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Subject: Types of IRB Review
Division: IRB
Date: March 1, 2012

IRB Policy 105.1: HUMAN SUBJECTS RESEARCH

Policy

The IRB Chairperson, with assistance from the IRB Administrator, will determine whether research constitutes human subjects research. Investigators must submit a protocol to the IRB office, so that the IRB Chairperson and Administrator can make an independent determination if the research involves human subjects or not.

Definition of "Research"

HHS regulations define *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Definition of "Human Subject"

HHS regulations define *human subject* as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)).

- *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 the subject.

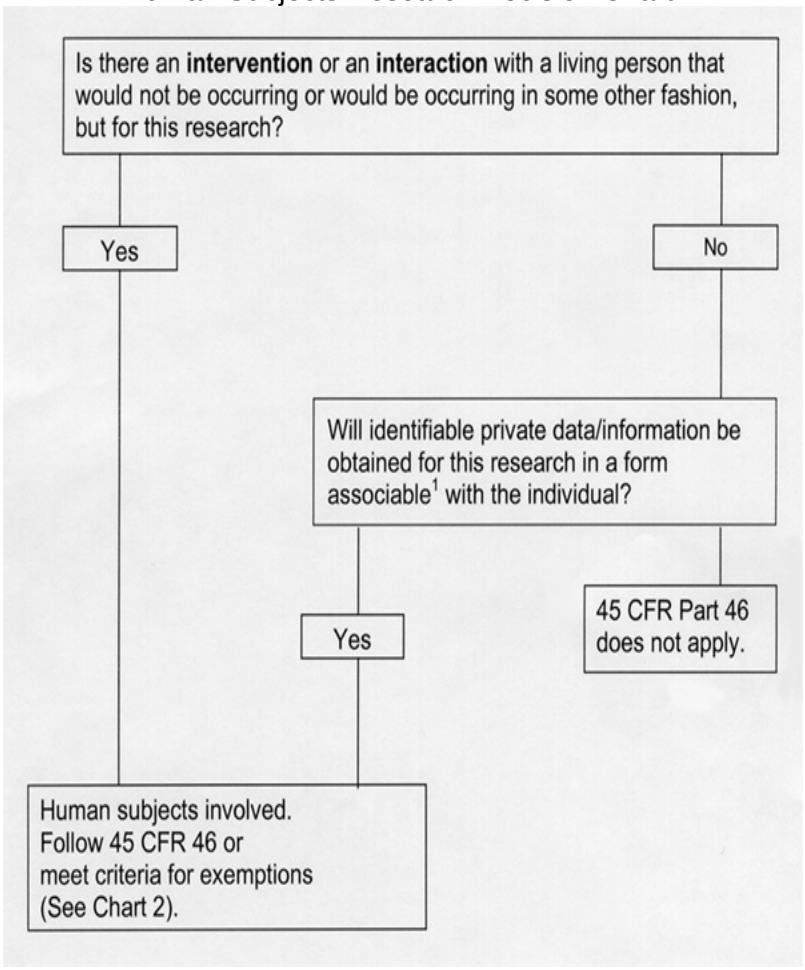
- *Private Information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taken place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect 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.

Determining if a Protocol Involves Human Subjects Research

Obtaining identifiable private information or identifiable specimens for research purposes constitutes

human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. FRI interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Human Subjects Research Decision Chart:



[1]That is, the identity of the subject is or may readily be ascertained or associated with information.

Coded Private Information

FRI does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

2. the investigator cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

    a) the investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (the IRB does not need to review and approve this agreement);

b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

This policy applies to existing private information and specimens, as well as to private information and specimens to be collected in the future for purposes other than the currently proposed research. The following are examples of private information or specimens that will be collected in the future for purposes other than the currently proposed research: (1) medical records; and (2) ongoing collection of specimens for a tissue repository.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human subjects under the HHS regulations. Unless this human subjects research is determined to be exempt under HHS regulations at 45 CFR 46.101(b), IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent under HHS regulations at 45 CFR part 46.116(c) or (d).

Residual Body Fluids, Tissues and Recognizable Body Parts

Research on existing specimens ("on the shelf" or frozen) without identifying information (e.g., no names, initials, hospital number, etc.) should be submitted to the IRB for review. Such research may be considered under expedited review, or may be exempted, but the application should be submitted for review and must include a short description of the research and where the tissue is coming from.

Protocols Lacking Definite Plans For Human Involvement

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:

   a) Training programs in which individual training projects remain to be selected or designed.
   b) 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.

2. The IRB can give "General Approval" to programs like those mentioned above with the understanding that the specific research protocol will be submitted to them once it has been developed. "General Approval" is not appropriate for individual projects or to meet grant deadlines.

Responsibility

The IRB Chairperson, with assistance from the IRB Administrator, will determine whether specific research protocols constitute human subjects research.

Applicable Regulations and Guidelines

45 CFR 46.102(d)
45 CFR 46.102(f)

OHRP Guidance on Research Involving Coded Private information or Biological Specimens, October 16, 2008