BayCare Health System
Institutional Review Board **Federalwide Assurance_00006065_**

Humanitarian Use Device Accountability Form

IRB File #: _____ **Report Date _____**

Please type and complete all questions below.
Tab and arrow through application to appropriate blank. The fields will expand if needed.

1. General Information

Principle Investigator: Phone:

Coordinator: Phone and Email:

2. HUD General Information

Title: Sponsor:

HUD NO:

3. Please Report to the IRB - Check all that apply

_____ Any Safety Notification on Device Since the last Approval Period (Date of Last Approval)

_____ Any Change in Device Notification from the Sponsor Since Last Approval

_____ List of Approved Physicians using the Device at each Site:

4. Device Accountability Information

Number of Device(s) in Stock (If Applicable)	
Size and Expiration date of Device(s)	
How many Device(s) Used Since Last Approval	
List Identification Number, Physician's name and date for Device(s) Used Since Last Approval	
# of Device(s) Deployed Successfully	
Was any Device Deployed Unsuccessfully	

Please List the following Device information (Check box if question applies):

☐ This HUD **does not** place the subjects at a greater risk than initially noted in the last IRB approved submission.

☐ This HUD **does** place subjects at a greater risk than initially noted in the last IRB approved submission. *****

***** If this HUD does place the subjects at higher risk, please provide additional explanation below and list any precautions taken, or procedural changes. (Please tab down, continue to type space will expand).

Signature: