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. As humanitarian devices must be IRB reviewed using some of the same rules as clinical studies, updated information is required. This form is for the physician user.

**Inclusion of the following item(s) are required for review. Checkmark each that you have attached:**

This form, signed on paper  Updated CV or Medical License, if applicable

**MAKE A COPY FOR YOUR REGULATORY FILE.**

**Submit to:** [**submit@eandireview.com**](mailto:submit@eandireview.com)

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| 1. Submission Information | |
| **A.1. E&I Approval Number** | **A.3. Complete the rest of this form** **regardless of what is selected below** |
| Final Report: I will not be using this humanitarian device again. |
| **A.2. IRB Expiration Date** | Continuing Review: I would like continued access to this humanitarian device. |
| Other: |

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

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| 1. Primary Physician User | | | |
| C.1. Primary Physician User | | | |
| Name (with degrees) |  | E&I prefers to send correspondence by email.  Regulatory correspondence should be sent by… | |
| Company/Facility Name |  | Fax |  |
| Mailing Address |  | Email |  |
| City, State, Zip |  |  |  |
| Phone |  |  | |
| C.2. Contact Person (if different than the Primary Physician User) | | | |
| Name (with degrees) |  | Phone |  |
| Title |  | Cell |  |
| Company/Facility Name |  | Fax |  |
| Mailing Address |  | Email |  |
| City, State, Zip |  |  |  |

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| 1. Performance Site and Other Users | | | | | |
| D.1. Where will the device be used? | | | | | |
| Site Name |  | Regulatory correspondence should be sent by… | | | |
| Location Address |  | Fax | |  | |
| City, State, Zip |  | Email | |  | |
| Director’s Name & Title |  |  ***Current*** contact person at the site is required. | | | |
| Has there been a change in IRB jurisdiction since the last IRB review? | No or  Yes – Please explain: | | | | |
| Was the device used at a site other than the one listed above by you or your secondary physician users? | No or  Yes – Please explain: | | | | |
| **D.2.** **Secondary Physician Users**  You have the option to list secondary (other) physician users under your responsibility below…  **By not completing section D.2 or attaching a list, you are confirming there are no additional users or sites.** | | | | | |
| Name (with degrees): |  | | Email/Fax: | |  |
| Previouly approved? | Yes or  No – Please include their CV, medical license and mailing address | | | | |
| Will he/she use the same performance site listed on section D.1? | Yes or  No – Please explain: | | | | |
| **D.3. More Sites or Secondary Physician Users?** Attach a list if there is more than one site or multiple users. | | | | | |

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| 1. Device – Update Information | | |
| E.1. Changes: Is there new information or changes since the last review of this device? | | |
| Changes to the FDA Regulatory Device Status | | No or  Yes – Please describe: |
| New Information about safety | | No or  Yes – Please describe: |
| New Information about efficacy | | No or  Yes – Please describe: |
| New informational materials for patients | | No or  Yes – Please describe: |
| E.2. Activity: Device Use and Accountability since your last IRB review | | |
| How many Devices have you received? |  | |
| How many Devices do you have remaining? | Are they stored in a well-controlled place?  Yes  No | |
| How many Devices have you (or your secondary physician) used? | If “0” – you may skip the two following questions | |
| Was this device used outside it’s approved indication?  No or  Yes – Please explain: | | |
| Did anything unexpected or unanticipated occur with its use?  No or  Yes – Please describe: | | |

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| 1. User – Update Information | |
| F.1. Changes: Since your last IRB review have you made or had any changes affecting: | |
| Your stock or patent position with the device company? | No or  Yes – Please describe: |
| Your license or privileges, or legal problems affecting your practice? | No or  Yes – Please describe: |

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| --- | --- | --- |
| G. Signature and Assertion | | |
| * The information provided in this form is true to my knowledge and will be updated as necessary. * I am the Primary Physician User responsible for this submission. | | |
| Signature | Printed Name | Date |