FRANKLIN UNIVERSITY

DESCRIPTION OF ACTIVITIES THAT NEED IRB REVIEW

In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a Franklin University employee (faculty or staff) or student conducts human research. This section describes Franklin University's policies and procedures for determining the types of activities that qualify as human research and therefore require prior IRB review and approval.

DEFINITIONS

Department of Health and Human Services (DHHS)/Common Rule

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)]. 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 subjects (DHHS)*:** A living individual about whom an investigator (whether professional or student) conducts research:

(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 obtaining the information to constitute research involving human subjects.

A ***Principal Investigator (PI)*** may be a Franklin University faculty or staff member. Students cannot be principal investigators on their research projects.

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.

2. The investigator is responsible for making a preliminary decision regarding whether his/her activities meet the Department of Health and Human Services (DHHS) definitions of both “research” and “human subjects”.

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

4. In cases where it is not clear whether the study requires IRB review, the IRB Office may ask the investigator to send a memorandum to the IRB by e-mail or hard copy detailing the proposed research. In complicated cases, the IRB may ask the investigator to complete and submit an application to the IRB for a decision. The IRB Manager, 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 policy/regulation. The IRB may contact the applicable regulatory agency for assistance in making the determination.

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