Quick Reference for IRB Members: Evaluating Medical Devices in Human Subjects Research

Section 201(h) of the Food, Drug & Cosmetic Act (FD&C) defines a device as:

Medical Device: Any instrument, apparatus, implement, machine, contrivance, implant, invitro reagent, or other similar or related article, including any component, part, or accessory, which is—

- Recognized in the **official National Formulary,** or the **United States Pharmacopeia**, or any supplement to them,
- 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

Key Considerations for IRB approval

Is the device being investigated?

Not all studies using devices are investigating the device itself. A device is considered investigational when:

- The study is designed to evaluate the safety or effectiveness of the device
- The study collects data about the device itself

A device is NOT investigational when:

- It is used only to make measurements as part of a study not about the device
- It is used to test a physiological principle with no data collected about the device
- It is used for clinical purposes only with no intent to collect safety or effectiveness data

Regulatory Categories

Research involving assessment of a medical device's safety or effectiveness must fall into ONE of these categories:

Category	Description	Requirements	Examples/Criteria
IDE Exempt Studies	Studies that don't require an IDE application to FDA	• IRB approval required • No FDA submission required	• Legally marketed device used per FDA-approved labeling • Consumer preference testing or modifications • Diagnostic devices meeting specific criteria
Significant Risk (SR) Device Studies	Studies with devices that present potential for serious risk to subjects	• Full IDE application to FDA required • FDA approval needed before study begins • Full IRB approval required • IDE approval considered granted 30 days after FDA receipt unless notified earlier	**Devices that…** ➢ are implants ➢ support or sustain human life ➢ are substantially important for diagnosis, treatment, or disease prevention ➢ present potential for serious risk **Examples:** • pacemakers, urological stints, electroconvulsive therapy devices, implantable prostheses, surgical lasers, tracheal tubes
Non-Significant Risk (NSR) Device Studies	Studies with devices that do not present potential for serious risk	• IRB approval serves as an "abbreviated IDE" • No formal FDA submission required • Can proceed upon IRB approval	**Examples:** • low power lasers for pain treatment, daily wear contact lenses, jaundice monitors for infants, wound dressing, Foley catheters

Investigational Device Exemption (IDE)

- An FDA approved IDE permits a device that would otherwise be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. The term "exemption" in this case means exempt from laws prohibiting unapproved products to move in interstate commerce.
- IDE regulations (21 CFR 812) may apply for studies designed to: support marketing applications; collect safety and effectiveness information; and studies of an unapproved device or a new intended use of an approved device, even if no marketing application is planned.

Abbreviated IDE Requirements:
For NSR devices, the sponsor/investigator must:

1. Label the device in accordance with 812.5
2. Obtain IRB approval after presenting why the device is not an SR device
3. Ensure proper informed consent and documentation
4. Comply with monitoring requirements (21 CFR 812.46)
5. Maintain required records and make required reports
6. Ensure participating investigators maintain required records and reports
7. Comply with prohibitions against promotion and other practices

Note on 510(k) Device Studies: These may be conducted without an IDE when used in accordance with FDA-cleared labeling. If clinical data are necessary to demonstrate substantial equivalence, the clinical study must comply with IDE, IRB and human subjects protection regulations.

IRB Responsibilities

When reviewing a device study, the IRB must:

1. Determine if FDA regulations apply
2. For applicable studies, determine which regulatory category applies:
    a. IDE Exempt
    b. Significant Risk (SR)
    c. Non-Significant (NSR)
3. For SR/NSR determination—fully convened IRB makes SR or NSR determination:
    a. Review sponsor/investigator ’s risk designation and justification
    b. Consider the device description and prior investigation reports
    c. Evaluate the investigational plan and subject selection criteria
    d. Make the final determination at a convened IRB meeting
    e. Document the determination in meeting minutes
4. For SR determinations:
    a. Inform the investigator and sponsor/investigator in writing
    b. Verify FDA IDE approval before allowing the study to begin
    c. Important note—If the FDA disagrees with an IRB’s SR determination, the IRB may decide if it wants the study to proceed NSR
5. For NSR determinations:
    a. Apply review criteria at 21 CFR 56.111
    b. The study may begin without FDA IDE submission once IRB approved

Risk Assessment Guidance

When determining if a device study is SR or NSR, consider:

- The proposed use of the device in the investigation, not just the device alone
- The nature of the harm that may result from use of the device
- Whether potential harm could be life-threatening or result in permanent impairment
- Any procedures required by the study and their potential risks
- The potential harm from both the procedure and the device itself

Expedited Review Eligibility

Device studies may qualify for expedited review when:

- The device and its use present no more than minimal risk to subjects,

AND

- Either:
    - An IDE application is not required (documented by FDA or meeting IDE exemption criteria)
    - The device is FDA-cleared/approved and used according to its approved labeling

References

Carilion Clinic Institutional Review Board. (2023). Investigational Devices: Investigational Device Exemption, Significant/Non-Significant Risk Devices, Humanitarian Use Devices, Emergency Use, Compassionate Use (SOG 4.2). https://www.carilionclinic.org/investigationalusedevice

Northwestern University Institutional Review Board (n.d.). Guidance on the use of investigational medical devices human subjects research. Retrieved from https://irb.northwestern.edu/docs/guidance-on-the-use-of-investigational-medical-devices-in-human-subjects-research.pdf.

U.S. Food and Drug Administration. (n.d.). Is my product medical device? Retrieved from https://www.fda.gov/media/131268/download#:~:text=Page%205-,Definition%20of%20a%20Medical%20Device,vitro%20reagent%2C%20or%20other%20similar