IRB Appendix E - Devices

Rev. August 2016

Complete this form to request inclusion of medical devices (e.g., instruments, implants, in vitro reagents, etc.) in the proposed research or to request approval for a Humanitarian Use device. *Include only those devices that are to be used as part of the research protocol (except for Humanitarian Use devices), i.e., not those used for routine care or evaluation.* Use a separate form or section for each device.

- Provide a copy of the device manufacturer's approved labeling (e.g., package insert, device label, descriptive and informational literature, operations manual, etc.).
- Provide documentation of all applicable FDA approvals/exemptions for the investigational or research use of the devices, as requested below. Copies of any correspondence to and from the FDA must be provided to the IRB. ***Final IRB approval cannot be granted until regulatory status is confirmed.***

For more information on the requirements for conducting research involving medical devices, see Device Advice on FDA website.

Principal Investigator: _____

Project Short Title: _____

Please select the category (A or B) of your device. Within that category, all questions must be answered.

☐ A. FDA Approved Devices

☐ B. Investigational Devices or Investigational Use of Approved Devices

Section A. FDA Approved Devices - Devices cleared for marketing and used according to intended use.

Note: If the research involves more than one FDA approved device, print an additional page of this appendix and label as "FDA approved device #2."

1. Provide the following information:

Name of Device:		
Regulatory Status:	☐	510(k) (i.e., "substantially equivalent" to a marketed device)
	☐	510(k) exempt
	☐	PMA (pre-market approval)
Device Classification:	☐	I (e.g., bandages, examination gloves, hand-held surgical instruments)
	☐	II (e.g., wheelchairs, infusion pumps, surgical drapes)
	☐	III (e.g., replacement heart valves, silicone breast implants, implanted stimulators)
Proposed Use:		

2. Provide a brief description of the device.

3. Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

4. Summarize the potential adverse effects (including serious warnings and more common adverse effects).

Section B. Investigational Devices or Investigational Use of Approved Devices - Devices that are investigational, modified, or proposed new intended uses.

Note: If the research involves more than one investigational device, print an additional page of this appendix and label as "Investigational device #2."

1. Provide the following information:

Name of Device:	
Manufacturer:	
Device Status:	☐ Investigational
	☐ Approved, but its use in this research is investigational
Proposed Use:	

2. This device research should be determined to be

Choose either **Significant Risk**, **Nonsignificant Risk** or **IDE Exempt**. Complete only **ONE** section:

☐ **Significant Risk (SR)** - (e.g., sutures, cardiac pacemakers, hydrocephalus shunts, orthopedic implants)

a. Investigational Device Exemption (IDE) number:

b. State who holds the IDE (i.e., sponsor, investigator, other):

c. Provide protocol-specific documentation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) of the IDE number. ***IRB approval cannot be granted until documentation of the IDE (for SR device studies) has been provided.***

d. Describe the process for investigational device accountability, storage, and record keeping to ensure that the device will be used according to the approved protocol, under the direction of approved investigator(s).

e. For an investigator-held IDE, describe the process for assuring compliance with FDA regulations pertaining to sponsors (e.g., record keeping, reporting).

☐ **Non-significant Risk (NSR)** - (e.g., daily-wear contact lenses, lens solutions, dental scalers, foley catheters)

Provide supporting documentation from sponsor regarding why the device does not pose a significant risk.

☐ **IDE Exempt**

a. Category (1 --7):

b. Explain how the device is exempt from the requirements of 21 CFR 812.2(c) for this research.

3. Provide a brief description of the device.

4. Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

5. Summarize the potential adverse effects (including serious warnings and more common adverse effects).