Oklahoma State University Center for Health Sciences
Institutional Review Board
1111 W. 17th St
Tulsa, OK 74107
918-561-1400

Modification of Approved Humanitarian Use Device (HUD)

Use to request a modification to previously approved Humanitarian Use Device.	
IRB Reference Number	
Protocol Name	
Investigator	
Primary Contact	

Provide one copy of the following documents if affected by the modification:	Version # and/or Date as applicable	Check if Submitted	Check if NA
Humanitarian Use Device (HUD) Application		☐	☐
Copy of FDA's HDE approval		☐	☐
Protocol or summary of plan for use		☐	☐
Device description		☐	☐
Product labeling		☐	☐
Patient consent form, if applicable		☐	☐
All written information related to the HUD to be provided or meant to be seen or heard by patients.		☐	☐
Other:		☐	☐

Summarize the modification or attach a summary:

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