1 PURPOSE

1.1 This guidance establishes the process for using Humanitarian Use Devices (HUDs) at Sharp HealthCare (SHC).

1.2 The guidance begins when a physician anticipates using an HUD.

1.3 The guidance ends when the physician no longer intends to use the HUD.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 A physician may use an HUD at SHC when agreeing to the following:

3.1.1 The HUD will be used for treatment, diagnosis, or research in accordance with the labeling of the device, intended purpose and in the designated population for which the Food and Drug Administration (FDA) approved its use. An HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals per year in the United States.

3.1.2 The patient must be informed that the HUD is a device authorized under Federal law for use; however, the effectiveness of the device for a specific indication has not been demonstrated.

3.1.3 The informed consent of the patient or the patient's legally authorized representative will be obtained when the use of the HUD involves research or when it is required by the sponsor and/or SHC Institutional Review Board (IRB).

3.1.4 Prospective SHC IRB committee review and approval is required – regardless of intended use. The use of an HUD does not constitute research unless the physician or health care provider intends to collect data from its use.

4 RESPONSIBILITIES

4.1 The physician or their designee, the IRB specialists, and the IRB committee members carry out these procedures.

5 PROCEDURE

5.1 The physician or designee completes and submits *FORM: Initial IRB Review Application (HRP-211)* to the IRB.

5.2 Physician presents HUD to the IRB committee at an assigned IRB meeting date and time.

5.3 Physician does not begin using HUD on patients until after receipt of IRB approval letter.

5.4 Physician or designee is responsible for fulfilling continuing review requirements as instructed in the initial IRB approval letter using *FORM: Continuation Request or Final Closure Report (HRP-212)*.

5.5 Physician or designee is responsible for reporting adverse events and unanticipated problems that result from the use of an HUD per the SHC IRB unanticipated problems reporting requirements, see *GUIDANCE: Non-Compliance and Other Reportable Unanticipated Problems Involving Risks to Subjects or Others (HRP-024)*. For reporting unanticipated problems to the SHC IRB, use *FORM: Unanticipated Problem or Event Report (HRP-214)*.

5.6 Physician or designee is responsible for reporting to the FDA any information received or otherwise made aware of, from any source, that reasonably suggests that an HUD has or may have caused or contributed to the death or serious injury of a patient. The physician or designee is to report such findings to the FDA as soon as possible, but no later than 10 working days after the physician first learns of the event or problem. This reporting is, in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR 803.30.

5.7 Physician or designee is responsible for submitting any modifications to the HUD or clinical use of an HUD to the SHC IRB using *FORM: Modification Request (HRP-213)*.

5.8 Use of an HUD in an emergency that cannot wait for SHC IRB review and approval may be handled using *GUIDANCE: Emergency Use Review (HRP-023)*. The HUD may only be used in an emergency if it meets the FDA criteria (21 CFR 56.104 (d)) and the HUD is not used outside its approved labeling.

6 MATERIALS

6.1 GUIDANCE: Emergency Use Review (HRP-023)
6.2 GUIDANCE: Non-Compliance and Other Reportable Unanticipated Problems Involving Risks to Subjects or Others (HRP-024)
6.3 FORM: Initial IRB Review Application (HRP-211)
6.4 FORM: Continuation Request or Final Closure Report (HRP-212)
6.5 FORM: Modification Request (HRP-213)
6.6 FORM: Unanticipated Problem or Event Report (HRP-214)

7 REFERENCES

7.1 21 CFR 803.30
7.2 21 CFR 56.104 (d)

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.