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| **RESEARCH SAFETY REPORT FORM** | | | |
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| Significant Safety Issue (SSI): *A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.*  Suspected Unexpected Serious Adverse Reaction (SUSAR): *An adverse reaction that is both serious and unexpected.*  Unanticipated Serious Adverse Device Effect (USADE*): A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.*  **Without undue delay and no later than 72 hours** of becoming aware of the event, the **Principal Investigator** (PI) must report to the institution all SSI’s occurring at local site and SSI’s occurring at an external site implemented as an USM, as an amendment or as a temporary halt/early termination of a trial.  **Within 72 hours** of becoming aware of the event, the **PI** must report to the institution all SUSARs and USADEs arising from a local site.  **Within 72 hours,** the **sponsor** must notify the Human Research Ethics Committee (HREC) of a SSI implemented as an Urgent USM, as an amendment or as a temporary halt/early termination of a trial. All other SSIs must be notified **within 15 days** of the sponsor instigating or being made aware of the issue.  **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 |
|  |  |  |  |
| Sponsor contact name | Enter text | Sponsor email | Enter text |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
|  |  |  |  |
| Trail coordinator name | Enter text | Trail coordinator email | Enter text |
|  |  |  |  |
| 1. **REPORT** | | | |
|  |  |  |  |
| Report type | Select one | | |
|  |  |  |  |
| 1. **DETAILS OF SITE WHERE THE SAFETY EVENT OCCURRED** | | | |
|  |  |  |  |
| Site name | Enter text | PI name | Enter text |
|  |  |  |  |
| 1. **DETAILS OF THE SAFETY EVENT** | | | |
|  |  |  |  |
| Start date of event | Select date | End date of event | Select date |
|  |  |  |  |
| Relationship to investigational product (clinical trials only) | | Select one | |
|  |  |  |  |
| Is a Data Safety Monitoring Board appointed to the project? (clinical trials only) | | Select one | |
|  |  |  |  |
| Was the event described as a risk in the informed consent process? | | Select one | |
|  |  |  |  |
| Could the event materially impact the continued ethical acceptability or conduct of the project? | | Select one | |
|  |  |  |  |
| Provide a description of the event | Enter text | | |
|  |  |  |  |
| Describe any impact on participant safety | Enter text | | |
|  |  |  |  |
| Describe any impact on the conduct of the research project | Enter text | | |
|  |  |  |  |
| Provide any other relevant information | Enter text | | |
|  |  |  |  |
| 1. **DETAILS OF ANY ACTION TO DATE/TO BE TAKEN** | | | |
|  |  |  |  |
| Action type 1 | Select one | | |
|  |  |  |  |
| Action type 2 (if applicable) | Select one | | |
|  |  |  |  |
| Action type 3 (if applicable) | Select one | | |
|  |  |  |  |
| Specify other action taken (if applicable) | Enter text | | |
|  |  |  |  |
| Specify any further action to be taken (if applicable) | Enter text | | |
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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. | | | |
|  |  |  |  |
| *I hereby declare that the foregoing is true and correct:* | | | |
|  |  |  |  |
| PI or sponsor authorised delegate (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 providing a signature.**  **The sponsor authorised delegate reporting an SSI (if not the submitter) must be copied into the submission email in lieu of providing a signature.** | | | |