[**Investigational Devices**](https://www.uthscsa.edu/vpr/services/glossary#Investigational-Devices)

**(FDA approved or unapproved)**

*FDA Regulations describe devices approved and not yet approved for marketing as potentially being investigational devices. An investigational device exemption (IDE)is required for an investigational device to be shipped lawfully for the purpose of conducting research. However certain exemptions may apply.*

(COMPLETE ONE FORM FOR EACH DEVICE)

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: Device Information:** This is device # insert # of insert # total devices that will be used in this study. | | | |
| **1.a. Generic Name of the Device** | | | **Brand Name / Manufacturer(s)** |
| insert generic name of device | | | insert trade name of device /  insert name of device manufacturer |
| Provide a brief narrative description of the device: | | insert description of device | |
| Select the option below that **best** describes the device use in this study: | | | |
|  | **Choice A.** This is a device that is approved by the FDA. In this study, the device will be used for an indication not in the FDA labeling *(new indication).*  Complete Sections 1.b. & 3 | | |
|  | **Choice B.** This is a device that is not approved by the FDA *(investigational)* for any indication.  Complete Section 3 | | |

***\*\*NOTE\*\**** *include a copy of the following materials with your IRB application: FDA approved labeling information (Form S, IRB application checklist), device brochure, instruction manual, or information from the manufacturer describing the device (Form CC, IRB application checklist). As appropriate, include supporting documents reporting prior investigations with the device.*

|  |  |
| --- | --- |
| **1.b. Has the FDA approved this device for any use in humans? If yes, select the type of FDA approval:** | |
|  | **Cleared 510(k) or Cleared Premarket Notification (PMN)**  The device is cleared for marketing in the U.S., a letter has been issued from the FDA stating “substantial equivalence” to a predicate device. (**Note:** Please refer the sponsor to the [FDA website](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm) if help is needed to determine if a 510(k) submission by sponsor is required.) |
|  | **Approved Premarket Approval (PMA)**  All devices categorized as class III are subject to PMA requirements. An approved PMA is a license to market a particular medical device. (**Note:** A Product Development Protocol (PDP) is an alternative procedure for obtaining [FDA](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm) approval of certain Class III devices. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Section 3: Investigational Device Exemption (IDE) Information** | | | | | | |
|  | Has an IDE already been approved by or submitted to the FDA for the use of this device in this investigational treatment? | | | | | |
|  |  | **No** Date submitted to the FDA: Insert date Date received by the FDA: Insert date | | | | |
|  |  | **Name of IDE Requester** | | Insert name of IDE requester | | |
|  |  | Has the local PI contracted with the IDE holder to perform any sponsor obligations? | | | yes or no - N/A if PI is the IDE holder | |
|  |  | Is the IDE Holder also the local investigator? | | | yes or no | |
|  |  |  | | | | |
|  |  | **Yes** | | | | |
|  |  | If Yes, provide the following information **–** skip B | | | | |
|  |  | **IDE Number** | Insert IDE # or PENDING | | | |
|  |  | **Name of IDE Holder** | Insert name of IDE holder | | | |
|  |  | Has the local PI contracted with the IDE holder to perform any sponsor obligations? | | | | yes or no - N/A if PI is the IDE holder |
|  |  | Is the IDE Holder also the local investigator? | | | | yes or no |
|  |  |  | | | | |