Research Governance Unit

Calvary Adelaide Hospital

Calvary Central Districts Hospital

Calvary North Adelaide Hospital

CONTINUING THE MISSION OF THE SISTERS OF
THE LITTLE COMPANY OF MARY

SITE SPECIFIC REQUIREMENTS

Calvary Health Care has several site specific requirements which must be addressed when submitting an application. The below information has been divided into the following sections:

Table of Contents

1. IMPORTANT INFORMATION

Please be advised that as of 08 December 2020, all ethics and governance applications for Calvary Health affiliated facilities are reviewed under the jurisdiction of St Vincent's Hospital Melbourne (SVHM), Victoria as the reviewing Human Research Ethics Committee.

Prior to submission to the HREC of SVHM, researchers must submit the following:

- "CHCA Research Governance Submission Form – Part A"
- Email completed form to: SA-CHCA-HREC@calvarycare.org.au for endorsement of the research proposal to be undertaken at a Calvary Hospital in Adelaide.
- If the research proposal is endorsed, an endorsement letter will be provided to the researcher. This endorsement letter must be submitted to the HREC of SVHM, along with the other documents required for HREC submission.

2. HUMAN RESEARCH ETHICS APPLICATION FORM (HREA)

The purpose of the ethics application form is to enable the HREC to consider whether the research project is ethically and scientifically acceptable, and whether it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

Please navigate to the following website to complete the HREA:

- **NHMRC Version**: https://hrea.gov.au/

Include the site(s) St Vincent's Hospital (Melbourne) (SVHM) HREC is responsible for:

- Calvary Adelaide Hospital (CAH)
- Calvary Central Districts Hospital (CCDH)
- Calvary North Adelaide Hospital (CNAH)
- Other (please specify)

Researchers are reminded that:

1. Prospective study participants at Calvary Health Care facilities must be approached in the first instance by a staff member of Calvary Health and only with the permission of the patient's treating clinician.

2. Only those investigators who are specifically listed within the application form as being able to obtain informed consent should do so. Obtaining informed consent must not be delegated to anyone else.

3. USE OF IONISING RADIATION

The Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) is designed to ensure that researchers proposing to expose research participants to ionizing radiation provide information that allows consent to be properly considered by research participants and Human Research Ethics Committees.

Section 2.1.7 of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice: Exposure of Humans to Ionising Radiation for Research Purposes states

For all studies that involve the use of Ionising Radiation the Use of Ionising Radiation Form needs to be completed.

Ionising Radiation that is NOT Addition to Standard Care

If the use of ionising radiation in research is not additional to standard care at Calvary Health Care sites, the following form must be use and submitted to the reviewing HREC:

- Notification to the Reviewing HREC: Use if Ionising Radiation in a Research Project

Ionising Radiation that is ADDITIONAL to Standard Care

If the use of Ionising radiation in research is additional to standard care at Calvary Health Care sites, the research team must provide a copy of the independent assessment report conducted by a Medical Physicist.

4. PARTICIPANT INFORMATION & CONSENT FORM (PICF)

GENERAL

All PICFs submitted for review must incorporate the format, layout and standard phrases contained within the PICF templates available from the following website:

https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources

All Calvary Health Care site PICFs must incorporate the Calvary Health Care logo in the top right hand corner of the front page, as well as on the consent page.

Calvary | Health Care Adelaide

Hospitality
Healing
Stewardship
Respect

All PICFs must be written in second person singular (i.e. as if you were speaking to the reader) using simple language consistent with a reading age of 14. All medical, scientific or technical terms must be explained.

A separate PICF must be written for any additional and optional genetic analysis (pharmacokinetics, pharmacogenetics/genomics, pharmacodynamics etc), as well as additional and optional tissue collection/banking or procedures which are in addition to the core study protocol. It must clearly state that these types of procedures are optional and additional to the main study, and that participants can still take part in the main study without having to participate in the optional components.

HEADERS / FOOTERS

All PICFs must contain the version number, date and page number (page x of x) within the header or footer for accountability. Please note that multi-site studies should contain a reference to the master document, as well as the site specific governance version.

Example:

[Protocol No][Site] Specific PICF [type eg. Main] Ver. X.X Date DD/MM/YYYY [Site Specific Template]
[Protocol No]National Mutual Acceptance PICF Ver. X.X Date DD/MM/YYYY [Master Template]
Page xx of xx

Form for Withdrawal of Participation

All PICFS must either have the form for withdrawal of participation in the PICFs or as a separate document for submission.

SITE SPECIFIC STANDARD PHRASES

Complaints and Research Participant Rights

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

Complaints contact person

Name	Dr Mark McCarthy
Position	Director of Mission, Calvary Health Care Adelaide
Telephone	08 8405 3624
Email	Mark.McCarthy@calvarycare.org.au

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 and HREC Executive Officer details

Reviewing HREC name	St. Vincent's Hospital Melbourne HREC
Position	HREC Executive Officer
Telephone	03 9231 2394
Email	research.ethics@svhm.org.au

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

Local HREC Name	Calvary Health Care Adelaide RGO
Name	Toni-Ann Miller
Position	Research Governance Manager
Telephone	08 8250 4111
Email	Toni-Ann.Miller@calvarycare.org.au

Advice on Avoiding Pregnancy (if applicable)

Calvary Health Care is a Roman Catholic health service. It is acceptable within Catholic teaching to counsel a woman and/or her partner to avoid becoming pregnant when either the woman or partner is undergoing treatment that might affect an embryo/foetus. It is not acceptable to counsel a woman or her partner to use a contraceptive for the express intention of making intercourse infertile.

Calvary Health Care therefore, does not accept any statements in the application (e.g. participant information sheet, scientific description etc) to the effect that participants must practice methods of contraception or avoid pregnancy.

For studies where pregnancy must be avoided please use the Catholic Health Australia's' approved wording outlined below:

Patient Information and Consent Form Statement where pregnancy must be avoided: Recommended Template for Catholic Institutions

The effects of *[Name of investigational product]* on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least *[number]* months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of *[number]* months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

Retention of Records

The retention of research related records must comply with the Australian Code for the Responsible Conduct of Research (2007) and the Health Records Act which specifies that *the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:*

Types of Project	Retention Period after Project End
Short-term research projects that are for assessment purposes only, such as research projects completed by students	12 months
Clinical Trials	15 Years or more
Areas such as Gene therapy	Retained Permanently
Work has community or heritage value	Retained permanently, preferably within a national collection

Please note that the State Records Act requirement for the retention of research records is different from University requirements.

State Records Act 1997 – More than 7 Years after completion of a study

University Requirement - 5 Years after completion of a study

Calvary Health Care follows the State Records Act hence all records must be retained for a minimum of seven (7) years if conducted at Calvary Health Care sites.

5. CONTRACTS AND AGREEMENTS

All clinical trials, human research, investigator initiated and collaborative studies must provide a research agreement for review/authorization. Depending on the type of research the following template below must be used. If these templates cannot be used, please contact the Research Governance Unit for advice.

Types of Research	Template	Website
• Clinical Trials • Human Research • Collaborative Group Studies • Investigator Initiated Research	Medicines Australia – Clinical Trial Research Agreement	https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/
• Medical Device trial	Medical Device Medical Technology Association (MTAA)	https://www.mtaa.org.au/clinical-investigations-research-agreements

The following are the details for Calvary Health Care sites to be inserted as appropriate:

- **Calvary Adelaide Hospital**

Name of Institution:	Calvary Health Care Adelaide Limited, trading as Calvary Adelaide Hospital
Address:	120 Angus Street, Adelaide, SA, 5000
ABN:	85 106 314 229

- **Calvary North Adelaide Hospital**

Name of Institution:	Calvary Health Care Adelaide Limited, trading as Calvary North Adelaide Hospital
Address:	89 Strangways Tce, North Adelaide, SA, 5006
ABN:	85 106 314 229

- **Calvary Central Districts Hospital**

Name of Institution:	Calvary Health Care Adelaide Limited, trading as Calvary Central Districts Hospital
Address:	25-37 Jarvis Road, Elizabeth Vale, SA, 5112
ABN:	85 106 314 229

Calvary Health Care Involvement	**Electronic Copy submitted for signing via:**	**Signature to be present on CTRA**
A Calvary Health Care facility is a participating site in the study	1x e-copy (signed electronically with either Adobe/Docu-sign)	- Sponsor - Principal Investigator
Calvary Health Care is the Sponsor for the study		- No signature to be present. - PI needs to ensure that the CTRA has been discussed with participating site and that mutual agreement has been reached by all parties. - Study team is required to send back one of the original fully executed CTRA to SVHM RGU

Please note that only the Director of Mission – Dr Mark McCarthy can sign off on behalf of the institution.

6. INSURANCE AND INDEMNITY

All multi-site **Sponsored Clinical Trials** must provide appropriate levels of insurance/indemnity.

Calvary Health Care requires the use of the Medicines Australia Standard Indemnity Form. Where the trial is being reviewed as a multisite study, the Medicines Australia HREC Review Only Form of Indemnity is also required for each site which will accept the ethical approval.

Please state the Indemnified Party as follows:

- **Calvary Adelaide Hospital:**
  Calvary Health Care Adelaide Limited, trading as Calvary Adelaide Hospital, 120 Angus Street, Adelaide, SA, 5000, ABN: 85 106 314 229

- **Calvary North Adelaide Hospital:**
  Calvary Health Care Adelaide Limited, trading as Calvary North Adelaide Hospital, 89 Strangways Tce, North Adelaide, SA, 5006, ABN: 85 106 314 229

- **Calvary Central Districts Hospital:**
  Calvary Health Care Adelaide Limited, trading as Calvary Central Districts Hospital, 25-37 Jarvis Road, Elizabeth Vale, SA, 5112, ABN: 85 106 314 229

INSURANCE

To comply with the minimum insurance requirements, sponsored research must provide a copy of the certificate of currency (or insurance certificate) which contains the following information:

- The type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance
- The full legal name of the Australian entity acting as the sponsor
- The full legal name of the insurer (which must be approved by the Australian Prudential Regulation Authority or a foreign equivalent). All insurers are required to hold Standard & Poor's financial rating of not less than 'A-'.
- The period of insurance
- That the insurance coverage allows for a minimum of AUD$10 million for any one occurrence and in the annual aggregate
- That the insurance coverage contains an excess/deductible, or self-insured retention amount LESS than AUD$25,000 for each and every claim or series of claims arising out of one original cause.

Post Marketing Study/Phase IV Clinical Trial

A Standard Indemnity is not required if the Australia Medicine Clinical Trial Research Agreement – Phase 4 is used.

An insurance covering study will not need to be provided but the general insurance covering the Sponsor Company will need to be provided.

7. CLINICAL TRIAL NOTIFICATION (CTN)

The CTN will be required for the following:

- any medicine not entered on the Australian Register of Therapeutic Goods (ARTG), including any new formulation, strength or size, dosage form, name, indications, directions for use or type of container of a medicine already in the ARTG
- any medical device not entered in the ARTG, including any new design specification, model, technology, material or treatment modality of a medical device already in the ARTG
- any biological not entered in the ARTG:
    - including any new applicable standards, intended clinical use or principal manufacturer of a Class 1 or 2 biological already in the ARTG
    - including any new product name, dosage form, formulation or composition, therapeutic indication, type of container or principal manufacturer of a Class 3 or 4 biological already in the ARTG
- a therapeutic good already in the ARTG that is used beyond the conditions of its marketing approval including labelling.

a) For Commercially Sponsored/Investigator Initiated Study – It is the Sponsor/Investigator's responsibility to submit the CTN to the TGA. A copy of the submitted CTN will need to be submitted to the Research Governance Unit after Ethics and Governance Approval has been granted for the study.

The following are the details to be entered into the CTN application:

HREC Name	St Vincent's Hospital Melbourne Human Research Ethics Committee
HREC Contact Officer	Dr. Tam Nguyen, Executive Officer of Research
HREC Code	EC00343
Contact Phone Number	03 9231 2394
Contact Email	research.ethics@svhm.org.au

Calvary Adelaide Hospital
Location: 120 Angas St, Adelaide 5000, SA

Name of Approving Authority:	Calvary Health Care Adelaide Ltd, operating as Calvary Adelaide Hospital
Approving Authority Contact Officer:	Ms Tanya Brooks
Approving Authority Contact Position:	General Manager, Calvary Adelaide Hospital
Approving Authority Contact Phone:	08 8227 7000

Calvary Central Districts Hospital

Location: 25-37 Jarvis Road, Elizabeth Vale 5112, SA

Name of Approving Authority:	Calvary Health Care Adelaide Ltd, operating as Calvary Central Districts Hospital
Approving Authority Contact Officer:	Mr Lachlan Ophof
Approving Authority Contact Position:	General Manager, Calvary Central Districts Hospital
Approving Authority Contact Phone:	08 8251 4111

Calvary North Adelaide Hospital

Location: 89 Strangways Terrace, North Adelaide 5006, SA

Name of Approving Authority:	Calvary Health Care Adelaide Ltd, operating as Calvary North Adelaide Hospital
Approving Authority Contact Officer:	Mr Steve Farrall
Approving Authority Contact Position:	General Manager, Calvary North Adelaide Hospital
Approving Authority Contact Phone:	08 8239 9100

b) Calvary Health Care is the Sponsor – Calvary RGO will assist the Investigator to make the submission to the TGA.

Please send an email to SA-CHCA-HREC@calvarycare.org.au for assistance.

Payment to Calvary Research Governance Unit is required by the research team for lodging a CTN application.

8. THE PROCESS TO OBTAINING ETHICAL AND GOVERNANCE APPROVAL

FOR HIGH RISK STUDIES

When will you need Ethical Approval?

Ethical approval is required before conducting research. St Vincent's Hospital Melbourne (SVHM) is able to grant ethical approval on behalf of Calvary Health Care Adelaide for the following study sites participating in the study:

- Calvary Adelaide Hospital
- Calvary Central Districts Hospital
- Calvary North Adelaide Hospital

The Process to Obtaining Governance Approval

When will you need Governance Approval?

Governance approval is required before conducting any research at Calvary Health Care sites, provided ethical approval has been obtained from the SVHM HREC. For Single Site Ethics applications for Calvary Sites only, Governance approval may be granted at the same time as Ethics.

Important note:

Once Ethics approval has been granted by SVHM HREC, researchers must submit the following:

- "CHCA Research Governance Submission Form – Part B"
- Email completed form to: SA-CHCA-HREC@calvarycare.org.au for endorsement of the research proposal to be undertaken at a Calvary Hospital in Adelaide.
- If the research proposal is endorsed, an endorsement letter will be provided to the researcher. This endorsement letter must be submitted to the HREC of SVHM, along with the other documents required for HREC submission.

Additional Resources

Calvary HREC Website:

https://www.svhm.org.au/research/researchers/calvary-health-care-adelaide-hrec

NHMRC HREA:

https://hrea.gov.au/

NHMRC Approved PICF Templates:

https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources

NHMRC National Statement (2007 – updated 2018):

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

NHMRC Australian Code for the Responsible Conduct of Research 2018:

https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

Medicines Australia CTRA:

https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

Medicines Australia Indemnity:

https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/