IRB Policy 19: IRB Device Policy
Revision Date: May 15, 2007, revised January 27, 2011, revised October 15, 2015, revised January 11, 2016

I. Summary Policy

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB is that all applicable rules and regulations will be followed in the review/approval of any trials using investigational devices.

II. Definitions

A Significant Risk (SR) device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. A Non-Significant Risk (NSR) device investigation is one that does not meet the definition for a significant risk study.

NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the Institutional Review Board (IRB) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure. For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the IRB are required. In addition, informed consent must be obtained for either type of study [21 CFR part 50].

III. Submission

When a study involving a device is received, the IRB coordinator verifies the New Protocol Submission xform for an IDE number. If no IDE number is recorded, the IRB Coordinator contacts the PI to obtain any additional available documentation. The IRB Coordinator creates a “More Information” Event in IRBManager and notes the need for IDE Determination. The Device Worksheet is used by IRB Chair/Vice-Chair as a tool to evaluate device studies.

Under FDA regulations, research that is conducted to determine the safety or effectiveness of a device must have an IDE issued by the FDA, unless the device meets the requirements for an abbreviated investigational device exemption

(IDE) (21 CFR 812.2(b)(1)) or the research meets one of the five exemptions from the requirement for an IDE (21 CFR 812.2(c)).

The device is exempt from the IDE requirements only if one of the following categories is met. If none of the categories is met, the device is not exempt from an IDE.

1 Devices, other than transitional devices, in commercial distribution prior to May 28, 1976, when used or investigated in accordance with labeling in effect at that time or Devices, other than transitional devices, introduced into commercial distribution on or after May 28, 1976, that the FDA determines to be substantially equivalent to a device in commercial distribution prior to May 28, 1976, and which is used or investigated in accordance with approved labeling;

2. A diagnostic device (including in vitro diagnostic products in compliance with 21 CFR 809.10(c)if the testing:

a. Is non-invasive
b. Does not require an invasive sampling procedure that presents significant risk
c. Does not by design or intention introduce energy into a subject, and
d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

3. Devices 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 the subject at risk.

4. Custom devices, as defined by FDA in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

If an IDE is required, validation of an IDE will be done by determining that the IDE number matches the Sponsor protocol, communication from the Sponsor, or communication from the FDA. In the case of a Researcher who holds the IDE, the number must match information provided by the FDA. An investigator's brochure will not be used for validation because one investigator brochure often covers multiple IDEs.

IV. Medical Investigational Device determinations

In reviewing studies involving medical devices, the Medical Campus ETSU/VA IRB will make two determinations:

(1) whether a device study represents a significant or non-significant risk; and
(2) whether the study should be approved.

These questions will be considered separately because the issues involved in making these decisions are quite different. Determining whether a device study poses a significant risk will be based solely on considerations of risk to subjects, while IRB approval of the study is based on many factors. The Checklist- Non-Significant Risk Device is used to assist with this determination.

The initial assessment of whether or not a device study presents a non-significant risk (NSR) is made by the sponsor. In addition to receiving a completed Form 103, narrative, informed consent, protocol and investigator's brochure (if available), the IRB must receive a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the IRB deems necessary to make its decision. The IRB must also be informed whether other IRBs have reviewed the proposed study, and what determinations were made. In addition, the IRB must be informed of the FDA's assessment of the device's risk if such an assessment has been made. If the sponsor considers that a study is NSR, the sponsor must provide the IRB an explanation of its determination and any other information that may assist the IRB in evaluating the risk of the study. The sponsor must provide the IRB with a risk assessment and the rationale used in making its risk determination [21 CFR 812.150(b)(10)].

For any device protocol considered (by FDA) to present significant risk, an IDE number will be required prior to submission to the ETSU/VA IRB for initial review. Conversely, if the FDA has made a determination of non-significant risk, than a copy of the determination letter received from FDA should be submitted with the protocol.

The IRB may also consult with FDA for its opinion. The IRB uses its expertise, information in the FDA regulations and guidelines, and the risk evaluation provided in the application to determine the risk category.

The IRB may agree or disagree with the sponsor's initial NSR assessment. If the IRB agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE application to FDA.

If the IRB disagrees and determines that the device is SR, the IRB informs the investigator and the sponsor in writing of this decision and its basis. The sponsor should notify FDA that an SR determination has been made. If the IRB determines that a device study is SR, the study **may not** begin until both the IRB and FDA approve the investigation. The study can be conducted as an SR investigation following FDA approval of an IDE application.

The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses an SR, the IRB considers the nature of the harm that may result from 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 participant must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB considers the potential harm that could be caused by the procedure in addition to the potential harm caused by the device.

FDA has the ultimate decision in determining if a device study is SR or NSR.

If the IRB decides the study is Significant Risk,

1. The IRB Coordinator forwards a letter to notify the sponsor and investigator of the decision that the study is significant risk.
2. The IRB tables the study until an IDE is obtained by the sponsor.
3. After IDE is obtained and submitted, the convened IRB reviews the study.

If the IRB decides the study is Non-Significant Risk,

1. IRB proceeds to review study applying requisite criteria [21 CFR 56.111]

Minutes of IRB meetings must document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.

If the investigator or organization is acting as the sponsor, the investigator or sponsor must follow all the additional regulatory requirements of sponsors. The IRB must evaluate whether the investigator knows how to follow the additional regulatory requirements of sponsors. In order to determine this evaluation, the IRB requires any investigator acting as the sponsor to read the FDA's "Responsibilities for Sponsors of Significant Risk Device Studies, Responsibilities for Sponsors of Non-Significant Risk Device Studies" ,"Responsibilities for Investigators of Significant Risk Device Studies, Responsibilities for Investigators of Non-Significant Risk Device Studies" published on-line at http://www.fda.gov/cdrh/devadvice/ide/print/responsibilities.html. The IRB receives an signed attestation that the investigator/sponsor has read this document prior to issuing final study approval.