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 device, or you are using a medical device which is not approved by the FDA.

IDE Determination Criteria	True	False
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 *and* meets *at least one* of the following four criteria: 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. **If TRUE, the investigator must submit an IDE application to the FDA.** **If FALSE, the use of the device in the study poses non-significant risk[2]. 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).**		
The study investigates an FDA-approved device used in accordance with its approved labeling. **If TRUE, the study is an "Exempted Investigation" and an IDE is not required.**		
The study investigates a diagnostic device (e.g., an assay[1]) that is 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.**		

1. Assays are classified as medical devices by the FDA.
2. The IRB must agree that the use of the device poses non-significant risk, and this must take place at a full board meeting.