

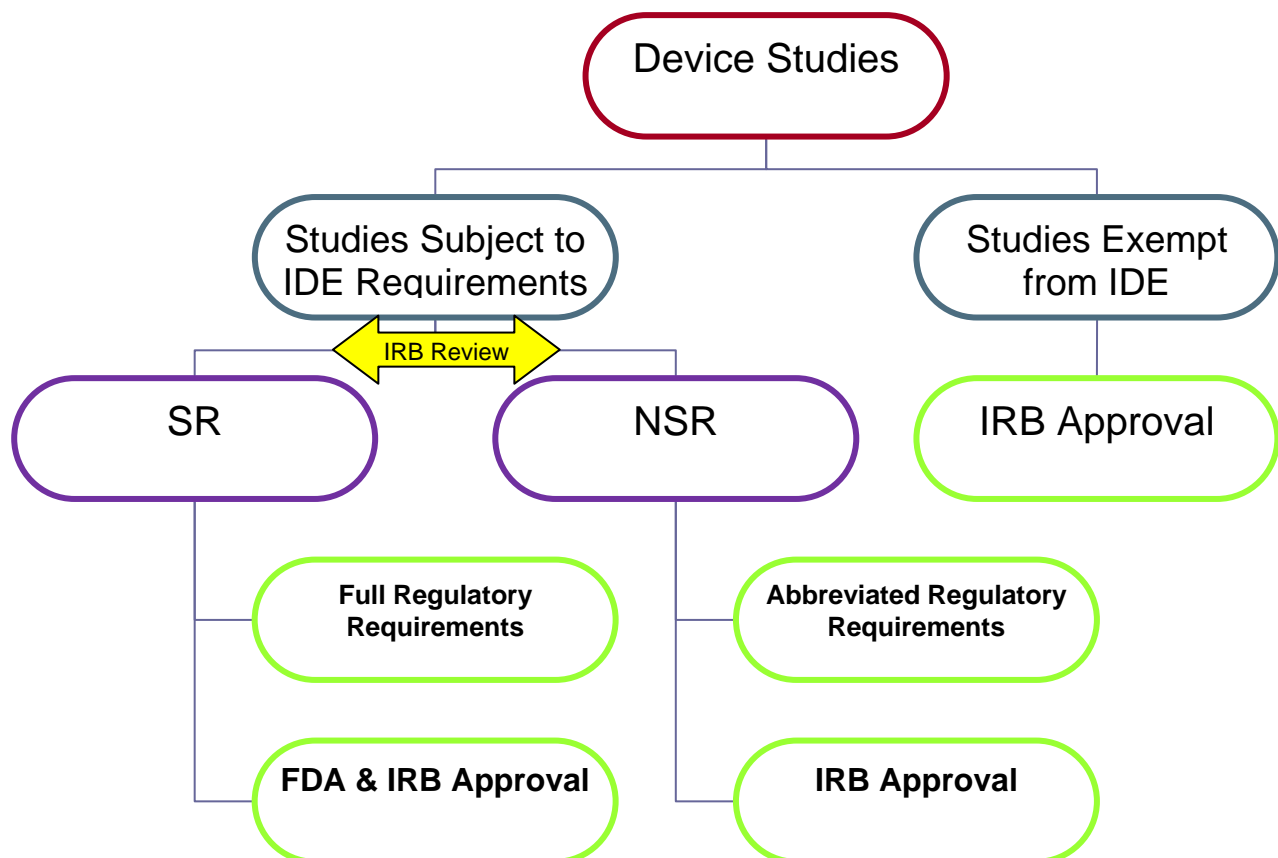
Summary of FDA Regulations on Investigational Device Exemptions and Exemption from IDE Requirements (21 CFR 812)

An **investigational device exemption (IDE)** allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA.

Investigations covered under the IDE regulation are subject to differing levels of regulatory control depending on the level of risk. The IDE regulation distinguishes between significant risk (SR) and nonsignificant risk (NSR) device studies. Submit the device information and investigational plan to the IRB for concurrence with the sponsor's SR/NSR determination.

The Investigational Device Exemptions (IDE) regulations describe the following types of device studies:

- Studies exempt from IDE requirements
- Studies subject to IDE requirements-
 - SR device research with formal IDE submission to FDA
 - NSR device research which with IRB approval is "**considered**" to have an approved IDE (sometimes referred to as an Abbreviated IDE). In this case the IRB acts as a surrogate for FDA.



Is an IDE Needed?

Not typically needed	Yes, would be indicated
Practice of Medicine	Studies that support research or marketing applications
Basic physiological research - Device is used to: <ul style="list-style-type: none"> • test a physiological principle • as a tool to address a research question No intent to: <ul style="list-style-type: none"> • collect safety and effectiveness data on the device • develop the device for marketing 	Studies of new indications for an approved device <ul style="list-style-type: none"> • Different age population • New condition or disease • Different area of the body • Change in indication (treatment, diagnosis, prevention) • Significant design changes
IDE exempt studies (see below)	Study results will be submitted to FDA

Studies Exempt from IDE

No IDE is required if the study meets one of the exemption categories in [21 CFR 812.2\(c\)](#) that apply to human research. All criteria under each category must be true in order to meet the exemption category. IRB review and informed consent are still required.

Category 1-2

A clinical investigation with approved devices used in accordance with labeling. The device may have been approved for commercial distribution before May 28, 1976 or deemed substantially equivalent to a device commercially approved before May 28, 1976.

Category 3

A clinical investigation with *in vitro* diagnostic devices, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:

- (i) is noninvasive;
- (ii) does not require an invasive sampling procedure that presents significant risk;
- (iii) does not by design or intention introduce energy into a subject; and
- (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. 21 CFR 812.2(c)(3).

Category 4

A clinical investigation with a marketed device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, unless testing is for determining safety and efficacy and/or puts subjects at risk.

Category 7*

A clinical investigation of a custom device as defined in 21CFR812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

*Category 5 & 6 do not apply to human research.

Submission and Regulatory Requirements for SR and NSR Device Studies	
Clinical studies with SR devices must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with NSR devices must be approved only by the IRB before the study can begin. Ongoing regulatory requirements apply to both.	
Significant Risk Device Studies (standard IDE)	
Definition	<p>A significant risk device means an investigational device that:</p> <ul style="list-style-type: none"> • Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; • Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; • Is 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; or • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. (21 CFR 812.3(m))
FDA Submission Requirements	<p>Sponsors are responsible for making the initial risk determination and ensuring the investigator presents it to the IRB.</p> <p>Unless FDA has already made a risk determination for the study, the IRB must review the sponsor's SR or NSR determination and modify the determination if the IRB disagrees with the sponsor.</p> <p>If FDA has already made the risk determination, the IRB does not need to duplicate this effort.</p> <p>Sponsors of investigational SR device studies must have an IDE application approved by FDA and IRB approval of the study before they may proceed.</p>
Ongoing Regulatory Requirements	<p>SR device studies must follow all regulatory requirements in the IDE regulations in 21 CFR 812.</p> <ul style="list-style-type: none"> • Responsibilities of Sponsors for Significant Risk Device Studies • Responsibilities of Investigators for Significant Risk Device Studies • ORI Summary of FDA Requirements For Investigators Who Are Also Considered Sponsors of New Devices (pg. 1-2)
Nonsignificant Risk Device Studies (abbreviated IDE)	
Definition	An NSR device study is one that does not meet the definition for an SR device study.

FDA Submission Requirements	<p>Sponsors are responsible for making the initial risk determination and ensuring the investigator presents it to the IRB.</p> <p>Unless FDA has already made a risk determination for the study, the IRB must review the sponsor's SR or NSR determination and modify the determination if the IRB disagrees with the sponsor. If FDA has already made the risk determination, the IRB does not need to duplicate this effort.</p> <p>However, if FDA has not made the risk determination or the IRB disagrees with the NSR determination made by a sponsor, then the IRB must notify the investigator and, where appropriate, the sponsor, that the study involves a significant risk device.</p> <p>If the IRB agrees with the NSR determination and approves the study, the study is "considered" to have an approved application for IDE. No formal submission to FDA is required. The IRB serves as an FDA surrogate for NSR studies.</p>
Ongoing Regulatory Requirements	<p>NSR device studies must follow abbreviated regulatory requirements in 21 CFR 812.2(b).</p> <ul style="list-style-type: none"> • Responsibilities of Sponsors of Nonsignificant Risk Device Studies • Responsibilities of Investigators for Nonsignificant Risk Device Studies • ORI Summary of FDA Requirements For Investigators Who Are Also Considered Sponsors of New Devices (pg. 2-3)

Where questions still exist, sponsor-investigators should contact the appropriate FDA review division for guidance.

Contacts for Center for Devices and Radiological Health

- 800-638-2041 or 301-796-7100
- IDE Inquiries: 301-796-5640
- dsmica@cdrh.fda.gov

The FDA website outlines the FDA's Procedure for responding to inquiries regarding need for an IDE -

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm126598.htm

Sources:

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

Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors [Frequently Asked Questions About Medical Devices](#), January 2006

Code of Federal Regulations, [Title 21 CFR 812](#), Investigational Device Exemptions

PRIM&R webinar, Investigational Device Exemption Overview, Marian Serge, RN, Division of Bioresearch Monitoring, Office of Compliance CDRH, FDA, 2009.

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