**[](http://bit.ly/2K2xeNU)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 DATE  dd-mm-yyyy | STOP DATE  dd-mm-yyyy | SEVERITY | RELATIONSHIP | ACTION TAKEN | OUTCOME OF AE | EXPECTED (Y/N) | \*SAE  (Y/N) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Participant had no adverse events (to be completed at the end of study):  NONE *\*Fill out SAE form if Yes is answered.*

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

Adverse Event (AE) Report Form Key

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 |

|  |
| --- |
| **DISCLAIMER**  Any articles, templates, or information provided by Smartsheet on the website are for reference only. While we strive to keep the information up to date and correct, we make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability with respect to the website or the information, articles, templates, or related graphics contained on the website. Any reliance you place on such information is therefore strictly at your own risk.  This template is provided as a sample only. This template is in no way meant as legal or compliance advice. Users of the template must determine what information is necessary and needed to accomplish their objectives. |