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HUMANITARIAN USE DEVICE RESEARCH PROTOCOL TEMPLATE

15.306 (HRP-503f)

INSTRUCTIONS

This template should be used by clinicians planning to provide patients access to a Humanitarian Use Device (HUD). If the HUD is being used in a clinical investigation to evaluate its safety and effectiveness, either for the HDE-approved indication(s) or for a different indication, use instead the Interventional Protocol Template 15.301 (HRP-503a).

> ***A Humanitarian Use Device (HUD) is 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".*** *(21 CFR 814.3(n))*

- ✓ **[BLUE]** highlighted text guides you to construct a protocol so that the IRB can better understand what you are doing.
- ✓ [**RED]** highlighted text tells you when additional supporting documents must be uploaded to eIRB+.
- ✓ **Delete** all instructional text highlighted in **[BLUE]** and [**RED]** prior to uploading the protocol to eIRB+.

Need help?

Visit the Human Research Protection Program (HRPP) website https://go.rutgers.edu/HRPP-Toolkit to obtain referenced Toolkit Forms & Templates and https://go.rutgers.edu/HRPP-Guidance to obtain referenced Guidance documents. Contact your IRB Office at https://go.rutgers.edu/ContactUs if you need further assistance.

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STUDY INFORMATION

- **Title of Project:**
  [Add Name of HUD]
- **Name of Responsible Clinician**
  [Add Clinician Full Name and Credentials]
- **Clinician Div. & Dept.**
  [Add Division & Department]
- **Clinician Contact Info:**
  [Add Work Email, Address & Phone #]
- **Protocol Version and Date:**
  [e.g. v1 01.01.2021]
  [Be sure Protocol Title, Protocol# and Version Date appear in the footer]

1.0 Basic Device & Background Information

1.1 Device(s)

List the Humanitarian Use Device being used for clinical purposes under this protocol. Provide:

- The name of the device
- A description of the device and its intended uses
- The Manufacturer of the device
- The Humanitarian Device Exemption Number issued by FDA.

1.2 Background

Provide background information on the device:

- Marketing history
- Summary of studies using the device

(If the product labelling provides the necessary background information, simply direct the reader to the pages in the product labelling document that reflect the history & summary.)

UPLOAD to eIRB+ – (1) a copy of the Humanitarian Device Exemption approval order issued by FDA; (2) the manufacturer's product labelling and (3) the patient information packet that may accompany the Humanitarian Use Device.

2.0 Clinical Use

2.1 Clinical Use

Provide a description of how the device will be used in your clinical practice. Explain how it differs from the manufacturer's intended use, if applicable. Provide also:

- An outline of all HUD treatment procedures;
- List of other ancillary tests or procedures patients may undergo in addition to the procedure(s); and
- Any patient follow-up visits.

2.2 Inclusion/Exclusion Criteria

Describe the qualifying patient population. Provide the relevant demographic (e.g., age, ethnicity), biomedical (e.g., disease status, laboratory values, contraindications, warnings and precaution for use of the device, failure of alternative measures) or other characteristics relevant for inclusion and exclusion from use of the device.

Describe how patients will be screened for eligibility and by whom.

2.3 Risks of Harm and Potential Benefits to Health

Identify currently available devices or alternative forms of treatment available to patients. Explain the adverse effects on health—illness or injury—and potential health benefits to patients when using the Humanitarian Use Device versus the other available devices or alternative forms of treatment.

3.0 HUD Management

3.1 Clinician Qualifications

Provide a list of clinicians approved to use the device, along with their credentials reflecting they possess the qualifications necessary to use the HUD in clinical practice.

3.2 Training

Describe any special training required before use of this specific HUD in clinical practice. Specify who will provide the training (i.e., the manufacturer, the HDE holder, etc.). Outline your plan to ensure that all persons using the device in clinical practice complete the special training and refresher training, if necessary, and how evidence of training will be documented.

3.3 Clinical Sites

List the facility(s) where the HUD will be administered.

UPLOAD to eIRB+ – Site approvals for clinical use of the Humanitarian Use Device.

4.0 Device Accountability

4.1 Device Accountability & Storage Methods

Specify the location where HUD devices will be stored and secured. Indicate procedures around receipt, storage and dispensing for clinical care, as well as, who will be responsible for performing these procedures.

Outline your device accountability plan. Be sure it includes at least the following: patient name, physician name, device serial number, date of use, summary of use and any complications, including, explants, and circumstances around such events, should they occur.

UPLOAD to eIRB+ – the Device Accountability Plan.

5.0 Consent Process

5.1 Consent Document

Create [or obtain from the manufacturer] a document to review with patients (or their legally authorized representative) before they receive the HUD. Be sure the document includes the following information:

- Explanation that the Humanitarian Use Device is designed to diagnose or treat the disease or condition described in the HDE product labelling and that no comparable device is available to treat the disease or condition
- A description of any ancillary procedures associated with the use of the HUD
- An explanation of the mechanism of action of the HUD in relation to the disease or condition.
- Known risks or harm and discomforts and potential for therapeutic benefit

- A statement that indicates the patient (or their legally authorized representative) has received a copy of the product labelling information provided by the HDE holder
- The following statement appears in the document: "Humanitarian Use Device authorized by Federal Law for use in the [choose: treatment or diagnosis] of [state: specific disease or condition]. The effectiveness of this device for this use has not been demonstrated."
- Signature Section to document the patient (or their legally authorized representative) consent to use of HUD for clinical care. Follow the clinical site's conventions for documentation of consent unless directed by the IRB to document following an IRB documentation template. At a minimum, the patient's name, signature and date the patient reviewed with the clinician the use of the HUD in their care and consented to its use must be documented.

If a Patient Information Packet for the HUD is available and it reflects additional important information, add that information to the document.

5.3 Waivers of Consent or Consent Documentation – *Information Only*

No response necessary. **[NOTE**: Waivers of consent or consent documentation are not permitted in non-emergency situations. However, when HUD is used in emergent situations, patients or their legally authorized representative must be given information about the HUD after its use/receipt.]

5.4 Non-English-Speaking Patients

If patients who do not speak English will receive an HUD, describe your process to ensure that the information about the HUD that is provided to them will be in that language.

UPLOAD to eIRB+ – the consent form you will use to consent patients to receive a Humanitarian Use Device.

6.0 Privacy and Confidentiality Protections

6.1 Provisions to Protect the Privacy Interests of Subjects

Describe the steps that will be taken to protect patients' privacy interests. "Privacy interests" refers to a person's desire to place limits on who they interact with or provide personal information to about their care.

6.2 Data Security

Describe your plan to secure patients' information, information found in patient records, as well as, in non-patient records (such as in device accountability records or data sharing between the Site and the Manufacturer or HDE holder from accidental disclosure. Consider such strategies as such as staff training, transporting or transmitting data, methods to restrict access, password protection, encryption, use of key codes to separate identifiers from the data. Identify who will be responsible for each of these tasks.

7.0 Safety Reporting

Develop a plan to ensure adverse events are reported to the FDA and the Rutgers IRB in keeping with the medical device reporting requirements found at 21 CFR 803.

8.0 Bibliography

Include all references cited in the protocol.