



TRIGGERS FOR HUMAN SUBJECTS REVIEW:

According to the National Institutes of Health, human subjects review is required when research involves human (or animal) subjects that:

- Involves intervention of any sort with physical bodies
- Has any potential, whatsoever, of causing physical or psychological harm
- Involves clinical trials of any drug, medical treatment or medical device
- Is scientifically or ethically controversial

Human Subjects review will also be called into action if the research involves vulnerable populations, even when survey data or other non-invasive (or interventions) occur, such as research regarding:

- Pregnant women, human fetuses and neonates
- Prisoners
- Children
- Persons at risk for suicide
- Persons with impaired decisional capacity

OR when human specimens, cell lines or related data are involved.

According to Huston-Tillotson University's Research Standards Committee and Institutional Review Board, it can be very difficult to determine what constitutes Human Subjects Research.

The Common Rule offers the following definitions as guidance for determining human subjects research. The definitions are intentionally broad to include a wide range of research in hopes of capturing both the biomedical and humanities spectrums. These definitions are the starting point for anyone attempting to determine whether their research requires IRB review.

The *first* question is if your project is actually research as defined by the common rule:

"Research" as defined by DHHS is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Research" as defined by FDA means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

The *second* question to ask is if your project involves human subjects:

A human subject is defined by DHHS as a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

- **"Intervention"** as defined by DHHS regulations means 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. [45 CFR 46.102(f)]
- **"Interaction"** as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- **"Private information"** as defined by DHHS regulations means 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). [45 CFR 46.102(f)]
- **"Identifiable information"** as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

For more information see the [Office for Human Research Protections](#) and the [Food and Drug Administration](#).

If the answer to both questions is yes, then you need IRB approval to conduct research. Otherwise you need to ask these questions:

- Does the activity involve the use of a drug (including an approved drug or an over-the-counter drug), other than the use of an approved drug in the course of medical practice?
- Does the activity involve the use of a medical device (including an approved medical device), other than the use of an approved medical device in the course of medical practice? (Note that medical devices generally include devices intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, and devices intended to affect the structure or any function of the body of humans or other animals.
- Will data be submitted to the FDA or held for their inspection?

If the answer to one of the above questions is "yes," then you will need IRB approval to proceed.

I have contacted HT's Research Standards Committee and Institutional Review Board requesting their help in providing us a copy of their Human Subjects form for use on our campus. Pending response Ms. Jaya Soni . Director (OIPRA): 512-505-3019^[A1]