Guidance for Investigational Device Studies

Device studies are categorized into three types according to the Investigational Device Exemption regulations at 21 CFR 812:

- **exempt studies** – these studies are exempt from the requirements of 21 CFR Part 812. Examples of exempt studies include: consumer preference testing, testing of a device modification, and diagnostic device studies (e.g., in vitro diagnostic studies). Visit the links below for additional information.

- **significant risk (SR) device studies** – these studies require an approved IDE (Investigational Device Exemption) from the FDA and must comply with the regulations at 21 CFR 812. Please refer to the FDA Information Sheet Guidance “Significant Risk and Nonsignificant Risk Medical Device Studies” (linked below) for specific examples of SR device studies.

- **nonsignificant risk (NSR) device studies** – these studies must meet the abbreviated IDE requirements at 21 CFR 812.2(b). Please refer to the FDA Information Sheet Guidance “Significant Risk and Nonsignificant Risk Medical Device Studies” (linked below) for specific examples of NSR device studies.

You may need to acquire additional information and/or documentation from the study sponsor or the FDA to submit to the IRB, depending on what type of device study you have. The decision trees that follow will help you determine whether you have a device study, whether FDA regulations apply to your study, and what category your study falls into.

If you have questions about this document or specific questions about your study, please contact Misty White, IRB Coordinator, at 303.735.6652 or misty.white@colorado.edu.

**FDA Information Sheet Guidance:**

Frequently Asked Questions About Medical Devices

Significant Risk and Nonsignificant Risk Medical Device Studies

**Link to FDA regulations:**

21 CFR Part 812
Do I have a medical device?

Is it an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory?

- No
  - It is not a device as defined by the FDA. No further action is required.

- Yes
  - Is it recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement of them?
    - No
      - Is it investigational (i.e., not approved or cleared by the FDA)?
        - Yes
          - It is intended to affect the structure or any function of the body of man or other animals?
            - No
              - Is it dependent upon being metabolized for the achievement of its primary intended purpose?
                - Yes
                  - It is a medical device as defined by the FDA. Move to the next decision tree.
                - No
                  - Does it achieve its primary intended purpose through chemical action within or on the body of man or other animals?
                    - Yes
                      - It is a medical device as defined by the FDA. Move to the next decision tree.
                    - No
                      - It is not a device as defined by the FDA. No further action is required.

- Yes
  - It is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals?
    - No
      - Is it investigational (i.e., not approved or cleared by the FDA)?
        - Yes
          - It is a medical device as defined by the FDA. Move to the next decision tree.
        - No
          - Does it achieve its primary intended purpose through chemical action within or on the body of man or other animals?
            - Yes
              - It is a medical device as defined by the FDA. Move to the next decision tree.
            - No
              - It is not a device as defined by the FDA. No further action is required.
Do FDA regulations apply to my device study?

Does the study involve the following:

- In the United States, the use of a device in one or more persons that evaluates the safety or effectiveness of that device.
  - No
  - Yes

- Data regarding subjects or control subjects submitted to or held for inspection by FDA.
  - Yes
  - No

- Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA.
  - Yes
  - No

FDA regulations do not apply. No further action is required.

FDA regulations do apply. Move to the next decision tree.
Is the study of an already cleared medical device or a Premarket approval (PMA) approved device?

Is the device being used or investigated in accordance with the indications in the cleared labeling?

Is the study for a new use?

Does the study involve consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution?

Does the testing collect safety or effectiveness data?

Does the testing put subjects at risk?

Does the testing by design or intention introduce energy into a subject?

Is it a diagnostic device study (e.g., in vitro diagnostic study)?

Does the testing require an invasive sampling procedure that presents significant risk?

Is the study of a new use?

Not exempt. Move to next decision tree.

Not exempt. Move to next decision tree.

Exempt under 21 CFR 812.2(c)(1-2). You must provide documentation or justification for exemption with your submission. Contact the IRB for assistance.

Not exempt. Move to the next decision tree.

Exempt under 21 CFR 812.2(c)(4). You must provide documentation or justification for exemption with your submission. Contact the IRB for assistance.

Exempt under 21 CFR 812.(c)(3). You must provide documentation or justification for exemption with your submission.

Not exempt. Move to the next decision tree.

Yes

Not exempt. Move to the next decision tree.

No

Exempt under 21 CFR 812.2(c)(1-2). You must provide documentation or justification for exemption with your submission. Contact the IRB for assistance.

Not exempt. Move to the next decision tree.

Is the testing used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?

Is the testing noninvasive?

No

Is the study of an already cleared medical device or a Premarket approval (PMA) approved device?

Yes

No

Not exempt. Move to the next decision tree.

Exempt under 21 CFR 812.2(c)(1-2). You must provide documentation or justification for exemption with your submission. Contact the IRB for assistance.

Is my device study exempt from IDE regulation?
Is the device intended as an implant that presents a potential risk to the health, safety, or welfare of a subject?

Yes

Is the device purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject?

No

Is the device for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject?

Yes

Does the device otherwise present a potential for serious risk to the health, safety, or welfare of a subject?

Yes

The device is a Significant Risk (SR) Device. An Investigational Device Exemption (IDE) is required from the FDA. The study must follow all the IDE regulations at 21 CFR 812.

No

The device is a Nonsignificant Risk (NSR) device. The study must follow the abbreviated IDE requirements at 21 CFR 812.2(b). Please contact the IRB for details regarding what additional information is required for submission.