|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AE Recorder’s Initials & date** | **Adverse Event** | **Date of Onset** | **Intensity** | **Attribution to Study Treatment** | **Action take with study treatment** | **Is AE a result of a con med?** | **Other action taken for AE?** | **SAE or AESI?**  **If SAE, report required** | **Is event ongoing** | **Outcome** | **Outcome Date** | **PI Signature** |
|  |  |  | **1=mild**  **2= moderate**  **3= severe** |  | **1 = dose not changed**  **2 = drug interrupted**  **3 = drug withdrawn**  **4 = NA** |  | **1=none**  **2= hospitalization (new or prolonged)**  **3=Con med**  **4=Procedure** |  |  | **1 = Fatal**  **2 = Not recovered/resolved**  **3 = Recovered/Resolved**  **4 = Recovered/resolved w/Sequelae**  **5 = Recovering/Resolving**  **6 = Unknown** |  |  |
|  |  |  |  | Related  Not  Related |  | Yes  CM name: \_\_\_\_\_\_\_\_\_  No |  | AESI  SAE | Ongoing  □ Ongoing EOS |  |  |  |
|  |  |  |  | Related  Not  Related |  | Yes  CM name: \_\_\_\_\_\_\_\_\_  No |  | AESI  SAE | Ongoing  □ Ongoing EOS |  |  |  |
|  |  |  |  | Related  Not  Related |  | Yes  CM name: \_\_\_\_\_\_\_\_\_  No |  | AESI  SAE | Ongoing  □ Ongoing EOS |  |  |  |
|  |  |  |  | Related  Not  Related |  | Yes  CM name: \_\_\_\_\_\_\_\_\_  No |  | **AESI**  **SAE** | Ongoing  □ Ongoing EOS |  |  |  |

□ Check if no AEs reported during the study.