Use for newly proposed use of Humanitarian Use Device

Please refer to the PPMH IRB Policy "Humanitarian Use Devices (HUD)" for more detailed information about the use of Humanitarian Use Devices. The HUD and its proposed use with PPMH must be reviewed and approved by a convened meeting of the PPMH IRB.

Protocol / Product Name:

Principal Investigator: (name of person submitting application)

PI Address:

PI Telephone / Email:

Submission Date:

Humanitarian Use Device Information

Description of Device:

Description of FDA Approved Indications for the HDE:

HDE Number:

Sponsor:

Is this product U.S. FDA approved for use with humans? ☐ Yes ☐ No ☐ N/A

Has this product been submitted to any other IRB by the Principal Investigator listed above? ☐ Yes ☐ No

If yes, please list Institution and status of application:
(insert name of Institution)

Action: ☐ Approved ☐ Pending ☐ Disapproved

Status: ☐ To be started ☐ In progress ☐ Completed

Please identify any benefits / advantages to the patient:

Please identify significant adverse reactions and other risks:

Please identify alternative therapies:

Please Identify the Patient Population

Inpatients _____ Outpatients _____ Age Range: _____

Diagnosis(es):

1)

2)

3)

If INPATIENTS, will outpatient follow-up be required? ____ Yes ____ No

If YES, where will the patient be seen? ____ Outpatient ____ Office

If OUTPATIENTS, where will the patient be seen? ____ Outpatient ____ Office

Please list names of all personnel involved in the use of this Humanitarian Use Device Including Principal Investigator						
Name	Role in the research (e.g. co-investigator, research coordinator, statistician, etc.)	Involved in interpersonal contact communication with subjects, or access to private identifiable data?	Involved in consent process?	Research Ethics Training Source (NIH/NCI, CITI, Other) and Date Completed	Any potential or actual financial interest related to this research?	
					Yes	No
Ex: Sally Smith, MD	*Co-Investigator*	☒	☒	*NIH / May 2014*	☒	☐
Ex: John Doe	*Research Coordinator*	☒	☒	*CITI / December 2015*	☐	☒
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐

Have all applicants been trained in the use of this device? _____ Yes _____ No

Please submit signed and dated Curriculum Vitae, Medical License, and Certification of Training in the Use of this Device for All Applicants.

Other Documents

The following documents must be submitted at time of application:

- FORM: PPMH IRB Application for Humanitarian Use Device Under a HDE
- Evidence of qualifications of the key personnel related to their role in this research (see above section)
- The HUD manufacturer's product labeling, patient package insert, and/or other pertinent manufacturer informational materials.
- The FDA HDE approval letter.
- Proposed Patient Clinical Consent form, or rationale for exemption from the form. This form shall incorporate the following:
    - A description of an HDE/HUD approval process; e.g., "Your medical care will involve the use of (specify device), which has been approved by the U.S. Food and Drug Administration (FDA) as a Humanitarian Use Device (HUD). A HUD is a device used to diagnose or treat a disease or condition that affects fewer than 4,000 individuals in the United States per year and for which no comparable device is available. The FDA approves the clinical use of a HUD based primarily on evidence that it does not pose a significant risk of injury to the patient and that the potential benefit of the device to the health of the patient outweighs the risks of its use. The FDA approval of a HUD is based on limited data documenting its effectiveness in humans.
    - A description of the HUD and how this device will be used in the clinical setting. Based on this description, it should be clear to the patient why he/she is a candidate for the use of the device.
    - A discussion of possible risks, side effects, and/or adverse events associated with the HUD and its proposed clinical use.
    - A discussion of the possible benefits associated with the clinical use of the HUD.

- A discussion of any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical application of the HUD.
- A statement that the patient has read the package insert and/or patient information sheet for the HUD.
- Voluntary Consent statement(s) with patient signature and date lines.
- Physician Certification statement with physician signature and date lines.

Principal Investigator Acknowledgement
I agree to use the Humanitarian Use Device in accordance with applicable regulations and the PPMH IRB's policies and procedures. I understand that IRB approval is required for any modifications of the device and/or proposed clinical use of the device.
P.I.'s Name: _____ Date: _____
Electronic Signature:

IRB Review of Application for Humanitarian Use Device (HUD) (Completed by IRB Office Only)	
Date of Receipt: _____	Is the Application Complete with Required Documents? ☐ Yes ☐ No
Report returned to Investigator (indicate reason):	
Full Board Review (date): _____	
Humanitarian Use Device (HUD) Approved ☐ Humanitarian Use Device (HUD) Denied ☐	

Submit Form