|  |  |  |  |
| --- | --- | --- | --- |
| RESEARCH AMENDMENT REQUEST FORM | | | |
|  |  |  |  |
| 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) | | | |
|  |  |  |  |
| 1. PROJECT DETAIL | | | |
|  |  |  |  |
| HREC reference | Enter number | SSA reference | Enter number |
|  |  |  |  |
| MyIP reference | Enter number | Annual progress reporting is up to date | Select one |
|  |  |  |  |
| Project title | Enter text | | |
|  |  |  |  |
| PI name | Enter text | PI email | Enter text |
|  |  |  |  |
| Trial coordinator name | Enter text | Trial coordinator email | Enter text |
|  |  |
| Sponsor | Enter text |
|  |  |  |
| 1. AMENDMENT | | | |
|  |  |  |  |
| Amendment type | | Select one | |
|  |  |  |  |
| Brief overview of changes | Enter text | | |
|  |  |  |  |
| Reason for changes | Enter text | | |
|  |  |  |  |
| Did the sponsor initiate the amendment? | | | Select one |
|  |  |  |  |
| Do you believe the changes raise any ethical issues? | | | Select one |
|  |  |  |  |
| Do you believe the changes raise any privacy issues? | | | Select one |
|  |  |  |  |
| Describe ethical and/or privacy issues (if applicable) | Enter text | | |
|  |  |  |  |
| 1. PARTICIPATING SITES | | | |
|  |  |  |  |
| Does this amendment affect all sites approved by CALHN HREC? | | | Select one |
|  |  |  |  |
| List affected sites (if not all sites) | Enter text | | |
|  |  |  |  |
| 1. AMENDMENT DOCUMENTS | | | |
|  |  |  |  |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
| Enter document name | | Enter version number | Select date |
|  |  |  |  |
| 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 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 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. | | | |