**Howard University Institutional Review Board (IRB):**

**SERIOUS ADVERSE EVENT REPORTING FORM**

Do not leave fields blank. Please complete each field, indicating “N/A” as needed. When completing this form, refer to the IRB [Unanticipated Problem and Adverse Event Reporting Policy](http://www.orrchoward.com/IRB_PP_01_17_19_Section15.pdf). Please print after completion, sign and date, and submit to IRB with accompanying documentation to the IRB. Contact the IRB Office at (202) 865-8597 with any questions.

|  |  |
| --- | --- |
| IRB #:  | Principal Investigator:  |
| Protocol Title:  |
| Subject ID (Initials/Study ID#):       | SAE/UP reference name or number*(short name / number such as “hospitalization for pneumonia” or SAE/UP # M-A14-2)*:       |
| Report Type (check all that apply): [ ]  Internal *or* [ ]  External [ ]  Initial *or* [ ]  Follow-up  |

|  |  |  |
| --- | --- | --- |
| Date of Event:       | Date PI/research team learned of event:       | Date of Report:       |
| Is this report being submitted on time1, 2? *(within the required number of business days from the date the PI / research team learned of the event)* [ ]  Yes [ ]  No1. **An Unanticipated Problem must be reported within 7 business days of learning of the event.**
2. **A Serious Adverse Event (SAE) that is NOT an unanticipated problem must be reported within 15 business days of learning of the event.**
 |
| **If no**, please explain why the report is late and provide a corrective action plan to prevent late submissions in the future *(attach additional pages, as needed)*:      Have additional pages been attached?: [ ]  Yes [ ]  No |

**Summary description of the event:**

*Attach additional pages, as needed, along with other supporting documentation. Refer to the study subject by study ID # and/or initials – do not use subject name, medical record #, or other identifiers. Remove / black out all identifiers in attached reports*.

Have additional pages been attached?: [ ]  Yes [ ]  No

**A. *Serious Adverse Event (SAE)***

Nature of event (check all that apply):

[ ]  resulted in *death*

[ ]  was *life-threatening*

[ ]  resulted in *hospitalization* or *prolongation of existing hospitalization*

[ ]  resulted in a *persistent or significant disability/incapacitation*

[ ]  resulted in a *congenital anomaly/birth defect*

[ ]  may *jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed above*.

[ ]  **Event is a SAE:** Is one or more of the above 6 boxes checked?

 If yes, the event is a *SAE* – *check this box*.

**B. *Unanticipated Problem***

 Event (check all that apply):

[ ]  was *Unexpected*

[ ]  was *Related* or *Possibly Related* to participation in the study

[ ]  may place subject(s) or others at greater risk of harm than *previously* recognized

[ ]  **Event is an** **Unanticipated Problem:** Are **all 3** of the above boxes checked?

 If yes, the event is an *Unanticipated Problem – check this box.*

**C. Status of research activities**

Please check all that apply:

[ ]  No change in research activities

[ ]  All research activities have been temporarily and voluntarily stopped for all subjects

[ ]  Partial voluntary hold on some research activities for all subjects (please detail below)

[ ]  Voluntary hold on new subject enrollment only

If event is an *Unanticipated Problem*, please describe how subject safety for continuing research activities is being ensured, and describe corrective actions already taken to ensure safety of currently enrolled subjects:

**D. Study protocol and informed consent form(s) (ICFs)**

Please check all that apply:

Study protocol

Requires changes as a result of the event\* [ ]  Yes [ ]  No

ICF(s)

Requires changes as a result of the event\* [ ]  Yes [ ]  No

|  |
| --- |
| **If no** protocol or ICF changes are required, and this is a report of anunanticipated problem or SAE that is related or possibly related to study participation, provide a brief justification for not making changes to the protocol or ICF and/or not notifying (re-consenting) subjects:       |
| **If yes** (protocol and/or ICF changes are required): Do currently enrolled subjects require notification or re-consenting as a result of the event\*?[ ]  Yes [ ]  NoDetail when and how notification and/or re-consent will occur (*e.g.*, at next clinic appointment, immediate telephone notification to subjects):       |

\* All protocol and ICF revisions or other new materials (*e.g.*, a letter of subject notification) must be approved by the IRB before study enrollment can proceed, and, when indicated, subject participation in study activities may continue.

*This form is for Howard University IRB reporting only.**Reporting requirements for outside agencies (for example, study sponsor, funding agency, FDA) are the responsibility of the Principal Investigator (PI).*

Report prepared by:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

 Signature

**PI Attestation:**

I have reviewed all of the information included in this report and confirm it is accurate based on review of all available information concerning the reported event.

Principal Investigator:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

 Principal Investigator’s Signature

**IRB Office Review – Office use only:**

[ ]  No further action required

[ ]  Request PI to submit follow-up regarding the SAE / UP, when available

[ ]  Additional information or clarification required

[ ]  Protocol and ICF changes will be reviewed separately

[ ]  Recommend further review by convened IRB

**Corrective Action Plan:** [ ]  **Applicable** [ ]  **Not Applicable**

[ ]  Corrective action plan determined to be acceptable

[ ]  Submission of a corrective action plan or revisions to the proposed corrective action plan required

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Signature of Reviewer Date

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Printed name of Reviewer