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| Safety Report | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| This form should be used for reporting any type of safety event that occurs during the conduct of a clinical trial or health/medical research project.  The **sponsor** is responsible for reporting a safety event to the reviewing Human Research Ethics Committee (HREC), in accordance with [*Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016)](https://www.nhmrc.gov.au/guidelines-publications/eh59).  The site Principal Investigator (PI) should provide a copy to the site Research Governance Officer (RGO) as required. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Research Project | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| HREC reference number | | e.g. HREC/17/Abc/123 | | |  | | HREC approval date | | | | | | | | | | | Select date | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Local reference number | | Enter text | | |  | | Date of this report | | | | | | | | | | | Select date | | | | | | | | | | | |
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| Project title | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Sponsor | | Enter text | | |  | | Sponsor telephone | | | | | | | | | | | Enter text | | | | | | | | | | | |
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| Sponsor contact (Aus) | | Enter text | | |  | | Sponsor email | | | | | | | | | | | Enter text | | | | | | | | | | | |
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| Coordinating Principal Investigator (CPI) for project | | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
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| Study coordinator | | Enter text | | |  | | Study coordinator email | | | | | | | | | | | Enter text | | | | | | | | | | | |
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| Is the project a clinical trial? | | | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site name (organisation) | | Enter text | | |  | | Principal Investigator (PI) | | | | | | | | | | | Enter text | | | | | | | | | | | |
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| State/Territory | | Enter text | | |  | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |
| Safety Event | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Type of safety event | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Action taken | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Event ID (local reference) | | Enter text | | |  | | Status of event | | | | | | | | | | | Select one | | | | | | | | | | | |
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| Start date of event | | Select date | | |  | | End date of event | | | | | | | | | | | Select date | | | | | | | | | | | |
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| Description of event | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Relationship to investigational product (clinical trial only) | | | | | Select one | | | | | | | | | | | | | | | | | | | | | | | | |
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| Could the event adversely affect safety of participants, or materially impact the continued ethical acceptability or conduct of the research project? | | | | | | | | | | | | | | | | | | Select one | | | | | | | | | | | |
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| Impact on participant safety | | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
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| Impact on conduct of the research project | | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
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| Impact on documentation for the research project | | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
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| Action(s) recommended | | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
| *If changes are made to any documents approved by the HREC ,submit the amended document(s) together with an Amendment Request Form (available from* [*www2.health.vic.gov.au/about/clinical-trials-and-research*](https://www2.health.vic.gov.au/about/clinical-trials-and-research)*) for review by the HREC.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clinical trial participant notification (Victoria) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *If the event is a Suspected Unexpected Serious Adverse Reaction (SUSAR) or Unanticipated Serious Adverse Device Effect (USADE) that affected a participant at a site in Victoria, the Victorian Managed Insurance Authority (VMIA) must be notified of the event using this form. When notifying VMIA, include the participant’s initials, date of birth and UR number. Refer to the VMIA website* [*www.vmia.vic.gov.au*](http://www.vmia.vic.gov.au)*.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Declaration | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Name | Enter text | |  | | | Email | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| Organisation | Enter text | |  | | | Telephone | | | | | | | | | | | Enter number | | | | | | | | | | | | |

**Signature**

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**Date** Select date

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| *Office use only* | | | | |
| Research office acknowledgement – HREC | | | | |
| Name | Enter text |  | Position | Enter text |
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**Signature**

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