|  |  |  |  |
| --- | --- | --- | --- |
| **RESEARCH DEVIATION REPORT FORM** | | | |
|  |  |  |  |
| Deviation: *Any breach, divergence, or departure from the requirements of good clinical practice or the clinical trial protocol.*  This report must be completed by the lead **Principal Investigator (PI) in collaboration with the sponsor** (where applicable)when reporting a deviation from the protocol or GCP occurring in a clinical trial or health/medical research project approved by the CALHN Human Research Ethics Committee (HREC).  Deviations arising from investigational medicinal products or investigational medical devices do not require reporting to CALHN Research Services **unless** they are considered serious breaches in which case they must be reported using the Research Serious Breach Report Form.  **Submit to** [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au) | | | |
|  |  |  |  |
| 1. **PROJECT DETAIL** | | | |
|  |  |  |  |
| HREC reference | Enter number | CALHN reference | Enter number |
|  |  |  |  |
| MyIP reference | Enter number | Project type | Select one |
|  |  |  |  |
| Project title | Enter text | | |
|  |  |  |  |
| Progress reporting is up to date | Select one |  |  |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
|  |  |  |  |
| Project coordinator name | Enter text | Project coordinator email | Enter text |
|  |  |  |  |
| 1. **SITE** | | | |
|  |  |  |  |
| Site name | Enter text | Site PI name | Enter text |
|  |  |  |  |
| 1. **DETAILS OF THE DEVIATION** | | | |
|  |  |  |  |
| Date of deviation | | | Select date |
|  |  |  |  |
| Provide a brief description of the deviation and risk assessment | Enter text | | |
|  |  |  |  |
| Provide any other relevant information | Enter text | | |
|  |  |  |  |
| Were any participants directly affected by the deviation? | | | Select one |
|  |  |  |  |
| Provide explanation of participants affected (if applicable) | Enter text | | |
|  |  |  |  |
| Specify action | Enter text | | |
|  |  |  |  |
| 1. **DECLARATION** | | | |
|  |  |  |  |
| The project is being undertaken in compliance with the approved proposal. | | | |
|  |  |  |  |
| The project is being conducted in keeping with the conditions of ethical approval and local governance and subject to any changes subsequently approved. | | | |
|  |  |  |  |
| The project is being conducted in accordance with International Council for Harmonisation and National Health and Medical Research Council Standards. | | | |
|  |  |  |  |
| The information provided in this report is complete and correct. | | | |
|  |  |  |  |
| *I hereby declare that the foregoing is true and correct:* | | | |
|  |  |  |  |
| PI | Enter text | Date | Select date |
|  |  |  |  |
| **The PI (if not the submitter) must be copied into the submission email in lieu of a signature.** | | | |