Reviewer Checklist - Risk Determination for Devices

Please see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812 for further information on IDE regulations.
Research involving a medical device does NOT require an IDE if the device meets one of the exemption categories listed below; however, these studies must follow regulations for IRB review and informed consent (21 CFR 50). Please indicate any revisions or necessary clarifications and your final determination in the area provided below.

Please select the most appropriate choice.

NOTE: Research involving a medical device does NOT require an IDE if the device meets one of the exemption categories listed below; however, these studies must follow regulations for IRB review and informed consent (21 CFR 50). Please select the most appropriate choice.

- ○ **Exemption #1**
  The medical device was in commercial distribution immediately before May 28, 1976; and the FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976; and the medical device is being used or investigated in accordance with the indications in labeling in effect at that time of commercial distribution.
- ○ **Exemption #2**
  The medical device was introduced into commercial distribution on or after May 28, 1976; and the FDA has determined the medical device to be substantially equivalent to a medical device in commercial distribution immediately before May 28, 1976; and the FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976; and the medical device is being used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. (PMA or 510(k) approval)
- ○ **Exemption #3**
  The medical device is a diagnostic device; and the sponsor will comply with applicable requirements in §809.10(c); and the testing is noninvasive; and the testing does not require an invasive sampling procedure that presents significant risk; and the testing does not by design or intention introduce energy into a subject; and the testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- ○ **Exemption #4**
  A medical device undergoing one of the following: consumer preference testing, testing of a modification, or testing of a combination of two or more medical devices in commercial distribution; and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ○ **Exemption #5**
  Device intended solely for veterinarian use
- ○ **Exemption #6**
  The medical device is shipped solely for research on or with laboratory animals and labeled in accordance with §812.5(c).
- ○ **Exemption #7**
  The medical device is a custom device meaning all of the following are true: the medical device necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist and the medical device is not generally available to, or generally used by, other physicians or dentists and the medical device is not generally available in finished form for purchase or for dispensing upon prescription and the medical device is not offered for commercial distribution through labeling or advertising and the medical device is intended for use by an individual patient named in the order of a physician or dentist.
  One of the following is true: the medical device is to be made in a specific form for that patient or the medical device is intended to meet the special needs of the physician or dentist in the course of professional practice.
  The medical device is NOT being used to determine safety or effectiveness for commercial distribution.
- ○ **Post Approval Device Studies**
  The medical device has received marketing approval from the FDA; however, the FDA has requested additional testing. The post approval letter specifying this testing must be provided.
- ○ **Non-Significant Risk Device (NSR) - IDE from IRB or FDA required**
  It is determined that this device study is a Non-Significant Risk device (click here). The PI/Sponsor will conduct this study in accordance with the abbreviated requirements of the IDE regulations (21 CFR 812.2(b)). Please click here for a list of examples of NSR and Significant Risk devices, www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf.
- ○ **Significant Risk (SR) Device - IDE from FDA Required**
  It is determined that this device study is a Significant Risk device study and requires an IDE (please click here for an Important Note). This device study does not meet federal regulations of Non-Significant Risk, nor does it meet one of the federal Exemption categories listed above.

Clear

If an IDE (Investigational Device Exemption) from the FDA is required, has the number been provided and verified for this study?

- ○ Yes
- ○ No

Clear

- The IRB accepts the FDA letter, sponsor letter or other sponsor-generated document with the IDE number listed (e.g. company protocol) as verification of an IDE.

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*