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| **SAFETY EVENT REVIEW FORM** | | | |
| **Project Title/HREC #:** | Insert full project title/Insert HREC#. | | | |
| **PID #:** | Click or tap here to enter text. | **SAE #:** *(if applicable)*: | Click or tap here to enter text. |
| **SAE Term:**  *As per the SAE Term reported on the Expedited Safety Report Form* | Click or tap here to enter text. | | | |
| **Date of Onset:** | Click or tap to enter a date. | **SAE Severity Grade:** | Click or tap here to enter text. |

1. **SAE ASSESSMENT REGARDING RELATEDNESS AND EXPECTEDNESS TO STUDY INTERVENTION**

|  |  |  |
| --- | --- | --- |
| **1.1 Protocol Intervention** | Insert name of Protocol Intervention | |
| **1.2 Is this SAE ‘Related’ to Protocol Intervention?**  *Related means that a causal relationship between the intervention(s) and the adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.* | | ☐ Yes - *complete Q1.3*  ☐ No – *Skip to Q2.0* |
| **1.3 If related to Protocol Intervention, is this SAE ‘Expected’?**  *Expected means the event is consistent in nature and severity with the applicable IB/PI or is a known possible complication of non-therapeutic good intervention.* | | ☐ Yes ☐ No |

1. **OUTCOME OF REVIEW** *(Tick all that apply)*

|  |  |  |  |
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| **2.1 Is further Action Required?** | | ☐ Yes ☐ No | |
| **2.2 Is this event a SUSAR or URSAE or USADE?**  *Delete terms that are not applicable to study intervention* | | ☐ Yes[¹](#REPORTING) ☐ No | |
| **2.3 Is this event a Significant Safety Issue (SSI)?** | | ☐ Yes[²](#REPORTING) ☐ No | |
| 1. Is this event an Urgent Safety Measure (USM)? | | ☐ Yes[³](#REPORTING) ☐ No | |
| 1. Does the Protocol require amending? | | ☐ Yes ☐ No | |
| 1. Do the Participant Information and Consent Forms require amending? | | ☐ Yes ☐ No | |
| 1. Is a temporary halt or early termination of the trial required? | | ☐ Yes ☐ No | |
| **2.4 Other Action Required**? | | ☐ Yes *– Complete below*  ☐ No *– Skip to 3.0* | |
| Details of action plan in response to SAE | | | |
| ¹*Report SUSARs and USADEs to TGA within 7 days of becoming aware of the event if fatal/life-threatening, otherwise report within 15 calendar days* | ²*Please report to TGA, HREC and all site PIs within 15 days of becoming aware of event* | | ³ *Report to TGA, HREC and RGO within 72 hours of becoming aware of event* |

1. **SAE REVIEWED BY:**

|  |  |
| --- | --- |
| **Reviewer Name:** | Reviewer Name |
| **Reviewer Signature:** |  |
| **Date of Review:** | Click or tap to enter a date. |

**Please return one signed copy to the *[Insert Name]* Study Coordinator at** [***[insert***](mailto:[insert) ***email address]*** **within 24 hours of review.**

*[If applicable, also include instructions to provide copy of report to study DSMB]*