DESCRIPTION: IRBs must review studies at regular intervals to determine if – in light of any changes in the study or the world around it – it remains approvable. The IRB is looking to the HDE holder for core information about the device and its use and status. User physicians will be asked to report their activity individually.

**Inclusion of the following items is always required for review. Checkmark each that you have attached:**

 [ ]  This form, signed electronically or on paper [ ]  A current risk evaluation

 [ ]  The complete packet sent to device user physicians including all consent information

**Submit to:** **submit@eandireview.com**

**MAKE A COPY FOR YOUR STUDY CORRESPONDENCE FILE.**

|  |
| --- |
| 1. Dates
 |
| E&I Approval Number |       | IRB Expiration Date |       | Date - Last Possible Submission  |       |

|  |
| --- |
| 1. Identification: The Humanitarian Device
 |
| B.1. The Device  |
| Device Name |       |
| Device Company |       |
| HDE Number |       |

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| --- |
| 1. Sponsor Contact
 |
| C.1. Primary Contact  |
| Name (with degrees): |       | Phone |       |
| Title:  |       | Cell |       |
| Company:  |       | Fax |       |
| Mailing Address:  |       | Email |       |
| City, State, Zip: |       |  |  |
| C.2. Compliance Director |
| Name (with degrees): |       | Phone |       |
| Title:  |       | Cell |       |
| Company: |       | Fax |       |
| Mailing Address: |       | Email |       |
| City, State, Zip: |       |  |  |
| C.3. Type of report Regardless of what is checked here, please complete the rest of the form. |
| [ ]  | Final Report. The company will not be seeking a continued HDE for this device.  |
| [ ]  | Continuing Review. The company would like to offer continued access to this humanitarian device. |
| [ ]  | Other:       |

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| 1. Device Evaluation
 |
| External Events: Describe changes or new information since the last IRB review. Mention changes that are on the horizon. |
| D.1. FDA regulatory status | [ ]  None or       |
| D.2. New information about safety | [ ]  None or       |
| D.3. New information about efficacy | [ ]  None or       |
| D.4. New information about alternatives | [ ]  None or       |
| D.5. New patient information materials  | [ ]  None or       |

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| 1. Device Physician Users
 |
| E&I is asked to evaluate applications of user physicians. In this section, we seek information on what steps you have taken and what is left to the IRB. Does your company representative: |
| E.1. Select or exclude physicians on any basis, such as their specialty area? | [ ]  No or [ ]  Yes – Please describe:       |
| E.2. Evaluate their current medical license? | [ ]  No or [ ]  Yes – Please describe:       |
| E.3. Complete the E&I application form for them at least in part? | [ ]  No or [ ]  Yes – Please describe:       |

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| --- |
| 1. Activity – Updated Information
 |
| F.1. Changes: Since your original application have you made or had any changes affecting: |
| Is any research being done to support a marketing application? | [ ]  No  | [ ]  Yes – Please describe:       |
| Is the device marketed for other indications? | [ ]  No  | [ ]  Yes – Please describe:       |
| F.2. FDA History |
| Has the FDA issued any notices about the device? (e.g., IDE, warning letter, guidance, etc.) | [ ]  No  | [ ]  Yes – Please describe:       |
| Has the FDA issued any notices about the company? | [ ]  No  | [ ]  Yes – Please describe:       |
| F.3. IRB History |
| Has any IRB refused permission to use this device? | [ ]  Yes [ ]  No – Please describe:       |
| Has any institution refused permission to use this device | [ ]  Yes [ ]  No – Please describe:       |
| F.4. Relations with user physicians |
| Have you received any complaints about any E&I reviewed physicians? | [ ]  No [ ]  Yes– Please describe:       |
| Have you monitored or inspected any E&I reviewed physicians? | [ ]  No [ ]  Yes– Please describe:       |
| F.5. Device Supply |
| Number of devices sent to E&I reviewed physician users? |      : attach a list of physicians with number of units sent |
| Number of devices used by E&I reviewed physician users? |       |
| F.6. Device Experience |
| Did anything unexpected or unanticipated occur at *any* (not just E&I) site? | [ ]  No or       |
| How many devices were used for other than the labeled use? | [ ]  Unknown or        |

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| Signature and Assertion |
| * The above information is true to my knowledge and will be updated as necessary.
* I am submitting this information on behalf of the HDE holder
* The company will remain in contact with the IRB and will report any Unanticipated Problem involving the device or its use to the IRB promptly.
 |
| Signature | Printed Name      | Date      |