving Human Subjects Need Institutional Review Board Review and Approval?” and “UK Guide for Determining When Protocols Involving Coded Private Information or Biological Specimens Meet the Federal Definition of Human Research,” and applicable federal policy/regulation(s).
5. The ORI communicates the decision of the IRB or the ORI to the investigator. If the investigator has concerns regarding the decision, he/she may submit a written appeal to the ORI that includes justification for the concerns. The appeal and justification are reviewed by the IRB or its official

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #12</b>	<b>TITLE: Determination of Activities That Need IRB Review</b>	<b>Page: 5 of 5</b>

designee(s) and the official decision provided to the investigator by the ORI. The appeal determination is final.

### **REFERENCES**

21 CFR 56.102

45 CFR 46.102

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