|  |
| --- |
| **RESEARCH PROJECT ANNUAL PROGRESS REPORT FORM** |
|  |  |  |  |
| In accordance with the National Human and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2023,* it is the researchers’ responsibility to provide reports of the progress of approved research projects at least annually, and related to the degree of risk to participants, to review boards and the institution.This report must be completed by the lead **Principal Investigator** **(PI)** for all clinical trials and health/medical research projects approved by the CALHN Human Research Ethics Committee (HREC). The report is due on the anniversary of HREC approval. This report incorporates both CALHN ethics and CALHN governance review. Continuation of CALHN ethics approval and CALHN governance authorisation (where applicable) is contingent on submission of this report, due **within two weeks** of the approval anniversary. Where an **external site(s)** is participating, the site PI must also report to their institution via their local Research Governance Office. Failure to comply may result in suspension of the project.**Submit to** **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 |
|  |  |  |  |
| Ethics approval date | Select date | Ethics approval end date | Select date |
|  |  |  |  |
| Anticipated date of completion | Select date |  |  |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
|  |  |  |  |
| Trial coordinator name | Enter text | Trial coordinator email | Enter text |
|  |
|  |
| Sponsor | Enter text |
|  |
| Does this project contribute to Research Translation? | Select one  |
| *Research Translation is when a project informs new programs, treatments, services or health policy.* |
|  |  |  |  |
| 1. **PROJECT RESOURCING (CALHN Sites Only)**
 |
|  |  |  |  |
| Project funding | Select one |
|  |  |  |  |
| Where a grant period ended during the reporting year, specify how the project will continue to be resourced | Enter text |
|  |
| Grant MyIP reference (if applicable) | Enter text |
|  |  |  |  |
| 1. **REPORT**
 |
|  |  |  |  |
| *CALHN governance authorisation dates are extended in line with the ethics approval period.* |
|  |  |  |  |
| Report type | Select one |
|  |  |  |  |
| Report period start date | Select date | Report period end date | Select date |
|  |  |  |  |
| Sites included in this reportList individual sites approved by CALHN HREC | Enter text |
|  |
| Have any sites not provided site-specific information required for this report? | Select one |
|  |  |  |  |
|  |  |  |  |
| 1. **PROJECT PROGRESS**
 |
|  |  |  |  |
| *Provide a brief update on the progress to date. Include where applicable: an explanation if the project has not commenced or is on hold; and rationale for any participant withdrawal.* |
|  |  |  |  |
| Summary of progress | Enter text |
|  |
| 1. **CLINICAL TRIALS**
 |
|  |  |  |  |
| *For targeted and actual numbers provide a cumulative total for all sites approved by this HREC since commencement* |
|  |  |  |
| Trial status | Select one |
| Annual Safety Report Submitted (if applicable) | Select date |
| Data Safety Monitoring Board Recommendation Submitted (if applicable) | Select date |
|  |  |  |  |
| Current approved protocol | Enter version number |  | Select date |
|  |  |  |  |
| Current approved investigator brochure | Enter version number |  | Select date |
|  |  |  |  |
|  |  |  |  |
| Current approved master participant information consent form(s) | Enter version number |  | Select date |
|  |  |  |  |
| Date of first site initiation visit at a site approved by this HREC | Select date |
|  |  |  |  |
| Date first participant was enrolled at a site approved by this HREC | Select date |
|  |  |  |  |
| Target participant enrolment number | Enter number |
|  |  |  |  |
| Actual participant enrolment number | Enter number |
|  |  |  |  |
| Number of participants withdrawn from the project by the sponsor or investigator (if applicable) | Enter number |
|  |  |  |  |
| Number of participants who withdrew themselves from project voluntarily (if applicable) | Enter number |
|  |  |
| Number of Aboriginal / Torres Strait Islander participants enrolled (if applicable) | Enter number |
|  |  |  |  |
| 1. **HEALTH/MEDICAL RESEARCH PROJECTS**
 |
|  |  |  |  |
| *For targeted and actual numbers provide a cumulative total for all sites approved by this HREC since commencement* |
|  |  |  |  |
| Project status | Select one |
|  |  |  |  |
| Is this a low risk project? | Select one |
|  |  |  |  |
| Current approved protocol | Enter version number |  | Select date |
|  |
| Current approved master participant information consent form(s) (if applicable) | Enter version number |  | Select date |
|  |  |  |  |
| Date project commenced at a site approved by this HREC | Select date |
|  |  |  |  |
| Date first participant was consented at a site approved by this HREC (if applicable) | Select date |
|  |  |  |  |
| Targeted participant number (if applicable) | Enter number |
|  |  |  |  |
| Actual participant number (if applicable) | Enter number |
|  |  |  |  |
| Targeted record number (if applicable) | Enter number |
|  |  |
| Actual record number (if applicable) | Enter number |
|  |  |  |  |
| Targeted sample number (if applicable) | Enter number |
|  |
| Actual sample number (if applicable) | Enter number |
|  |  |  |  |
| Number of participants withdrawn from the project by the investigator (if applicable) | Enter number |
|  |  |  |  |
| Number of participants who withdrew themselves from project voluntarily (if applicable) | Enter number |
|  |  |
| Number of Aboriginal / Torres Strait Islander participants enrolled (if applicable) | Enter number |
|  |  |  |  |
|  |  |  |  |
| 1. **DECLARATION**
 |
|  |  |  |  |
| The project is being undertaken in compliance with the approved proposal. |  |
|  |  |  |  |
| The project is being conducted in keeping with the conditions of approval of the HREC and local governance, and subject to any changes subsequently approved. |
|  |  |  |  |
| Any safety events and/or deviations have been reported to relevant bodies in accordance with NHMRC standards and as defined by CALHN. |
|  |  |  |  |
| All records have been maintained and stored in accordance with common law, legislative, ethical, and current best practice requirements. |
|  |  |  |  |
| The project is being conducted in accordance with International Council for Harmonisation and NHMRC standards. |
|  |  |  |  |
| The information provided in this report is complete and correct. |
|  |  |  |  |  |
| *I hereby declare that the foregoing is true and correct:* |  |
|  |  |  |  |
| PI name | Enter text | Date | Select date |
|  |  |  |  |
| **The PI (if not the submitter) must be copied into the submission email in lieu of providing a signature.** |