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| **RESEARCH SERIOUS BREACH REPORT FORM** | | | |
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| Serious breach: *A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project.*  **Within 72 hours** of being notified of the serious breach (confirmed by the sponsor), the **Principal Investigator (PI)** must report to the institution a serious breach occurring at a local site.  **Within 7 days** of confirming the serious breach, the **sponsor** must use this form to report a confirmed serious breach occurring during the conduct of a clinical trial to the CALHN Human Research Ethics Committee (HREC).  **Submit to** [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au) | | | |
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| 1. **PROJECT DETAIL** | | | |
|  |  |  |  |
| HREC reference | Enter number | CALHN reference | Enter number |
|  |  |  |  |
| MyIP reference | Enter number | Annual progress reporting is up to date | Select one |
|  |  |  |  |
| Project title | Enter text | | |
|  |  |  |  |
| Sponsor name | Enter text | Sponsor phone number | Enter number |
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| Sponsor contact name | Enter text | Sponsor email | Enter text |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
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| Trial coordinator name | Enter text | Trial coordinator email | Enter text |
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| 1. **REPORT** | | | |
|  |  |  |  |
| Report type | Select one | | |
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| 1. **DETAILS OF THE INSTITUTION/INDIVIDUAL COMMITTING THE SERIOUS BREACH** | | | |
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| Institution name | Enter text | Individual name (if applicable) | Enter text |
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| 1. **DETAILS OF THE SERIOUS BREACH** | | | |
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| Date of serious breach | Select date | Site (if applicable) | Enter text |
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| Impact category 1 | | Select one | |
|  |  |  |  |
| Impact category 2 (if applicable) | | Select one | |
|  |  |  |  |
| Impact category 3 (if applicable) | | Select one | |
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| Number of participants directly affected as a proportion of total number of participants enrolled e.g. 1/10 (if applicable) | | | Enter number |
|  |  |  |  |
| Provide explanation of where, how and when the serious breach occurred and how it was identified | Enter text | | |
|  |  |  |  |
| Provide any other relevant information | Enter text | | |
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| 1. **DETAILS OF ANY ACTION TO DATE** | | | |
|  |  |  |  |
| Provide detail of any investigations you/others are conducting | Enter text | | |
|  |  |  |  |
| Provide detail of the outcome of those investigations if completed (or details of when they will be available/reported) | Enter text | | |
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| Explain how the serious breach will be reported in the final report/publication | Enter text | | |
|  |  |  |  |
| Specify any corrective and preventative action implemented to ensure the serious breach does not occur again | Enter text | | |
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| *\*If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with projected timelines for completion and provide any further information in a follow-up report.* | | | |
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| 1. **DECLARATION** | | | |
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| The project is being undertaken in compliance with the approved proposal. | | | |
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| The project is being conducted in keeping with the conditions of ethical approval and local governance and subject to any changes subsequently approved. | | | |
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| The project is being conducted in accordance with International Council for Harmonisation and National Health and Medical Research Council standards. | | | |
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| The information provided in this report is complete and correct. | | | |
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| *I hereby declare that the foregoing is true and correct:* | | | |
|  |  |  |  |
| PI or sponsor authorised delegate name (whichever is relevant to the submission type) | Enter text | Date | Select date |
|  |  |  |  |
| **The PI (if not the submitter) must be copied into the submission email in lieu of a signature.**  **The sponsor authorised delegate (if not the submitter) must be copied into the submission email in lieu of providing a signature.** | | | |