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| Non-serious Breach - Deviation Report | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| A **Deviation** is any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol and does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial. Deviations that are considered to be a **serious breach** should be reported using the **Serious Breach Report Form (Sponsor).**  To fulfil ICH-GCP requirements any **deviations** are to be reported to the **sponsor**. Not all deviations require reporting to the reviewing HREC but sites should decide according to site policy. A copy of this report should be provided to the Research Governance Officer (RGO) at the Principal Investigator’s site.  The **sponsor** in collaboration with the site Principal Investigator should complete this form to report a non-serious breach - deviation. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Research Project | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| HREC reference number | | | e.g. HREC/17/Abc/123 | |  | | HREC approval date | | | | | | | | | | | Select date | | | | | | | | | | | | |
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| 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 name | | | 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 | |  | |  |  |  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |  |  |  | |  |  | |  |
| Details of Non-serious Breach - Deviation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Record the date that the non-serious breach - deviation occurred  |  | | --- | | Select date |   **Brief explanation of the non-serious breach – deviation and risk assessment** | | | | | | | | | | | | | | | | | | |
|  | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Were any participants directly affected by the non-serious breach - deviation | | | | | | | | | | | | | | | | | | Select one | | | | | | | | | |
| |  |  | | --- | --- | | **If yes, provide an explanation** | Enter text |  Are there any actions recommended by the sponsor | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Specify action** | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
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| Declaration | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *To be completed by Sponsor/CRO 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 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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**Signature**

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| *Office use only (if applicable)* | | | | | | |
| Research office acknowledgement – HREC | | | | | | |
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