

## **SECTION 7: MEDICAL DEVICE STUDIES**

### **Section 7.1 Significant Risk Device**

### **Section 7.2 Non-Significant Risk Device**

### **Section 7.3 Determination as to Category of Risk**

The Investigational Device Exemption (IDE) regulations (21 CFR part 812) describe two types of device studies, “significant risk” (SR) and “nonsignificant risk” (NSR).

### **SECTION 7.1 SIGNIFICANT RISK DEVICE**

A 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 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.

### **SECTION 7.2 NON-SIGNIFICANT RISK DEVICE**

A 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,” to identify a study that may be reviewed through the expedited review procedure.

### **SECTION 7.3 DETERMINATION AS TO CATEGORY OF RISK**

The IRB, regardless of the classification (SR or NSR) of the device assessed by the sponsor, must make its own assessment of the classification based on the proposed use of the device in a study, and not on the device alone. This must be accomplished **prior** to submission for full board review. An investigator considering participation in a device study must provide the Chair of the IRB with the following information:

1. Reports of prior investigations conducted with the device.
2. The proposed investigational plan.
3. A description of subject selection criteria.
4. Monitoring procedures.  
Information from the sponsor regarding risk assessment and the rationale used in making its risk determination.
5. If the device is already FDA approved, information on whether or not this is an “off-label” use of the device.

The IRB Chair may agree or disagree with the sponsor’s initial assessment. If the Chair agrees with the sponsor’s initial NSR assessment, the investigator will be notified in writing that the study may then be submitted for full board review (for confirmation of NSR classification and review of the study). If the Chair assesses the device as SR, the investigator and the sponsor will be notified in writing of the SR decision. The sponsor must notify the FDA that a SR determination has been made. The study can be submitted for full board review only after the sponsor has received FDA approval of an IDE application. If this is an investigational or “off-label” use of the device, the investigator must also comply with federal requirements for submission of an IDE, unless all of the conditions in 21 CFR 312.2(b)(1) are met.