Investigational Device Guidance

How to complete Section 6 of the IRB application:

Section A: Select the option that best describes your research. Important: If you are collecting safety and/or effectiveness data about a device, the IDE requirements apply. If you are using a device as "tool", the IDE requirements do not apply.

Section B: Once you've determined that the IDE requirements apply, provide information from the FDA about your device. If you have not submitted an application to the FDA, select #4 and complete section C.

Section C: Use this section to request an exemption from the IDE requirements OR a Non-significant risk (NSR) determination from the IRB. In addition to responding the questions in the application, you must also complete the Device Worksheet. A copy of the Device Worksheet can be found here.

Complete Device Information Table and upload all required documents, as required.

A **medical device** is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, 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, 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 any of 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 any of its primary intended purposes."

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data (generally to support marketing application). Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

FDA device regulations would generally not apply to studies:
1) Using a device to test a physiologic principle where no data is collected about the device or to develop the device for marketing;
2) Using a device to address a research question and no data is collected about the device;
3) Using a device for clinical purposes (e.g., monitor a side effect, measure treatment progress);
as long as there is no intent to collect safety and/or effectiveness data *or* develop the device for marketing.

EXEMPT INVESTIGATIONS

See 21 CFR 812 (c) **Exempted investigations.** This part, with the exception of 812.119 (i.e., disqualification of a clinical investigator) does not apply to investigations of the following categories of devices (i.e. studies are exempt from the IDE regulations if any of the following apply):

(1) Pre-amendment (pre-1976) devices
(2) 510(k)-cleared (i.e., substantially equivalent) or PMA approved devices if ***used in accordance with approved labeling***
(3) A **diagnostic device (examples: assays, software, algorithms, etc.)** 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 (i.e., correlation studies)**
(4) A device undergoing **consumer preference testing** if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
(5) A device intended **solely for veterinary use**.
(6) A device shipped **solely for research on or with laboratory animals** and labeled in accordance with 812.5(c).
(7) A **custom device** as defined in 812.3(b), **unless the device is being used to determine safety or effectiveness for commercial distribution**

21 CFR 812 (b) ***Custom device* means** a device that:
(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
(2) Is not generally available to, or generally used by, other physicians or dentists;
(3) Is not generally available in finished form for purchase or for dispensing upon prescription;
(4) Is not offered for commercial distribution through labeling or advertising; and
(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

INVESTIGATIONAL DEVICE NOT EXEMPT UNDER 21 CFR 812 (c) → FULL BOARD for SR/NSR DETERMINATION (unless risk determination already made by FDA.) If study does not meet SR criteria, then = NSR.
★Risk assessment is based on device as used in the study; not just the device. Determination must be made for each separate study.

21 CFR 812.3(m) **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.

NOTE: "Minimal Risk" is an IRB term and should not be confused with "Non-Significant Risk"; these have different meanings and should not be used interchangeably.

Device Decision Tree

Does the research involve the clinical investigation of a device to determine its safety and effectiveness?

FDA device regulations would generally not apply to studies:

1) Using a device as a tool to test a physiologic principle where no data is collected about the device or develop the device for marketing;
2) Using a device as a tool to address a research question and no data is collected about the device;
3) Using an FDA-approved device for clinical purposes (e.g., monitor a side effect, measure treatment progress), as long as there is no intent to collect safety or effectiveness data or develop the device for marketing. (i.e., device is used as a tool in the trial and not object of study).

YES → **FDA Investigational Device Requirements may apply**

Then ask

Is study exempt from IDE Regulations? (*See "Exempt Investigations" above.*)

Yes → Do all research procedures present no more than minimal risk OR the device is cleared/approved for marketing and being used in accordance with it cleared/approved labeling?

NO → **FDA Investigational Device Regulations DO NOT apply**

Yes → May be reviewed by the IRB under Exp. Cat # 1 if the IRB determines that the research poses no greater than minimal risk

No → Must be reviewed by the convened IRB

No → Must be reviewed by the convened IRB to make a SR/NSR determination (*See "Significant Risk Device" definition above.*)

NSR → Full Board determines study is NSR: Study has abbreviated IDE; Investigator is not required to submit to FDA.

Research must follow Abbreviated IDE requirements at 21 CFR 812 (b): **(i)** Labels the device in accordance with § 812.5; **(ii)** Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval; **(iii)** Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under part 50 and documents it, unless documentation is waived by an IRB under § 56.109(c); **(iv)** Complies with the requirements of § 812.46 with respect to monitoring investigations; **(v)** Maintains the records required under § 812.140(b) (4) and (5) and makes the reports required under § 812.150(b) (1) through (3) and (5) through (10); **(vi)** Ensures that participating investigators maintain the records required by § 812.140(a)(3)(i) and make the reports required under § 812.150(a) (1), (2), (5), and (7); and **(vii)** Complies with the prohibitions in § 812.7 against promotion and other practices.

SR → Full Board determines study is SR: FDA-approved IDE needed; Research must follow 21 CFR 812