

**Oklahoma State University Center for Health Sciences**

**Institutional Review Board**

**1111 W. 17th St**

**Tulsa, OK 74107**

**918-561-1400**

**Continuing Review Progress Report for Humanitarian Use Device (HUD)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Use for continuing review of a HUD.**  **If modifications are being requested, submit a separate request for a modification.** | | | | | | |
| **Name of Device:** | | |  | | | HDE # |
| **IRB Number:** | | |  | | | |
| **Physician:** | | |  | | | |
| **Primary Contact:** | | |  | | | |
| **Enrollment Status** | | | | | | |
| **Total number of patients enrolled:** | | | | Since activation | Since last approval | |
| Total locally: | | | |  |  | |
| Total all sites: | | | |  |  | |
| **Financial Interest Declaration** | | | | | | |
| Yes | No | Do any physicians have a significant financial interest related to the manufacturer that was not disclosed in a previous application? *If yes, attach an explanation.* | | | | |
| **Please answer the following questions related to the use of the HUD** | | | | | | |
| Yes | No | Since the last IRB review, has the status of the HUD for the device changed? *If yes, attach a summary description of those changes.* | | | | |
| Yes | No | Since the last IRB review, have patients experienced any benefits? *If yes, attach a summary of the benefits experienced by patients.* | | | | |
| Yes | No | Since the last IRB review, have there been any unanticipated problems involving risks to patients or others since the last IRB review? *If yes, attach a summary of unanticipated problems involving risks to patients or others.* | | | | |
| Yes | No | Since the last IRB review, have any patients withdrawn or stopped use of the HUD? *If yes, attach a summary of the numbers of withdrawals/terminations and their reasons.* | | | | |
| Yes | No | Since the last IRB review, have any patients or others complained about the use of the HUD? *If yes, attach a summary of the number and nature of the complaints.* | | | | |
| Yes | No | Since the last IRB review, have there been any publications in the literature relevant to the risks or potential benefits of the HUD? *If yes, attach a summary of these publications.* | | | | |
| Yes | No | Since the last IRB review, has there been any other relevant information regarding the HUD, especially information about risks associated with the HUD? *If yes, attach a copy or summary of this information.* | | | | |
| Yes | No | Since the last IRB review, have there been any modifications or amendments to the HUD IRB submission? *If yes, attach a summary description.* | | | | |
| Yes | No | In the opinion of the physician, have the risks or potential benefits of the HUD changed? *If yes, attach a summary description of those changes.* | | | | |
| Yes | No | Have all problems that require prompt reporting been submitted as required? *If no, attach a summary explanation of why.* | | | | |
| **Physician Acknowledgment** | | | | | | |
| I agree to use the Humanitarian Use Device in accordance with applicable regulations and the organization’s policies and procedures. | | | | | | |
| Physician Signature: Date: | | | | | | |