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| Annual Safety Reportfor a clinical trial involving an investigational medicinal product or investigational medical device | | | | | | | | |
| This form should be used by the **sponsor** to provide the reviewing Human Research Ethics Committee (HREC) with a summary of the evolving safety profile of the project.  The sponsor is responsible for reporting to the reviewing HREC, in accordance with [*Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016)](https://www.nhmrc.gov.au/guidelines-publications/eh59). | | | | | | | | |
| 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 |
|  | | | | | | | | |
| Project title | | Enter text | | | | | | |
|  | | | | | | | | |
| Sponsor | | Enter text | |  | | Sponsor telephone | | Enter text |
|  | | | | | | | | |
| Sponsor contact (Aus) | | Enter text | |  | | Sponsor email | | Enter text |
|  | | | | | | | | |
| Coordinating Principal Investigator (CPI) for project | | | | Enter text | | | | |
|  | | | | | | | | |
| Study coordinator name | | Enter text | |  | | Study coordinator email | | Enter text |
| Safety Profile | | | | | | | | |
| Description and analysis of new /relevant safety findings | | | | Enter text | | | | |
|  | | | | | | | | |
| Implications of the safety findings on the risk and benefit of the project | | | | Enter text | | | | |
|  | | | | | | | | |
| Describe any measures, taken or proposed, to minimise risk | | | | Enter text | | | | |
|  | | | | | | | | |
| Comment from sponsor | | Enter text | | | | | | |
| Safety Monitoring | | | | | | | | |
| Has the safety monitoring plan been reviewed or adapted in the past 12 months? | | | | | | | | Select one |
| *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/clinical-trial-research/monitoring-reporting)*) for review by the HREC.* | | | | | | | | |
| Has the safety monitoring plan been implemented? | | | | Select one | | | | |
|  | | | | | | | | |
| Does the project have a Data and Safety Monitoring Board (DSMB) or a designated safety committee/monitor? | | | | | | | | Select one |
|  | | | | | | | | |
| How many times has the DSMB or safety monitor reviewed the project in the past 12 months? | | | | Enter number | | | | |
|  | | | | | | | | |
| Have all relevant communications from the DSMB or safety monitor been submitted to the reviewing HREC? | | | | Select one | | | | |
| *If the recommendation of the DSMB or safety monitor has not yet been submitted to the reviewing HREC, attach it to this report.* | | | | | | | | |
| Comment on safety monitoring *(optional)* | | | | Enter text | | | | |
| Investigator’s Brochure (or Other Reference Safety Information) | | | | | | | | |
| *The reference safety information for a research project may be contained in an investigator’s brochure, product information, instructions for use or clinical investigational plan.* | | | | | | | | |
| Has the investigator’s brochure (or other reference safety information) been reviewed? | | | | | | | | Select one |
|  | | | | | | | | |
| Does the investigator’s brochure (or other reference safety information) require an update with new and relevant information? | | | | | | | | Select one |
| *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/clinical-trial-research/monitoring-reporting)*) for review by the HREC.* | | | | | | | | |
| Investigational Medicinal Product | | | | | | | | |
| Is the investigational product on the Australian Register of Therapeutic Goods (ARTG)? | | | | | | | | Select one |
|  | | | | | | | | |
| If No, describe the safety profile of the investigational medicinal product | | | | Enter text | | | | |
| Declaration | | | | | | | | |
| *To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.* | | | | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in accordance 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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| Comment | Enter text | | | |
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**Signature**

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| Research office acknowledgement – RGO | | | | | | |
| Name | | Enter text |  | Position | | Enter text |
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| Comment | | Enter text | | | | |
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**Signature**

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**Date** Select date

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