CALHN SITE SPECIFIC PARTICIPANT INFORMATION SHEET/CONSENT FORM (PICF) GUIDELINES

This guideline has been developed for general use by all research staff.

Documents needed when submitting PICFs for review:

- HREC Approval Letter/Email(s) and subsequent Amendment approval letters (if applicable) with approved master PICFs listed.
- 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 for creating Site Specific PICFs:

- Save a copy of the clean Master PICF and label this copy 'Site Specific Tracked'.
- Open the 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.

Formatting - Footers:

- Ensure that the version and date in the site-specific PICF aligns with the most recently approved HREC master PICF.
- 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

Logos

CALHN logos can be accessed from the Corporate Templates page on the CALHN Intranet.

Government of South Australia
Health
Central Adelaide Local Health Network

PARTICIPANT INFORMATION SHEET

Data Management - Storage:

Investigator Initiated and Sponsored Clinical Trials

- All research data, including electronic records, should be retained for 15 years after research completion or last contact, whichever is later.
- Gene therapy and associated areas, if it has community or heritage value – data must be kept permanently.
- The PICF should outline, at a minimum, the duration for which data will be retained, where it will be stored, the level of identifiability of the data, state the authorised personnel/institutions with access, security measures, and the format in which data will be stored.

Sample Management - Storage:

Investigator Initiated and Sponsored Clinical Trials

- The PICF should outline, at a minimum, the duration for which samples will be retained, where they will be stored, the level of identifiability of the samples, state where samples will be analysed, state the authorised personnel/institutions with access, security measures, and method of destruction.

South Australian laws:

Privacy Law

- This statement is usually under the section 'What will happen to the information about me?'.
- Ensure that the following clause is included in the Site Specific PICF:

> *'In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.'*

SA Pregnancy data law

- For pregnancy PICFs, research data must be kept for 33 years. Please update the pregnancy Site Specific PICF to state this.
- Records concerning individuals under legal disability* destroy 33 years after the last contact according to General Disposal Schedule No. 28.
  **A person is under a "legal disability" while the person remains a child.*

CALHN clauses:

- It is a CALHN requirement to include the following clause:

  'Your participation in this study shall not affect any other right to compensation you may have under common law.'

Further information & who to contact:

- **Please use the following 3 tables and wording.**

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor *[insert name]* on *[mobile number]** or any of the following people:

Clinical contact person#

Name	*[Name]*
Position	*[Position]*
Telephone	*[Telephone]*
Email	*[Email]*

***Mobile number must be contactable 24 hours**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research, HREC Executive Officer and Complaints Contact^

^If CALHN is not the reviewing HREC, please use the details of the reviewing HREC in this section.

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

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Local Research Governance Officer Contact

Name	Ms Bernadette Swart
Position	Manager, CALHN Research Services

Telephone	(08) 7117 2209
Email	Health.CALHNResearchMonitoring@sa.gov.au

#Clinical contact person:

- Must have a direct line to a coordinator or the PI
- Please ensure the study participant is provided information on how to contact the study doctor out of office hours, if mobile phone is not provided

CONSENT FORM

Consent Statements:

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.

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 the witness section if it is not required for your project.**

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

Signature

Date _____