

When do activities need Institutional Review Board (IRB) review and approval?

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 University of Kentucky (UK) IRB.

Research: “A systematic investigation designed to develop or contribute to generalizable knowledge” [45CFR 46.102(d)]

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” [45 CFR 46.102(f)]

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 FDA, or results are intended to be part of an application for research or marketing permit” [21 CFR 56.102]

Human Subjects (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 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) NOTE: This definition includes use of tissue specimens even if they are unidentified.

In cases in which VA regulations or those of any other federal agency apply, institutional oversight of the activity follows the definitions for “research” and “human subjects” as defined by VA regulations [VA Handbook 1200.05] or the relevant agency as appropriate.

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].

The following are examples of human subject research studies that must be reviewed and approved by the UK IRB.

Masters thesis/Doctoral dissertation: graduate work which involves research on human subjects or a clinical investigation and results in a thesis or dissertation.

Pilot studies: pilot studies involving human subjects are considered human subject research and require IRB review.

Clinical research: involves research to increase scientific understanding about normal or abnormal physiology, disease states or development and to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention. Vaccine trials, medical device research and cancer research are all types of clinical research.

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.

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, monitoring, and reporting programs. Other methods are retrospective review of medical, public health and/or other records.

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.

The following activities may or may not meet the definitions of “research” and “human subjects” and require IRB review. Definitions to aid in the clarifications of “human subject” appear at the end of the document:

Quality Assurance/Quality Improvement Activities: activities that attempt to measure the effectiveness of programs or services may constitute human subject research and require IRB review if they are designed or intended to contribute to generalizable knowledge. Individuals must be certain that their activities are not human research. The IRB or designated ORI staff have the sole authority to determine whether an activity is human research. Individuals who are uncertain whether an activity is human research must contact the IRB for a determination. The investigator is responsible for submitting the description of the activity to the IRB. If such studies are designed for internal UK quality assurance or program evaluation, with no external application or generalization, IRB review is not required.

Class Projects: projects or assignments involving collection of data from human subjects may or may not meet the definition of research. Course instructors are responsible for making the decision whether the activities meet the definition of “research” (i.e. determining if the activities are systematic and will contribute to generalizable knowledge). For assistance, faculty are encouraged to contact the ORI.

Repository Research, Tissue Banking, and Databases: research utilizing stored data or materials (cells, tissues, fluids, and body parts) from individually identifiable living persons must be reviewed by the IRB. However, if the investigator can not readily ascertain the identity of the subject from whom the data or materials originated, the research may not meet the definition of “human subject”. The exception would be use of tissues or specimens in FDA regulated device studies. The FDA device regulations include ‘unidentified tissue specimen’ in the FDA device definition of human subject. Individuals must be certain that their activities are not human research. The IRB or designated ORI staff have the sole authority to determine whether an activity is human research. Individuals who are uncertain whether an activity is human research must contact the IRB for a determination. Researchers are responsible for submitting requests to the IRB.

Case Reports: medical information collected from a clinical activity rather than a research activity and presented on no more than three (3) patients does not need IRB review. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The investigation is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that UK Medical Center HIPAA privacy rules are adhered to in order to protect the confidentiality of the patient(s). Retrospective chart reviews that incorporate data collection and data analysis to answer a research question must undergo IRB review. Case reports involving more than three (3) patients must undergo IRB review.

Definitions to determine “human subjects” according to 45 CFR 46.102(f)

Intervention: includes physical procedures such as blood samples, x-rays; or the manipulation of the environment in order to stimulate certain types of behavior

Interaction: includes interpersonal communication between the investigator and subject through surveys, interviews, administration of educational tests etc.

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: a context in which an individual can reasonably expect that no observation or recording is taking place or information that is provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

For questions regarding applicability of the requirements for IRB review, please contact the Office of Research Integrity, 315 Kinkead Hall, Ph: 257-9428, fax: 257-8995, email: hbullo@uky.edu