University of Virginia IRB for Health Sciences Research

# Humanitarian Use Device Continuing Review Checklist

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| **IRB-HSR# or UVA Study Tracking#       PI:**  **Reviewer:       Meeting Date:** |

*References to assist in your review:* [*Humanitarian Device Exemption (HDE) Regulation: Questions and Answers*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program)*;* [*Frequently Asked Questions About Medical Devices*](https://www.fda.gov/media/75381/download)*. This checklist should only be used when the use of the HUD does not include a clinical investigation to evaluate the safety or effectiveness of the device.*

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| 1. **What is the approved indication of this Humanitarian Use Device (HUD)** |
| 1. **Have the local uses of the HUD been in accordance with the indications approved by the IRB and any required conditions?** |
| 1. **Based upon the information provided, does the risk associated with the HUD remain justified by the potential benefit to the patient?**   *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.* |
| 1. **Based upon the information provided, does the proposed plan by the investigator to provide patients with information about the HUD prior to or after use remain acceptable?**   Review the consent/information sheet provided to the patient. |
| 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 - LIST**  *(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* |