HEALTH SCIENCE CENTER

IDE EXEMPTION WORKSHEET

For Determining if an Investigational Device Exemption is Required

There are 4 types of clinical studies involving medical devices that do not require that an IDE from the FDA be obtained. 1) Studies involving approved devices used with their approved labeling or devices that are substantially equivalent to currently marketed devices. 2) Studies involving approved devices that are determine by the FDA to pose nonsignificant risks to patients. 3) The legally marketed device is used within the practice of medicine. 4) Specific IDE-exempt studies as outline below. IRB approval is required before the study may commence.

IDE EXEMPTION CRITERIA	YES	NO
1. The study involves a legally marketed device when used in accordance with it labeling		
2.a. The study involves a diagnostic device that complies with the labeling requirement of 21 CFR 812.10(c)		
2.b. The study is noninvasive		
2.c. The study does not require an invasive sample procedure that presents significant risk		
2.d. The does not by design or intention introduce energy into a subject		
2.e. The study is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure		
3. The study involves consumer preference testing, testing of a modification, or testing of a combination of devices if the devices are legally marketed devices and if testing is not for the purpose of determining safety or effectiveness and does not put subject at risk.		
4. The device is intended solely for veterinary use		
5. The device is shipped solely for research with laboratory animals and contains the label “CAUTION – Device for investigational use in laboratory animal or other tests that do not involve human subjects.		