**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A”. Do not deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

**HUD TITLE:**

**PRINCIPAL INVESTIGATOR/RESPONSIBLE CLINICIAN:**

Name

Department

Telephone Number

Email Address

**HUD SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Primary Objective** |  |
| **HDE #** |  |
| **HDE Holder** |  |
| **Type of Consent** |  |

**REVISION HISTORY:**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**DEVICE:**

*List the Humanitarian Use Device being used for clinical purposes under this protocol.*

*Provide:*

* *The name of the device*
* *A description of the device and its intended uses*
* *The Manufacturer of the device*
* *The Humanitarian Device Exemption Number issued by FDA.*

**PRIMARY OBJECTIVES:**

* *Describe the purpose, specific aims ,and/or objectives.*

**BACKGROUND:**

*Provide background information on the device:*

* *Marketing history*
* *Summary of studies using the device*

***UPLOAD*** *to RSP Gateway*

* *A copy of the Humanitarian Device Exemption approval order issued by FDA;*
* *the manufacturer’s product labelling, and*
* *the patient information packet that may accompany the Humanitarian Use Device.*

**CLINICAL USE:**

*Provide a description of how the device will be used in your clinical practice. Explain how it differs from the manufacturer’s intended use, if applicable.*

*Provide also:*

* *An outline of all HUD treatment procedures;*
* *List of other ancillary tests or procedures patients may undergo in addition to the procedure(s); and*
* *Any patient follow-up visits.*

**INCLUSION AND EXCLUSION CRITERIA:**

*Describe the qualifying patient population.*

*Describe how patients will be screened for eligibility and by whom.*

*Provide the relevant demographic (e.g., age, ethnicity), biomedical (e.g., disease status, laboratory values, contraindications, warnings and precaution for use of the device, failure of alternative measures) or other characteristics relevant for inclusion and exclusion from use of the device.*

*Indicate whether you will include or exclude each of the following special populations:*

* *Adults unable to consent*
* *Individuals who are not yet adults (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*
* *Vulnerable Populations*

**RISKS OF HARM AND POTENTIAL BENEFITS TO HEALTH:**

*Identify currently available devices or alternative forms of treatment available to patients.*

*Explain the adverse effects on health—illness or injury—and potential health benefits to patients when using the Humanitarian Use Device versus the other available devices or alternative forms of treatment.*

**HUD MANAGEMENT:**

**Clinician Qualifications**

*Provide a list of clinicians approved to use the device, along with their credentials reflecting they possess the qualifications necessary to use the HUD in clinical practice.*

**Training**

*Describe any special training required before use of this specific HUD in clinical practice. Specify who will provide the training (i.e., the manufacturer, the HDE holder, etc.).*

*Outline your plan to ensure that all persons using the device in clinical practice complete the special training and refresher training, if necessary, and how evidence of training will be documented.*

**UPLOAD** to RSP Gateway

* A copy of the HUD-specific training log/verification for each clinician.

**Clinical Sites**

*List the facility(s) where the HUD will be administered.*

**DEVICE ACCOUNTABILTY AND STORAGE:**

*Specify the location where HUD devices will be stored and secured.*

*Indicate procedures around receipt, storage and dispensing for clinical care, as well as, who will be responsible for performing these procedures.*

*Outline your device accountability plan. Be sure it includes at least the following: patient name, physician name, device serial number, date of use, summary of use and any complications, including, explants, and circumstances around such events, should they occur.*

**CONSENT PROCESS:**

*Create [or obtain from the manufacturer] a document to review with patients (or their legally authorized representative) before they receive the HUD. Be sure the document includes the following information:*

* *Explanation that the Humanitarian Use Device is designed to diagnose or treat the disease or condition described in the HDE product labelling and that no comparable device is available to treat the disease or condition*
* *A description of any ancillary procedures associated with the use of the HUD*
* *An explanation of the mechanism of action of the HUD in relation to the disease or condition.*
* *Known risks or harm and discomforts and potential for therapeutic benefit*
* *A statement that indicates the patient (or their legally authorized representative) has received a copy of the product labelling information provided by the HDE holder*
* *The following statement appears in the document: “Humanitarian Use Device authorized by Federal Law for use in the [choose: treatment or diagnosis] of [state: specific disease or condition]. The effectiveness of this device for this use has not been demonstrated.”*

***NOTE****: When the HUD is used in emergent situations, patients or their legally authorized representative must be given information about the HUD after its use/receipt.*

**PRIVACY & CONFIDENTIALITY:**

**Provisions to Protect the Privacy Interests of Subjects**

*Describe the steps that will be taken to protect patients’ privacy interests. “Privacy interests” refers to a person’s desire to place limits on who they interact with or provide personal information to about their care.*

**Data Security**

*Describe your plan to secure patients’ information, information found in patient records, as well as, in non-patient records (such as in device accountability records or data sharing between the Site and the Manufacturer or HDE holder from accidental disclosure).*

* *Consider such strategies as such as staff training, transporting or transmitting data, methods to restrict access, password protection, encryption, use of key codes to separate identifiers from the data. Identify who will be responsible for each of these tasks.*

*List the specific HIPAA identifiers you will record in your research files. Note: It will be necessary to obtain HIPAA authorization to record this information.*

**SAFETY REPORTING:**

*Develop a plan to ensure adverse events are reported to the FDA and the Wright State IRB as required by the medical device reporting requirements found at 21 CFR 803.*

**REFERENCES:**

*Add references*