WAYNE STATE UNIVERSITY

Human Investigation Committee

Human Participant Research
How is it Defined?

Is this research? The decision process:

1	The first question a principal investigator (PI) must ask is whether or not a "research activity" is being proposed. Contact the HIC Education Office should assistance be required in making this determination. (Note: An investigator cannot exempt his/her research project from HIC review and concurrence. Instead, the HIC chairperson or his/her designee must determine that a project is eligible for exemption. (See HIC Policy/Procedure "Exempt Procedures").
2	The second question is whether or not the "research activity" involves interacting or intervening with living individuals or their identifiable private information (see Part A #3 below).
3	If the activity involves the FDA, Part B (below) provides the appropriate definition.
4	If the activity involves the Department of Defense (DoD) or one of its components, the definition of "Experimental Subject" should be used in determining if the research meets the criteria for human subject research.
5	When the questions in Part A or Part B (below) can be answered "yes," a research proposal must be submitted to the IRB for review.

Criteria for initial IRB review and approval of research protocols are set forth by HHS regulations at 45 CFR 46.111, 38 CFR 18.111, FDA regulations at 21 CFR 56.111, DoD Directive 3216.02, and include: determining the level of risk to the participant, potential benefits, informed consent process and documentation, and safeguarding the participant's rights and welfare (i.e., safety monitoring, equitable selection, protection of privacy and confidentiality and special protections for vulnerable populations). Criteria for review, based on the type of protocol being submitted, will also comply with regulations or guidance for a specific federal agency, as appropriate (i.e., ICH-GCP, Department of Defense, the Department of Education, the Department of Energy, the Department of Justice, and the Environmental Protection Agency).

Definitions

***Experimental subject** (as defined by the Department of Defense)* – "An activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32CFR.210.102 (f) reference (c). Examples of interventions or interactions include, but are not limited to: a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose."

Generalizable knowledge – Determination as to whether the activity will contribute to "generalizable knowledge" is often based on whether the data will be dissemination by means of publication or presentation. This should not be the sole factor used to make determination. In general, OHRP gives guidance that if the data will be used to draw conclusions related to a larger entity, then the activity is considered "research."

Systematic investigation – A systematic investigation may include research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, 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.

PART A:

A.	The activity is "Human Participant" (subject) research according to the Department of Health and Human Services (DHHS) regulations when either <u>1 and 2 below are true</u> Or 1 <u>& 3 below are true</u>.
1.	The activity is a systematic investigation including research development, testing and evaluation and is designed OR contributes to generalizable knowledge AND
2.	The data the PI is planning to obtain are about living individuals obtained through any or all of the following means: o Physical procedures performed on individuals o Manipulation of individuals o Manipulation of individuals' environments o Communication with individuals, OR o Interpersonal contact with individuals OR

3.	The data is individually identifiable because: o The identity of the participant is or may readily be ascertained by the PI OR o The identity of the participant is or may readily be associated with the information And the data is private because: o It is about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place OR o The individual has provided information for specific purposes and can reasonably expect that the information will not be made public (i.e., medical record).

PART B:

B.	An activity is "Human Research" according to the FDA regulations when it involves an FDA regulated test article because one or more of the following are true:
1.	The activity involves the use of a drug other than the use of a marketed drug in the course of medical practice, with "drug" meaning: o An article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them; o An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; o An article other than food that is intended to affect the structure or any function of the body of humans or other animals, AND o The drug is either not approved by the FDA for marketing, or the drug is not being used in the course of medical practice. OR
2.	The activity involves the use of a medical device, other than the use of a marketed medical device in the course of medical practice, with "device" meaning: o The device is recognized in the official National Formulary, the United States Pharmacopoeia, or any supplement to them; o The device is intended for use in the diagnosis of disease or other conditions; or in the cure, mitigation, treatment, or prevention of disease in humans or other animals; o The device s intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes; AND o The medical device is not approved by the FDA for marketing or the medical device is not being used in the course of medical practice. OR

3.	The activity is otherwise subject to FDA regulations because: o Data from the activity will be submitted to, or held for inspection by the FDA; o The activity involves an FDA regulated article of one or more of the following: Food or dietary supplement that bears a nutrient content or health claim Food or color additive for human consumption Infant formula Biological product for human use Electronic product for human use Other article subject to the FD&C Act AND
4.	The activity involves human participants because one or more of the following are true: o The test article will be used on one or more humans; OR o The test article is a medical device, used on human specimens, the activity is done to determine the safety or effectiveness of the device, and data from the activity will be submitted to, or held for inspection by the FDA.

References

45 CFR 46.	Federal code of regulations (the "Common Rule")
45 CFR 46.102 (d)	Determination of research
45 CFR 46.102(f)(2)	Determination if human subjects are involved in research
32 CFR 219	DoD implementation of 45 CFR46, Subpart A – criteria for exemption
DoD Directive 3216.02	DoD defines additional requirements for human subject research supported by the Department of Defense