**NON-LOCAL SERIOUS ADVERSE EVENT (SAE) REPORT - CHREB**

**Ethics ID#** Click here to enter text.

**Complete Study Title:** Click here to enter text.

1. **Complete the following table:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Manufacturer’s SAE# and report type (initial/follow up/final)** |  **Date of Report (mm/dd/yyyy)** | **Country** | **Diagnosis of SAE** |  **Relationship to study drug/device/procedure (Possible, probable or definite)** |
| Click here to enter text. | Click here to enter a date. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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1. **As the Principal Investigator (PI), I have examined the above non-local SAEs and see a possible harmful trend to be concerned about:** Yes\* [ ]  No [ ]  Unknown [ ]

***\*NOTE:*** *If yes, please upload a letter specifying the possible harmful trend.*

1. **I have reviewed the above non-local SAEs and:**

Local ICF is still satisfactory [ ]  Local ICF needs to be modified\*\* [ ]

***\*\*NOTE:*** *If ICF changes are required, please submit any changes as a modification. In the modification, please indicate that a corresponding non-local SAE report was submitted.*

*Supporting documentation should be retained by the PI and be made available upon request unless required by the Sponsor or deemed necessary by the PI.*