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

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| **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** *(refer to approved protocol definitions for exact reporting requirements)***:** |
| 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.:       | Report Date:       |
| Case Description Summary:       |
|  |
| **ADVERSE EVENT CLASSIFICATION** *(according to sponsor report)***:** |
| [ ] Serious [ ] Unexpected [ ] Related/Potentially Related [ ] Affect Conduct of Study *[ ] Downgrading previous report*\* Please only submit events that are serious **&** unexpected **&** related/potentially related **&** affect conduct of study.  If the event does not meet all four 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:** |
| Analysis of the significance of the current adverse experience in light of previous reports:       |
| Outline of any proposed protocol changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the unanticipated problem:       |
| Patient Outcome: [ ] Resolved without sequelae [ ] Resolved with sequalae [ ] Unresolved [ ] Death [ ] Unknown |
|  |
| **PRIMARY INVESTIGATOR SIGNATURE:** |

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| ***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 |  |