**Humanitarian Use Devices:**

**Guidance for completion of the eIRB application**

Use of Humanitarian Use Devices (HUDs) must be reviewed and approved by the IRB, even when the HUD is being used for clinical care *only.* The eIRB application, which was built for human subjects research studies, can be difficult to complete for HUDs. **This guidance document is intended to assist in completion of the eIRB application for HUDs that are being used solely for the provision of clinical care.** It highlights questions that need to be answered in a potentially unexpected way for these types of applications. It does not address every question in the application.

Begin the application in eIRB as any other study application would be initiated using the “New Study” button in the left-hand margin after logging into eIRB.

**Section 1 – Study Identification Information**

2.0 – Short Title: Include HUD at the end of the short title to easily identify the study is a HUD

**Section 2 – Human Subjects Research**

1.0 – select “no”

2.0 – select "no”

3.0 – select “yes”

4.0 – select “no”

**Section 4 – Review Type – Study Review Type**

Select “Full IRB Review”

**Section 5 – Study Protocol**

Upload the device manual and any safety sheets or brochures.

**Section 6 – Study Populations – Study Subjects**

1.0 – Include the number of patients the device will be used on.

3.0 – State that the project does not involve research and then state where the clinical procedure will take place.

7.0 – 9.0 – Describe the clinical population of patients the device will be used on. For item 9.0 specifically, focus on what clinical scenario would result in the use of this device. This is often the indication for the device. “Exclusions” may be contraindications for the use of the device.

**Section 7 – Funding**

Funding and Sponsorship – Study Costs Smartform - Include who is paying for the device.

**Section 8 – Application Checklist**

“Devices” should be the only selected item in the application checklist.

**Section 9 – Other Study Specifics**

**Study Procedures**

For both questions here, answer to indicate that this question is not applicable as the use of the HUD is not part of a research study.

**Study Risks and Precautions**

1. – List the risks outlined for the device.

2.0 and 3.0 – Note that patients will be followed/monitored after the procedure but that this is not a research study, so no data or safety monitoring plans are being utilized.

**Potential Benefits**

1.0 – Answer based on clinical benefits. We would expect this to be “yes” if it has been deemed appropriate for a HUD to be used clinically.

2.0 – State that this is a HUD.

**Section 11 – Consent Process**

1.0 – Answer “yes” to question 1.0, but then state in responses in subsequent sections that research consent will not be obtained but that a clinical consent form will be provided.

7.0 – Upload the clinical consent to treat for the particular HUD.

**Section 12 – Privacy**

**Privacy and Confidentiality**

1.0 – Answeragain that no research data is being collected because this is not a research study. State that everything related to the device and its associated procedures will be in the patient's electronic medical record as with standard clinical care and that only clinical personnel who already have access to the patient's EMR will have access to the details of the device and surgical procedure.

2.0 – Select "password protected network storage".

4.0 – Select that research participation WILL be documented in Epic. This selection is important to ensure billing compliance.

**Protect Health Information (PHI) for Research**

1. – Select “None of the above 18 identifiers will be used/disclosed for this research study”.

**General Comments**

Upload the FDA letter and any other required documents listed in the policy that have not been uploaded elsewhere.