**Medical Devices Use**

**Form # KSU-IRB 010-E**

**The Local Committee of Ethics of Research on Living Creatures in King Saud University Institutional Review Board (KSU-IRB) requires the fulfillment of the regulations below in all proposals involving the use of Medical Devices (transponders, pumps, etc.):**

*Please respond to the following points:*

1. **Identify anatomical site where the device will be located:**

|  |
| --- |
|  |

1. **Describe the device. Identify any active ingredients/chemicals (mercury, etc.) contained with the device:**

|  |
| --- |
|  |

1. **What is the size (dimensions) of the device?**

|  |
| --- |
|  |

1. **Describe the method by which the device will be implanted:**

|  |
| --- |
|  |

1. **Will the device be recovered/retrieved?**  ☐ yes ☐ no

If yes, describe how the device will be recovered/retrieved:

|  |
| --- |
|  |

1. **What ‘Risk’category the device belongs?**

**Low risk, Medium risk, High risk**

|  |
| --- |
|  |

1. **Describe the risks as stated.**

|  |
| --- |
|  |

1. **Describe the following elements associated or mentioned on the device.**
* Field Safety Corrective Action (SFDA)/adverse event reportable

|  |
| --- |
|  |

* Serious public health threat (SFDA) document

|  |
| --- |
|  |

1. **Provide following details.**
2. **Manufacturer**

 Manufacturer’s Address of origin

 Authorized Representative/ Distributor in Saudi Arabia

|  |
| --- |
|  |

1. **Valid MDMA (Medical Device Marketing Authorization)**

 Manufacturer Identification Number of SFDA

 Medical Devices Marketing Authorization Number

|  |
| --- |
|  |

1. Issuing Date by SFDA: Day (00)/Month (00)/Year (0000)
2. Expiry Date by SFDA: Day (00)/Month (00)/Year (0000
3. **Medical devices description**

|  |
| --- |
|  |

1. **Quantity of device for study site(s) at KSU/KKUH/KAUH** *(Optional)*

|  |
| --- |
|  |

1. **SFDA Official NUMBER.**

**Serial Number(s) / Batch Number(s)**

|  |
| --- |
|  |

1. **Does this device apply to Investigational Device Exemption (IDE)?c** Yes / No

Please detail:

|  |
| --- |
|  |

 **Name Principal Investigator. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*For more information, please visit the website of Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm\_Policies*)*