IRB Process for Making Determinations for Investigational Devices Used in NIH protocols

Relevant terms related to investigational device determinations

Investigation	Investigational device	Investigational device exemption
A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device (21 CFR 812.3(h))	A device, including a transitional device, that is the object of an investigation. (21 CFR 812.3(g))	• Refers to the regulations under 21 CFR 812 • An approved IDE means the IRB (and FDA for significant risk devices) has approved the sponsor's study application, and all the requirements under 21 CFR 812 are met

Decision process

1. Once the protocol has been determined to include use of an investigational device (see above), the next question is **whether the device is exempt from IDE regulations** as it is being used in a clinical investigation (in humans). Criteria for IDE exemption include any of the following:
   - Legally marketed devices when used in accordance with FDA labeling which can be confirmed via these databases: PMA approval, 510(k) approval and Class I/II exemptions
   - 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).**

	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 & 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
Required approval	IDE from FDA ***and*** IRB approval	IRB approval
Applicable FDA regs (+ 45 CFR 46)	Full IDE regulations at 21 CFR 812	Abbreviated IDE reg (21 CFR 812.2(b))

FDA *Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies* (January 2006)

IRB DEVICE DETERMINATION FLOW DIAGRAM