

Participant Information and Consent Form Guidelines

Documents needed when submitting PICFs for review:

- HREC Approval Letter/Email(s)
- Master PICFs (Clean & Tracked)
- Site Specific PICFs (Clean & Tracked)
- **Please Note:** To acquire approval, all documents listed above need to be attached even if the reviewing HREC is CALHN. This allows for the review to be undertaken efficiently and effectively.

Instructions to creating Site Specific PICFs:

- Save a copy of the clean Master PICF and label this copy 'Site Specific Tracked'.
- Open up Site Specific Tracked document and turn on tracked changes.
- Ensure that tracked changes are on when making any changes to the document and not are not just used for the footers, so that the Governance Officer can clearly see changes made throughout the body of the document.
- Once finished making changes, 'save as' the document and rename as the 'Site Specific Clean'. Then accept all of the tracked changed and save again.

Footers:

- Ensure that the HREC Approval Letter, Master and Site Specific PICFs all have the same date that has been approved on the HREC Approval Letter.
- Desirable footer format:

RAH/TQEH/CALHN Participant Information Consent Form/Sheet, Version XX, dated XX
XXXX XXXX

Based on Master Participant Information Consent Form/Sheet, Version XX, dated XX
XXXX XXXX

SA Privacy Laws:

- Usually under 'Can I see my study records?'
- Ensure that this is updated to 'In accordance with relevant Australian and/or South Australian privacy and other relevant laws'.

Consent Forms:

- The NHMRC website has standardised templates available for download and Sponsors/Principal Investigators are encouraged to use these templates.
<https://nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources>
- If the NHMRC template is not utilised, SA Health's Legal Governance and Insurance Services (LGIS) requires that **one of the following fundamental clauses be included** to ensure adherence with the principals of informed consent:
 - I understand the purposes, procedures and risks of the evaluation described in the trial/project.
 - I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks as described within it.
 - Details of procedures and any risks have been explained to my satisfaction.

Section 20 Further Information & Who to contact

- Please ensure you are using the correct tables.

Internal Ethics – CALHN HREC

- Where a study has been reviewed by CALHN HREC, the complaint contact details must be the Executive Officer of the reviewing Ethics Committee.

Reviewing HREC approving this research and HREC Executive Officer details

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	Executive Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	Executive Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

External Ethics

- Where a study has been reviewed by an external (non-CALHN) HREC, the CALHN Research Governance Officer must be added as a site complaints contact.

Reviewing HREC approving this research and HREC Executive Officer details

HREC Name	External HREC details
Contact	
Telephone	(XX) XXXX XXXX
Email	

Complaints Contact - CALHN Research Governance Officer

Name	Ms Bernadette Swart
Position	Manager, CALHN Research Office
Telephone	(08) 7117 2209
Email	Health.CALHNResearchGovernance@sa.gov.au

Email Quick Parts/Template for PICFs Submission:

- Save the below as a 'Quick Part'/ template for PICF reviews.
- Using this format will help to save time and identify what needs to be acknowledged and what needs to be approved for use.
- This format provides the RGO with all the information needed to identify the correct study.
- The only documents that need to be approved by Research Governance are Site Specific PICFs. All other documents will just be acknowledged.

Subject:

- MYIPXXXXX | PI: Doe, John | Study: ABC | HREC# | PICFs Amendment Version XX

Body:

Dear RGO,

RE:	Study Title
Protocol:	ABC
PI:	Doe, John
HREC:	HREC/
SSA:	SSA/
CALHN Research Office Reference:	MyIP: XXXXX

Please find attached for **review** and **acknowledgement**:

Document	Version	Date
HREC Approval Letter	-	26 March 2019
Protocol Amendment 1	2.0	11 July 2019
Administrative Letter	-	19 June 2019
Main Master PICF (Clean & Tracked)	2.0	03 April 2019

Please find attached for **review** and **approval**:

Document	Version	Date
Main RAH PICF (Clean & Tracked)	1.0	21 August 2019

Kind Regards,

Email Signature