**Local SAE Report Form** \* No acknowledgment of receipt will be issued unless further action is required.

|  |
| --- |
| **STUDY INFORMATION:** |
| Ethics No.:       | Primary Investigator Name:       |
| Complete Title of Project Including Protocol Number:       |
| Ethics Approval Date:       | Study is: [ ] Ongoing [ ] Closed to Enrollment | No. subjects enrolled:       |
|  |
| **SAE Description:** |
| Report Type: **[ ]** Initial [ ] Follow Up *(No.* *, Initial Report Date:* *)* |
| Event: [ ] Death [ ] Life-threatening [ ] Hospitalized / Prolonged Hospitalization [ ] Important Medical Event [ ] Persistent or Significant Disability/Incapacity [ ] Congenital Anomaly/Birth Defect |
| SAE Report No. OR Subject No.:       | Event Date:       |
| Case Description Summary:       |
|  |
| **EVENT CLASSIFICATION:** |
| [ ] Serious [ ] Unexpected [ ] Related/Potentially Related *[ ] Downgrading previously reported event*\* Please only submit events that are serious **&** unexpected **&** related. If the event does not meet all three classifications, do not submit. |
| Justification that the event is serious AND unexpected for this protocol, AND related/potentially related to the study drug:       |
|  |
| **INVESTIGATOR ACTIONS:** |
| Implications of the SAE on the continuation of the study and any further actions that may be required:       |
| Response to the SAE:       |
| Patient Outcome: [ ] Resolved without sequelae [x] Resolved with sequalae [ ] Unresolved [ ] Death [ ] Unknown |
|  |
| **PRIMARY INVESTIGATOR SIGNATURE:** |

|  |
| --- |
| ***For HREBA – CTC Use Only:*** |
| *[ ]  No further action required* *[ ]  Request further information  (date request sent to investigator:      )**[ ]  Committee discussion required  (date of discussion:      )**[ ]  Document filed (date filed:      )* |

 |
|  |  |       |  |
|  | Date |  |