**Humanitarian Device Exemption (HDE)**

**Progress Report**

|  |
| --- |
| **Request for Continued Use of a Humanitarian Use Device (HUD)** |

Form Instructions:

* Humanitarian Device Exemption ([HDE](https://www.uthscsa.edu/vpr/services/glossary#Humanitarian-Device-Exemption)) authorizes a manufacturer to market a Humanitarian Use Device ([HUD](https://www.uthscsa.edu/vpr/services/glossary#Humanitarian-Use-Device))
* Every Section below must be completed. Information is ONLY for this local site.
* The Form A-1 must be signed by the Principal Investigator. Sub Investigators or other individuals are NOT sufficient.
* Subjects’ names or other identifying information (medical record numbers, etc.) must not appear in this Report or in any correspondence with the IRB.
* This report form must be completed on a computer.
* Submit the following: 1) a signed form A-1, 2) all applicable attachments (as directed on the form), and 3) an electronic copy of this form and any applicable attachments. Retain a copy of the submission package for your files.
* Incomplete submissions will result in a delay in the re-approval process and could jeopardize the current approval status resulting in a lapse and suspension.

|  |  |
| --- | --- |
| **1. Date:** |  |

|  |  |
| --- | --- |
| **2. Title** |  |

**3. Name and Address of Principal Investigator (PI):**  *(This is the primary contact information used by the IRB. Indicate where mail can most reliably reach the PI. Even though HDE use is not research, the IRB uses the term PI to designate the person responsible for overseeing the HDE/HUD use locally.)*

|  |  |
| --- | --- |
| PI Name *(Last Name, First Name, MI):* |  |
| Employer(s): *Example: UTHSCSA 50%, VA 50%)* |  |
| Department: |  |
| Room # & Bldg: |  |
| Mail Code #**:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **4. Additional Contact Information** |  |  |  |
| PI’s Telephone#: |  | PI’s Pager Number: |  |
|  |
| 1. PI’s e-mail address:
 |  | PI’s FAX Number: |  |
|  |
| 1. PI’s Position Title:
 |  |  |
|  |
| 1. PI’s Point of contact name &
2. e-mail:
 |  | Point of Contact Phone Number: |  |

|  |
| --- |
| **5**. List all **individuals authorized to use the device independently**.  |
| **Name (first last)** | **Degree/Salutation** | **US License(s)***e.g., MD, RN, etc* | **Employer(s)** |
|  |  |  |  |

|  |
| --- |
| **6**. During this review period, **have there been any changes**, no matter how minor, to the use of this HUD, including the indications, locations or patient population? |
|  | **No.** Go to Question 7. |
|  | **Yes.** *If yes, select one****. For either choice, complete question 6.*** |
|  | All changes implemented have been previously reported to and approved by the IRB. |
|  | The changes described below have been implemented but were not submitted to or approved by the IRB. |
|  | a. Give a brief description of the change(s) made | b. Explain why IRB approval was not obtained prior to making the change(s) |
|  |  |

|  |
| --- |
| **7**. Provide a summary of **previously approved amendments** or modifications since the last review below: |
| **Date of amendment**  | **Brief Summary of Changes** |
|  |  |

|  |  |
| --- | --- |
| **8**. The IRB allows a few minor modifications as part of this progress report. The changes allowed are limited to:**a)** the list of study personnel *(not including the PI)*; **b)** the names and contact information provided in previously approved documents used to obtain consent; and/or**c)** addition of new wording from the current HSC or VA consent template to consents that are based on older versions of the template**[Submit a separate amendment for all other modifications]****Have you included any of these minor modifications with this progress report?***(All other modifications must be submitted as a separate amendment request)* |  |
|

|  |
| --- |
|  |

 | **No.** Go to Question 9. |
|

|  |
| --- |
|  |

 | **Yes.**  Choose from the options listed below and check all that apply. |
| **Minor Modifications Requested During Continuing Review** *(Amendment Form Not Required)* |
|

|  |
| --- |
|  |

 | **Update to Providers** (not including the PI). Submit a revised HUD application showing the addition or removal of providers.  |
|  | **Describe the experience/knowledge/training and expertise using this or similar devices for all providers, being added.** |
|  |

|  |
| --- |
|  |

 | N/A. No providers are being added  |
|  |

|  |
| --- |
|  |

 | The tracked changes version of the HUD Application form includes a description for each provider.  |
|  |

|  |
| --- |
|  |

 | A description of the experience/knowledge/training and expertise using this or similar devices for each provider is listed below. |
|  | Provider **a.**: |
|  | Provider **b.**: |
|  | Provider **c.**: | *Insert new row(s) if more than 3 providers are added.* |
|  | **Does the change in personnel require a revisions to the document(s) used to consent subject?**  |

|  |
| --- |
|  |

 | **Yes -** attached revised document(s) used to consent subject (track changes) |

|  |
| --- |
|  |

 | **No** |
|

|  |
| --- |
|  |

 | **Update name(s) and/or contact information in the document(s) used to consent subject**. *Attach a revised consent form (track changes and clean versions)*Summarize changes here **🡪**:  |
|

|  |
| --- |
|  |

 | **Update a consent form with new IRB approved wording from the latest consent template**. *Attach a revised consent form (track changes and clean versions)*Summarize changes here **🡪**:  |

|  |
| --- |
| **9**. Have you identified minor revisions (e.g., update approved provider list, locations, etc.) that you would like to make as part of this progress report?  |
|  | **No.** Go to Question 10. |
|  | **Yes.** The changes are detailed in the attached amendment form and revised documents as required.  |

**Local Patient Information**

|  |
| --- |
| NOTE: You should compare all information entered in this report with what has been previously reported to the Board. If you discover that there are discrepancies with or errors in previously reported information, please attach a separate cover letter explaining the differences. |

|  |
| --- |
| **10**. **Number of patients** **diagnosed or treated with the HUD.**  |
| **Local***(at this site)* | **Total Number** |
| **A.** How many patients have you diagnosed or treated with the HUD **since last IRB review?** |  |
| **B.** How many patients have you diagnosed or treated with the HUD **since the IRB originally approved the use?** *[If this is the first progress report, this number should be the same as A, above. If not the first report, this number*  *should equal the total from your last report plus B above]* |  |
| **C.** How many patients are **currently** being diagnosed or treated? |  |
| **Discontinued Use***(at this site since the last IRB review)* | **Total Number** |
| **D.** How many patients discontinued use due to an [Adverse Event](https://www.uthscsa.edu/vpr/services/glossary#Adverse-Event) (AE), *except death*? |  |
| **E.** How many patients discontinued use by their choice? |  |
| **F.** How many patients were discontinued by PI (i.e., subject non-compliance, disease progression, etc.)? |  |
| **G.** How many patients died during their participation period? |  |
| **H.** How many patients have completed diagnosis/treatment and are no longer being followed? |  |

|  |
| --- |
| **11**. **Detailed description** of the reason for **discontinued use** noted above since the last IRB review. |
|  | **N/A** – No patients have discontinued use since the last IRB Review. Go to Question 12. |
| **Detailed Description of the Reason for Discontinued Use** | **Total number per reason** |
| *For example, for patients who discontinued due to AE – describe the actual AE(s) experienced that lead to stopping further use; for those who stopped by choice, describe their stated reason(s)* | *How many patients stopped continued use for each reason listed?* |
|  |  |

**Consent**

|  |
| --- |
| NOTE: Please enter information related to the consent process and documentation. |

|  |
| --- |
| **12**. **Did patient(s) or patients’ legally authorized representative receive the IRB approved information prior** tothe use of the device? (e.g., informed consent form, patient brochure, etc.) |
|  | N/A. No patients to date. Go to Question 18 |
|  | Yes.  |
|  | No. **If no, explain here 🡪**  |

**Summary of Device Use**

|  |
| --- |
| NOTE: Provide a summary of the device use since the last IRB review. |

|  |
| --- |
| **13**.Summary of**Provider Experiences** using the device ***since last IRB review.***  |
| Summarize your experiences using the device since the last IRB review. |
| **Describe here 🡪**  |
| **14**.Summary of**Patients Diagnosed or Treated with the device** ***since last IRB review.***  |
| Summarize the types of patients diagnosed or treated with the device.  |
| **Describe here 🡪**  |

|  |
| --- |
| **15**. **Patients' response** to the device since the last IRB review. Please describe how patients responded to and tolerated the device. ***Your******Answers should be substantive.*** |
| Were any patients diagnosed or treated with this device during the period of time since the last IRB review?*Choose one* |
|  | **No.**   |
|  | **Yes.** If **Yes**, answer the following questions: |
| **(a)** How has the device use **affected** the patients since the last IRB review?  |
| **Explain here 🡪**  |
| **(b)** Have patients had any **comments or complaints** about the device use since the last IRB review? |  | **Yes** |  | **No** |
| If **yes**, provide details here**🡪**  |

**Adverse Events**

|  |
| --- |
| NOTE: Review your records related to adverse events since the last IRB review to answer the following questions. |

|  |
| --- |
| **16**. Was there any indication that the **device may have caused or contributed** to a death or serious injury *since the last IRB review*? |
|  | **No.** Go to Question 17 |
|  | **Yes.** **If yes**, provide a brief description of each event? |
| **Date Reported****to Sponsor and FDA** | **Brief description of the event** |
|  |  |
| **17**. Was there any indication that the device may have **malfunctioned** and would be likely to cause or contribute to a death **or** serious injury if the malfunction were to recur *since the last IRB review*? |
|  | **No.** Go to Question 18 |
|  | **Yes.** **If yes**, provide a brief description of each event? |
| **Date Reported****to Sponsor and FDA** | **Brief description of the event** |
|  |  |

|  |
| --- |
| **18**. **Roles and Responsibilities of Staff** – *Check to indicate agreement with the statement* |
|  | I have reviewed the roles and responsibilities for all members approved to use the device in relation to their level of training, specific license, and clinical credentials. **I certify that the members remain qualified by training and experience as appropriate to their intended use of this device.**  |

|  |
| --- |
| **19.** List of **Institutions Under UTHSCSA IRB Jurisdiction** – Check All That Apply |
| [Institutions Affiliated with the UTHSCSA IRB](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution)  (IRB of Record) “UTHSCSA IRB Affiliated Institutions” |
| **Check all that apply** | **Name of Institution / Study Site** **(list all participating sites below)** |
|
|  | **UTHSCSA**  |
|  | Including any of the following: School of Medicine, CTRC at UTHSCSA (IDD or SWOG), FIRST Program / GCRC (Carrington Bldg.), Dental School, School of Nursing, Graduate School of Biomedical Sciences, School of Allied Health, Research Imaging Center (RIC), College of Pharmacy, UT Austin, UT Medicine, Regional Academic Health Center (RAHC)click here to type Other |
|  | **South Texas Veteran’s Healthcare System (STVHS)** |
|  | Including any of the following: Audie Murphy Medical Center, General Clinical Research Center (GCRC), Outpatient Clinics Division, Kerrville |
|  | **University Health System (UHS)** |
|  | Including any of the following: University Hospital, University Health Center Downtown, University Center for Community Health (UCCH), UCCH/Texas Diabetes Institute (TDI), University Family Health Centers, UHS Breast Imaging Ctr / CTRC, Correctional Health Care Services |
|  | **Christus Santa Rosa Health Care (CSRHC)****(UTHSCSA PI only)**Including: CHART Center / GCRC |
|  | **Baptist Healthcare System (BHS)****(UTHSCSA PI or Family Medicine Program only)** |
|  | **Texas Biomedical Research Institute (TBRI)** |
|  | **Southwest Research Institute (SwRI)** |
|  | **Other Institution(s)** **Covered by UTHSCSA IRB Sharing Agreement****Insert Name(s):** click here to type (names) |

|  |
| --- |
| **20**. Which items are being attached to this Progress Report? *Check all that apply.* |
| X | Form A-1 Multipurpose Signature Assurance Sheet - **Required** |
|  | Most recently approved Consent Form(s), patient labeling, or patient brochure |
|  | Amendment Form with applicable attachments |
|  | Other: (describe) |