SOP 401a: DEFINITION OF RESEARCH INVOLVING HUMAN SUBJECTS

DEFINITIONS

a) Human Subjects Research subject to FDA Regulation

Activities are human research subject to FDA regulations when they meet the FDA definition of "clinical investigations" and involve a "subject" as defined in FDA regulations.

Under FDA regulations activities are "clinical investigations" when they involve:

a. Use of a drug other than the use of an approved drug in the course of medical practice
b. Use of a medical device other than the use of an approved medical device in the course of medical practice
c. Gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product.

In the above criteria "approved" means "approved by the FDA for marketing."

Under FDA regulations, individuals are considered "subjects" when they become a participant in research, either as a recipient of the test article or as a control. If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

b) Human Subjects Research subject to DHHS regulation

Activities are human subject research subject to DHHS regulations when they meet the DHHS definition of "research" and involve a "subject" as defined in DHHS regulations.

DHHS defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of his policy, the following activities are not considered research:

- 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.
- 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.[1]
- 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.
- Authorized optional activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Under DHHS regulations "subjects" means a living individual about whom an investigator (whether professional or student) conducting 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 or 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

[1] 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).

investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

POLICY

The University of Utah defines research involving human subjects as any one of the following:

(1) Human subject research subject to FDA regulation;
(2) Human subject research subject to DHHS regulation.
(3) Human subject research that meets the DHHS definition of research, regardless of the source of funding.

The University of Utah IRB will review all research conducted at the institution and its affiliates when it meets this definition.

The University of Utah has agreed to a federalwide assurance (FWA) to apply the Health and Human Services regulations and terms of the assurance to all federally funded research conducted at the institution. Generally, the University of Utah IRB will apply the Health and Human Services regulations to all human subject research conducted at the institution and its affiliates, regardless of the source of funding. Research that is not federally funded and that is outside of the FWA is subject to the same scrutiny except where otherwise described in University of Utah IRB policy.

Research that does not meet the definition of research involving human subjects must be determined by the IRB staff, not an individual investigator (see exceptions below). Investigators must complete and submit a Request for Non-Human Subject Research Review with any applicable documents.

Research projects involving analysis of secondary data from pre-approved, publicly available datasets/repositories will not require prior University of Utah IRB approval (see Investigator Guidance Series: Secondary Analysis of Existing Datasets on IRB website). Medical Case Reports may not require prior University of Utah IRB approval (see SOP 408).

The IRB administrator reviews claims of research which do not meet the definition of research involving human subjects. Determinations of "non-human subject research" are made by the IRB administrator who may consult with the IRB Chair or IRB Director, if necessary. A determination of non-human subject research is based on regulatory criteria and documented. All research activities that appear to be subject to DHHS and/or FDA regulations require IRB review as with any other new study application.

PROCEDURES

1. **Non-Human Subject Research Activities**

1.1. An Investigator who wishes to conduct research activities, or activities which he/she feels does not meet the regulatory definition of human subject research must submit a

Request for Non-Human Subject Research Review through the ERICA online system unless the research project is one which the University of Utah IRB does not require a submission (see exceptions above).

1.2. The IRB administrator reviews all information submitted by the investigator. The IRB administrator uses the IRB internal checklist (Determining Human Research According to FDA/DHHS Regulations) to document the review. Additional information may be requested via the ERICA system, as needed.

1.3. If a determination of "non-human subject research" is made by the IRB administrator, the investigator is notified via the ERICA online system.

1.4. If the IRB administrator determines that the project meets the regulatory definition of human subject research, the review proceeds as with any other new study application.