**Study Title**: ***Click here to enter text.***

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|  | Institutional Review Board**HUMANITARIAN USE DEVICE / INVESTIAGTIONAL DRUG*****INITIAL, AMENDMENT*, OR *CONTINUING* REVIEW**Return to the Office of Research Integrity1055 N. Curtis RoadBoise, ID 83706Phone: (208) 367-8897Phone: (208) 367-2233Nancy.Heaton@saintalphonsus.org  |
| Confidential pursuant to Idaho Code |

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| **Date of Application:** Click here to enter a date. | **IRB Number if known:** Click here to enter text. |

**Name of Device/Drug:** Click here to enter text.

**Type of Request:** Choose an item. **(click on the "choose an item" and a drop down will appear)**

***(Please note for Initial Submission Full Board Review Required)***

[ ]  **Initial Submission *(Full Board)*** [ ]  **Amendment** [ ]  **Continuing Review**

**Clinician Contact Information: MEDICAL LICENSE REQUIRED**

1. Name:Click here to enter text.

**Role: Choose an item. (click on the "choose an item" and a drop down will appear)**

**If Role is Other:** Click here to enter text.

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| **Phone:** Click here to enter text. | **Fax:** Click here to enter text. |
| **Company Name:** Click here to enter text. | **Address:** Click here to enter text. |
| **Email:** Click here to enter text. |

1. Name:Click here to enter text.

**Role: Choose an item. (click on the "choose an item" and a drop down will appear)**

**If Role is Other:** Click here to enter text.

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| **Phone:** Click here to enter text. | **Fax:** Click here to enter text. |
| **Company Name:** Click here to enter text. | **Address:** Click here to enter text. |
| **Email:** Click here to enter text. |

1. Name:Click here to enter text.

**Role: Choose an item. (click on the "choose an item" and a drop down will appear)**

**If Role is Other:** Click here to enter text.

|  |  |
| --- | --- |
| **Phone:** Click here to enter text. | **Fax:** Click here to enter text. |
| **Company Name:** Click here to enter text. | **Address:** Click here to enter text. |
| **Email:** Click here to enter text. |

1. Name:Click here to enter text.

**Role: Choose an item. (click on the "choose an item" and a drop down will appear)**

**If Role is Other:** Click here to enter text.

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| --- | --- |
| **Phone:** Click here to enter text. | **Fax:** Click here to enter text. |
| **Company Name:** Click here to enter text. | **Email:** Click here to enter text. |
| **Mailing Address:** Click here to enter text. |

**Device Information**

**Manufacturer Information:**

**Name:** Click here to enter text.

**Mailing Address:** Click here to enter text.

|  |  |  |
| --- | --- | --- |
| **Phone:** Click here to enter text. | **Fax:** Click here to enter text. | **Email:** Click here to enter text. |

1. **Date of HUD designation:** Click here to enter a date.
2. **How many patients have received the device/drug at SARMC since the last review?** Click here to enter text.
3. **Have any unanticipated serious adverse events occurred in patients who received this device since the last IRB review?** [ ]  **No** [ ]  **Yes, Date(s) reported to the IRB 1.** Click here to enter a date.

 **2.** Click here to enter a date.

1. **Have there been any new contraindications, warnings or precautions for the use of the device/drug issued by the manufacturer since the last review?** [ ]  **No** [ ]  **Yes, *Please attach a copy.***

**Documents to include with this request:**

[ ]  **Medical License for all Clinicians (**If not already on file**)**

[ ]  **Device/Drug Brochure/Package Insert (**as appropriate per submission**)**

[ ]  **Patient Brochure/Information (**as appropriate per submission**)**

[ ]  **FDA letter(s) received since last review (**as appropriate per submission**)**

[ ]  **Informed Consent Form (**as appropriate per submission**)**

[ ]  **Medical Device Report, if applicable (**as appropriate per submission**)**

**Statement of Integrity**

**By signing this form, I certify that the information provided is both complete and accurate. As the requestor for this use, I understand that I have the ultimate responsibility to ensure protection of the rights and welfare of human subjects. I am aware that it is my responsibility to be aware of the current Saint Alphonsus Health System, state and federal requirements related to Humanitarian Use Devices/Investigational New Drugs. I agree to comply with Saint Alphonsus policy and procedure requirements and those imposed by the Saint Alphonsus IRB, as well as any applicable Federal, State, and local laws pertaining to human subjects. My signature below affirms that the use of this HUD/IND as described in this application will not contribute data to any ongoing research project or clinical investigation.**

Click here to enter text.

**Principal Investigator / Clinician (Typed/Printed Name)**

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** Click here to enter a date.

***Principal Investigator / Clinician's Signature Signature Date***

***Please visit the IRB website for all of your resources and forms at*** <http://www.saintalphonsus.org/forms-and-resource>