



Continuing Review Progress Report for Humanitarian Use Device (HUD)

Use for continuing review of a HUD. If modifications are being requested, submit a separate request for a modification.		
Name of Device:		HDE #
IRB Number:		
Physician:		
Primary Contact:		
Enrollment Status		
Total number of patients enrolled:	Since activation	Since last approval
Total locally:		
Total all sites:		
Financial Interest Declaration		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Do any physicians have a significant financial interest related to the manufacturer that was not disclosed in a previous application? <i>If yes, attach an explanation.</i>
Please answer the following questions related to the use of the HUD		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, has the status of the HUD for the device changed? <i>If yes, attach a summary description of those changes.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have patients experienced any benefits? <i>If yes, attach a summary of the benefits experienced by patients.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have there been any unanticipated problems involving risks to patients or others since the last IRB review? <i>If yes, attach a summary of unanticipated problems involving risks to patients or others.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have any patients withdrawn or stopped use of the HUD? <i>If yes, attach a summary of the numbers of withdrawals/terminations and their reasons.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have any patients or others complained about the use of the HUD? <i>If yes, attach a summary of the number and nature of the complaints.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have there been any publications in the literature relevant to the risks or potential benefits of the HUD? <i>If yes, attach a summary of these publications.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, has there been any other relevant information regarding the HUD, especially information about risks associated with the HUD? <i>If yes, attach a copy or summary of this information.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Since the last IRB review, have there been any modifications or amendments to the HUD IRB submission? <i>If yes, attach a summary description.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	In the opinion of the physician, have the risks or potential benefits of the HUD changed? <i>If yes, attach a summary description of those changes.</i>
Yes <input type="checkbox"/>	No <input type="checkbox"/>	Have all problems that require prompt reporting been submitted as required? <i>If no, attach a summary explanation of why.</i>
Physician Acknowledgment		
I agree to use the Humanitarian Use Device in accordance with applicable regulations and the organization's policies and procedures.		
Physician Signature:		Date: