

# CALHN Post Approval Guidelines for Researchers

This document has been created to outline the CALHN post approval guidelines. Please send all post approval enquiries to [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au).

## Introduction

### What is Research Ethics?

The ethical review of research is an important step in ensuring the quality of research and maintaining the welfare of research participants. It is a requirement that all research conducted at South Australian public health organisations, or involving staff or clients of South Australian public health organisations, including regional health services, hospitals, community health services, public health clinics and associated programs, complies with the [National Statement on Ethical Conduct in Human Research](#).

### What is Research Governance?

Research governance is a framework through which institutions are accountable for the research they allow to be conducted under their auspices. Research governance is concerned with the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements, and promotes good research culture and practice.

## CALHN HREC Amendments

Amendment Type	Required Documents	Links to Resources
Protocol	-Research Amendment Request Form -Updated version of Protocol (Clean and Tracked)	Click <a href="#">here</a> to access the Research Amendment Request Form template.  Click <a href="#">here</a> to access the CALHN Research Protocol Guideline.
Investigator Brochure	-Research Amendment Request Form -Updated version of Investigator Brochure (Clean and Tracked)	Click <a href="#">here</a> to access the Research Amendment Request Form template.
Change of Principal Investigator (PI)	-Research Amendment Request Form -CV of the new PI (2 Years) -GCP of the new PI (Mandatory for Clinical Trials) - Study Team Declaration	Click <a href="#">here</a> to access the Research Amendment Request Form template.  Click <a href="#">here</a> to access the CALHN Study Team Declaration template.
Patient Information Consent Form (PICF): Master	-Research Amendment Request Form -Updated version of PICFs (Clean and Tracked)	Click <a href="#">here</a> to access the Research Amendment Request Form template.  Click <a href="#">here</a> to access NHMRC PICF Interventional-Self Guidelines.



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		Click <a href="#">here</a> to access LNR PICF Guideline.
Patient Information Consent Form (PICF): Site-Specific	-Research Amendment Request Form -Updated version of PICFs (Clean and Tracked)	Click <a href="#">here</a> to access the Research Amendment Request Form template.  Click <a href="#">here</a> to access NHMRC PICF Interventional-Self Guidelines.  Click <a href="#">here</a> to access LNR PICF Guideline.
Addition of Investigator	-Research Amendment Request Form <u>CALHN Investigators:</u> -CV -GCP (mandatory for clinical trials) -Study Team Declaration <u>Non-CALHN Investigators:</u> -CV -GCP (mandatory for clinical trials) -Study Team Declaration -Police Check (if going to be on site) -Confidentiality Deed (if in contact with patient/access to patient data)	Click <a href="#">here</a> to access the Research Amendment Request Form template.  Click <a href="#">here</a> to access the CALHN Study Team Declaration template.  CALHN Confidentiality Deed template is available upon request. Please email the post monitoring inbox.
Addition of Site	-Research Amendment Request Form -CV and GCP of site Principal Investigator	Click <a href="#">here</a> to access the Research Amendment Request Form template.
Other	-Research Amendment Request Form -Documents requiring review	Click <a href="#">here</a> to access the Research Amendment Request Form template.

## CALHN HREC Reporting

Report Type	Required Documents	Links to Resources
CALHN lead HREC Annual Reports	-Research Project Annual Progress Report Form	Click <a href="#">here</a> to access the CALHN Annual Report template.
CALHN lead HREC Final/Site Closure Report	-Research Project Annual Progress Report Form	Click <a href="#">here</a> to access the CALHN Final/Site Closure Report template.

## CALHN HREC Safety Reporting

Report Type	Required Documents	Links to Resources
Development Safety Update Report (DSUR)	-Annual Safety Report and/or Development Safety Update Report	Click <a href="#">here</a> to access the CALHN Research Safety Report Form.



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Please note: DSURS are not required where CALHN is RGO only	Please note: The PI and research team contact must be copied into the submission email	
Significant Safety Issue (SSI)	-CALHN Research Safety Report  Please note: The PI and research team contact must be copied into the submission email	Click <a href="#">here</a> to access the CALHN Research Safety Report Form.
Serious Breach	-Research Serious Breach Report Form  Please note: The PI and research team contact must be copied into the submission email	Click <a href="#">here</a> to access the CALHN Research Serious Breach Report Form.
Third Party Serious Breach Notification	-Research Suspected Breach Report Form (Third Party)  Please note: The PI and research team contact must be copied into the submission email	Click <a href="#">here</a> to access the CALHN Research Suspected Breach Report Form (Third Party).
Suspected Breach	-CALHN Research Suspected Breach Report Form (Third Party)	Click <a href="#">here</a> to access the CALHN Research Suspected Breach Report Form (Third Party).
Significant Safety Issue (SSI) at a CALHN Site	-CALHN Research Safety Report	Click <a href="#">here</a> to access the CALHN Research Safety Report Form.
Protocol Deviation at a CALHN Site	-Complete the CALHN Research Protocol Deviation Form	Click <a href="#">here</a> to access the CALHN Research Deviation Report Form.
Investigator Brochure (IB)	-Research Amendment Request Form -Updated version of Investigator Brochure (Clean and Tracked)	Click <a href="#">here</a> to access the Research Amendment Request Form template.
For more information on Safety Reporting please refer to the CALHN Safety Monitoring and Reporting for Clinical Trials Involving Therapeutic Goods and Reporting Serious Breaches of Good Clinical Practice or the Protocol for Clinical Trials Involving Therapeutic Goods <a href="#">here</a> .		

## RGO Amendments (External Lead HREC)

Amendment Type	Required Documents
RGO Amendment	-Approved Submitted Documents e.g. Protocol/ PICF/ IB (Clean and Tracked) -HREC Approval of Submitted Documents
Certificate of Currency	-Certificate of Currency Document  Please note: Lead HREC Approval Letter is not required for Certificates of Currency



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## RGO Reporting

Report Type	Required Documents	Links to Resources
RGO Annual Reports	-Research Project Final Report/Site Closure Form -Lead HREC Approval	Refer to lead HREC template.
RGO Final/Site Closure Report	-Research Project Final Report/Site Closure Form -Lead HREC Approval	Refer to lead HREC template.

Please refer to the email contacts below for your enquiry:

- For Governance enquiries contact: [Health.CALHNResearchGovernance@sa.gov.au](mailto:Health.CALHNResearchGovernance@sa.gov.au)
- For Ethics enquiries contact: [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au)
- For Clinical Trials enquiries contact: [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au)
- For LNR enquiries contact: [Health.CALHNResearchLNR@sa.gov.au](mailto:Health.CALHNResearchLNR@sa.gov.au)
- For Grant enquiries contact: [Health.CALHNResearchGrants@sa.gov.au](mailto:Health.CALHNResearchGrants@sa.gov.au)
- For Post Monitoring enquiries contact: [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au)



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## Generic Email Template for Submissions

Subject line: Annual Report or Amendment | myIP number: | PI: | Study title:

Dear Post Monitoring, (Please specify whether this is for Ethics or Governance)

<b>Project Title:</b>	
<b>Protocol:</b>	
<b>CPI/PI:</b>	
<b>HREC Reference:</b>	
<b>CALHN Reference:</b>	
<b>MyIP Number:</b>	

Document	Version	Date

Regards,

XXX

## For more information

CALHN Research Office, Research Support Officer

Annual Reports Telephone: (08) 7117 2218

Amendments Telephone: (08) 7117 2223

Post Monitoring Email: [Health.CALHNResearchMonitoring@sa.gov.au](mailto:Health.CALHNResearchMonitoring@sa.gov.au)



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