

Human Research Determination Checklist

DHHS REGULATIONS

- I.** The activity involves research because all of the following are true (**A & B**):
 - A.** The activity is a systematic investigation, including research development, testing and evaluation;
 - B.** The activity is intentionally designed to develop **OR** contribute to generalizable knowledge.

- II.** The activity involves human participants because both of the following are true (**C & D**):
 - C.** **The data the investigator is planning to obtain are about living individuals;**
 - D.** **Either or both of the following is true (1 or 2)**
 - 1.** The investigator plans to obtain the data through one or more of the following, one of the following must be applicable (**a, b, c, d, or e**):
 - a.** Physical procedures performed on those individuals
 - b.** Manipulation of those individuals
 - c.** Manipulation of those individuals' environments
 - d.** Communication with those individuals
 - e.** Interpersonal contact with those individuals

 - 2.** **The information to be obtained is both of the following must be true (a & b):**
 - a. Private** because either of the following is true (**i or ii**):
 - i.** The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place;
 - ii.** The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)

 - b. Individually identifiable** because either of the following is true (**i or ii**):
 - i.** The identity of the participant is or may readily be ascertained by the investigator;
 - ii.** The identity of the participant is or may readily be associated with the information

- The activity is “human participant research” because (**I and II**) are true (45 CFR 46).
- The activity is not “human participant research” because (**I or II**) is false (45 CFR 46).

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FDA REGULATIONS

- I.** The activity involves an FDA regulated test article because one or more of the following is true (**A, B, or C**):
 - A.** The activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice, both of the following are true (**1 & 2**):
 - 1.** The activity will involve the use of a drug, meaning one of the following must be true (**a, b, c, or d**):
 - a.** An article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them
 - b.** An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals
 - c.** An article (other than food) intended to affect the structure or any function of the body of humans or other animals
 - d.** An article intended for use as a component of any article specified in the above items
 - 2.** Either of the following is true (**a or b**):
 - a.** The drug is **NOT** approved by the FDA for marketing
 - b.** The drug is **NOT** being used in the course of medical practice
 - B.** The activity involves the use of a medical device, other than the use of an marketed medical device in the course of medical practice, both of the following must be true (**1 & 2**):
 - 1.** The activity will involve the use of a medical device, meaning one of the following must be true (**a, b, or c**):
 - a.** Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
 - b.** 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
 - c.** Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary 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
 - 2.** Either of the following is true (**a or b**):
 - a.** The medical device is **NOT** approved by the FDA for marketing
 - b.** The medical device is **NOT** being used in the course of medical practice
 - C.** The activity is otherwise subject to FDA regulation meaning both of the following must be true (**1 & 2**):
 - 1.** Data from the activity will be submitted to, or held for inspection by, the FDA.

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- 2.** The activity involves an FDA-regulated article one or more of the following must be applicable (**a, b, c, d, e, or f**):
 - a.** Food or dietary supplement that bears a nutrient content or a health claim
 - b.** Food or color additive for human consumption
 - c.** Infant formula
 - d.** Biological product for human use
 - e.** Electronic product for human use
 - f.** Other article subject to the FD&C Act

- II.** The activity involves human participants because one or more of following is true (**A or B**):
 - A.** The test article will be used on one or more humans

 - B.** All of the following are true (**1, 2, 3, & 4**):
 - 1.** The test article is a medical device
 - 2.** The medical device will be used on human specimens
 - 3.** The activity is being done to determine the safety or effectiveness of the device
 - 4.** Data from the activity will be submitted to, or held for inspection by, the FDA.

- According to FDA regulations the activity is “human participant research” because (**I and II**) are true.

- According to FDA regulations the activity is not “human participant research” because (**I or II**) is false.