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**

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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:       |

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| 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
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| 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
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| 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      |