RESEARCH INVOLVING DEVICES

3/29/2021

Research investigating or evaluating devices must be conducted under an IRB approved protocol, under the direction of the approved investigator(s) and must comply with FDA regulations.

The definition of a 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:

- recognized in the official National Formulary, or the United States Pharmacopoeia, 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 any of its primary intended purposes."

Please note the term "device" does not include software functions excluded pursuant to section 520(o) of the Federal Food, Drug, And Cosmetic Act. More information regarding "Software as a Medical Device" can be found at: https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

When the research is conducted to determine the safety or effectiveness of a device the IRB will confirm and document for each device that either:

1. The device has a valid IDE number. The IDE for each device must be supported by one of the following:

   - The sponsor protocol imprinted with the IDE number
   - A written communication from the sponsor documenting the IDE number
   - A written communication from the FDA documenting the IDE number – *(required if an investigator listed on this protocol holds the IDE)*

   OR

2. The device fulfills the requirements for an abbreviated IDE [Criteria in 21 CFR 812.2(b)(1)]

   - The device is not a banned device

- The device is labeled by the sponsor in accordance with the FDA Investigational Device Exemptions at 21 CFR 812.5
- The sponsor will obtain 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
- The sponsor will ensure that each investigator participating in the investigation of the device obtains from each subject under the investigator's care, consent as required by FDA Regulations on the Protection of Human Subjects (21 CFR 50) and documents it, unless documentation is waived by the IRB

- The sponsor will comply with the requirements of the FDA Investigational Device Exemptions at 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor will maintain the records required under the FDA Investigational Device Exemptions at 21 CFR 812.140(b) (4) and (5) and makes the reports required under the FDA Investigational Device Exemptions at 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor will ensure that participating investigators maintain the records required by the FDA Investigational Device Exemptions at 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in the FDA Investigational Device Exemptions at 21 CFR 812.7 against promotion and other practices.

OR

3. The device fulfills one of the IDE exemption categories [Criteria in 21 CFR 812.2(c)]:

A. The device, other than a transitional device, was introduced into commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time
B. The device, other than a transitional device, was introduced into commercial distribution on or after May 28, 1976, that FDA had determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that was used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence
C. The device is a diagnostic device and the sponsor will comply with applicable requirements in 21 CFR 809.10(c) and the testing:
    - Is noninvasive
    - Does not require an invasive sampling procedure that presents significant risk
    - Does not by design or intention introduce energy into a participant
    - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure
D. The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing was not for the purpose of determining safety or

effectiveness and does not put participants at risk

E. The device is intended solely for veterinary use
F. The device is shipped solely for research on or with laboratory animals and labeled in accordance with the FDA Investigational Device Exemptions at 21 CFR 812.5(c)
G. The device is a custom device as defined in the FDA Investigational Device Exemptions at 21 CFR 812.3(b) and is not being used to determine safety or effectiveness for commercial distribution.

It is the policy of the DUHS IRB to make SR/NSR device determinations for every investigational medical device study reviewed, except when the study is exempt from IDE regulations. Please refer to the policy entitled "*Significant Risk or Non-Significant Risk Device Determinations by the DUHS IRB"* for details.

Combination Products

A combination product includes:
(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

For those research studies using Combination Products, the IRB considers the Primary Mode of Action ("PMOA"), as defined in 21 CFR Part 3, or, in cases where it is impossible to determine PMOA, the primary therapeutic benefit, and uses this consideration in its review of the need for an IDE and/or IND for this Combination Product. The IRB is ultimately guided by the FDA's determination of any IND/IDE requirements for the Combination Product.

Investigator-Held IDE

An investigator in a proposed research project who is also the IDE holder is a sponsor-investigator and is responsible for complying with both FDA sponsor and investigator regulations, and the DUHS Policy on Responsibilities of an Investigator

Who is also a Sponsor.

Control, Handling and Documentation of Devices Used in Investigations

As part of their submission, investigators must provide a description of their process for control, handling and documentation of devices investigated or evaluated in the proposed research study. A member of the IRB will evaluate whether the proposed plan is adequate.
For control, handling and documentation of investigational devices, investigators use an IRB-approved plan.

When Questions Arise During the IRB Approval Process or During the Course of an Investigation

If the IRB determines that an IDE is required for a Duke investigator-initiated clinical research study, then approval of the protocol will not be granted unless the FDA-provided IDE number has been registered with the Duke Regulatory Affairs and Quality (ORAQ) office, and the sponsor-investigator has completed training with ORAQ staff.

If, after a study begins, it is found that an IDE is required (e.g., based on a regulatory assessment or adjudication by an external IRB, etc.), further accrual to the study will be put on hold until an IDE is obtained and registered with Duke's Office of Regulatory Affairs and Quality (ORAQ), any required investigator training is completed, and the IRB has approved resumption of accrual to the study.

If the IRB is in doubt about the requirement for an IDE, the investigator must inquire about the issue with the FDA. All correspondence with the FDA about the necessity of an IDE must be shared with the IRB via the electronic IRB system. The study will not be approved by the IRB until either an IDE has been issued by FDA and registered with ORAQ and any required investigator training is completed, or FDA has confirmed that an IDE is not required.

Previous Version Date(s): 9/30/2008, 1/17/2011, 4/12/2011, 6/1/2011, 2/24/2016