



Application for Humanitarian Use Device (HUD)

Use for newly proposed use of Humanitarian Use Device. <i>If the protocol evaluates the safety or effectiveness of a HUD, STOP and contact the IRB.</i>			
Protocol Name:			
Investigator:			
Primary Contact:			
Documents included in this submission	Version # and/or Date as applicable	Check if Submitted	Check if NA
Humanitarian Use Device (HUD) Application		<input type="checkbox"/>	
Copy of FDA's HDE approval.		<input type="checkbox"/>	<input type="checkbox"/>
Protocol or summary of plan for use		<input type="checkbox"/>	<input type="checkbox"/>
Device description		<input type="checkbox"/>	<input type="checkbox"/>
Product labeling		<input type="checkbox"/>	<input type="checkbox"/>
Patient consent form, if applicable		<input type="checkbox"/>	<input type="checkbox"/>
All written information related to the HUD to be provided or meant to be seen or heard by patients.		<input type="checkbox"/>	<input type="checkbox"/>
Other:		<input type="checkbox"/>	<input type="checkbox"/>
Humanitarian Use Device Information			
HUD Name	HDE #	Manufacturer	
FDA Approved Indication			
Ensure that the application includes communication from the sponsor or the FDA with the HDE number.			

Names of all research personnel involved in the use of the Humanitarian Use Device					
Complete and attach a "Contact Information" form for all new research individuals and individuals with updated information.					
Name of Research Personnel	Role in the research	Contact with patients or access to private identifiable data?	Involved in the consent process?	Does this person have a financial interest related to the research?	
				Yes*	No
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- "Financial Interest Related to the Research" means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:
 - Ownership interest of any value including, but not limited to stock and options exclusive of interests in publicly traded diversified mutual funds.
 - Compensation of any amount including but not limited to honoraria, consultant fees, royalties or other income.
 - Proprietary interest of any value including, but not limited to, patents, trademarks, copyrights and licensing agreements.
 - Board or executive relationship, regardless of compensation.
- If there is a known conflict of interest, provide a copy of the pre-determination and management plan regarding the financial disclosure.

Physician Acknowledgement	
I agree to use the Humanitarian Use Device in accordance with applicable regulations and the organization's policies and procedures.	
Investigator signature	Date