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| **RESEARCH AMENDMENT REQUEST FORM** | | | |
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| This form must be used by lead **Principal Investigator (PI)** the when submitting an amendment to clinical trial or health/medical research project approved by the CALHN Human Research Ethics Committee.  Amendment submissions incorporate both CALHN ethics and CALHN governance review. Where an **external site(s)** is participating, the site PI’s must also report amendments to their institution via their local Research Governance Office.  **Submit to** [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au) | | | |
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| 1. **PROJECT DETAIL** | | | |
|  |  |  |  |
| HREC reference | Enter number | SSA reference | Enter number |
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| MyIP reference | Enter number | Project type | Select one |
|  |  |  |  |
| Project title | Enter text | | |
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| Annual progress reporting is up to date | Select one |  |  |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
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| Trial coordinator name | Enter text | Trial coordinator email | Enter text |
| Program | Enter text | Department | Enter text |
| Sponsor | Enter text |
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| 1. **AMENDMENT** | | | |
|  |  |  |  |
| Amendment type 1 | | Select one | |
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| Amendment type 2 (if applicable) | | Select one | |
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| Amendment type 3 (if applicable) | | Select one | |
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| Amendment type 4 (if applicable) | | Select one | |
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| Amendment type 5 (if applicable) | | Select one | |
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| Brief overview of changes | Enter text | | |
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| Reason for changes | Enter text | | |
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| Did the sponsor initiate the amendment? | | | Select one |
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| Do you believe the changes raise any ethical issues? | | | Select one |
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| Do you believe the changes raise any privacy issues? | | | Select one |
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| Describe ethical and/or privacy issues (if applicable) | Enter text | | |
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| 1. **PARTICIPATING SITES** | | | |
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| Does the amendment affect all sites approved by this HREC? | | | Select one |
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| List affected sites (if not all sites) | Enter text | | |
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| 1. **AMENDMENT DOCUMENTS** | | | |
|  |  |  |  |
| Enter document name | | Enter version number | Select date |
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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 Medical Research Council standards. | | | |
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| The information provided in this report is complete and correct. | | | |
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| *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.** | | | |