**Study Title: IRB #:
Principal Investigator: Subject ID\*:**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse event** | **Start and stop dates** | **Serious** | **Severity****(Oncology Studies, Use CTCAE 1-5 system)** | **Relationship to study agent** | **Expected?** | **Action taken with the study agent** | **If Serious, date PI became aware** | **Was the SAE reported to the sponsor?** | **Was the SAE reported to the IRB?**  | **PI initials and date** | **Comments/PI Initials at AE Closure** |
|  | Start:Stop: | [ ] Yes[ ]  No  |   | □Not related□Possibly related Related□Related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other: |  | [ ]  No [ ] YesDate: | [ ]  No [ ] YesDate: |  |  |
|  | Start:Stop:  | [ ] Yes[ ]  No  |  | □Not related□Possibly related Related□Related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other: |  | [ ]  No [ ] YesDate: | [ ]  No [ ] YesDate: |  |  |
|  | Start:Stop: | [ ] Yes[ ]  No  |  | □Not related□Possibly related Related□Related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other: |  | [ ]  No [ ] YesDate: | [ ]  No [ ] YesDate: |  |  |
|  | Start:Stop: | [ ] Yes[ ]  No  |  | □Not related□Possibly related □Related□Unknown  | [ ] Yes[ ]  No  | [ ]  None[ ]  Reduced [ ]  Interrupted[ ]  Discontinued [ ]  Other: |  | [ ]  No [ ] YesDate: | [ ]  No [ ] YesDate: |  |  |

**Instructions**

1. Adverse events (AEs) begin to be collected and assessed after the subject signs the informed consent form and should be followed until event resolution.
2. The Principal Investigator (PI) or Sub-Investigator to whom the PI has delegated adverse event assessment should complete the assessment/evaluation of each AE and sign/date this assessment. If the AE is still ongoing at the time of assessment, then the PI should sign again in the last column when the AE is closed/resolved.
3. Each adverse event should be listed on separate rows. Don’t combine symptoms-i.e. “Flu with shortness of breath.” Flu would be listed as one event, shortness of breath as another event.
4. **Start date** is when subject first experiences or exhibits symptoms/manifestations of adverse events.
5. **Stop date** is when AE becomes resolved, or reaches a stable condition that is unlikely to improve.
6. A **Serious Adverse Event (SAE)** is an adverse event that results in any of the following outcomes:
	1. Death;
	2. Life threatening;
	3. Permanent disability;
	4. Inpatient hospitalization or prolongs existing hospitalization (NOTE: ER visits are not SAEs)
	5. Congenital Anomaly/Birth defect.
7. In oncology studies, severity is assessed by the CTCAE system with AEs graded as 1 (least severe)-5 (most severe). For non-oncology studies, use the protocol definitions to rate severity. If the protocol doesn’t require severity assessments, remove column. **NOTE: DETERMINING SEVERITY IS NOT THE SAME AS DETERMINING THE SERIOUSNESS OF ADVERSE EVENTS**.
8. To determine the relationship/causality of the AE to the test article (drug, device or procedure), the Investigator should consider the following:
	1. Known side effect(s) of test article (look for this info in Protocol, ICF, IDB)
	2. Timing of the AE in relationship to test article:
		1. The PI should look at the sequence of time, from the drug’s administration, device’s implantation or activation, or procedure and the onset/stopping of the AE.
9. An AE may be considered “unexpected” in terms of nature, severity and frequency, if:
	1. It is not listed in the current protocol, investigator’s brochure, consent form, or other relevant sources of information such as product labeling and package inserts; or if
	2. It is not characteristic of the subject population being studied and it is not consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject, and the subject’s predisposing risk factor profile.
10. Follow the protocol guidelines regarding SAE reporting requirements to sponsor.
11. For IRB reporting, typically SAEs that are unexpected and related/possibly related to the study intervention should be promptly reported to the IRB (i.e. within 24 hours of PI becoming aware).