# **APPENDIX B:** Single-site Sample Serious Adverse Event Form

Version\_November 2020

## SAMPLE SERIOUS ADVERSE EVENT FORM

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| **Protocol Number:** |
| **Protocol Title:** |
| 1. **Principal Investigator Name:** 2. **Phone #:** 3. **Fax:** 4. **E-mail:** |
| 1. **Participant ID:** |
| 1. **Participant Age:** |
| 1. **Participant sex:** 2. ☐ Male 3. ☐ Female 4. ☐ Unknown 5. ☐ Undifferentiated |
| 1. **Type of report:** 2. ☐ Initial 3. ☐ Follow-up # |
| 1. **Serious Adverse Event (SAE) name or diagnosis:** *(one or two words, full description is provided in Question 7)* |
| 1. **Brief narrative summary of the event including:** *(A brief but clear description of relevant signs, symptoms, and objective findings. The current best assessment resulting from the findings and the plan including any appropriate further diagnostic workup to be undertaken and plan of treatment including if it should be started immediately or based on further workup. The planned timing for the workup and any decision points about treatment should be included. The investigators current (working) diagnosis with rationale which can then be modified based on additional workup to a final diagnosis.**Attach description if more space needed*). |
| 1. **Date of report** (dd/mmm/yyyy)**:** |
| 1. **Date discovered** (dd/mmm/yyyy)**:** |
| 1. **SAE onset date** (dd/mmm/yyyy): |
| 1. **SAE stop date** (dd/mmm/yyyy):  or check if Ongoing ☐ |
| 1. **Did the participant receive the study intervention prior to this SAE?** 2. ☐ Yes; If yes, last date study intervention given (dd/mmm/yyyy): 3. ☐ No 4. ☐ N/A |
| 1. **Action taken with the study intervention due to SAE:** 2. ☐ None 3. ☐ Dose decreased 4. ☐ Dose increased 5. ☐ Dose delayed 6. ☐ Discontinued permanently 7. ☐ Discontinued temporarily 8. ☐ Other, brief description: |
| 1. **What medications or other steps (i.e., procedures, tests) were taken to treat participant due to this SAE?** (*Note: please list or provide separately with concomitant medications/treatments and laboratory results if there are too many to record here*) (Please provide medical records if possible): |
| 1. **Was this SAE unexpected?** (*An unexpected event is one that is not described in the protocol, informed consent or package insert/Investigator Brochure):*     1. ☐ Yes    2. ☐ No |
| 1. **Criteria met for this SAE (21 CFR 312.32(a))**[[1]](#footnote-2): 2. ☐ Death – date of death (dd/mmm/yyyy): 3. ☐ Life-threatening 4. ☐ Inpatient hospitalization or prolongation of existing hospitalization 5. ☐ Persistent or significant incapacity or substantial disruption of the ability to conduct  normal life functions 6. ☐ Congenital anomaly/birth defect 7. ☐ Required intervention to prevent permanent impairment 8. ☐ Other important medical event that jeopardized participant, and may require medical/surgical intervention to prevent one of the outcomes listed in “a” through “e” above.  Specify: |
| 1. **Severity of SAE:** 2. ☐ Mild 3. ☐ Moderate 4. ☐ Severe |
| 1. **Relationship of SAE to study intervention:** *(relatedness criteria on the AE and SAE form should match)* 2. ☐ Not related (clearly not related to the intervention) 3. ☐ Possibly/Probably (may be related to the intervention) 4. ☐ Definitely related (clearly related to the intervention) |
| 1. **Have similar SAEs occurred on this protocol?** 2. ☐ Yes; If yes, how many?   Provide a description:   1. ☐ No |
| 1. **What steps do you plan to take as a result of the SAE reported above?** *(Provide documentation to the IRB for review and approval of any of the steps checked below)* 2. ☐ No action 3. ☐ Modification of consent documents to include a description of newly recognized risks  (site and/or study wide) 4. ☐ Revised protocol to eliminate apparent immediate hazards to participants 5. ☐ Notify current enrolled participants 6. ☐ Suspension of enrollment of new participants 7. ☐ Other, specify: |
| 1. **Does this event meet the definition of an unanticipated problem (per OHRP definition[[2]](#footnote-3))?** 2. ☐ Yes *(i.e., SAE is unexpected and definitely related or possibly/probably related)* 3. ☐ No   *\*****If yes, complete separate Unanticipated Problem form.*** |

**PI Signature**:

**Date** (dd/mmm/yyyy):

1. The criteria for a serious adverse event or serious suspected adverse reaction in FDA regulations is defined at 21 CFR 312.32(a): <https://www.fda.gov/media/79394/download>. [↑](#footnote-ref-2)
2. From HHS Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems>. [↑](#footnote-ref-3)