Albert Einstein College of Medicine

Investigational Device Procedure

I. Purpose

This Procedure outlines requirements for research involving investigational devices at Albert Einstein College of Medicine ("Einstein" or "College of Medicine").

II. Scope

The following Procedure covers all research involving the use of investigational devices under the auspices of the Einstein IRB.

III. Definitions

Investigational Device: A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. As further stated, a device is any healthcare product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for *in vitro* diagnosis.

Investigational Device Exemption (IDE): An FDA-approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

Significant Risk (SR) Device: 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; or
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; or
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: An investigational device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.

IV. Procedure

Use of an investigational device in a clinical trial to obtain safety and effectiveness data must be conducted according to the FDA's IDE regulations (21 CFR 812) and other applicable FDA regulations.

When reviewing studies involving the use of a medical device, the IRB must determine the appropriate category of FDA regulation.

If no safety or efficacy data is being collected about the device, then the device does not meet the definition of an investigational device.

If safety and efficacy data is being collected, the device is considered an investigational device. The protocol will fall under one of three categories of FDA regulation: exempt from the IDE regulations, non-significant risk (NSR) device, or significant risk (SR) device.

If the investigational device fulfills one of the IDE exemption categories listed below, the protocol may be exempt from IDE regulations:

1. A legally marketed device when used in accordance with its labelling
2. A diagnostic device if it complies with the labeling requirements in 21 CFR 809.10 and if the testing:
    a. Is noninvasive; Does not require an invasive sampling procedure that presents significant risk;
    b. Does not by design or intention introduce energy into a subject; and
    c. Is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.
3. The device is a custom device and is not being used to determine safety or effectiveness for commercial distribution
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.
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 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
8. 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.

If the investigational device does not fulfill one of the exemption categories, it must be categorized as either an NSR or SR device. Both significant and non-significant risk device studies must be reviewed at a convened IRB meeting. If the FDA has already made the SR or NSR determination for the device, the agency's determination is final, and the IRB does not need to make a risk determination. If the FDA has not, the IRB must make a formal determination during a convened meeting regarding the appropriate category.

The risk determination should be based on the proposed use of the device in an investigation, and not on the device alone. In deciding if a study poses a significant risk, an IRB must consider the nature of the harm that may result from the use of the device. Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device.

Non-Significant Risk Device – Abbreviated IDE Requirements

Research involving the use of an NSR device must be conducted in accordance with the "abbreviated" requirements of the IDE regulations as described in 21 CFR Sec. 812.2(b). FDA approval of the IDE for NSR devices is not required. The FDA considers an investigation of an NSR device to have an approved IDE when the IRB makes the NSR determination and approves the study.

The following are required to fulfill the requirements for an abbreviated IDE:

- The device may not be a banned device.
- The sponsor labels the device in accordance with 21 CFR 812.5
- The sponsor 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.
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, consent under 21 CFR 50 and documents it, unless documentation is waived.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- 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);
- The sponsor ensures that participating investigators 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); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

Significant Risk Device – FDA-Issued IDE Requirements

Research involving the use of a SR device must be conducted in accordance with the full requirements of the IDE regulations and must have an approved IDE from the FDA. To document the IDE number, the

IRB requires written communication from the FDA. Investigator's brochures may not be used to validate an IDE. Other documentation may be accepted at the discretion of the Director or his or her designee.

If an investigational device study does not already have an FDA-approved IDE and the IRB makes an SR determination, the IRB will require that the PI obtain an IDE from the FDA before issuing final approval.

V. Effective Date

Effective as of: 30 August 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.