# **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 = Mild2 = Moderate3 = Severe | 1 = Definitely related2 = Possibly/ Probably related3 = Not related | 1 = None2 = Discontinued permanently3 = Discontinued temporarily4 = Dose decreased5 = Dose increased6 = Dose delayed7 = Other, specify | 1 = Recovered, without treatment2 = Recovered, with treatment3 = Still Present, no treatment4 = Still Present, being treated5 = Residual effect(s) present-no treatment6 = Residual effect(s) present-being treated7 = Subject Died | 1 = Yes2 = No | 1 = Yes2 = No(If yes, complete SAE form) | 1 = Yes2 = 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**

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