

HAC Policies and Procedures

What Is An Investigational Device?

Investigational devices are medical devices used in a research study to determine the safety and/or effectiveness of the medical device.

What Are The Device Regulations?

Device studies must be conducted according to the requirements of the Investigational Device Exemption (IDE) regulations (21 CFR 812).

How Are Investigational Devices Classified?

Investigational devices are classified as either posing a significant risk (SR) or non-significant risk (NSR). Please note the following information:

1. The HAC may determine a device to be a SR even if the sponsor considers the device to be NSR.
2. The HAC will review the sponsor's risk (SR or NSR) justification.
3. The HAC will notify the investigator via a formal letter of their determination of risk.
4. It is the investigator's responsibility to notify the sponsor of determination or risk by the HAC.
5. The HAC may approve SR device studies only after an IDE approval is obtained by the sponsor.

What Is A Non-Significant Risk (NSR) Device?

A non-significant risk (NSR) device is one that does not present a potential for serious risk to the subject's:

- Health
- Safety
- Welfare

What Are Some Examples Of NSR Devices?

Some examples of NSR devices include most daily wear contact lenses, lens' solutions, heel cups, antibacterial surgical garments, incontinence devices, oral training splints, and ultrasonic tooth cleaners. An investigation of a NSR device is considered to have an approved IDE if the sponsor meets the requirements of the IDE regulations unless the Food and Drug Administration (FDA) notifies the sponsor. These regulations require:

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- Prospective HAC approval
- Written informed consent

What Is A Significant Risk (SR) Device?

A significant risk (SR) device is one that DOES present a potential for serious risk to the subject's:

- Health
- Safety
- Welfare

What's the Definition of SR Devices?

SR devices are usually defined as:

- Implantable devices
- Devices used in supporting or sustaining human life
- Devices of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health

What Are Some Examples Of SR Devices?

Examples (not all inclusive) of SR devices are:

- Catheters (other than urological)
- Ventilators
- CPR devices
- TMJ prostheses
- Stents
- Lithotripters
- Sutures and absorbable bandages/materials
- ECT devices
- Extended wear contact lenses
- Pacemakers
- Contraceptive devices
- Most laser systems
- Most hemodialysis systems

Are SR Device Studies Required To Meet The Full IDE Requirements?

Research that uses SR devices must meet the full IDE requirements including the submission of an IDE application to the FDA.

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Is HAC Approval Required Prior To Conducting Clinical Trials Using A SR Device?

Yes. HAC approval is required prior to conducting clinical trials of the investigational device. A more complete listing of requirements is found at the following web link www.fda.gov/cdrh/d861.html.

Who Decides If A Device Is Significant (SR) Or Non-Significant Risk (NSR)?

The HAC will decide whether a study should be approved and will determine if the device presents a significant or non-significant risk.

The HAC reviews the total risks of the device to decide the level of risk. If the device is used with a procedure that involves risk, the HAC will consider the risks of the procedure as well as the risks of the device.

Some studies that use NSR devices may also be considered minimal risk studies and may be reviewed through the expedited review procedure. However, full Committee review is required for all SR device studies as the FDA and the HAC consider SR device studies present more than minimal risk.

What Is A Humanitarian Use Device?

On June 26, 1996, the FDA issued a final ruling to enforce the provisions of the Safe Medical Devices Act of 1990 regarding humanitarian use devices (HUDs). This regulation became effective on October 24, 1996. A HUD device is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. Because a device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations, the FDA developed and published the regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

The regulation provides for the submission of a humanitarian device exemption (HDE) application which is similar to a premarket approval (PMA) application in both form and content, but is exempt from the effectiveness requirements of a PMA.

A HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. However, the application must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.

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An approved HDE authorizes marketing of the HUD. **However, a HUD may only be used after HAC approval has been obtained for the use of the device for the FDA approved indication.** The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

What Form Do We Complete for a Device Study?

Please complete the HAC Form 105, Investigational Device Information Sheet.

How Are Device Studies Different from Drug Studies?

Device studies use an investigator agreement while drug studies require the use of the Form FDA 1572.

Device studies use the term “Class while drug studies use the term “Phase” for each timeline of the drug’s progression while.”

Device studies utilize a manufacturer’s brochure or pamphlet while drug studies will provide either a package insert or an investigational new drug brochure.

What About Radiation Emitting Devices?

These types of studies must undergo additional review by the Human Use Subcommittee of the Radiation Safety Committee. Special arrangements must be made with the Radiation Safety Department prior to bringing the device on campus.

How Does The HAC Document The Rationale Of NSR/SR Determination?

Documentation can be found in the HAC meeting minutes.

What are the Responsibilities for Studies in which an IDE is Required?

1) For studies in which the sponsor is the IDE holder, the investigator is required to:

a) Provide a copy of the IDE filing from the sponsor

b) Provide documentation from the sponsor or FDA that the IDE is required, or the device meets the IDE exemptions, or an abbreviated IDE is required is valid

Note that this documentation should be included in the initial submission for the study. HAC approval will not be granted without this required documentation.

2) For studies in which the investigator is the IDE holder and assumes sponsor responsibilities, the following procedure should be followed:

a) The investigator will include in the protocol submission the following parts written to the specifications identified Title 21—Food and Drugs, Chapter 1—Food and Drugs

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Administration, DHHS, Subchapter H—Medical Devices, Part 812 – Investigational Device Exemptions, Subpart C- Responsibilities of Sponsors

b) The PI must send a copy of all correspondence to and from the FDA in the initial submission, including investigator reports. A letter from the FDA regarding the IDE or IDE status is also required for HAC approval.

c) The HAC will ensure that at initial and continuing review, that these elements are in compliance with:

- § 812.40 - General responsibilities of sponsors.
- § 812.42 - FDA and IRB approval.
- § 812.43 - Selecting investigators and monitors.
- § 812.45 - Informing investigators.
- § 812.46 - Monitoring investigations.
- § 812.47 - Emergency research under 50.24 of this chapter.
- § 812.100 - General responsibilities of investigators.
- § 812.110 - Specific responsibilities of investigators.
- § 812.119 - Disqualification of a clinical investigator.

d) Investigators must contact the Office of Human Research Protection to schedule a meeting to confirm that the PI is knowledgeable on the requirements associated with:

ii. 21 CFR §812. Investigational Device Exemptions

e) Investigators assuming sponsor responsibilities are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).