**ADVERSE EVENT (AE) REPORT FORM**

|  |  |
| --- | --- |
| STUDY TITLE |  |
| PROTOCOL NO. |  | PATIENT ID |  | DATE |  |
| SITE |  | SITE NUMBER |  |

This form captures adverse events of a single participant throughout the study.

| ADVERSE EVENT | START DATEdd-mm-yyyy | STOP DATEdd-mm-yyyy | SEVERITY | RELATIONSHIP | ACTION TAKEN | OUTCOME OF AE | EXPECTED (Y/N) |  \*SAE (Y/N) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
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Participant had no adverse events (to be completed at the end of study): [ ]  NONE *\*Fill out SAE form if Yes is answered.*

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|  |  |  |
| Print Name of Principal Investigator | *Signature of Principal Investigator* | *Date* |

Adverse Event (AE) Report Form Key

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| --- | --- | --- | --- | --- |
| CODE | SEVERITY | RELATIONSHIP | ACTION TAKEN | OUTCOME OF AE |
| 00 |  | Not related | None |  |
| 01 | Mild | Unlikely related | Does modification | Resolved |
| 02 | Moderate | Possibly related | Medical intervention | Recovered with minor sequelae |
| 03 | Severe | Probably related | Hospitalization | Recovered with major sequelae |
| 04 | Life-threatening | Definitely related | Intervention discontinued | Ongoing treatment |
| 05 |  |  | Other, describe | Condition worsening |
| 06 |  |  |  | Death |
| 07 |  |  |  | Unknown |

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