University of Virginia IRB for Health Sciences Research

# Humanitarian Use Device

(Non-Emergency-Full Board Review)

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| **IRB-HSR# or UVA Study Tracking#       PI:**  **Reviewer:       Meeting Date:** |
| Contact the IRB staff BEFORE the IRB meeting if you are missing any documents or have any questions. |

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| REVIEWER’S ORAL PRESENTATION  *The reviewer should state the following during their oral presentation to the IRB.*  *Planned responses must also be typed below.* |
| 1. **PRESENTATION SUMMARY** |
| 1. **What is the approved indication of this Humanitarian Use Device (HUD) and has the study team confirmed that the device will only be used according to the approved indications?**   Comments: |
| 1. **Risk/Benefit Analysis: Do you feel the risk benefit analysis is acceptable?**   *Review the risks to patients that are described in the product labeling and other materials, the proposed procedures to ensure that risks are minimized, and evaluate whether the risks are reasonable in relation to the potential benefits to patients.*  Comments: |
| 1. **Do you feel the consenting process for the use of this HUD is adequate and appropriate for this patient population?**   Comments: |
| 1. **Should any additional requirements be implemented?**   *The IRB may specify limitations on the use of the device, require additional screening and follow up procedures, require interim reports to the IRB or set other conditions or requirements as appropriate to minimize risks to patients and ensure the safe use of the device.*  Comments: |

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| **Motion -Initial Review** |
| **Approve for one year**  **Approve for one year with suggestions -**  *(e.g. typographical errors that do not affect the understanding of the information*  **Approvable with conditions and review by Chair or IRB member designee**  *PI will need to submit revised documents. Examples of items that require review by IRB chair include asking for a section of the patient information packet to be rewritten at a lower reading level to ensure that risks are accurately described, etc.*  **Deferred**  *PI will need to re-submit additional information to be reviewed future IRB-HSR Meeting.*  *PI may be asked to attend future meeting to answer questions.*  *Examples of items that may require a deferral: patient information packet, Product brochure*  **Disapproved**  *The investigator may attend a future IRB-HSR meeting to defend the submission if he/she wishes to pursue the use of the Humanitarian Use Device. Study will be re-submitted under a new UVa Study Tracking number.*  **By entering my name below, I confirm I have no conflicts with this submission.**  \_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_     \_\_\_\_\_\_\_\_\_\_\_  **Reviewer Name Date** |
| ***Note: For IRB Staff-Meeting Minutes:***  *Use approval criteria at 21 CFR 56.111–Consideration of the patient’s need for the HUD–Likelihood that device is appropriate for the patient’s condition or disease state* |