# **APPENDIX A:** Single-site Sample Adverse Event Form

Version\_November 2020

## SAMPLE ADVERSE EVENT FORM

### Study Name

|  |  |
| --- | --- |
| **Participant ID:** | **Date (dd/mmm/yyyy):** |

**H****as the participant had any Adverse Events (AEs) during this study? ☐ Yes ☐ No *(If yes, please list all AEs below)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity** | **Study Intervention  Relationship**[[1]](#footnote-2) | **Action taken with Study** **Intervention due to AE** | **Outcome of AE** | **Unexpected\*** | **Serious** | **Unanticipated Problem (UP)** |
| 1 = Mild  2 = Moderate  3 = Severe | 1 = Definitely related  2 = Possibly/ Probably related  3 = Not related | 1 = None  2 = Discontinued permanently  3 = Discontinued temporarily  4 = Dose decreased  5 = Dose increased  6 = Dose delayed  7 = Other, specify | 1 = Recovered, without treatment  2 = Recovered, with treatment  3 = Still Present, no treatment  4 = Still Present, being treated  5 = Residual effect(s) present-no treatment  6 = Residual effect(s) present-being treated  7 = Subject Died | 1 = Yes  2 = No | 1 = Yes  2 = No  (If yes, complete SAE form) | 1 = Yes  2 = No  (If yes, complete UP form) |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Event** | **AE Onset** **Date** | **AE Stop** **Date** | **Severity** | **Relatedness** | **Action taken with study intervention due to AE** | **Outcome** | **Unexpected?** | **Serious?** | **UP?** | **Initials** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

1. Please note if an AE is unexpected **and** is related or possibly/probably related  **and** suggests that the research places participants or others at a greater risk of physical or psychological harm than was previously known or recognized (if the AE is serious, then the answer to the third criteria is always yes), it is an **unanticipated problem**.

   **SS\_Adverse Event Form**

   ***Version\_November 2020*** [↑](#footnote-ref-2)