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| **RESEARCH PROJECT FINAL REPORT / SITE CLOSURE REPORT FORM** |
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| In accordance with the National Human and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* (updated 2018), it is the researchers’ responsibility to provide a final report of the outcome for completed research projects and for all site closures to review bodies 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).This report incorporates both CALHN ethics and CALHN governance review. Where the report pertains to completion or a site closure at an **external site**, the site **PI** must also report to their institution via their local Research Governance Office.**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 |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
|  |  |  |  |
| Trial coordinator name | Enter text | Trail coordinator email | Enter text |
|  |  |  |  |
| 1. **REPORT**
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|  |  |  |  |
| Report type | Select one | Reason | Select one |
|  |  |  |  |
| Sites included in this report | Enter text |
|  |  |  |  |
| For completed projects, have any sites not provided site-specific information required for this report? | Select one |
|  |  |  |  |
| 1. **PROJECT COMPLETION (completion of project at all sites approved under this HREC)**
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|  |  |  |  |
| Date of completion | Select date |
|  |  |  |  |
| Summary of outcome | Enter text |
|  |  |  |  |
| 1. **SITE CLOSURE (one site closing in a multi-site project)**
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|  |  |  |  |
| Date of site closure | Select date |
|  |  |  |  |
| Site name | Enter text | PI name | Enter text |
|  |  |  |  |
| 1. **PROJECT TERMINATION OR SITE TERMINATION**
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|  |  |  |  |
| Provide reasons for termination | Enter text |
|  |  |  |  |
| Were participants informed of the termination? | Select one |
|  |  |  |  |
| Describe measures taken to ensure participants have not been disadvantaged as a result of the termination (if applicable) | Enter text |
|  |  |  |  |
| 1. **CLINICAL TRIALS**
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|  |  |  |  |
| Targeted 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 |
|  |  |  |  |
| 1. **HEALTH/MEDICAL RESEARCH PROJECTS**
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|  |  |  |  |
| Is this a low risk project? | Select one |
|  |  |  |  |
| Where are the project data/results and samples (if applicable) stored?  | Enter text |
|  |  |  |  |
| Which institution owns the project data/results and samples (if applicable)? | Enter text |
|  |  |  |  |
| 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 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 |
|  |  |  |  |
| 1. **DECLARATION**
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| The project is/has been undertaken in compliance with the approved proposal. |
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| The project is/has been conducted in keeping with the conditions of approval of the HREC and local governance, and subject to any changes subsequently approved. |
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| Any safety events and/or non-serious breaches - deviations have been reported to relevant bodies in accordance with NHMRC standards and as defined by CALHN. |
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| All records have been maintained and stored in accordance with common law, legislative, ethical, and current best practice requirements. |
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| 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.** |