Office of Human Research Protection
Institutional Review Board
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Greenville, SC 29605

DEVICES – GUIDANCE

Definition

A medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

1. 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
2. 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.

Medical devices include, but are not limited to, pacemakers, dialysis equipment, breast implants, bandages, thermometers, glucose pumps, wheelchairs, scalpels, IVD devices and contact lenses.

A "device" is any device used for clinical research that is supplied by the sponsor of the trial for use in an IRB approved protocol. It is the joint responsibility of the investigator and the Institutional Review Board to ensure that an IDE from FDA is in place if necessary for a medical device or an in vitro diagnostic (IVD) device. In the event that an investigator declines to contact FDA about the need for an IDE, the IRB may, in its discretion, require the investigator to contact FDA and obtain a determination regarding the need for an IDE as a condition of IRB approval.

IRB Determination

In addition, the IRB will make the regulatory determinations regarding whether a device constitutes a significant or non-significant risk device as appropriate.

- ***Significant risk*** (***SR***): A SR device study is defined by the regulations (21 CFR 812.3) as one that presents a potential for serious risk to a participant. In order to conduct a SR study, the sponsor must submit an IDE to the FDA as well as obtain IRB approval prior to study initiation.
- ***Non-significant risk*** (***NSR***): A NSR study, on the other hand, does not. In order to conduct an NSR study, an investigator must first submit a proposal to the IRB. If the IRB concurs with the investigators/sponsor's NSR determination, the study may be initiated upon their final approval.

If the IRB agrees with the NSR determination and approves the study, the study is "**considered**" to have an approved application for IDE. No formal submission to FDA is required. The IRB serves as an FDA surrogate for NSR studies. NSR device studies must follow **abbreviated regulatory requirements** in 21 CFR 812.2(b).

The Principal Investigator (or sponsor of the study) must then comply with the abbreviated requirements under 21 CFR 812.2(b):

(1) The sponsor labels the device in accordance with 21 CFR 812.5 and must bear the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use."
(2) The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device was not a significant risk device, and maintains such approval.
(3) The sponsor ensures that investigators participating in an investigation obtain and document informed consent from each subject under the investigator's care (under 21 CFR 50), unless documentation was waived.

(4) The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations.
(5) The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10).
(6) The sponsor ensures that participating investigator (if different from the sponsor) maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7).
(7) The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

For assistance in making a significant risk (SR) and nonsignificant risk (NSR) determinations, contact FDA or visit the FDA web pages FDA Device Advice and FDA's Information Sheets on Medical Devices, or download "FDA's Information Sheet Guidance regarding significant risk and non-significant risk medical device studies" (PDF) and/or "FDA's Frequently Asked Questions About Medical Devices" (PDF).

Studies Exempt from IDE
No IDE is required if the study meets one of the exemption categories in 21 CFR 812.2(c) that apply to human research. All criteria under each category must be true in order to meet the exemption category. IRB review and informed consent are still required.

Category 1-2
A clinical investigation with approved devices used in accordance with labeling. The device may have been approved for commercial distribution before May 28, 1976 or deemed substantially equivalent to a device commercially approved before May 28, 1976.

Category 3
A clinical investigation with in vitro diagnostic devices, if the sponsor complies with applicable requirements in 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. 21 CFR 812.2(c)(3).

Category 4
A clinical investigation with a marketed device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, unless testing is for determining safety and efficacy and/or puts subjects at risk.

Category 7*
A clinical investigation of a custom device as defined in 21CFR812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution. *Category 5 & 6 do not apply to human research.

Where questions still exist, investigators should contact the appropriate FDA review division for guidance.

Contacts for Center for Devices and Radiological Health
• 800-638-2041 or 301-796-7100
• IDE Inquiries: 301-796-5640

• dsmica@cdrh.fda.gov

The FDA website outlines the FDA's Procedure for responding to inquiries regarding need for an IDE - https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide

Investigational Device Accountability

Clinical investigators (NSR) must maintain the records of each subject's case history and exposure to the device under 812.140(a)(3)(i). Case histories include case report forms and supporting data, including signed and dated consent forms and medical records, including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Records must include documents demonstrating informed consent and, for any use of a device the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history of each individual must document that informed consent was obtained prior to participation in the study.

1. Device Ordering

The Principal Investigator identified on the IRB approved protocol will be the physician under which the investigational device will be ordered. The device will be ordered as per the sponsor's instructions. The order will supply all information required to accurately fill the order and permit proper recording.

2. Device Control and Storage

All investigational devices will be stored under control of the Principal Investigator. This may be in the Principal Investigator's office or in a laboratory.

3. Prior Authorization

The physician will obtain formal written participant consent and authorization prior to using any investigational device. This consent process and document must have documented IRB approval.

4. Supervision of Device Use

An investigator can permit use of the investigational device only with participants under his/her supervision and cannot not supply an investigational device to any person not authorized under the IDE regulations to receive it.

5. Device Dispensing

The Principal Investigator, or designated specialized laboratory, will be responsible for dispensing the investigational device per protocol and department policies and procedures. Each protocol has its own device supply. The transfer of devices between protocols is prohibited. If this is required, the sponsor of the trial must be notified, and approval granted.

For NCI-sponsored device trials, if under extenuating circumstances devices are transferred between studies, a device transfer form must be completed. All pertinent device accountability records will be maintained by the PI or designated specialized laboratory.

6. Device Disposal

Upon completion or termination of a clinical investigation or the investigator's part of the investigation or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or dispose of the device as the sponsor directs. Used investigational devices will be destroyed according to the department's waste handling procedures. Any unused/unopened investigational devices will be returned to the trial sponsor for destruction, unless authorized by the trial sponsor to destroy on site.