Mass General Brigham

HUMAN RESEARCH AFFAIRS

RESEARCH INVOLVING INVESTIGATIONAL DEVICES

BACKGROUND

The Mass General Brigham IRB Office assesses the use of investigational devices in research studies and makes a device determination when a study plans to test the safety and/or efficacy of an investigational device (non-FDA approved/cleared device, or in some instances for an FDA-approved/cleared device being used off-label).

When a device is used within the context of a research study but its safety and/or efficacy are not being directly investigated within the proposed research, the device may be considered an "Ancillary Device" or the IRB may determine that the IDE regulations do not apply.

The Investigational Device Exemptions (IDE) regulation (21 CFR 812) describes three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies. This guidance outlines the IRB's decision-making process pertaining to the two types of studies that are subject to the IDE regulation – the SR and NSR studies, as well as device studies that are exempt from the IDE requirements, and devices to which the IDE regulations do not apply.

The following section outlines the regulatory considerations and possible IRB device determinations.

Is my Device considered a medical device?

Investigators must determine whether the device that is being proposed for use in a research study meets the following definition of a medical device:

> 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, or intended to affect the structure or any function of the body.

The device is considered "investigational" if it is a device, including a transitional device, that is the object of an investigation. Transitional devices are devices that were regulated by the FDA as drugs prior to the May 28, 1976, the date the FDA Medical Device Amendments were signed into law. Any device that was approved by the FDA New Drug Application process is now governed by the FDA PMA regulations.

If the device in question does meet this definition of a medical device, it must be determined if researchers will be collecting safety and/or efficacy data on the device itself. Safety or effectiveness data are considered to be collected if the study plans to evaluate the device's safety and/or ability to diagnose (predict), treat, prevent, cure mitigate a disease, OR affect the structure or function of the body. This is true regardless of whether or not the device is FDA approved. In contrast, devices used as tools to collect data to examine a physiological principle are not subject to FDA regulations.

What is a Significant Risk (SR) Device Study?

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. For all clinical evaluations of investigational devices, unless exempt or deemed a Nonsignificant Risk (NSR), the IDE must already be in place with the FDA before the study is initiated.

Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- 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
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. B.

What is a Nonsignificant Risk (NSR) Device Study?

An NSR device is an investigational device that does not meet the definition of a significant risk device. If an IRB finds that an investigational medical device study poses a NSR, the sponsor does not need to submit an IDE to FDA before starting the study. If the IRB determines that the proposed study is an NSR study, the IRB may proceed to review the study under 21 CFR 56.109 and 21 CFR 56.111. FDA considers an NSR device study to have an approved IDE when the IRB concurs with the nonsignificant risk determination and approves the study and when sponsors meet the abbreviated requirements at 21 CFR 812.2(b). Consequently, in most cases, FDA is not aware of non-significant risk device studies.

Device Studies that are Exempt from the IDE Regulations

In accordance with 21 CFR 812.2(c), sponsors and investigators of certain studies are exempt from the requirements of 21 CFR Part 812:

> *Exempted investigations. This part, with the exception of § 812.119, does not apply to investigations of the following categories of devices:*
>
> (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.
>
> (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.

(3) A diagnostic device, 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.

Studies of a cleared device for a new use must comply with the human subject protection (informed consent and additional safeguards for children in research), IRB, and IDE regulations. Similarly, studies of a PMA (post market approval) approved device are exempt from the IDE requirements if the device is being studied for the indications in the approved labeling.

What are Ancillary Devices?

Ancillary devices are devices that are used in the context of a research study to perform tasks such as obtain measurements, collect data or monitor research participants, but whose safety and/or efficacy are not directly being investigated for the purposes of the research study.

Ancillary devices that are FDA approved/cleared, are considered standard hospital inventory, to be used in a manner consistent with their labeling and how they are used in standard clinical practice do NOT need to be accounted for on either a Device Form OR the Ancillary Device Form in Insight.

Ancillary devices that are FDA approved/cleared but are considered NON-hospital inventory must be listed on the Insight Ancillary Device Form.

NOTE: A non-FDA approved/cleared medical device, irrespective of whether or not it is standard hospital inventory, cannot be used within a research protocol to facilitate or support ancillary procedures performed strictly for research purposes because the safety and/or efficacy of such a device has not been properly vetted for clinical use. Therefore, it cannot be assumed that it would be safe and efficacious to use in the context of a research study. This applies to devices that are used to collect data or study human physiology as those data or physiological results cannot be relied upon.

Devices to which the IDE Regulations Do Not Apply

The IRB may determine that the IDE Regulations do not apply to a particular device when that device's safety and/or efficacy are not being directly investigated within the proposed research study, or the device does not meet the definitions of SR or NSR devices, and does not fit within the IDE Exempt options outlined by the FDA.

For example, the IRB may determine that the IDE regulations do not apply to a non-FDA approved device that is being used as a tool to measure data or study human physiology.

How do I properly reflect the use of my Device in my Insight submission?

A Device Form must be completed in Insight to account for any device(s) that are being used in an investigational nature within a particular research study. Investigators are to complete the Form in the manner that best represents their intended use of the device but note that the IRB will make the ultimate device determination and may therefore require changes to the Device Form.

The Device Form is organized in a manner that first assesses whether the investigator plans to test the safety and/or efficacy of the device, if the device will be used as a Humanitarian Use device, OR if the device will be used as a tool to measure data or study human physiology. Sub-sections become open depending upon which option is chosen.

IRB Office Review and Determination

The IRB Office initiates this assessment at the time of Screening and aims to identify and communicate any additional requirements related to the use of the device to the Investigator *before* the full IRB review takes place. This includes the possibility of identifying that an investigational device may be considered a Significant Risk device and requiring that the investigator query the FDA in order to obtain their input about whether or not an IDE should be sought for the use of the device in this particular research study.

Any supporting documents, such as Device Brochures, must be provided to the IRB Office by being uploaded to the “Attachments” page of the Insight submission.

The investigator may provide information to support their independent assessment of the various possible device determinations but per Mass General Brigham policy the IRB Office may or may not concur with this assessment and will make a device determination.

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