Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Reviewing Studies with Medical Device

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What is a Medical Device?

(Section 201(h) of the FD&C Act)

- Any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - Recognized in the official National Formulary, or the United States Pharmacopoeia, 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, or
  - Intended to affect the structure or any function of the body, and which does not achieve any of its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
- Software/mobile apps may be considered medical devices

Medical Device Examples

Surgical laser

Sutures

Pacemaker

Diagnostic aids such as reagents and test kits for *in vitro* diagnosis

Investigational Device

- An **investigational device** is a medical device that is undergoing clinical trials to evaluate safety and/or effectiveness (21 CFR 812)

- The regulations require that devices be classified as:
  - **Significant Risk (SR)** or
  - **Non- Significant Risk (NSR)**

Investigational Device Exemption (IDE)

- An **Investigational Device Exemption (IDE)** allows the investigational device to be used in a clinical study to collect safety and effectiveness data.
- Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.
- All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

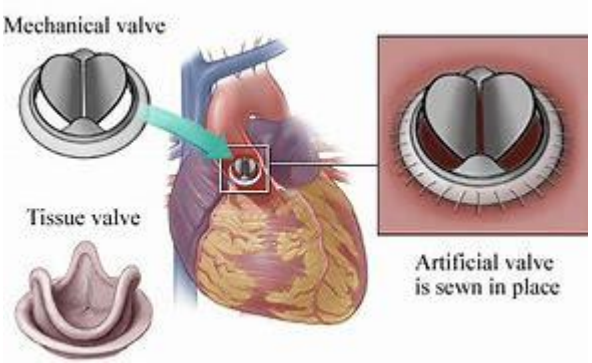
Significant Risk (SR) Devices
(21 CFR 812.3)

1. Intended to be implanted into a human
2. Use in supporting or sustaining human life
3. Of substantial importance in diagnosing, curing, mitigating, or treating a disease, or otherwise prevents impairment of human health
4. Otherwise presents serious risk to the health, safety, or welfare of a subject

Significant Risk (SR) Device in Research

- For use of SR Device in research, the sponsor must submit an **Investigational Device Exemption (IDE) application** to the FDA per 21 CFR 812.20
- There is no specific form for this purpose, but the regulations list elements required in the application
- The trial cannot begin until the FDA grants an IDE and the IRB grants approval for the study
- By definition, a study with SR Device poses **more than minimal risk** to the human subjects and requires convened IRB review

Significant Risk Devices Examples



Replacement heart valve

Root canal filling resin if chloroform is used as an ingredient in the device

Knee joint patellofemorotibial polymer/metal/ metal constrained cemented prosthesis

Cranial electrotherapy Stimulator when use to treat depression

Non-Significant Risk Devices
(21 CFR 812.3)

1. By default, NSR device does not meet the criteria of significant risk
2. It is considered to have an approved Investigational Device Exemption (IDE) application (that is, no application is filed with the FDA)
3. The IRB must agree that the study meets the criteria for NSR
4. The clinical trial of an NSR device requires IRB approval, informed consent, and proper study monitoring. NSR devices are studied without FDA oversight if the sponsor complies with the abbreviated requirements [21 CFR 812.2 (b)]

Non-Significant Risk Devices Examples

Conventional catheters

Dental Filling Materials

Menstrual pads or tampons

Transcutaneous electric nerve stimulation (TENS) devices

Making the SR vs. NSR Determination

- The IRB must make two separate decisions, based on different criteria:

1. Is the investigation approvable or not?
   - Criteria are the same as those used to evaluate any proposed research project

2. Does the device present SR or NSR?

Making the SR vs. NSR Determination (cont.)

- The IRB should review relevant information at a convened meeting:
  1. Description of the device
  2. Proposed investigational plan
  3. Subject selection criteria
  4. Informed Consent with required elements by FDA
- The IRB may agree or disagree with the sponsor's/PI's initial assessment.
- The IRB should document its SR or NSR determination in the meeting minutes. The minutes should describe its reasoning for said determination.

CHECKLIST – 418 – Non-Significant Risk Device

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CHECKLIST - 418 – Device Risk Determination

The purpose of this checklist is to support the IRB in making the device risk determination.

1. **Significant Risk Device Study**

☐ **N/A or** ☐ **All of the following conditions are met:**

1.A. ☐ The device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.

Provide protocol specific findings justifying this determination:

1.B. ☐ The device 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.

Provide protocol specific findings justifying this determination:

1.C. ☐ The device 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.

Provide protocol specific findings justifying this determination:

1.D. ☐ The device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Provide protocol specific findings justifying this determination:

2. **Non-Significant Risk Device Study**

☐ **N/A or** ☐ **The device meets none of the above criteria.**

Provide protocol specific findings justifying this determination:

Basis for Risk Determination

- Should be based on the proposed use of the device and not on the device alone
  - E.g., Daily wear contact lenses are considered NSR devices in normal daily use. If subjects are required to wear them for sleeping overnight for a study, then they would be considered SR device because the potential risk of harm (eye injuries) increased
- Consider the potential harm the procedure could cause as well as the potential harm caused by the device

The Determination

- The IRB may agree or disagree with the Sponsor's/ PI's initial risk assessment.

1. If the IRB agrees with NSR determination - the PI may proceed without FDA approval after the IRB approves the study
   - This is considered an **abbreviated Investigational Device Exemption (IDE)**

2. If the IRB disagrees with NSR determination - the PI must seek an **Investigational Device Exemption (IDE)** from the FDA and then return to the IRB before the investigation may take place.

Abbreviated Investigational Device Exemption (IDE)

(If the IRB agrees with the Sponsor's (PI's) risk determination)

WORKSHEET – 307 – DEVICES – Q5 – Abbreviated IDE

5	**Abbreviated IDE** (Check if **"Yes"** All must be **"Yes"**)
☐	The device is not banned by the FDA.
☐	The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)
☐	The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[vi]
☐	The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46)
☐	The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)
☐	The investigator will not market or promote the device. (21 CFR §812.7)

Investigational Device Exemption (IDE)

(If the IRB disagrees with the Sponsor's (PI's) risk determination)

WORKSHEET – 307 – DEVICES – **Q6 – Investigational Device Exemptions (IDE)**

All criteria under one category must be "YES"

6	**IDE Exemptions** (Check if **"Yes"**. All criteria under one category must be **"Yes"** for a category to be met. If none of the categories is met, the device is not exempt from an IDE.)	
Cat. #1	☐	The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.)
	☐	The device is FDA-approved/cleared.[vii]
	☐	The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.
Cat. #2	☐	The device is a diagnostic device.
	☐	The sponsor will comply with applicable requirements in 21 CFR 809.10(c).
	☐	The testing is noninvasive.[viii]
	☐	The testing does not require an invasive sampling procedure that presents significant risk.
	☐	The testing does not by design or intention introduce energy into a subject
	☐	The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure.
Cat. #3	☐	The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
Cat. #4	☐	The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

Investigational Device Exemption (IDE) (cont.)

- The sponsor (PI) is responsible for making the initial risk determination and presenting it to the IRB
- Unless the FDA has already made a risk determination for the study, the IRB must review the sponsor (PI) SR or NSR determination
- If the FDA has already made SR or NSR determination, it is **final**

UGA Supplemental Device Form

SUPPLEMENTAL DEVICE FORM

An IRB Submission will require additional review in compliance with the Food and Drug Administration (FDA) regulation for device use if it meets all of the following:

1. The study involves the use of device that meets the definition of a medical device (i.e., an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent/diagnostic, or other similar or related article, including a 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, or intended to affect the structure or any function of the body).
2. The device is the subject of the research or clinical study.
3. The research or clinical study will evaluate the effectiveness and/or safety of the device.

It is important to note that:

- Safety or effectiveness data are collected if evaluating the device's safety/ability to **diagnose (predict), treat, prevent, cure or mitigate a disease, or affect the structure or function of the body**. For example, a study of a new device that is not FDA approved or cleared (for marketing); or an approved/cleared device (or established device) being studied for a new indication or use.
- FDA regulations, as described above, apply even if the new device may still be in the developmental stage and is not considered to be in commercial distribution.
- FDA regulations, as described above, will apply even if the device is marketed or not.
- Devices used as a tool to collect data to examine a physiologic principle are not subject to FDA regulations if no data is collected about the device (e.g., MRI).

The purpose of this form is to gather additional information on the device and its use in this study so that the IRB can determine the applicability of the FDA regulations, whether use of the device is exempt from the FDA requirement to obtain an Investigational Device Exemption (IDE) prior to beginning the research, and the required level of IRB review. Complete a separate form for each investigational device that will be used in this study. Please refer to the UGA IRB Guidance on FDA-Regulated Research for additional information.

IRB Study #:

Name of PI:

2. **Is the device still being developed or is it already commercially available?**
   - ☐ **In Development.** Provide name and institution/affiliation of the device developer:
   - ☐ **Commercially Available.** Provide name of vendor (and if applicable, include its URL or webpage).

3. **Will the data/information obtained from this study be submitted to the FDA as part of an application for a research or marketing permit?**
   - ☐ **NO**. If No, what is the objective intent of the device manufacturer or developer for the data/information obtained from the use of the device in this study?
   - ☐ **YES**. If Yes, describe briefly the plans for submission of a marketing/research permit application to the FDA. Include if this is a requirement for prior submission to the FDA; or, it is not subject to requirement for prior submission to the FDA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

SECTION I: IDE Exemptions

A. Is this a lawfully marketed device, i.e. subject of a cleared 510(k) or premarket approval application (PMA), which is unchanged from its approved or cleared form?
   - ☐ No. **Skip to B.**
   - ☐ Yes. Will the device be used in accordance with the FDA-cleared indications, with no modifications?
     - ☐ Yes. Upload the device Instructions for Use showing the device's cleared indications. **Use of the device is exempt from the IDE requirements. STOP - this form is complete.**
     - ☐ No. Continue to B.

B. Is the device a non-invasive diagnostic device?
   A non-invasive device or procedure is one that does not by design or intention: (1) penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. ***If you are obtaining samples by one of the methods listed in 1 or 2 above, the test is invasive and you should answer NO.***
   - ☐ No. Skip to C.
   - ☐ Yes. **Answer all questions (a-d) below.**

Helpful Links

- Medical Devices (21 CFR Subchapter H, Part 800-898)
- Medical Device Classification
- CDHR Learn: How is My Medical Device Classified?
- Guidance on FDA-Regulated Research
- Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors
- Checklist 418 – Non-Significant Risk Device
- Worksheet 307 – Devices
- UGA Device Supplemental Form

Thank you!