REGULATIONS
Human Subject Research

RESEARCH?

Definitions

OHRP:
45 CFR 46.102(d) Research means **systematic investigation**, including research development, and testing and evaluation, designed to develop or contribute to **generalizable knowledge.**

FDA:
21 CFR 50.3(c), 21 CFR 50.102(c),

Clinical investigation means any **experiment that involves a test article and one or more human subjects** and that either is subject to requirements for prior **submission to the Food and Drug Administration** under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the **results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration** as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.
where:

- 21 CFR 50.3(j), 56.102(l) **Test article** means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act…

VA:
(VHA handbook 1200.05**)**: Research means testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. Also by the Common Rule (38 CFR 16).

HUMAN SUBJECT?

Definitions

OHRP:
45 CFR 46.102(f) **Human Subject** 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.

FDA:
21 CFR 50.3(e),56.102(g) **Human Subject** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

Unidentified samples used in In Vitro Diagnostic (IVD) devices: IVD device investigations may be exempt from the IDE requirements of 21 CFR 812 if they are properly labeled and meet the criteria set forth in 21 CFR 812.2(c)(3). However, such studies are still subject to the FDA regulations and IRB review requirements if the research is to support an application for research or marketing of the device (see 21 CFR 50.1), even if the samples to be used are not individually identifiable. The FDA regulations define a *subject* to include a human on whose specimens an investigational device is used. (see 21 CFR 812.3(p)). Thus, an IVD study to support a premarket submission to the FDA is considered a human subject investigation and is subject to IRB review under 21 CFR parts 50 and 56). See FDA Guidance at http://www.fda.gov/cdrh/oivd/guidance/1588.html which makes clear that although they are exempt from 21 CFR 812, IRB review is needed, along with other criteria, to obtain a waiver of informed consent for IVD studies using left-over specimens that are not individually identifiable.

VA:
(VHA handbook 1200.05): **Human Subject** means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)).

and

Referring to data or specimens:

OHRP: *based on* 45 CFR 46.102(f)
Obtained through intervention or interaction with living individual
intervention: *physical procedures for gathering data such as physical exams, venipuncture, x-rays, manipulation of the individual's environment (e.g., light, temperature) for research purposes*
interaction: *communication or interpersonal contact between investigator and the individual*
OR
associated with ***individually identifiable private information***
identifiable: *identity of the individual is or may readily be ascertained by the investigator, or associated with the information*
private information: *includes information about behavior that occurs in a context in which the individual may 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).*

Definitions