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

(If there are any questions regarding what does or does not require UK IRB review contact ORI at 859-257-9428)

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.

REGULATORY DEFINITIONS:

Research (DHHS): "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes or not. For example, some demonstration and service programs may include research activities". [**45 CFR 46.102(l)**]

Human Subjects (**DHHS)**: "A living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains uses studies, analyzes, or generates identifiable private information or identifiable biospecimens." [**45 CFR 46.102(e)**]

- 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.
- 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: 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 and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).
- 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.

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 health related outcomes. [**45 CFR 46.102(b)**]

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 56.102(p)**] (Medical Devices) NOTE: This definition includes use of tissue specimens even if they are unidentified.

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 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**].

Table 1: Examples of What Does and Does Not Require UK IRB Review and Approval Prior to Initiation of Research.

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
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.	YES
Medical Practice	Standard practice, innovative care, or off-label use of FDA-approved drugs, biologics, devices and other articles or substances that are used in the normal course of medical practice, provided the activity does not involve systematic collection of safety or efficacy data, and is limited to prevention, diagnosis, mitigation, treatment, or cure of disease in affected individuals.	NO
Emergency Use of an Investigational Drug or Device	Institutional Policies do not permit research activities to be started, even in an emergency, without prior IRB acknowledgement. 1. This does not limit the physician's ability to deliver emergency care. The physician may deliver such care, but the data derived from such care may not be used in any prospectively conceived research. 2. Emergency care involving investigational drugs, devices or biologics must meet the Food and Drug Administration (FDA) criteria. (see Emergency Use SOP for further guidance: https://www.research.uky.edu/uploads/ori-c30250-emergency-use-sop-pdf)	IRB Chair or designee notification
Humanitarian Use Device (HUD)	Both clinical and investigational use of a HUD device.	YES
Pre-Review of Clinical Data Sets	Preliminary activities typically designed to help the Investigator refine data collection procedures. This data is to be included in the analysis or publication.	YES
	Activities (e.g., review of medical data, queries, etc.) intended only to assess the feasibility of future research. *Note that UK or other "covered entity" will need to obtain researcher certifications for a review preparatory to research for HIPAA compliance purposes.*	NO
Repositories (e.g., data, specimen, etc.)	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.	YES
Public Health Surveillance Activities	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).	NO

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Newborn dried blood spots	Submit a not human research (NHR) request form to ORI for a determination of need for IRB review. If subject population has received notification that private information will be used for research purposes (e.g., HIPAA Privacy Notice), IRB review may not be required.	YES
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 may include secondary research with data collected through surveillance, monitoring, and reporting programs. Other methods are retrospective review of medical, public health and/or other records.	YES
Research Involving Only Decedents	Research involving only data or tissue obtained from individuals who are deceased prior to the conduct of the research. There must not be any interaction or intervention with living individuals, or collection of private data or specimens associated with living individuals. Under HIPAA regulations, researchers within the UK or other "covered entity" must obtain a HIPAA waiver of authorization for review of identifiable protected health information (PHI).	NO *(contact Privacy Officer for HIPAA requirements)*
	Research involving fetal tissue.	YES
Standard Diagnostic or Therapeutic Procedures	The collection of data about a series of established and accepted diagnostic or therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge. (See Case Report for exceptions)	YES
	An alteration in patient care or assignment for research purposes.	YES
	A diagnostic procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient or student but not for the purposes of research. (See Case Reports)	NO
Case Report - Clinical	Report about three or fewer clinical experiences or observations identified in the course of clinical care, provided that it does not involve safety or efficacy data on FDA regulated products (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE. Case reports are generally done by retrospective review of medical records and highlights a unique treatment, case or outcome. Please note: UKMC HIPAA policies apply to this project. Please contact UK's Privacy Officer for assistance in complying with UKMC's HIPAA policies.	NO
Case Report – College of Education (COE)	COE research in early childhood, special education, counselor education, etc., by nature, involves small numbers of participants from specialized populations. These projects are often designed to contribute to generalizable knowledge such as informing evidence-based practice (EBP), including potential future EBP. As such, these projects meet criteria as human subject research.	YES
Case Report - Other	Report about experiences or observations associated with three or fewer individuals.	NO

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Quality Assurance and Quality Improvement (QA/QI) Activities - Clinical or Procedures (Federal guidance on QA/QI activities is available at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/)	A QA/QI activity that involves introducing an untested or innovative practice or intervention, for not only the purpose of improving quality, but also for establishing scientific evidence to determine how well the practice/intervention achieves its intended results.	YES
	Systematic, data-guided activities designed to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices at the University of Kentucky. The individual conducting the activity is in a position to affect change. If there is intent to disseminate results beyond UK, please contact ORI for further guidance.	NO
Quality Assurance and Quality Improvement (QA/QI) Activities - Non-Clinical (Federal guidance on QA/QI activities is available at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/)	A QA/QI activity that involves introducing an untested or innovative practice or intervention, for not only the purpose of improving quality, but also for establishing scientific evidence to determine how well the practice/intervention achieves its intended results.	YES
	Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs at the University of Kentucky. The individual conducting the activity is in a position to affect change. Examples include teaching evaluations or customer service surveys. Contact ORI with questions or additional guidance.	NO
Innovative Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants [more than three (3)]. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely to enhance the well-being of an individual patient or client and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual.	NO *(unless FDA regulations requiring IRB approval apply such as use of: articles (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE)*
UK functioning as the Coordinating Center for a Multi-Center Research Project	UK is *not* an enrolling site and the UK PI has agreed to serve as the coordinating center for a multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
	UK *is* an enrolling site and the UK PI has agreed to serve as the coordinating center for the multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
Establishing Subject Pools	Activities with the purpose of recruiting subjects for future research studies.	YES

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Pilot Studies	Pilot studies involving human subjects are considered human subjects research.	YES
Research Using Publicly Available Data Sets	Use of publicly available data sets that exist without identifiers, or where individuals identified would not have an expectation of privacy. "Publicly available" is defined as information shared without conditions on use. This may include data sets that require payment of a fee to gain access to the data.	NO
NIH-funded Research that generates large-scale genomic data	Research that falls under the NIH Genomic Data Sharing (GDS) Policy: Research that generates large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data. Examples can be found in the Supplemental Information to the **NIH Genomic Data Sharing Policy.**	YES
Research on Organizations	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not include identifiable private information about individual members, employees, or staff of the organization.	NO
Community Service Projects	Donated service or activity that is performed by someone or a group of people solely for the benefit of the public or its institutions.	NO *(but if human subjects data are collected during the activity to be used for research protocols, submission is required to the IRB)*
Secondary use of research data	Analysis of data gathered for a previous research protocol not related to current proposal and the data are de-identified. Investigator and study personnel cannot ascertain the identity of subjects who initially provided the data. De-identified means removal of the 18 identifiers recognized by the HIPAA regulations which can be found under the HIPAA De-identification Certification Form at the following link: **HIPAA De-identification Guidance**	NO *(but if data has direct or indirect identifiers, submission is required to the IRB)*
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.	YES
Oral History	Interviews concerning the past that collect and interpret the voices and memories of people as a method of historical documentation and that are preserved by placement in some form of repository or archive for access by other researchers. Includes the collection and use of information that focus directly on the specific individuals about whom the information is collected without extending that information to draw generalizations about other individuals or groups. Research activities conform to the Principles of Best Practices of the Oral History Association: **OHA Best Practices**	NO *(but exercise of professional ethics is expected)*

ACTIVITIES	DESCRIPTION	SUBMISSION

		REQUIRED TO IRB
Oral History Research	Activity involves collecting and using information about individuals for the purpose of drawing generalizations about such individuals or a population of which they are members, Studies using methods such as participant observation and ethnographic studies which gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong. https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html	YES
Journalism	Scholarly and journalistic activities (e.g., 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; or on the collection, verification, reporting, and analysis of information or facts on current events, trends, issues or individuals involved in such events or issues. There is no intent to test hypotheses, and activities cannot reasonably be characterized as comprising systematic investigation. Research activities should be consistent with the Code of Ethics of the Society of Professional Journalists http://www.spj.org/ethicscode.asp	NO *(but exercise of professional ethics is expected)*
Master's thesis/ Doctoral Dissertation/ Capstone	Graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research or a capstone.	YES
Student Practicum and Internship (Professional schools within UK which actively seek opportunities for their students to become involved in "real world" activities or work assignments that will introduce them to and, in some cases, provide practical experiences in their chosen profession)	A practicum/internship that falls within the work scope of a local, state, or federal agency (*e.g.* Public Health Agency) or employment by private industry involving data collection for non-research purposes. No *a priori* research design or intent.	NO *(but professional standards apply)*
	Use of or access to human subjects data previously collected for non-research purposes (perhaps through a circumstance like the one above) in a systematic investigation designed to contribute to generalizable knowledge, one indicator of which is publication.	YES
	Independent research project not falling within the scope of a previously approved project.	YES
	Participation with or providing services to a UK PI conducting IRB-approved research. No work outside the scope of the IRB approval.	YES (*Modification to protocol to add student if providing research assistance at level of study personnel)*
Classroom Assignments Involving Human Subject Research	Activities that may create new knowledge or are intended to contribute to generalizable knowledge (e.g. via publications, articles, posters, conference presentations or capstone dissemination), are human subject research requiring prospective IRB review and approval. Activities done solely for educational purposes, (e.g., teach research methods, demonstrate course concepts), with no intent to disseminate or contribute to generalizable knowledge generally does not require review. Course instructors should contact ORI for guidance in these instances.	YES

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Internet Research	Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified and data are collected through intervention or interaction with research subjects.	YES
	Research involving online interactions with or data collection from internet community members that may expect a level of privacy and confidentiality such as vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors, etc.). Also includes data collected where an individual cannot be directly identified and data are collected through intervention or interaction with research subjects.	YES

IF UNSURE WHETHER IRB REVIEW AND APPROVAL IS NEEDED, SUBMIT A NOT HUMAN RESEARCH (NHR) DETERMINATION FORM TO ORI

For a determination on whether your project constitutes human research and is therefore subject to review by the University of Kentucky IRB, submit an NHR Form available on REDCap. Upon completion of the questionnaire, your responses submit to the Office of Research Integrity (ORI). Someone may also contact you with additional questions to help qualify the official determination.

Adapted from the University of Michigan Vice President for Research Operations manual (http://www.hrpp.umich.edu/om/Part4.html)
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