Participant Information Sheet/Consent Form Research Governance Review 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. 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 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 'What will happen to the information about me?'
- 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.

Clinical contact person

- Must have a direct line to a coordinator or the PI.
- Please do not use Switchboard.

Witness

A witness is only required under certain circumstances – (Required if the participant is unable to read or if a legally acceptable representative is unable to read, section 4.8.9 of Guidance on Good Clinical Practice CPMP/ICH/135/95). Remove if not required.

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

Storage

Investigator Initiated and Sponsored Clinical Trials

- Research data must be retained for 15 years
- Gene therapy and associated areas, if it has community or heritage value – data must be kept permanently

Pregnancy data

- Research data must be kept for 33 years

Further Information & Who to Contact

- Please ensure you are using the correct tables.

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

Links/Resources

- NHMRC Participant Information Sheet/Consent Form Templates https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources