Quick Reference for Researchers: 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

Is Your Study Investigating a Device?

Not all studies using devices are investigating the device itself:

Your device IS 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

Important note about non-traditional devices: Some protocols use items not generally considered medical devices (such as Fitbits or virtual reality), while others involve software, algorithms, or artificial intelligence that may be considered devices depending on their impact on participants. If you're unsure whether your technology qualifies as a device, consult with the HRPO/IRB office.

Regulatory Categories & Requirements for Researchers

When investigating a medical device's safety or effectiveness, your study must fall into ONE of these categories:

Note: An application to FDA to use a device in a study to collect safety or effectiveness data is called an investigational device exemption (IDE). The FDA regulations also detail certain categories:

Category	Description	Requirements	Examples/Criteria
IDE Exempt Studies	Studies that don't require an IDE application to FDA	• Submit for fully convened IRB approval • 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	• Submit full IDE application to FDA • Obtain FDA approval before study begins • Submit study for fully convened IRB approval • 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	• Submit study to fully convened IRB for review and NSR determination • No formal FDA submission required • Can proceed upon fully convened IRB approval	**Examples:** • low power lasers for pain treatment, daily wear contact lenses, jaundice monitors for infants, wound dressing, Foley catheters

Investigational Device Exemption

- FDA approved IDE permits a device that otherwise would 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.

Documentation Requirements for Researchers

For SR Studies—IDE Verification Documentation:

You must provide at least one of the following to the IRB:

- Your study protocol submitted to the FDA, including an IDE number
- Communication from the FDA with verification of the IDE
- When the IDE is held by the sponsor/investigator:
    - Sponsor/investigator ’s protocol specifying the IDE number
    - Communication from the sponsor/investigator verifying the IDE number

For NSR Studies—Abbreviated IDE Requirements:

As the researcher/sponsor/investigator, you must:

1. Label the device in accordance with 812.5
2. Obtain fully convened 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.

Preparing Your IRB Submission

When submitting your device study to the IRB, be prepared to provide:

1. **Documentation of device regulatory status**
    a. For commercially available devices:
        i. FDA clearance/approval documentation
    b. For investigational devices:
        i. IDE information or rationale for exemption/NSR
2. **Risk assessment information**
    a. Describe the proposed use of the device in your investigation

b. Document the nature of potential harm that may result from device use
c. Explain whether potential harm could be life-threatening or result in permanent impairment
d. Detail any procedures required by the study and their potential risks
e. Assess potential harm from both the procedure and the device itself

3. **If proposing an NSR determination**
    a. Provide justification for why your device study should be considered NSR
    b. Include relevant prior investigation reports or clinical data

Expedited Review

Your device study may qualify for expedited review when:

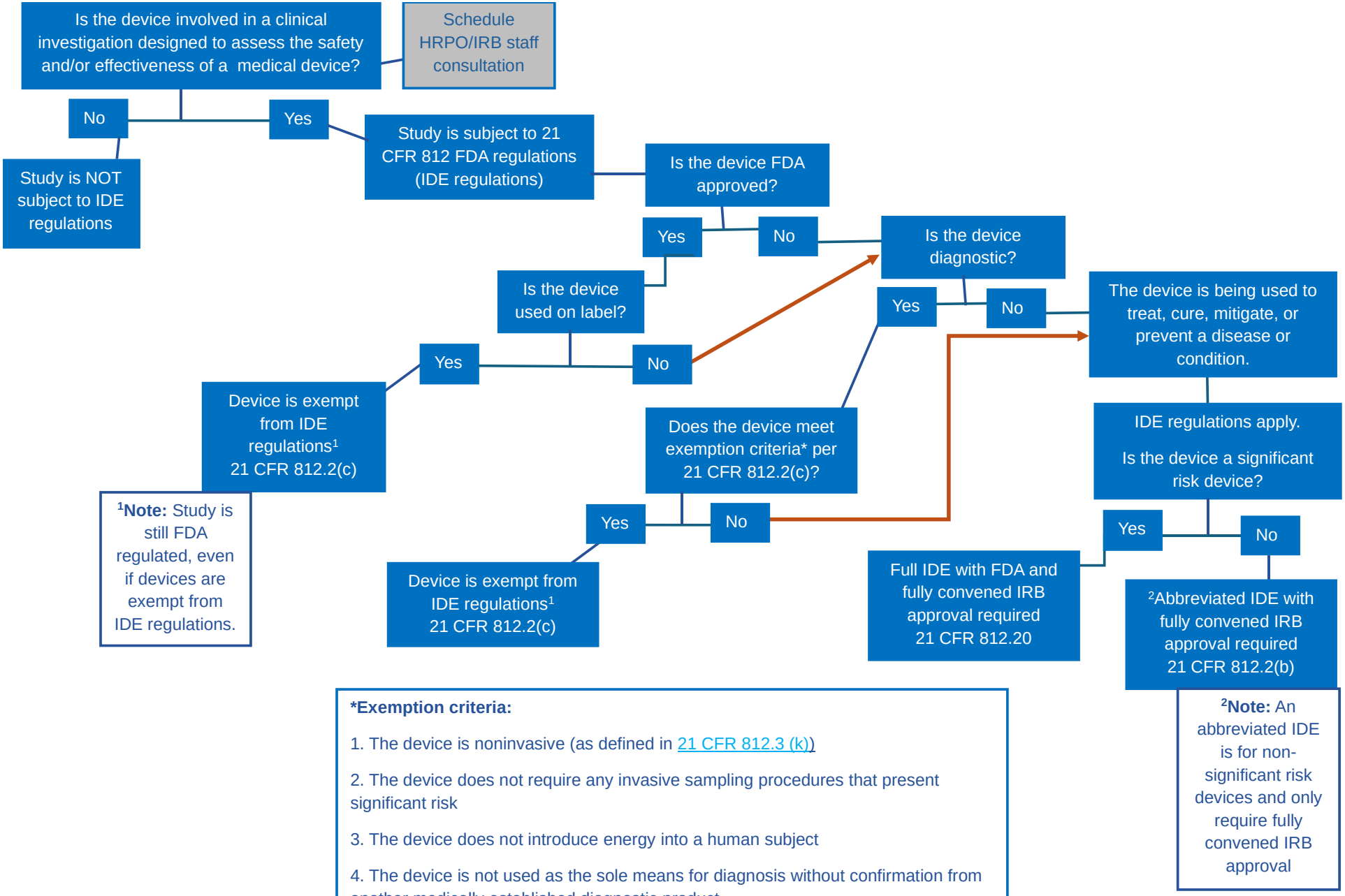
- The device and its use present no more than minimal risk to subjects,

AND

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

Additional Resources for Investigators

- **Carilion Clinic IRB**: Available for consultations and regulatory assistance. Early consultation is highly recommended. Email IRB@carilionclinic.org to schedule and/or answer questions.
- **U.S. Food and Drug Administration Division of Industry and Consumer Education (DICE):** The Division of Industry and Consumer Education (DICE) answers questions (by phone and email) from the medical device industry and consumers of medical devices and radiation-emitting electronic products. Email: DICE@fda.hhs.gov
- **U.S. Food and Drug Administration, Device Advice:** Comprehensive Regulatory Assistance



***Exemption criteria:**

1. The device is noninvasive (as defined in 21 CFR 812.3 (k))
2. The device does not require any invasive sampling procedures that present significant risk
3. The device does not introduce energy into a human subject
4. The device is not used as the sole means for diagnosis without confirmation from another medically established diagnostic product

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

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