

**Oklahoma State University Center for Health Sciences**

**Institutional Review Board**

**1111 W. 17th St**

**Tulsa, OK 74107**

**918-561-1400**

**Modification of Approved Humanitarian Use Device (HUD)**

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| --- | --- | --- | --- | --- | --- |
| **Use to request a modification to previously approved Humanitarian Use Device.** | | | | | |
| **IRB Reference Number** | |  | | | |
| **Protocol Name** | |  | | | |
| **Investigator** | |  | | | |
| **Primary Contact** | |  | | | |
| **Provide one copy of the following documents if affected by the modification:** | | | **Version # and/or Date**  **as applicable** | **Check if Submitted** | **Check if NA** |
| Humanitarian Use Device (HUD) Application | | |  |  |  |
| Copy of FDA’s HDE approval | | |  |  |  |
| Protocol or summary of plan for use | | |  |  |  |
| Device description | | |  |  |  |
| Product labeling | | |  |  |  |
| Patient consent form, if applicable | | |  |  |  |
| All written information related to the HUD to be provided or meant to be seen or heard by patients. | | |  |  |  |
| Other: | | |  |  |  |
| **Summarize the modification or attach a summary:** | | | | |

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| **Physician Acknowledgement** | |
| I agree to use the Humanitarian Use Device in accordance with applicable regulations and the organization’s policies and procedures. | |
| Investigator signature | Date |
|  |  |