DIRECTIONS FOR HUMANITARIAN USE DEVICE (HUD) SUBMISSION

Initial HUD applications must be submitted for full board review using the eProtocol application at:

https://ksprodweb.ovpr.wayne.edu/

Please note that you will need a letter of approval from the applicable scientific review committee for the following institutions/departments:

- DMC
- Karmanos
- Veterans Administration
- Any other internal review that may be required by your department, but not required by the IRB.

Check the IRB website for full board meeting submission deadlines.

Submit the following documents as attachments in eProtocol:

- Humanitarian Use Device Form
- Humanitarian Use Device Consent Form
- HUD product labeling, clinical brochure, and/or any information provided by the sponsor
- FDA HDE approval letter
- Letter of Approval from applicable scientific review committee (see above)
- Any materials being given to the patient

IRB ADMINISTRATION OFFICE
87 E. Canfield, Second Floor
Office (313) 577-1628
Detroit, MI 48201
http://irb.wayne.edu

Humanitarian Use Device (HUD) Form

- All IRB submission forms must be the current version on the IRB website. Check the form date (and always download the current version from http://irb.wayne.edu/forms-requirements-categories.php.
- *If you do not access your @wayne.edu e-mail, **forward your @wayne.edu e-mail** to your @med.wayne.edu, or @karmanos.org, etc. e-mail in order to receive important e-mail communications regarding your study **OR** go to **Academica** and enter the e-mail account that you wish to use. All personnel must be listed for the eProtocol Personnel Information section with a WSU Access ID. If personnel need a WSU Access ID, request this by emailing WSUIRBInfo@wayne.edu
- The IRB committee deadlines are available at: https://research.wayne.edu/irb/meetings-deadlines
- **CITI training must be completed by the Physician and all personnel prior to IRB approval**.
- Please call us if you have any questions along the way: (313) 577-1628.

Section A: Principal Investigator/Physician Information (PI)

1.	Name of PI:	In completing the eProtocol application, COI and Obligations statements the PI agrees to accept primary responsibility for the scientific and ethical conduct of the procedures, as approved by the IRB, and abide by the IRB's policies and procedures. Activities cannot begin until the investigator has received documentation of IRB review and final approval	
	Phone:		*E-mail:
	Department:		
	Division:		PI's Pager:
	Campus Address:		

Section B: Submission Details

2.	Name of Coordinator (if applicable):		☐ N/A
	Phone:		*E-mail:
3.	Form completed by:		Title:

	Phone:	*E-mail:
4.	Project Title (should include the label "HUD"):	
5.	eProtocol IRB#	Date of eProtocol Submission:

Section C: Sponsor Information

6.	Sponsor:	
	Sponsor Contact Name:	
	Sponsor Address, City, State, Zip Code:	
	Phone:	

Section D: Site/Location of Device Use

7.	Check **all** applicable sites at which this device will be used.	☐ Children's Hospital of Michigan ☐ Detroit Receiving Hospital/University Health Center ☐ DMC Heart Hospital ☐ Harper University Hospital ☐ Huron Valley/Sinai Hospital ☐ Hutzel Women's Hospital ☐ Kresge Eye Institute ☐ Michigan Orthopedic Specialty Surgery Hospital ☐ Rehabilitation Institute of Michigan ☐ Sinai-Grace Hospital ☐ Barbara Ann Karmanos Cancer Institute ☐ John D. Dingell Veterans Administration Medical Ctr. ☐ Other:

NOTE: An **approval letter** must accompany the application from facilities that require scientific review prior to submission to the IRB. Scientific review committees are in place to review all research being conducted at or from researchers from (1) the Veterans Administration Medical Center (Clinical Investigation Committee), (2) the Department of Psychiatry and Behavioral Neuroscience (Departmental Review Board), (3) the Karmanos Cancer Institute (Protocol Review Committee) for review of all cancer-related research, and (4) Detroit Medical Center (Research Review Authorization). **Please attach the approval letter(s).**

Section E: Device Information

8.	Name of Device:	Generic: Trade Name:
9.	FDA HDE Number	
10.	Date of HUD designation	
11.	What are the indications for use of the HUD? Include the disease or condition the device is intended to treat or diagnose.	
12.	Are you requesting to use the device under a clinical investigation (i.e., research involving one or more subjects to determine the safety or effectiveness of the HUD)? ☐ Yes- If yes, the full requirements for IRB review and informed consent apply (21 CFR 50 and 56) as well as other applicable regulations. ☐ No- The HUD will be used for treatment purposes only.	

13.	Provide a description of the device.

14.	Describe the device accountability plan that includes receiving, storing, dispensing, and final disposition and accountability of the device

15.	How is the physician qualified to use this device?

16.	List any contraindications, warnings, and precautions for use of the device.

17.	List the risks of using this device. (include these risks in the Humanitarian Use Device Consent)
18.	What are the benefits for using this device?

19.	Are there any alternatives for using the device? ☐ **Yes** ☐ **No** If Yes, describe the alternatives:
20.	Provide any additional information about the device, if applicable.

Section F: Patient Information

21.	Describe the proposed clinical consent process:	
22.	Indicate what kind of information will be given to the patient, if any. (Attach a copy of each)	☐ Educational materials ☐ HUD brochure ☐ Other
23.	Is there a possibility that the HUD product will be used in an emergency situation?	☐ Yes ☐ No
	a. If Yes, how will informed consent be obtained in emergency situations?	

Section G: eProtocol Submission

24.	**eProtocol Application Guidance**	**Protocol Checklist section:**
		☐ Select Humanitarian Use Device
		
		Protocol Information –Consent Information section
		☐ Attach Humanitarian Use Device Informed Consent
		☐ Describe Clinical Consent Process
		
		Protocol Information-Data Safety and Monitoring section
		• Select "No" to the questions:
		  ○ Is this a treatment study?
		  ○ Is this an intervention study?
		
		Protocol Information-Drugs and Devices section
		☐ Select Treatment
		☐ For justification state "Humanitarian Use Device"
		
		Protocol Information Attachments section
		Attach the following:
		☐ Physician's CV/Resume
		☐ Humanitarian Use Device (HUD) Form
		☐ A copy of the HDE approval letter from the FDA
		☐ HUD product labeling, clinical brochure, and/or any information provided by the sponsor
		☐ Letter of approval from scientific review committee (if applicable)
		☐ The patient information packet for the HUD
		☐ Any other relevant materials (e.g., training certificates) as identified in the Application Form
		
		The following sections in eProtocol are <u>NOT</u> required for HUD submissions:
		
		• Background, Rationale, Data Analysis, and Procedures and Recruitment section
		• Recruitment Process, Participant Compensation, and Costs section
		• HIPAA section

For sections in eProtocol that are not required for HUD submissions, state or select "N/A"		