MetroWest Medical Center IRB
85 Lincoln Street, Framingham, MA 01702

Humanitarian Use Device (HUD) Submission Form

For new projects involving the use of Humanitarian Use Devices

Date: _____

Section A: General Information	
MD Name:	Phone Number
MD Office Address:	Email address:
Hospital where device will be used:	Hospital Address:
HUD #	HUD Holder
HUD Title	

Section B: Physician must submit the following documentation: (Check all that apply)	
☐	FDA HDE approval letter
☐	The HUD Manufacturer's product labeling, clinical brochure, and/or other pertinent manufacturer informational materials
☐	A statement from HUD Manufacturer that specifies the use of the HUD will be limited to the clinical indication(s) listed in the FDA-approved product labeling
☐	Patient Information Packet (if available from HUD Manufacturer)
☐	Institutional Official Approval Letter
☐	Information describing the Physician's clinical experience or any training required/completed as required by the HUD Manufacturer (if applicable)
☐	Copy of CV and License for all Investigators who may use the device at this facility

Other Physicians that may use HUD: Please list all others and their affiliation. **(Click Tab to add additional boxes.)**	
MD Name:	

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I certify that the information included in this report and its attachments is correct:

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Email Address:	
	Principal Investigator Signature
Date:	Signature:

- **PLEASE EMAIL COMPLETED FORMS AND REQUIRED DOCUMENTS TO MWMCIRB@mwmc.com you will receive an acknowledgement once all required information has been submitted.**

Submission Checklist

	INCLUDE THE FOLLOWING WITH ALL SUBMISSIONS
	Any required Documents from Section B
	Current Curriculum Vitae for Principal Investigator *(signed and dated)*
	All HUD submissions require a letter from site CEO acknowledging the use of the device at the site
	Copy of Medical License for Principal Investigator
	Informed Consent Form (if applicable)

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Physician Statement of Principles

HUD Title:	
Responsible Physician:	

As part of my responsibility, I agree to promptly report to MWMCIRB, and/or the FDA and the HDE Holder, the following events, for my own uses of the HUD, and for those uses of the HUD by all MWMCIRB-approved physicians listed on the HUD Review Certificate:

1) Any instance where the device may have caused or contributed to death or serious injury of a patient;
2) Modifications to the HUD or to the Device Labeling;
3) Any instance of serious or continuing noncompliance with the regulations, or the requirements or determinations of the MWMCIRB;
4) Any off-label or emergency use of the HUD; and,
5) Any suspension or termination of MWMCIRB approval.

In addition, I agree to make Continuing Review reports no less than annually to the MWMCIRB on the use of the HUD listed above.

If there is a reason for me to deviate from these precepts, I will seek prior approval in writing from the MetroWest Medical Center Institutional Review Board.

_____ _____

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Responsible Physician (Signature) **Date**