FRANKLIN UNIVERSITY

DESCRIPTION OF ACTIVITIES THAT NEED IRB REVIEW

Franklin University complies with applicable federal, state, and institutional policies and procedures. The Franklin IRB adheres to federal regulations detailed in 45 CFR 46 - Protection of Human Subjects. All IRB policies and procedures are structured around these guidelines and ethical research principles generally.

Prior to project implementation, the IRB reviews any undertaking in which a Franklin University employee (faculty or staff) or student conducts human subjects research. The IRB is charged with the comprehensive review of research proposals to ensure each project meets rigorous ethical standards, demonstrates a sound research design, and (for doctoral projects) details how the research satisfies the appropriate doctoral program learning outcomes. This section describes Franklin University's policies and procedures for determining the types of activities that qualify as human subjects research and therefore require prior IRB review and approval.

DEFINITIONS

These definitions are copied from the US Department of Health and Human Services (HHS)/Common Rule - 45 CFR 46.102.

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. For purposes of this part, the following activities are deemed not to be research:

(1) 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.

(2) 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 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).

(3) 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 investigative purposes.

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

***Human subject*:** A living individual about whom an investigator (whether professional or student) conducting research:

Effective Date: 02/13/2019
Older Versions: 02/13/2019, 03/11/2020, 03/28/2022
Last Reviewed and Modified: 11/20/2024

(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.

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 the information to constitute research involving human subjects.

A ***Principal Investigator (PI)*** may be a Franklin University faculty or staff member. If a Franklin University faculty or staff member is conducting collaborative research with external investigators and Franklin University is the IRB of record, the Franklin University employee must serve as the Principal Investigator.

Doctoral candidates are Principal Investigators for their research. Dissertation chairs serve as Co-Principal Investigators. Other students (i.e., undergraduate and master's) cannot be Principal Investigators on their research projects and require a faculty PI to lead the study.

PROCEDURES

Human Subjects Research Determinations

1. It is the responsibility of each investigator to seek IRB review and approval prior to the initiation of any research activities involving human participants. In almost all cases, this includes making secondary data requests.

2. A faculty or staff investigator is responsible for making a preliminary decision regarding whether his/her activities meet the US Department of Health and Human Services (HHS) definitions of both "research" and "human subjects". Student investigators who are conducting studies for doctoral dissertations, regardless of whether the project meets federal definitions of human subjects research or other regulatory criteria, are required to submit protocols to the IRB for review and approval.

3. The investigator may contact IRB staff for advice on the applicability of the federal regulations, state laws, and Franklin University policy.

4. In cases where it is not clear whether the study requires IRB review, the IRB Office may schedule a meeting with the investigator or ask the investigator to provide additional written details regarding the proposed research. In complicated cases, the IRB Office may ask the investigator to complete and submit an application to the IRB for a decision. The IRB Manager, IRB staff, and if necessary in

consultation with the IRB Chair or his/her designees, make the final determination whether the activities meet the federal definitions using applicable federal regulations and guidance. The IRB Office may contact the applicable regulatory agency, research compliance professionals, or other experts in the appropriate field for help in making a determination.

5. The IRB Office communicates the decision of the IRB to the investigator.