**SERIOUS ADVERSE EVENT SAFETY REPORT/SAFETY REPORTING**

**USE OF THIS FORM**

This form is for the reporting of suspected unexpected serious adverse reactions in sponsored clinical trials.

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text. | **PROTOCOL TITLE:** Click here to enter text. |
| **DATE OF THIS REPORT:** | Click here to enter a date. |
| **PRINCIPAL INVESTIGATOR:** | Click here to enter text. |
| **THERAPEUTIC PRODUCT NAME:** | Click here to enter text. |
| **NUMBER OF ADVERSE EVENTS INCLUDED IN THIS REPORT:** | Click here to enter text. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of Event** | **Event Name** | **Location** | **Event Related according to PI?** | **Did Participant remain in study?** |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal [ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |
| Click here to enter a date. | Click here to enter text. | [ ]  The Royal[ ]  External | ☐ Yes ☐ No | ☐ Yes ☐ No |

As a result of the above-mentioned events, there will be a change to the Protocol, consent form(s), and/or other study documents:

☐ Yes ☐ No

If yes, please list the documents that will be submitted to the REB for review:

Click here to enter text.

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*As the PI or Site Investigator, I confirm that the above information is true and accurate.*

*I confirm that this study has been conducted in compliance with TCPS2, ICH Good Clinical Practice Guidelines (ICH-GCP) and all applicable regulations and institutional policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Qualified/Principal Investigator Signature** **Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***