**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 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 | |  |