FDA Regulations: Drugs, Medical Devices, & Test Articles

Office of Research Integrity & Compliance | Version 2
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The IRB has determined that all drugs, non-approved medical devices, and test articles used on human beings are considered human subjects research and must be reviewed initially by the IRB.

Drugs

The study involves an FDA regulated test article because:

1. This activity involves the use of a drug, including the use of a marketed drug in the course of medical practice.
2. This activity involves the use of a drug meaning:
    a. An article recognized in the official US Pharmacopoeia, official Homeopathic Pharmacopoeia of the US 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.
3. The drug is NOT approved by the FDA for marketing.
4. The drug is NOT being used in the course of medical practice.

Medical Device

The activity involves the use of a medical device, other than the use of a marketed medical device in the course of medical practice.

1. The activity will involve the use of a medical device, meaning one of the following:
    a. Recognized in the official National Formulary, or the US Pharmacopoeia, or any supplement to them.
    b. Intended for use in the diagnosis of disease or other conditions, or 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 its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon metabolized for the achievement of any of its primary intended purposes.
2. The medical device is NOT approved by the FDA for marketing.
3. The medical device is NOT being used for the course of medical practice.

The activity is otherwise subject to FDA regulation.

1. Data from the activity will be submitted to, or held for inspection by the FDA.
2. The activity involves an FDA-regulated article. One or more of the following:
    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. Other article subject to the FD & C Act
3. The activity involves human participants because:
    a. The test article will be used on one or more humans; AND/OR
    b. All of the following are true:
        i. The test article is a medical device
        ii. The medical device will be used on human specimens
        iii. The activity is being done to determine the safety or effectiveness of the device
        iv. Data from the activity will be submitted to, or held for inspection by the FDA