

Investigational Device Exemption (IDE) Decision Tool for investigators

Use the table below to guide whether you need to submit an IDE application to the FDA if you are investigating the safety and efficacy of a medical deviceⁱ, or you are using a medical device which is not approved by the FDA. The FDA defines a “medical device” as, “[a]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” which is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

If you are studying a non-medical device’s ability to diagnose, cure, mitigate, treat, or prevent disease, it may require an IDE. If you have questions about whether the device you’re studying is a medical device, contact COMIRB at COMIRB@ucdenver.edu.

IDE Determination Criteria	True	False
<p>The study involves an investigational device or investigates the safety and efficacy of an FDA-approved device that presents a potentially serious risk to the health, safety, or welfare of a subject <i>and</i> meets <i>at least one</i> of the following four criteria:</p> <ol style="list-style-type: none"> 1. The device is intended as an implant; 2. The device is purported or represented to be for a use in supporting or sustaining human life; 3. The device is intended for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; 4. The device is used in a way that otherwise presents a potentially serious risk to the health, safety, or welfare of a subject. <p>If TRUE, the investigator must submit an IDE application to the FDA.</p> <p>If FALSE, the use of the device in the study poses non-significant riskⁱⁱ. The study is considered by the FDA to have an approved application for an IDE and must be conducted in accordance with the Abbreviated IDE Requirements at 21 CFR 812.2.(b).</p>		
<p>The study investigates an FDA-approved device used in accordance with its approved labeling.</p> <p>If TRUE, the study is an “Exempted Investigation” and an IDE is not required.</p>		
<p>The study investigates a diagnostic device (e.g., an assayⁱⁱⁱ) that is</p> <ol style="list-style-type: none"> 1. Non-invasive; and 2. Does not introduce energy into a subject; and 3. Is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure; and 4. Complies with the labeling requirements at 21 CFR 809.10(c). 		

If all of the above are TRUE, the study is an “Exempted Investigation” and an IDE is not required.		
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ⁱ The FDA defines a “medical device” as, “[a]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” which is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease. In some cases, a product that is not currently marketed or intended for use as a medical device may still meet the definition above, depending on how it will be used in the context of a research study.

ⁱⁱ The IRB must agree that the use of the device poses non-significant risk, and this must take place at a full board meeting.

ⁱⁱⁱ Assays are classified as medical devices by the FDA.