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| **For REB Use Only** |  | HW_HC_3C(RGB)_NoTag cropped |
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**HOMEWOOD’S Research Ethics Board (REB)**

# **SERIOUS ADVERSE EVENT REB NOTIFICATION FORM**

*This form is available in MS WORD format and can be downloaded at: www.homewood.org*

**Handwritten submissions are NOT acceptable**

To be completed electronically, printed, signed and submitted to the Research Ethics Board. In the case of **on-site** adverse events, **three** copies of this form should be submitted while in the case of **off-site** events only **two** should be submitted. Adverse events from this site should be reported to the REB at the same time as reporting to the sponsor. Serious Adverse events occurring at this site will be reviewed by the Research Ethics Monitor.

**Date:**

**REB #:**

**Study Title:**

**Local Site Principal Investigator:**

**Number of Participants Recruited to Date at local site:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| This adverse event occurred (please select one): | | | | | | |
|  | | | | | | |
|  | On-Site | |  | Off-Site | | |
| * Three (3) copies submitted | | * Two (2) copies submitted | | |
|  | | | | | | |
|  | | | | | | |
|  | | | | | YES | NO |
| Is this a follow-up report to the initial report? | | | | |  |  |
| If yes, please indicate the date of the initial report: | |  | | | | |
|  | |  | | | | |
| Do these Adverse Events require changes to the protocol? | | | | |  |  |
| Do these Adverse Events require changes to the consent form? | | | | |  |  |
| Should Participants be notified of these Adverse Events? | | | | |  |  |
| Is this agent/drug used for other purposes outside this study? | | | | |  |  |
| Should the hospital pharmacy be made aware of these Adverse Events? | | | | |  |  |
| Is full REB review required? | | | | |  |  |

|  |
| --- |
| Principal Investigator Comments (explain): |
|  |

DECLARATION BY PRINCIPAL INVESTIGATOR

I warrant that this study will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the Ontario Personal Health Information Protection Act (PHIPA) 2004, and other relevant laws, regulations or guidelines, [e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6].

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name of Principal Investigator | Signature | Date |

TO BE COMPLETED BY THE RESEARCH ETHICS BOARD  
  
I acknowledge that the Homewood Hospital Research Ethics Board has received the documents listed above.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name of REB Member | Signature | Date |