UCLA OHRPP
Office of the Human Research Protection Program

Tip Sheet: Exemptions from IDE Requirements for Clinical Research

(last updated 8/30/11)

FDA Regulations 21CFR812.2 exempt investigations of the categories of devices listed below from the requirements to submit an Investigational Device Exemption (IDE) application to the FDA. The FDA considers non-significant risk devices to have approved IDE applications. These studies are ***not***, however, exempted from IRB review.

FDA Exempted Investigations of Devices

1. ***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.

2. **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.

3. A ***diagnostic device***, if the sponsor complies with applicable requirements in 21CFR809.10(c) and if the testing:
   a. Is noninvasive,
   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.

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 21CFR812.5(c).

7. A ***custom device*** as defined in 21CFR812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

Level of IRB Review

The level of IRB review will depend on the risk assessment of the study including the use of the device. Expedited category #1[1] may apply to minimal risk studies, while more than minimal risk studies will require review by a convened meeting of an MIRB full board.

[1] Clinical studies of … medical devices only when condition … (b) is met.
   a. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.