Participant Information Sheet/Consent Form Guidelines CALHN Ethics

Master and Site Specific

- Submit Site Specific PICFs and Master PICFS at the same time
- Submit clean and tracked copies of the PICFs

Logos

- The logo of the organisation that will own the study results should be used in the header of the PICF. If this is CALHN please ensure the current CALHN logo is used.

Footers:

- Desirable footer format:
  <SITE> 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 Law

- Usually under 'What will happen to information about me?'
  Ensure that this is updated to 'In accordance with relevant Australian and/or South Australian privacy and other relevant laws'

Consent Form

- The NHMRC website has standardised templates available for download and Sponsors/Principal Investigators are encouraged to use these templates.
- 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/desk line to a coordinator or the PI. Please do not use Switchboard or personal number.

Reviewing HREC and Complaints Contact Details

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	HREC Support 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	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

For multi-site NMA studies include the following table:

Local HREC Office Contact (Single Site – Research Governance Officer)

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

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:

Low Negligible Risk Projects

- Research data must be retained for a minimum of 5 years post study completion
- Electronic data should be stored on a 'shared departmental drive with password protection' and hard copy data should be stored in locked filing cabinets (or similar) only accessible to the study team.

- After the storage period has ended data should be permanently destroyed and the person responsible for ensuring this should be named.
- If data will be stored in an identifiable/de-identified-re-identifiable/anonymous format this should be clear. Identifiable data should be confidential.

Investigator Initiated Clinical Research and Sponsored Clinical Trials (Full committee review)

- 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

Data Storage

- Data must be stored at the institution that owns the study results. Please note, if data is identifiable it must be stored at CALHN unless consented.
- Electronic data should be stored on a 'shared departmental drive with password protection' and hard copy data should be stored in locked filing cabinets (or similar) only accessible to the study team.

Links/resources

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

- LNR Participant Information Sheet/Consent Form Guidelines
  https://www.rah.sa.gov.au/research/for-researchers/health-medical-research-project-submissions/expedited-review