IRB Review of Protocols Involving Investigational Devices

Medical Device [1] means an instrument apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which 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, *or*
- intended to affect the structure or any function of the body of man or other animals, *and*
- which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Investigational device is one, including a transitional device, that is the object of an investigation.

Investigational Device Exemption (IDE) allows clinical investigation of a device to determine safety and effectiveness. When a device has determined to be under an IDE, the device that otherwise would need to comply with performance standards or to have FDA approval can be shipped lawfully for the purpose of conducting investigation of the device. Requirements of 21 CFR 812 must be met.

Decision process

1. Does the device meet definition of a *medical* device? If yes, → Is the device, as it is being used in the protocol, **exempt from IDE regulations**?[2] In order to be exempt, it must include any of the following
   - ➢ Legally marketed devices when used in accordance with FDA labeling and confirmed via databases [3]
   - ➢ Diagnostic devices that comply with the FDA labeling requirements in §809.10(c) and if the testing:
     - is noninvasive
     - does not require an invasive sampling procedure that presents significant risk
     - does not by design or intention introduce energy into a subject *and*
     - is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure
   - ➢ Consumer preference testing, testing of a modification, or testing of a combination of devices if the devices are in commercial distribution AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk
2. If the investigational device is **not** IDE exempt**, it is subject to the IDE regulations** and, as used in the specific study, is considered **either Significant Risk (SR) or Non-Significant Risk (NSR).**

Requirements	Significant Risk (SR) Investigational Device	NSR Device
Criteria (21 CFR 812.3(m))	• intended as an implant & presents potential for serious risk to the health, safety, or welfare of a subject • purported/represented to be for use in supporting/sustaining human life and presents potential for serious risk to health, safety, or welfare of a subject • 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 health, safety, or welfare of a subject ***or*** • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject	Does not meet definition of an SR device study
Approval needed	IDE from FDA ***and*** IRB approval	IRB approval
Applicable FDA regs (+ 45 CFR 46)	Full IDE regulations at 21 CFR 812	Abbreviated IDE requirements

[1] It is also a medical device if it is recognized in the National Formulary, US Pharmacopoeia, or any supplement to them.
[2] Regulatory Guidance for Academic Research of Drugs and Devices (ReGARDD). *Is My Study Exempt* flow diagram
[3] See PMA approval, 510(k) approval and Class I/II exemptions.

IRB DEVICE DETERMINATION FLOW DIAGRAM