

Approved by IRB Executive Committee: February 11, 2009
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 AAHRPP Element I.3.C.

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. Gather 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.

Under DHHS regulations activities are “research” when they are a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under DHHS regulations “subjects” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

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.

POLICY

Research involving human subjects (participants) is defined as any one of the following:

- (1) Human subjects research subject to FDA regulation;
- (2) Human subjects research subject to DHHS regulation.

The University of Utah has agreed to a federal assurance to apply the Health and Human Services regulations and terms of the assurance to all research of the institution, regardless of the source of funding. Therefore the University of Utah IRB will review all research conducted at the institution and its affiliates when it meets the DHHS regulation of research.

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 an IRB new study application 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 does 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 subjects research must submit a proposal 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.

2 Protocols Lacking Definite Plans for Human Involvement

- 2.1 Certain types of activities are planned and written with the knowledge that human subjects may be involved, but without definite plans for such involvement. Examples of such proposed activities are:
 - Training programs in which individual training projects remain to be selected or designed.
 - Research, pilot or developmental studies in which the involvement of human subjects depends on such things as the completion of survey instruments or prior animal studies.
 - Institutional Support Programs where the selection of the project is the responsibility of the institution or program administrator. When supporting agencies require review and certification for such programs, protocols are to be submitted to the IRB with as much information as is available. The protocols must include assurances that additional information will be submitted when developed and, in the case of training grants, that all trainees will submit individual protocols if human subjects are to be used.
- 2.2 The IRB director may provide a letter of support with the understanding that the specific research protocol will be submitted to them once it has been developed. The letter of support does not imply approval of the IRB for these projects.