## SERIOUS ADVERSE EVENT REPORTING FORM

All Serious Adverse Events (SAEs) occurring in studies overseen by the CTSI DSMB, regardless of relationship to the study drug/device/procedure, must be reported within 10 working days of awareness (2 days for deaths). Please refer to the **adverse event reporting algorithms** at the end of this form.

**UCLA IRB #:**

**Study Title:**

**Principal Investigator:**

**Study drug/device/procedure (s):**

**Type of report:** [ ] Initial report [ ]  Follow-up report [ ]  Final report

**Subject Study #** \_\_\_\_\_ **Subject Initials** \_\_\_\_\_ Age \_\_\_\_\_ Sex \_\_\_\_\_

**Study site name:**

**The adverse event was:** [ ]  Serious [ ]  Unexpected [ ]  Both Serious and Unexpected

 [ ]  Other (please specify)

**Date of Event:** \_\_\_\_\_

**Event outcome** (check all that apply):

 [ ]  Death

 [ ]  Required or prolonged hospitalization

 [ ]  Life-threatening

 [ ]  Medically significant

 [ ]  Required intervention

 [ ]  Persistent or significant Disability

 [ ]  Congenital abnormality/birth defect

**Study treatment**

|  |  |  |
| --- | --- | --- |
| Name of treatment (drug/device/procedure) | Start date | Last treatment date (prior to SAE) |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |

 NOTE: Please include start and stop dates of all study treatments.

**Event Information**: List all symptoms, diagnosis, conditions etc. (e.g. diarrhea, bleeding, DVT)

|  |  |  |  |
| --- | --- | --- | --- |
| Symptom, diagnosis, etc. | Grade/severity**a** | Relationship to study drug/device/procedure**b, c** | Is the event described in the following?**d** |
| Investigator Brochure  | Protocol | Informed Consent Form |
| 1. |  |  |  |  |  |
| 2. |  |  |  |  |  |
| 3. |  |  |  |  |  |

**a** Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life-threatening/disability),

Grade 5 (death)

**b** Include one of the following relationships: Definitely related, probably related, possibly related, unlikely related, not related, unknown

**c** Include the study drug/device/procedure along with the relationship

**d** Indicate Yes or No or NA (for Investigator Brochure if there is no IB)

**Event Description**:

Provide a brief description of adverse event including any treatment provided to the subject. NOTE: This section must be completed. Reference to attached supporting documents (i.e. physician’s notes) does **not** replace the investigator’s description/summary and assessment. *A separate sheet may be attached if more space is needed.*

**Change in protocol:**

In your judgment is a change in your protocol necessary to reduce or eliminate risk to subjects?

[ ]  Yes (Please attach proposal)

[ ]  No (Please check appropriate box below)

[ ]  Protocol procedures are in place to reduce/eliminate risk

 [ ]  Other (please specify rationale below)

**Change in informed consent/assent document(s):**

Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of subjects?

[ ]  Yes (Please submit the revised documents to IRB for approval and use)

[ ]  No (Please check appropriate box below)

[ ]  Event noted in the current informed consent form

[ ]  Other (please specify rationale)

Signature of Principal Investigator Date

# DEFINITIONS

|  |  |
| --- | --- |
| **Adverse event:** an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention. | **Unexpected adverse event**: an event when the specificity or severity is not consistent with the investigator brochure or general investigative plan (protocol). |
| **Serious adverse event:** any event that may result in the following - death, a life threatening experience, a required or prolonged hospitalization, persistent or significant disability, congenital anomaly/birth defectand any event requiring intervention to prevent one of the outcomes listed above. | **Related** **adverse event:** when there is a reasonable possibility that the adverse event is caused by the drug/device/procedure. |

**Adverse Event reporting algorithms**

**Reporting of Internal Adverse Events (not including deaths) to the CTSI DSMB**

Study Overseen by CTSI DSMB? NO Do not submit to CTSI DSMB

YES

Is the event Serious? NO Report to CTSI DSMB in Summary Report

YES

Submit to CTSI DSMB within **10** working days of awareness

**Reporting of Internal Subject Deaths (occurring from the time of consent and until 30 days after study treatment) to the CTSI DSMB**

Study Overseen by CTSI DSMB? NO Do not submit to CTSI DSMB

YES

Submit to CTSI DSMB within **2** working days of awareness

**Reporting of External Adverse Event Reports (those reports issued by the study sponsor or drug manufacturer) to the CTSI DSMB**

Study Overseen by CTSI DSMB? NO Do not submit to CTSI DSMB

YES

Submit to CTSI DSMB within **10** working days of awareness