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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: 01-24-14

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 (DHHS)/Common Rule

Research: A systematic investigation designed to develop or contribute to generalizable knowledge [45CFR 46.102(d)]. Activities which 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. Some research development or testing and evaluation may also meet this definition.

Human subjects (DHHS): A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

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Intervention includes both physical procedures by which data are gathered (for example, 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

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 subjects (FDA): 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 subjects (FDA for medical devices): 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.

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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.

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 Department of Health and Human Services (DHHS) definitions of both “research” and “human subjects” and/or (b) the FDA definitions of both “clinical investigations” 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. (See attachment.)
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, the ORI or the IRB may ask the investigator to send a memorandum to the IRB/ORI by e-mail or hard copy detailing the proposed research. In complicated cases, the ORI or the IRB may ask the investigator to complete and submit an application to the IRB for a decision. The Director or IRB Chair or their designees make the final determination whether the activities meet the federal definitions using,

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as a guide, the documents, “When Do Activities Involving Human Subjects Need Institutional Review Board Review and Approval?”, “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. The IRB or ORI may require the investigator to contact the applicable regulatory agency to assist in making the determination.

5. The ORI communicates the decision of the IRB or the ORI to the investigator via phone, e-mail, or hard copy.

Delegated Determination Process

1. Data banks or specimen repositories may submit a request to the IRB for the bank/repository to be delegated the authority to make IRB review determinations for individuals or entities accessing the bank’s/repository’s material. The bank/repository submits a comprehensive protocol to the IRB for review and approval.
2. If approved, the designated individuals must complete initial training and are responsible for remaining up to date on UK and federal requirements. The IRB/ORI provide the designee with training regarding the regulatory framework and specific conditions that must be met in order for an activity to be designated as, ‘not human subject research requiring IRB review’.
3. In making the determination, the designee uses the documents, “When Do Activities Involving Human Subjects Need Institutional Review Board Review and Approval?”, “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.
4. If the designee is unsure whether activities need IRB review, the designee consults with ORI or IRB or can send the researcher to ORI/IRB for a determination.
5. The designee maintains and makes available for inspection by the ORI/IRB all determinations records.

REFERENCES

[21 CFR 56.102](#)
[45 CFR 46.102](#)