HUMANITARIAN USE DEVICE CHECKLIST

Children's Hospital of Philadelphia RESEARCH INSTITUTE

The purpose of this checklist is to help guide CHOP investigators in the regulatory pathways for using a Humanitarian Use Device (HUD)

Humanitarian Use Device (HUD): A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE): A HUD under an HDE is exempt from the requirement of establishing a reasonable assurance of effectiveness and will not expose patients to an unreasonable or significant risk of illness or injury. Approval of an HDE application is considered "FDA approval"
of the device.

HDE Holder: The HDE holder is responsible for ensuring that a HUD under an approved HDE is administered only in facilities having IRB oversight.

Investigational Device Exemption (IDE): An approved IDE means that the IRB (and FDA, for significant risk devices) has approved the sponsor's study application. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Use: Clinical Use refers to use of the HUD, off label or in accordance with its label, for treatment or diagnosis as part of clinical care (not for research purposes). Investigational use refers to research/clinical investigation involving a HUD, off label or in accordance with its label.

There are five (5) categories of HUD described below. Use the checklist that applies to your needs to determine regulatory requirements for using the HUD.

PI:

Study Title:

Date:

1. Clinical use of a HUD for treatment or diagnosis in accordance with the approved label

- ☐ The HUD is approved by the medical device manufacturer for use at CHOP, under the manufacturer's FDA-approved Humanitarian Device Exemption (HDE).
- ☐ The HUD is being used for clinical care, and not as part of an investigation.
- ☐ The consent form can be a clinical consent for clinical care
- ☐ The use of the HUD is submitted to the IRB, for full board review & approval before HUD use

2. Clinical use of a HUD for treatment or diagnosis, off label

- ☐ The above four points under #1 are applicable for the off-label clinical use of a HUD. The following four points need to be submitted to the IRB, as well.
- ☐ Documentation from the HDE sponsor allowing off-label clinical use
- ☐ Justification for the off-label use, including why alternative treatments are unsatisfactory
- ☐ Schedules to monitor the patient based on the patient's specific needs
- ☐ Information about the risks and probable benefits of the device for the proposed subject

3. Emergency use of a HUD for clinical care in a single patient

- ☐ The patient has a serious or immediately life-threatening disease or condition necessitating the use
- ☐ No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life
- ☐ There is either insufficient time to contact the FDA, or Chair or Vice-Chair of the IRB, or the Chair or Vice-Chair of the IRB has confirmed that there is insufficient time for the IRB to meet and approve the use
- ☐ HDE sponsor approval, independent assessment by uninvolved physician, informed consent of patient / Legally Authorized Representative
- ☐ The 5-day report is submitted to the IRB in accordance with CHOP IRB SOP 802
- ☐ The 5-day report is submitted to the FDA – IND/IDE Support can assist with submission

4. Investigational use of a HUD in accordance with its label

- ☐ Investigational use is in accordance with the approved label to collect safety and effectiveness data
- ☐ The investigator develops a research (not a clinical) informed consent form
- ☐ The investigator submits an application in eIRB in accordance with the Research Submission Requirements of CHOP IRB SOP 301
- ☐ The IRB application will be reviewed at a full board IRB meeting, with use dependent upon IRB approval

5. Investigational use of a HUD off-label

- ☐ Investigational use not in accordance with the label
- ☐ The investigator develops a research (not clinical) informed consent form
- ☐ The investigator submits an application in eIRB in accordance with the Research Submission Requirements of CHOP IRB SOP 301
- ☐ The IRB application will be reviewed at a full board IRB meeting
- ☐ Depending on the proposed use, the use may require submission of an IDE application to the FDA, or be conducted under abbreviated requirements for NSR devices

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For guidance on submission requirements, see the CHOP IRB Website (Humanitarian Use Devices)

CHOP IRB SOP 301 (Submission Requirements)
CHOP IRB SOP 409 (Determination of IND/IDE Requirement)
CHOP IRB SOP 412 (Humanitarian Use Device)
CHOP IRB SOP 802 (Exemption to the Requirement for Prior IRB Approval for Emergency Use)

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