|  |
| --- |
| **RESEARCH SUSPECTED BREACH REPORT FORM (THIRD PARTY)** |
|  |  |  |  |
| Suspected breach: *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.*This form should be used when **a third party** (e.g. institution/individual) wishes to report a suspected breach of Good Clinical Practice or the protocol directly to the CALHN Human Research Ethics (HREC) without reporting through the sponsor.**Submit to** Health.CALHNResearchMonitoring@sa.gov.au |
|  |  |  |  |
| 1. **PROJECT DETAIL**
 |
|  |  |  |  |
| HREC reference | Enter number | CALHN reference | Enter number |
|  |  |  |  |
| MyIP reference | Enter number |  |
|  |  |  |  |
| Project title | Enter text |
|  |  |  |  |
| CPI/PI name | Enter text | CPI/PI email | Enter text |
|  |  |  |  |
| Trial coordinator name | Enter text | Trial coordinator email | Enter text |
|  |  |  |  |
| 1. **REPORTER**
 |
|  |  |  |  |
| Reporter name | Enter text | Reporter phone number | Enter number |
|  |  |  |  |
| Reporter institution | Enter text | Reporter email | Enter text |
|  |  |  |  |
| Role in/connection to the project | Enter text |
|  |  |  |  |
| 1. **DETAILS OF THE INSTITUTION/INDIVIDUAL COMMITTING THE SUSPECTED BREACH**
 |
|  |  |  |  |
| Institution name | Enter text | Individual name (if applicable) | Enter text |
|  |  |  |  |
| 1. **DETAILS OF THE SUSPECTED BREACH**
 |
|  |  |  |  |
| Date of suspected breach | Select date | Site (if applicable) | Enter text |
|  |  |  |  |
| Provide an explanation of where, how and when the suspected breach was identified | Enter text |
|  |  |  |  |
| Provide any other relevant information | Enter text |
|  |  |  |  |
| 1. **DECLARATION**
 |
|  |  |  |  |
| There is good evidence that a serious breach has occurred or I have become aware that the sponsor may have committed a serious breach. |
|  |  |  |  |
| The information provided in this report is complete and correct. |
|  |  |  |  |
| *I hereby declare that the foregoing is true and correct:* |
|  |  |  |  |
| Reporters name | Enter text | Date | Select date |
|  |  |  |  |
| **The reporter (if not the submitter) must be copied into the submission email in lieu of providing a signature.** |