



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.
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).
3. If the activity involves the FDA, Part B provides the appropriate definition.
4. When the questions in Part A or Part B can be answered “yes,” a research proposal must be submitted to the IRB for review.

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 <u>1 & 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: <ul style="list-style-type: none"> ○ Physical procedures performed on individuals ○ Manipulation of individuals ○ Manipulation of individuals’ environments ○ Communication with individuals, or ○ Interpersonal contact with individuals <p>OR</p>

3.	<p>The data is individually identifiable because:</p> <ul style="list-style-type: none"> ○ The identity of the participant is or may readily be ascertained by the PI or ○ The identity of the participant is or may readily be associated with the information <p>And the data is private because:</p> <ul style="list-style-type: none"> ○ 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 ○ The individual has provided information for specific purposes and can reasonably expect that the information will not be made public (i.e., medical record).

B.	<p>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:</p>
1.	<p>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:</p> <ul style="list-style-type: none"> ○ 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; ○ An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; ○ An article other than food that is intended to affect the structure or any function of the body of humans or other animals, AND ○ The drug is either not approved by the FDA for marketing, or the drug is not being used in the course of medical practice. <p>OR</p>

2.	<p>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:</p> <ul style="list-style-type: none"> ○ The device is recognized in the official National Formulary, the United States Pharmacopoeia, or any supplement to them; ○ 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; ○ The device is 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 <ul style="list-style-type: none"> ○ 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. <p>OR</p>
3.	<p>The activity is otherwise subject to FDA regulations because:</p> <ul style="list-style-type: none"> ○ Data from the activity will be submitted to, or held for inspection by the FDA; ○ The activity involves an FDA regulated article of one or more of the following: <ul style="list-style-type: none"> 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 <p>AND</p>
4.	<p>The activity involves human participants because one or more of the following are true:</p> <ul style="list-style-type: none"> ○ The test article will be used on one or more humans; or ○ 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.