SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Humanitarian Used Devices	Effective: 2/19/2018
		Approved: 2/12/2018
SOP ID		Last Revised: 6/14/2018
IRB-SOP-702		Expiration: n/a

PURPOSE

The FDA requires IRB review and approval before a HUD is used, as well as continuing review of the use of the HUD. This procedure explains and establishes the process for the review and use of a Humanitarian Use Device (HUD).

SCOPE

This policy applies to all HUDs being used at Ascension Wisconsin IRB.

DEFINITIONS

See SOP: Definitions

PROCESS

1. **Submission of HUD Application**
   - **1.1.** A single Physician User must be identified to serve as the Principal Investigator (PI) on the HUD protocol and the PI must submit the HUD protocol for review and approval to the IRB prior to the use.
   - **1.2.** The HUD application must be submitted through the online IRB submission system with applicable supporting documents, such as the FDA HUD designation letter, as outlined in SOP: Materials for IRB Review (SOP-105).
   - **1.3.** A specific consent for use of the HDE/HUD is optional. If such a HDE/HUD-specific consent form is used, it should be generally modeled after other clinical consent forms for invasive procedures but should also include the following:
     - A description of the HDE/HUD approval process; e.g. a description of the HUD and how this device will be used in the clinical setting. Based on this description, it should be clear to the patient why he/she is a candidate for the use of this device.
     - A discussion of possible risks, side effects, and/or adverse events associated with the HUD and its proposed clinical use.
     - A discussion of the possible benefits associated with the clinical use of the HUD.
     - A discussion of any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical use of the HUD.
     - Voluntary Consent statement (s) with patient signature and date lines.
     - Voluntary Consent statement (s) with physician signature and date lines.

2. **Responsibilities of Physician Users**
   - **2.1.** Each physician who uses the HUD must have appropriate training, including HUD specific training and current completion of the CITI program HUD course (Note, CITI course requirement will be phased in as the CITI program is implemented).
   - **2.2.** Each physician user must be identified on the HUD application and provide a signed attestation of the Physician Users responsibility on the IRB application, prior to using the HUD.
   - **2.3.** Continuing Review
     - **2.3.1.** The PI must ensure continuing review of the HUD occurs within the timeframe as specified by the IRB.

2.3.2. If continuing approval is not obtained prior to IRB approval expiration, the use of the HUD must cease until such time that it can be reviewed.

2.3.3. Continuing Reports are submitted through the online IRB submission system using the IRB form and should include the following:

- The number of patients who received the HUD for all physicians/Principal Investigators listed on the project since last review.
- All unanticipated problems, including serious adverse events and deviations since the last review.
- Summary of actual benefits experienced by enrolled HDE patients.
- Any recent published/presented literature having a significant impact on the HUD's use and well-being of patients.
- Any audits conducted since the last review from a federal agency that identified significant deviations or problems.
- Any new conflicts of interest that have arisen since the last review.

2.4. Modifications to the HUD or Device Labeling

2.4.1. If the FDA grants approval for use of the HUD for additional clinical indications, IRB approval is required before the HUD can be used for these additional indications.

2.4.2. The PI must submit an amendment to add new physician users, prior to their use of the HUD.

2.4.3. Any modifications must be submitted though the online IRB submission system and should include any new materials such as FDA approval letters, modified consent from, new or modified manufacturer information.

3. Off-Label Use of a HUD in Emergency or Compassionate Use Situation

3.1. It is recognized that there may be circumstances in which the "off-label" use of a HUD may be necessary to save the life or protect the well-being of a patient. When this situation arises, the physician/PI should determine if the situation meets the requirements for emergency use. To make this determination and for additional information on how to proceed, see FORM: Emergency Use of a Humanitarian Use Device (HUD).

4. IRB Review

4.1. The use of a HUD must be initially reviewed at a convened IRB meeting.

4.2. The IRB must ensure that the proposed use is within the FDA-approved indication and that the use of the device does not exceed the scope of the FDA's approval.

4.3. FDA regulations require the IRB to conduct continuing review of the use of the HUD at intervals appropriate to the degree of risk, but no less than once every 365 days. Continuing reviews are typically conducted using the expedited review procedure, but may be assigned to a conveyed meeting for review.

REFERENCES

- 21 CFR 814
- 21 CFR 56.109(f)

RELATED MATERIAL

- SOP: Materials for IRB Review (SOP-105)
- FORM: Emergency Use of a Humanitarian Use Device (HUD)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	01/03/2018	New- Initial Integration Update	J. Blundon
02	6/14/2018	Updated SOP number	J. Blundon-Kirchen