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| Significant Safety Issue Notification Form | | | | |
| **To be completed and sent to the HREC for all clinical trials (therapeutic goods and non-therapeutic goods)**  *SSIs that have been implemented as an urgent safety measure1 should be reported within* ***72 hours*** *of the sponsor becoming aware of the issue.*  *All other SSIs should be reported within* ***15 calendar days*** *of the sponsor becoming aware of the issue.*  A measure required to be taken in order to eliminate an immediate h​azard to a participant’s health or safety. | | | | |
| **HREC reference number:** | | Click here to enter text. | **Date of this report:** | Click here to enter a date. |
| **Sponsor:** | | Click here to enter text. | **Date the SSI occurred:** | Click here to enter a date. |
| **Coordinating Principal Investigator:** | | Click here to enter text. | **SSA reference number:** | Click here to enter text. |
| **Project title:** | | Click here to enter text. | | |
| Details of the Significant Safety Issue (SSI) | | | | |
| Please provide all relevant details of the SSI.  Click here to enter text. | | | | |
| Actions resulting from the SSI (Check all that apply) | | | | |
|  | ***Implementation of an Urgent Safety Measure*** | | | |
| Please specify the urgent safety measure taken and why it was necessary.  Click here to enter text. | | | | |
|  | ***Notification of an amendment*** | | | |
| *Is the Notification of an Amendment Form provided with this report?*  Yes:  No: | | | | |
| *If No, describe the nature of any planned amendment (e.g. revised protocol or PICF) and the likely timeframe for submission of the Notification of an Amendment to the HREC.*  Click here to enter text. | | | | |
|  | ***Temporary halt of the trial for safety reasons*** | | | |
| *Please**describe the scope of the halt - e.g. suspension of recruitment or cessation/interruption of trial treatment/intervention.*  Click here to enter text. | | | | |
| *Please provide details of the number of participants still receiving treatment in Australia at the time of the temporary halt and their proposed management.*  Click here to enter text. | | | | |
|  | ***Early termination of the trial for safety reasons*** | | | |
| *Please provide details of the number of participants still receiving treatment in Australia at the time of early termination and their proposed management.*  Click here to enter text. | | | | |
| *Please also comment on the consequences of early termination for the evaluation of the study results and provide the anticipated date when the final progress report will be provided to the HREC, if not provided with this notification.*  Click here to enter text. | | | | |

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| Declaration | | | | |
| **I declare that the information provided above is true and accurate.**  **Reported by (please check one and provide your contact details below):** | | | | |
|  | **Sponsor** | | | |
|  | **Sponsor’s delegate: person or organisation authorised by the sponsor** | | | |
| **Organisation:** | | Click here to enter text. | **Contact Name:** | Click here to enter text. |
| **Telephone:** | | Click here to enter text. | **E-mail:** | Click here to enter text. |
| **Signature:** | |  | **Date:** | Click here to enter a date. |
| Official Use | | | | |
| **Acknowledgement of Receipt: The [HREC Name] acknowledges receipt of the above** | | | | |
| **Name:** | | Click here to enter text. | **Position:** | Click here to enter text. |
| **Signature:** | |  | **Date:** | Click here to enter a date. |