

SAFETY EVENT REVIEW FORM

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|---|---|--------------------------------|----------------------------------|
| 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: <i>As per the SAE Term reported on the Expedited Safety Report Form</i> | 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. |

1.0 SAE ASSESSMENT REGARDING RELATEDNESS AND EXPECTEDNESS TO STUDY INTERVENTION

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|---|--------------------------------------|--|--|
| 1.1 Protocol Intervention | Insert name of Protocol Intervention | | |
| 1.2 Is this SAE 'Related' to Protocol Intervention? <i>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.</i> | | | <input type="checkbox"/> Yes - complete Q1.3 <input type="checkbox"/> No – Skip to Q2.0 |
| 1.3 If related to Protocol Intervention, is this SAE 'Expected'? <i>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.</i> | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

2.0 OUTCOME OF REVIEW (Tick all that apply)

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|--|--|
| 2.1 Is further Action Required? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2.2 Is this event a SUSAR or URSAE or USADE? <i>Delete terms that are not applicable to study intervention</i> | <input type="checkbox"/> Yes ¹ <input type="checkbox"/> No |
| 2.3 Is this event a Significant Safety Issue (SSI)? | <input type="checkbox"/> Yes ² <input type="checkbox"/> No |
| a) Is this event an Urgent Safety Measure (USM)? | <input type="checkbox"/> Yes ³ <input type="checkbox"/> No |
| b) Does the <u>Protocol</u> require amending? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| c) Do the <u>Participant Information and Consent Forms</u> require amending? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| d) Is a temporary halt or early termination of the trial required? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2.4 Other Action Required? | <input type="checkbox"/> Yes – Complete below <input type="checkbox"/> No – Skip to 3.0 |

Details of action plan in response to SAE

¹Report SUSARs and USADEs to TGA within 7 days of becoming aware of the event if fatal/life-threatening, otherwise report within 15 calendar days

²Please 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

3.0 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 [\[insert email address\]](#) within 24 hours of review.

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