OHSU Policy

I. Policy

A. All studies involving investigational medical devices must be reviewed and approved for use in accordance with Federal regulations (FDA and OHRP) and Institutional policies. Clinical investigations of medical devices must comply with the Food and Drug Administration (FDA) informed consent and Institutional Review Board (IRB) regulations [21 CFR parts 50 and 56, respectively].

B. The IRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human subjects in research even when approval of the device has been granted by the FDA.

C. All clinical investigations of devices must have an approved Investigational Device Exemption (IDE) or have been determined to be exempt from the IDE regulation. Investigations that are exempted from 21 CFR 812 are described in §812.2(c) of the IDE regulation.

D. Unless exempt from the IDE regulations, an investigational device must be categorized as either “significant risk” (SR) or “nonsignificant risk” (NSR).
   1. The sponsor makes the initial determination that a device presents a nonsignificant or significant risk.
   2. The principal investigator (PI) submits the proposed study to the IRB for SR and NSR studies for formal determination of the appropriate SR/NSR category.
   3. If the IRB agrees that the study is NSR, a submission of an IDE application to FDA is not required but the sponsor is required to conduct the study in accordance with the “abbreviated requirements” of the IDE regulations [21 CFR 812.2(b)]. Unless otherwise notified by the FDA, an NSR study is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements.
   4. A SR device study may not commence until FDA has approved the IDE application and the IRB has approved the study.

E. During review of the research proposal, the IRB evaluates PI’s on these responsibilities and plans to control investigational devices.
   1. Each PI using an investigational medical device is responsible for control of the devices received in accordance with regulatory requirements.
   2. PI’s develop and submit to the IRB their plan for control, storage and accountability of the device.
   3. The investigator is responsible for implementing the plan as approved by the IRB.

Effective: 4/21/2008