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| **Study Information** | | |
| Title of Study: |  | |
| IRB ID: |  |  |
| Principal Investigator (PI): |  | |

\*\* (COMPLETE ONE FORM FOR EACH DEVICE) \*\*

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| **Section 1: Device Information** | | |
| **1.a Generic Name of the Device** | | **Brand Name / Manufacturer(s)** |
|  | |  |
| Provide a brief description of the device: |  | |
| Provide a brief description of the device indications: |  | |

***\*\*NOTE\*\**** Include a copy of the following materials with your IRB application:

* *FDA cleared labeling information, device brochure, instruction manual, or information from the manufacturer describing the device.*
* *Patient information/consent for Humanitarian Use Devices (HUD).*
* *As appropriate, include supporting documents reporting prior investigations with the device.*

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| **1.b Current FDA Marketing Status**  **For information on how to *classify* your medical device, click** [**here**](http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm)**.** | | | | | |
|  | **This is a Class I or II device that is exempt from the premarket notification [510(k)].**  Devices exempt from 510(k) are either: pre-amendment devices not significantly changed or modified or Class I/II devices specifically exempted by regulation.  This device can be found on the FDA’s [listing of medical devices exempt from 510(k) webpage](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm). | | | |
|  | **This is a Class I, II or III device that has been found substantially equivalent [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. | | | |
|  | **This is a Class III device that is being evaluated under an 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 approval of certain Class III devices. | | | |
|  | **This is a Humanitarian Use Device with an approved Humanitarian Device Exemption (HDE).** | | | |
| **Has the UTSA IRB previously approved the use of this HUD in another protocol?** | |
|  | Yes – *In the IRB protocol number under which the HUD was approved*. |
|  | No |

Continue to Section 2

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| **Section 2:** | | | **Determining whether the use of this device is *Exempt* from IDE requirements** |
| *Select the option below that* ***best*** *describes the device use in this study:* | | | |
|  | **Choice A.** This is an *in vitro* diagnostic device (IVD) that will be tested as part of this study. | | |
|  | This is an *in vitro* diagnostic device that:   * is labeled in accordance with [21 CFR 809.10(c)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=809.10) ***AND*** * is non-invasive; ***AND*** * does not require an invasive sampling procedure that presents significant risk; ***AND*** * does not by design or intention introduce energy into a subject; ***AND*** * will not be used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure | | |
|  | **Yes to all -** No IDE required. Stop - Do not complete Section 3. | |
|  | **No to any of the above** - An IDE is required. Go to Section 3 to determine the appropriate IDE submission process. | |
|  | **Choice B**. This is a device that was previously approved by the FDA. In this study, the device will be tested because there have been minor modifications made **or** the device has been combined with other approved devices. | | |
|  | This device was previously approved by the FDA, and in this study, **the device will be used in accordance with the FDA approved labeling** and tested either because:   * there have been minor modifications made that do not involve significant technical changes,   **OR**   * the device will be combined with other approved devices and **each will be used in accordance with the FDA approved labeling**. | | |
|  | **Yes to either –** No IDE required. Stop - Do not complete Section 3. | |
|  | **No to all -** An IDE is required. Go to Section 3 to determine the appropriate IDE submission process. | |
|  | **Choice C.** This is a basic physiologic device that will be used as a tool to investigate a physiological principle. | | |
|  | This is a basic physiologic device that:   * will be used as a tool to investigate a physiological principle, ***AND*** * will be used only to answer a research question, ***AND*** * will have no safety and effectiveness data collected on the device itself, ***AND*** * is not intended to be developed for marketing | | | |
|  | **Yes to all -** No IDE required. Stop - Do not complete Section 3. | | |
|  | **No to any of the above** - An IDE is required. Go to Section 3 to determine the appropriate IDE submission process. | | |
|  | **Choice D.** This is a humanitarian use device (HUD) that was previously approved by the FDA  (Humanitarian Device Exemption – HDE). | | |
|  | **The use of this device will be in accordance with the HDE approved indications.** | | |
|  |  | **Yes -** An IDE is required. Go to Section 3 to determine the appropriate IDE submission process. | |
|  | **No -** No IDE required. Stop - Do not complete Section 3. | |
|  | **Choice E.** 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 Section 3. | | |
|  | **Choice F.** This is a device that is approved by the FDA. In this study, the device will be tested and the data will be used to support research or marketing application to the FDA. Complete Section 3. | | |
|  | **Choice G.** This is a device that is not approved by the FDA *(investigational)* for any indication. Complete Section 3. | | |

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| **Section 3: Investigational Device Exemption (IDE) Information** | | | | |
|  | **A.**  Has an IDE already been approved by or submitted to the FDA for the use of this device in this study? | | | |
|  |  | **No** Skip to B. | | |
|  |  | **Yes** | | |
|  |  | If Yes, provide the following information butdo not address section 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  no  N/A if PI is the IDE holder |
|  |  | Is the IDE Holder also the local investigator? | | yes  no |
|  |  | If yes to either, refer to Step 1 and Step 2 forms for additional instructions. **WHAT STEP 1 OR STEP 2 FORMS?** | | |
|  | **B.**  Does the intended use of this device meet the definition of a **Significant Risk Device**? | | | |
|  |  | **Yes –** the device presents a potential for serious risk to the health, safety, or welfare of a subject **and**:  **(1)** is intended as an implant; ***or***  **(2)** is used in supporting or sustaining human life; ***or***  **(3)** is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; ***or***  **(4)** otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.  **An IDE issued by the FDA is required.** | | |
|  |  | **No –** the device does not present a potential for serious risk to the health, safety, or welfare of subjects/participants.  **The IRB application will fulfill the IDE submission requirements.**  *Provide a brief explanation why the device should be classified as Non-SR in the space below.* | | |
|  |  | Describe Here | | |