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| Suspected Breach Report Form (Third Party) | | | | | | | | | | |
| **Suspected Breach** is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.  Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC).  This form must be completed when a **third party** (e.g. individual / institution) wishes to report a suspected breach of Good Clinical Practice or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor. | | | | | | | | | | |
| Provide the following details | | | | | | | | | | |
| 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 | | | | | | | |
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| |  |  | | --- | --- | | Coordinating Principal Investigator (CPI) for project | Enter text | | | | | | | | | | | |
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| Reporter name | | | Enter text | | | | | | | |
|  | | | | | | | | | | |
| Organisation | | | Enter text | |  | | Contact details | Enter text | | |
|  | | | | | | | | | | |
| Reporter’s role in/connection to the project:  |  | | --- | | Enter text |  Details of the organisation/individual committing the suspected breach: | | | | | | | | | | |
|  | Enter text | | | | | | | |  |
|  | | | | | | | | |
| Details of the suspected breach **Provide:**   1. **A brief explanation of the suspected breach** | | | | | | | | |
|  | | | | | | | | |
|  | Enter text | | | | | | | |
|  | | | | | | | | |
| 1. **An explanation of where, how and when the suspected breach was identified**  |  |  | | --- | --- | |  | | |  | Enter text |  1. **Any further information**  |  |  | | --- | --- | |  | | |  | Enter text | | | | | | | | | |
| Declaration | | | | | | | | |
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| 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 | |  | |
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**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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**Date** Select date

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| Research office acknowledgement – RGO | | | | | | |
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**Signature**

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**Date** Select date

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