Determining If an Activity Requires IRB Review and Approval

Determining whether an activity requires IRB review depends on a number of factors that can be challenging for investigators to evaluate. The Franklin University IRB recommends that investigators always consult with the IRB Office prior to initiating a study. Failure to obtain IRB approval when required may result in automatic suspension or termination of research activities. Moreover, many journals require evidence of IRB review and approval as a condition for publication; the IRB Office cannot retroactively approve a protocol.

The table below serves as a guide to the IRB only. It is not a guarantee that your project does or does not require IRB review, and it is not a substitute for contacting the IRB Office to make an informed determination.

Note that ALL research designed and intended for use in a doctoral dissertation is considered research that must be reviewed and approved by the Franklin University IRB.

If you have questions about whether an activity requires IRB review, contact the IRB Office at 614-947-6037 or irb@franklin.edu.

Guidance

Any activity that meets the Department of Health and Human Services (DHHS) definition of both "research" and "human subjects" requires review and approval by the Franklin University IRB.

> **Research**: "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 or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(l)]
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> **Human Subjects**: "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)]
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> - ***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.

ACTIVITIES	DESCRIPTION	SUBMISSION TO IRB REQUIRED
Master's Thesis/ Doctoral Dissertation	Graduate studies that involve human subjects and result in a thesis or dissertation research	**YES**
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**
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 using the following link: https://www.hipaajournal.com/de-identification-protected-health-information/	**NO** *(but if data has direct or indirect identifiers, submission to the IRB is required)*
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**
Classroom Assignments/ Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge. (See Guidelines for Class Projects)	**NO** *(but instructors have an obligation to ensure students meet professional and ethical standards)*
Quality Assurance and Quality Improvement (QA/QI) Activities (Federal guidance on QA/QI activities is available at https://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. (See QA/QI Guidance)	**YES**
	Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs at Franklin University. The individual conducting the activity is in a position to effect change. Examples include teaching evaluations or customer service surveys. Contact the IRB Office with questions or for additional guidance. (See also QA/QI 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**
Pilot Studies	Preliminary activities typically designed to help the investigator refine data collection procedures. Pilot testing is considered to be a research activity as defined in 45 CFR 46.102(l): "research means a systematic investigation, **including research development, testing, and evaluation**."	**YES**
Establishing Subject Pools	Activities with the purpose of recruiting subjects for future research studies.	**YES**
Research Using Publicly Available Data Sets	Use of publicly available data sets that do not include information that can be used to identify individuals. "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**
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**
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: http://www.oralhistory.org/about/principles-and-practices	**NO** *(but exercise of professional ethics is expected)*
Oral History and Ethnographic 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. Includes studies using methods such as participant observation and ethnographic studies that 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.	**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	**NO** *(but exercise of professional ethics is expected)*

	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	
Case Studies	Report about experiences or observations associated with one or two individuals.	**NO**
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.	**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.	**NO**
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 Franklin or other "covered entity" must obtain a HIPAA waiver of authorization for review of identifiable protected health information (PHI).	**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**

Adapted from the University of Michigan Vice President for Research Operations manual (http://www.hrpp.umich.edu/om/Part4.html) and the University of Kentucky Office of Research Integrity (https://www.research.uky.edu/office-research-integrity/what-needs-irb-review)