Rev 07/19/16 kbk

# INVESTIGATIONAL DEVICES FORM

Please complete one form for each investigational device. You must attach the sponsors or manufacturers information about the device including the name, description, reports of any previous IRB reviews that the PI is aware of or the sponsor can provide, and documentation concerning known risks. This may include the Investigational Device Exemption (IDE) application.

**1. This is a:**

☐Significant risk device or diagnostic (Complete a)
☐Non-significant risk device or diagnostic (Complete b)
☐Humanitarian use device (Complete c)

**a. If a significant risk device:**

Name of the device(s):
IDA number:
IDE (Investigational Device Exemption) holder name (person/firm):
IDE Holder Address:

**b. If this study has been determined to be a non-significant risk device or diagnostic, please attach:**

- FDA 2891 (if a 510(k) exempt device or diagnostic
- FDA order of substantial equivalence (SE) (if a 510(k) was submitted)
- If none of the above is applicable, provide a letter of justification.

**c. If this is a Humanitarian Use Device (HUD)**

Name of the device(s):
HUD number:
HUD holder name (person/firm):
HUD holder address:
☐ HUD holder is Principal Investigator (if checked, attach HUD application to IRB submission)
☐Safety or efficacy data will be provided to the sponsor.

**2. The FDA has designated this device**

☐Category A
☐Category B
CMS code: