When Do I Need A Physician Sponsored Investigative Device Exemption (PSIDE) And How Do I Get It?

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The IDE Regulations

- Part 812 - Investigational Device Exemptions (IDE) Regulations apply to clinical studies performed in the US.
  - A clinical study is a standardized, systematic collection of safety and/or effectiveness data.
- IDE approval may be needed depending on:
  - the device’s approval status;
  - the intended clinical use; and
  - whether it is a significant risk or non-significant risk device.

Applicability of the IDE Regs to Clinical Studies

- Some clinical studies are exempted from the IDE regulations, for example:
  - The study of approved devices that are being used on-label
  - The testing of any combination of devices if the testing does not put subjects at risk and is not for the purpose of determining safety or effectiveness
- A clinical study of a non-significant risk device must follow abbreviated IDE requirements.
  - An NSR device is considered to have an approved IDE after IRB approval

Do I need an IDE?

Examples for Sponsor Investigators

Disclosures

No conflicts of interest to report.
When is an IDE Required? Example 1

A patient with prior CABG presents with myocardial ischemia and a high-grade stenosis in the vein graft to the right coronary artery.

- The clinician plans to use a legally marketed drug-eluting stent to treat the vein graft stenosis.
  - The stent is FDA-approved for the treatment of native coronary artery lesions.
  - The clinician plans to collect the information needed to monitor quality assurance.

Is an IDE Needed?

Determining the Need for an IDE Submission | YES | NO
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Does the device use involve: a) an off-label use of a medical device that has been approved/cleared by the FDA; or b) an Investigational Device? | | 

Although the device is being used off-label, the clinician does not plan to systematically collect safety and effectiveness data. This use would fall under practice of medicine (although clinical studies for this indication are encouraged) and no IDE is needed.

Example 2

Investigator-initiated research will study whether outcomes for a covered stent to treat stenoses at the venous anastomosis of A-V access grafts are affected by the access graft type.

- The covered stent and the two AV access grafts are FDA-approved/cleared and are being used in accordance with their labeling.
  - The covered stent labeling does not specify the brand of AVF graft with which it can be used.
- The clinician intends to publish the results.

Is an IDE Needed?

Determining the Need for an IDE Submission | YES | NO
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Does the research involve: a) an off-label use of a medical device that has been approved/cleared by the FDA; or b) an Investigational Device? | | 

Although the research constitutes a clinical study because the investigator plans to systematically collect safety and effectiveness data, the legally marketed devices are being used in accordance with their labels, so the study is exempted and no IDE submission is required.

Example 3

The first investigator intends to compare the performance of two approved coronary drug-eluting stents in the treatment of stenotic saphenous vein bypass grafts.

- The stents are FDA-approved for the treatment of native coronary artery lesions.
- The investigator intends to publish the results to help others decide which devices to use.

Is an IDE Needed?

Determining the Need for an IDE Submission | YES | NO
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Does the research involve: a) an off-label use of a medical device that has been approved/cleared by the FDA; or b) an Investigational Device? | | 

Is the Investigational Device a Significant Risk (SR) Device (per 21 CFR 812.3(m) and 812.20(a)(1))? | | 

If YES for an off-label use, an FDA approved IDE is required.
Determining Significant Risk

Yes

(a) Is the investigational device intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject?

No

(b) Is the investigational device 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?

Yes

(c) Is the investigational device 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?

No

(d) Does the investigational device otherwise present a potential for serious risk to the health, safety, or welfare of a subject?

If YES to any of questions (a) - (d), the study utilizes a Significant Risk Device and therefore requires IDE approval prior to study initiation.

An IDE is Needed

• Although the devices are commonly used off-label for the treatment of stenotic SVGs, the research constitutes a clinical study because the investigator plans to systematically collect safety and effectiveness data.

• The proposed prospective clinical study of these significant risk devices requires IDE and IRB approval prior to initiation.

Clinical studies do not fall under the definition of practice of medicine.

An IDE is Needed

• Once the physician modifies the endograft by making fenestrations in the marketed device, it becomes an investigational device.

• The new device also has a different intended use as compared to the marketed device.

• The only mechanism for using an investigational device is through application of the IDE regulations.

• Safety and effectiveness data should be systematically collected.

• The clinical study of the significant risk investigational device requires IDE and IRB approval prior to initiation.
IDE Application

The information to be included in an IDE application is listed in the regulations.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm

- sufficient information to justify the proposed study based on reports of prior investigations of the device
- an appropriate investigational plan
- adequate patient protection measures
- other required elements that address records and reports, study monitoring, and manufacturing information

IDE Application

- Contact Dorothy Abel or Dr. Carmen Gacchina Johnson.
  Dorothy.Abel@fda.hhs.gov Or Carmen.Gacchina@fda.hhs.gov
- Submit a PreSubmission with a draft of the IDE to obtain informal feedback from FDA to help finalize the proposal.

SVS Template for PSIDE Applications

- **Scope:** Endovascular grafts to treat short infrarenal neck, juxtarenal, and pararenal aortic pathologies
- **Content:** Provides an outline, pre-populated content, and suggestions for providing study-specific information
- **Benefits of template use:**
  - Reduce time spent in the Pre-Sub Process
  - Improve submission quality
  - VQI data capture - combined analyses

Email SVS to request the template at vascular@vascularsociety.org

This is not an FDA document and its use is not required.

Thank you!