Device Guidance [Page 1 of 2]

If FDA has made a determination, the determination can be accepted by the IRB [e.g. approved IDE, cleared 510(k)].

1. **Medical Device Determination:** Is the device a medical device?

   Per 21 U.S.C. 321(h), a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro 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.

   If this study involves a medical device, please read the following information.

2. **Clinical Investigation determination:** Does this study collect safety and/or effectiveness data for this particular device?

   21 CFR 812 (IDE regulations) “applies to all clinical investigations of devices to determine safety and effectiveness”. Per Sec. 812.3 (g) Definitions, “Investigational device means a device, including a transitional device that is the object of an investigation”.

   If safety and/or effectiveness are not studied for a device in this study and that particular device is not the object of this investigation, a device risk determination under the FDA regulation 21 CFR 812 will not be required and the remaining instructions listed below do not apply. The IRB review should include a review of the risks associated with the use of this device as part of the 45 CFR 46.111 criteria for IRB approval. **If this study determines safety and/or effectiveness of the device, please read the following information.**

3. **There are 3 types of device studies described in 21 CFR 812: exempt, significant risk & non-significant risk.**

   **Exempt Studies** – Investigations that are exempted from 21 CFR 812 are described in Sec. 812.2(c).
   - If a device is determined to be exempt from IDE regulations, the determination of risk is not necessary.
   - May qualify for expedited review.
   - Does not need an IDE application approved by FDA.

   | 812.2(c) Exempted investigations for these devices | (c) Exempted investigations. This part, with the exception of Sec. 812.119 (disqualification of a clinical investigator), does not apply to investigations of the following categories of devices*:
   | * Devices for veterinary use and used solely for research on animals have been omitted. |

   | 812.2(c)(1) A device in commercial distribution before May 28, 1976 | (1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time. |

   | 812.2(c)(2) Device substantially equivalent to one in distribution before that date | (2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. |

   | 812.2(c)(3) Noninvasive diagnostic device (MOST COMMON EXEMPTION) | (3) A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing:
   | (i) Is noninvasive,
   | (ii) Does not require an invasive sampling procedure that presents significant risk,
   | (iii) Does not by design or intention introduce energy into a subject, and
   | (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
   | Under 21 CFR 812.3(k) Noninvasive when applied to a diagnostic device or procedure, means one that does not by design or intention:
   | A. Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or 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.
   | B. Blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered noninvasive. |

   | 812.2(c)(4) Device undergoing consumer preference testing | (4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk. |

   | 812.2(c)(7) A custom device | (7) A custom device as defined in Sec. 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution. |

IRB Determinations – Device
Revised March 2013
**Device Risk Determination: If the device study is not exempt, is it an SR or NSR?**

The IRB must review the sponsor’s SR or NSR determination for every investigational medical device study reviewed. The convened IRB can disagree with the sponsor’s determination.

**Significant Risk (SR) device studies:**

- Full Committee review is always required.
- Must have an IDE application approved by FDA before they may proceed.
- Must follow 21 CFR 812.
- Researcher may include documentation of SR determination from the FDA, if on file.

SR determination must be based on seriousness of harm that may result from the use of the device in protocol related tests and procedures in addition to the harm that may be caused by the device alone.

Under 21 CFR 812.3(m) a **Significant risk device** means an investigational device that:

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. 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;
3. 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; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Non-Significant Risk (NSR) device studies:**

- Initial Full Committee review required for NSR determination.
  - If determined NSR, future reviews may be expedited via category 9 if the research involves no more than minimal risk and no additional risk are identified. This should be documented in the minutes at time of review.
- The sponsor does not need to submit an IDE to FDA before starting the study.
- Must follow the abbreviated requirements at 21 CFR 812.2(b) (IRB approval, labeling, AE reporting, records).

A **Non-Significant Risk (NSR) device** is an investigational device that does not meet the definition of a significant risk device.