UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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AAHRPP:	Element I.7.A., Element I.7.B., Element I.7.C. & Element II.4.C.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Humanitarian Use Devices

1.0 Objective

1.1. To describe the policies and procedures for the Institutional Review Board (IRB) review of a humanitarian use device (HUD) including clinical, emergency, compassionate, and investigational use.

2.0 General Description

2.1. The Food and Drug Administration (FDA) requires IRB review and approval before HUDs can be used for clinical or research purposes.

2.2. The University of Southern Maine (USM) IRB may approve the use of HUDs in the following situations:

2.2.1. Clinical use for treatment or diagnosis consistent with approved labeling;

2.2.2. Emergency use off-label or consistent with approved labeling;

2.2.3. Compassionate use off label;

2.2.4. Investigational use consistent with approved labeling; and

2.2.5. Investigational use off label.

3.0 Definitions

3.1. **Humanitarian Use Devices (HUDs)** are medical devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in not more than 8,000 individuals in the United States per year.

3.2. **Use** means the use of a HUD according to its approved labeling and indications.

3.3. **Investigational Use** means research involving a HUD.

3.4. Humanitarian Device Exemption (HDE) means that the device is approved for marketing but the approval is based on evidence of safety and probable benefit (rather than the higher standard of reasonable assurance of effectiveness).

3.5. Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), investigators and healthcare providers to execute this SOP.

5.0 Procedure

5.1. HUD Clinical Use for Treatment or Diagnosis Consistent with Approved Labeling

5.1.1. The healthcare provider responsible for the use of the HUD submits a completed IRB application to the ORIO.

5.1.2. The IRB reviews clinical use of a HUD in a convened meeting using all standard full-review criteria and procedures.

5.1.2.1. The IRB approves the use of the HUD device consistent with the scope of the FDA-approved labeling for groups of patients meeting clinical criteria.

5.1.2.2. The IRB may choose to require informed consent or allow use of a modified clinical consent or operative permit that is consistent with or combined with the approved labeling and/or patient information packet.

5.1.3. The healthcare provider seeks and the IRB provides continuing review using standard criteria and procedures.

5.1.3.1. The IRB may use expedited review procedures for continuing review.

5.1.4. The healthcare provider submits a report to the FDA and to the IRB whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

5.1.5. The healthcare provider labels and stores the HUD in a secure manner to ensure appropriate accountability and traceability and to clearly display any use limitations or restrictions designated by the IRB or HDE holder.

5.2. HUD Emergency Use for Both Off-Label or Approved Label Use

5.2.1. The healthcare provider submits an emergency use request directly to the IRB Chair in accord with the Emergency Use SOP.

5.2.1.1. However, if the immediate use of the HUD is, in the healthcare provider's opinion, required to preserve the life of the patient and time is not sufficient to obtain an assessment by the IRB Chair or designee, then the healthcare provider submits a report in writing within five working days as described below.

5.2.2. The IRB, IRB Chair, or medically-qualified IRB member designee assesses the request to determine whether it meets the following regulatory requirements for emergency use of a HUD in a single subject:

5.2.2.1. The patient has a life-threatening condition, or;
5.2.2.2. The patient has a serious medical condition that can reasonably be expected to benefit from the use of the HUD, and;
5.2.2.3. This is the best acceptable treatment alternative for the patient; and
5.2.2.4. Alternative treatments pose greater risks for the patient or are deemed to provide less benefit than the HUD.

5.2.3. The healthcare provider obtains informed consent from the patient or the patient's legally authorized representative using the IRB-approved consent form that is consistent with or combined with the approved labeling and/or patient information packet.

5.2.3.1. If the healthcare provider proposes to administer the test article in emergency use situations without informed consent, the request to the IRB Chair includes a statement certifying in writing that the proposed use meets all of the following:
5.2.3.1.1. The human subject is confronted by a life-threatening situation necessitating the use of the test article;
5.2.3.1.2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject;
5.2.3.1.3. Time is not sufficient to obtain consent from the subject's legal representative; and
5.2.3.1.4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

5.2.3.2. This statement should include an assessment from an independent physician who is qualified in the appropriate medical specialty.
5.2.3.2.1. If the immediate use of the HUD without informed consent is, in the healthcare provider's opinion, required to preserve the life of the patient and time is not sufficient to obtain the

independent determination by a qualified physician, then the independent evaluation must be included in writing in the five (5) working days report described below.

5.2.4. Within five (5) working days of the emergency use, the healthcare provider submits written notification of the use to the IRB including identification of the patient involved, the date of use and the outcome of the administration.

5.2.4.1. The convened IRB reviews the report consistent with procedures in the Emergency Use SOP.

5.2.5. If the healthcare provider fails to comply with this SOP, the IRB retrospectively reviews the situation.

5.2.5.1. The IRB determines if the test article administration met the regulatory definition and whether failure to comply with this SOP meets the IRB definition of noncompliance.

5.2.6. If the healthcare provider administering the emergency use HUD is not listed on the IRB approved HUD protocol, he/she identifies and informs the Principal Investigator (PI) on the protocol within five (5) working days of emergency use.

5.2.7. For emergency use of a HUD, the healthcare provider assumes the responsibilities of the HDE holder, monitors the patient, and reports the use of the HUD, including any safety-related information to the HDE holder or FDA.

5.2.8. The healthcare provider submits a report to the HDE holder or the FDA and to the IRB whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur

5.3. HUD Compassionate Use Off-Label Use

5.3.1. The healthcare provider responsible for the use of the HUD submits a completed IRB application to the ORIO.

5.3.2. The healthcare provider contacts the HDE holder to determine if any additional requirements or restrictions exist prior to use.

5.3.3. The IRB may approve a healthcare provider's application for the compassionate use of a HUD when the proposed use meets the following criteria:

5.3.3.1. The healthcare provider has determined:
5.3.3.1.1. There is no alternative device for the patient's condition;
5.3.3.1.2. Use does not violate existing restrictions or limitations; and
5.3.3.1.3. There is no emergency.

5.3.3.2. The healthcare provider has provided the HDE holder and the IRB with the following:
5.3.3.2.1. A description of the patient's condition and the circumstances necessitating treatment with the device;
5.3.3.2.2. A discussion of why alternative treatments are unsatisfactory; and
5.3.3.2.3. Assurances and information about patient protection measures.

5.3.4. The IRB reviews compassionate use in a convened meeting using all standard full-review criteria and procedures.

5.3.5. The healthcare provider obtains informed consent from the patient or the patient's legally authorized representative using the IRB-approved consent form that is consistent with or combined with the approved labeling and/or patient information packet.

5.3.6. The healthcare provider monitors the patient and submits a follow-up report including any safety-related information to the HDE holder or FDA.

5.3.7. The healthcare provider submits a report to the HDE holder or FDA and to the IRB whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

5.4. HUD Investigational Use Consistent with Labeling

5.4.1. The PI submits a completed IRB application to the ORIO.

5.4.1.1. The IRB reviews clinical use of a HUD in a convened meeting using all standard full-review criteria and procedures.
5.4.1.2. The IRB may approve a PI's application for the investigational use of a HUD device to collect safety and effectiveness data if within the scope of the FDA-approved labeling.

5.4.2. The PI must obtain informed consent consistent with all FDA-regulated clinical studies.

5.5. HUD Off-Label Investigational Use

5.5.1. The PI submits a completed IRB application to the ORIO.

5.5.1.1. The IRB reviews clinical use of a HUD in a convened meeting using all standard full review criteria and procedures.

5.5.1.2. The IRB may approve a PI's application for the investigational use of a HUD device beyond its approved labeling when in compliance with FDA requirements for the conduct of clinical investigations of devices.

5.5.2. The IRB follows procedures outlined in the Medical Device SOP for IRB review of significant risk and non-significant risk investigational device use.

5.5.2.1. If the HUD carries significant risk, the PI may conduct the study following FDA approval of an IDE application.

5.5.3. The PI obtains informed consent consistent with all FDA-regulated clinical studies.

6.0 References

6.1. 21 CFR 812;

6.2. 21 CFR 814;

6.3. 21 CFR 50.23;

6.4. 21 CFR 56.21;

6.5. Guidance for HDE holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff, Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; and Humanitarian Device Exemption (HDE) Program: Draft Guidance for Industry and Food and Drug Administration Staff