**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  No   1. **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  No  Detail 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