Site Specific Assessment (SSA) Application Form

1. **Document Checklist**

The following documents need to be submitted with the SSA Application Form to commence a site-specific assessment. Please select / tick the boxes to confirm you have provided the requested information:

**1.1 SSA Form**

All departments and/or services that will be utilised in conducting research are listed and costed

All questions in the SSA Application Form have been answered

Principal and Associate Investigator(s) have signed the declaration

Signed declaration from the Heads of Department where the research is going to be conducted

Signed declaration by Head of Supporting Department that is providing support services to the research project, but which does not have any member(s) on the research team

Signed declaration by the Authority for Data Provision: This form is to be completed by the person authorised to provide data services for research projects

**All researchers at an AHCL site**, including Principal Investigator, students, coordinators and associated investigators conducting this study at an AHCL site, have been listed on the SSA Form

Cover letter or cover email listing the following:  
*The Cover letter needs to be signed by the Principal Investigator (electronic signature is accepted). When submitting a cover email, the Principal Investigator must be cc’d*.

* Study Title
* Principal Investigator
* HREC reference number
* State whether this is a multi-centre study

Name of all documents submitted together with the SSA form  
*Documents must be listed by their actual file names, i.e. names need to be consistent with the file names listed on the HREC approval letter.*

*Please note: The Research Office will add a prefix when processing the submitted documents, e.g. PROTOCOL\_[document title].pdf. The prefix will appear on the approval letters.*

**1.2 HREC Approvals and Agreements**

Ethical approval of the project  
*AHCL accepts approval letters from NHMRC certified HRECs. We cannot accept approvals from NHMRC registered HRECs except from our own AHCL HREC.   
Please check this link to identify whether the approving HREC is certified*:  
<https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees>

Site approval confirmation (if not contained in the ethical approval letter) for Sydney Adventist Hospital or Adventist Healthcare Limited

Is an External Entity Agreement (EEA) with the approving HREC required?  
*An EEA is a Memorandum of Understanding between an external HREC and AHCL as a study site enabling the HREC to extend ethical approval to a site outside their jurisdiction. This is not an AHCL requirement, however if this a requirement of the approving HREC, AHCL will enter into an EEA.*

**1.3 Required Study Documentation**

**1.3.1** **Study documents submitted for site authorisation need to have HREC approval. Only the versions listed on the ethics approval letter will be authorised.**

***We DO NOT need HREC approval for site-specific versions of the PISCF and advertisement materials.*** *However please check with the approving HREC whether they need a copy of the documents authorised for site use.*

Study Protocol *(Latest version only)*

Investigator Brochure *(for Clinical Trials)*

Data collection forms as listed on the HREC approval letter *(if data is required from data collections under the custodianship of AHCL).   
NB: case report forms for clinical trials (or alike) do not need to be submitted to the Research Office*

Questionnaires *(if applicable)*

Participant Information Sheets and/or Consent Forms  
*AHCL expects that all PISCFs need to be written in plain language (Year 8 - 10 reading level) and should not exceed 20 pages (shorter is preferable). Please use an online tool such as the Flesch-Kincaid Grade Level readability tool or the Automated Readability Index readability tool to check the PISCFs comply with this site-specific requirement.*

**1.3.2** **Has the AHCL template PISCF been used?**   Yes  No

*Please note for ethical reviews by the AHCL HREC, the AHCL PICF template is mandated****.***

HREC approved Master version(s) *(latest version only)*

Site-Specific versions *(must contain the Adventist HealthCare Logo if to be used at an AHCL site; no logo required if used exclusively at private practice rooms)*

**1.3.3** **Are AHCL Research Office contact details listed on the PISCF for site-specific complaints?**

*Site specific PISCF only* Yes No

*Please list the Research Office contact details as follows:*

***Research Office Adventist HealthCare Limited***

***AHCL project ID:*** *(will be added by the Research Office upon receipt of the project application)*

***185 Fox Valley Road Wahroonga 2076***

***Phone 02 9480 9604 Email:*** [***research@sah.org.au***](mailto:research@sah.org.au)

**1.3.4**  **Waiver of Consent**

*Applies if participants cannot be consented into the study*

Proof of a HREC approved Waiver of Consent with confirmation that the Waiver of Consent has been approved under s95A of the Privacy Act 1988. This can be demonstrated via an email or noting on the HREC approval.

HREC approved justification for a [Waiver of Consent](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) addressing **paragraphs 2.3.10 a) – i)** of the NHMRC *National Statement on Ethical Conduct in Human Research (2023)*.

**1.3.5**  **Privacy**

Ideally research is conducted by obtaining the consent of participants prior to collecting, using or disclosing their personal information. Where this is impracticable, de-identified information should be used. Where neither of these options is available, it may be that personal information must be collected, used or disclosed without consent from the individual in order for the research, the compilation or analysis of statistics, or the management of a health service to proceed. If this is the case, it is necessary to obtain a HREC approved **Waiver of Consent**.

AHCL is a private institution and needs to comply with s95A of the Privacy Act 1988. If you have been granted a Waiver of Consent, or the study has been exempted from ethical review, ensure you complete **Section 2.9** of this form: Compliance with Section 95A of the Privacy Act 1988.

You can download a copy of the *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024)* via this link: <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>

AHCL reserves the right to decline access to data for research purpose in line with section A.1.6 of the *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024)*: *An organisation from which health information is sought, may always decline to agree to the use or disclosure of health information it holds for the purpose of research relevant to public health or public safety, even where the use or disclosure of that health information has been approved by an HREC in accordance with these guidelines.*

**1.3.6**  **Advertisement Materials (if applicable)**

*For example posters, flyers, brochures, screen clips of online advertisements etc that are to be used at AHCL facilities. Materials used at private practice rooms or externally to AHCL facilities, do not require governance authorisation.*

All advertisement materials that are to be displayed at an AHCL (web)site must contain the following sentence. This sentence must be clearly visible to the reader, in print as well as in an electronic format:

*“Approved by [provide HREC name and HREC study ID]; authorised to be conducted at an AHCL site [list RGO study ID]”****Eg:*** *Approved by Bellberry LTD HREC (ID XXXX), authorised to be conducted at an AHCL site (2020-XXX)*

If the marketing documents are not to be used at this site this should be explained in the cover letter/email and no site specific documents need to be created or submitted to the Research Office.

**1.3.7**  **Insurance**

Certificate of insurance from the sponsor *(for projects with commercial sponsorship)*

*As a minimum requirement, the Certificate of Currency needs to list the name of the insured organisation, the expiry date, the policy number, the name of the insurance company and the study title; please note the insured sum must be at least AU$10,000,000*.

Certificate of Currency for professional indemnity insurance

*For all AHPRA registered investigators on the study that are patient-facing and/or have the right to make decisions in regard to the study design and conduct. (Unless directly employed by AHCL)*.

Standard Indemnity Form; [MTAA](https://www.mtaa.org.au/clinical-investigation-research-agreements) or [Medicines Australia](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/).

**1.4 Other Required Documents**

Clinical Trial Research Agreement (CTRA, Medicines Australia) or Clinical Investigations Research Agreement (CIRA, Medical Technology Association of Australia) *(if applicable)*

*Refer to section on Clinical Trial specific-information for mandated wording for Schedule 2 and 4 or 7.*

*AHCL may initiate legal review of non-standard agreements for review. If you intend to use a non-standard agreement, please contact the Research Office as soon as possible. Commonly, if legal advice is sought this adds 4–6 weeks to the approval period.*

Investigator Institution Agreement

*This agreement needs to be submitted alongside all standard CIRAs or CTRAs and a template can be requested from the Research Office/ downloaded from the Research Office website at:* [*https://www.sah.org.au/research-governance-review/*](https://www.sah.org.au/research-governance-review/)

Budget: Detailed costing must be included *An explanation of how the research will be funded at the site must be provided to ensure adequate financial arrangements are planned. To assess the financial impact of the research, any costs incurred by the organisation need to be provided. There are many study or trial budget templates available on the internet. We recommend the NSW Health budget costing tool:* [*https://www.medicalresearch.nsw.gov.au/clinical-trials-budget-costing-tool/*](https://www.medicalresearch.nsw.gov.au/clinical-trials-budget-costing-tool/)

TGA issued Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) confirmation *(if applicable)*

*We note that CTN/CTA schemes can only be applied for after HREC approval and governance authorisation have been obtained.* ***Confirmation needs to be sent to the Research Office within 4 weeks of granting site authorisation.***

Site specific Radiation Safety Report if radiation exposure is over & above standard of care *(if applicable)  
The radiation report needs to state the radiation dose for the radiological procedures that are additional to the procedures undertaken for normal clinical management; whether the radiation dose exceeds the dose constraints in the Code of Practice; the risks associated with the radiation exposure in accordance with the advice in the Code of Practice; the level of benefit required from the research to justify the radiation exposure; and a statement relating to the risk of exposure that must be included in the Participant Information Sheet and Consent Form*.

CVs from all researchers listed on the SSA form; dated, signed and no older than 36 months   
 *Where one or more of the researchers are not employed by AHCL or accredited to work at an AHCL facility, a request for accreditation as* ***‘Affiliate – Research’*** *needs to be submitted to* [*accreditation@sah.org.au*](mailto:accreditation@sah.org.au) *before a Site Specific Application can be finalised. Please contact the Research Office if this is required.*

*Please carbon copy (cc) the Research Office into correspondence with the Accreditation Office.*

Good clinical practice training requirement  
*For* ***Prospective*** *studies: All investigators are required to provide current certification of completed GCP training. This is a condition of submitting a site-specific application.*

*For* ***Retrospective*** *studies: GCP certification for investigators is not required but is highly recommended.*

* Good Clinical Practice (GCP) Training: <https://gcp.nidatraining.org/>

*Free online training that is based on the updated (R2 revision) of the ICH GCP (6 hours to complete this training course)*

* Global Health Training Centre: <https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/> *Online training module with a short quiz at the end; it provides the new ICH E6 R2 Revision of GCP certificate, which sponsors and CRO are asking for (approx. 1 hour to complete this course)*

**1.5 Miscellaneous**

**Footer/ Version control information:**

The Protocol, Participant Information and Consent Forms, Investigator Brochures and customised questionnaires need to contain a footer or version control information displaying the study name/short name, version number of the document and release date.

**HREC approval**:

All submitted documents received HREC approval and the respective HREC letter/email forms part of this submission. The documents must be listed on the HREC correspondence.

1. **Application Form**

***OFFICE USE ONLY***  
AHCL Project Code:

**2.1 Project and HREC Details**

**Project Title in Full:**

**Short Title:**

**Protocol ID (if applicable):**

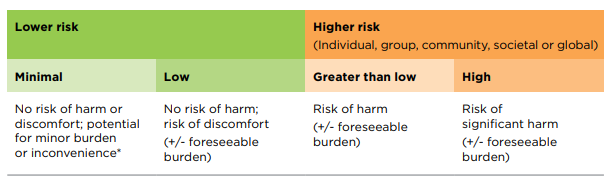
**Name of approving HREC:**

**HREC reference number:**

**Risk level** (refer to your ethics approval letter, and to the NHMRC *National Statement on Ethical Conduct in Human Research (2023)* Section 2, Chapter 2.1 Risk and benefit):

Lower risk – Minimal  Higher risk – Greater than low

Lower risk – Low  Higher risk – High

 *Source:* NHMRC *National Statement on Ethical Conduct in Human Research (2023)*

**Ethics approval period:** From *[DD MMM YYYY]* to *[DD MMM YYYY]*

Does the approving HREC grant approval for a one-year term only (aligning reporting with the date the HREC initially approved the study and renewing the approval upon receipt of progress reports?)

Yes  No

**Anticipated start and finish dates for research project at this site?**

Start date: *[DD MMM YYYY]* Finish date: *[DD MMM YYYY]*

**2.1.1 Description of the project in plain language**Give a concise and simple description (approximately 400 words) of the aims, background, and study design.

**2.1.2 What does this study/project aim to achieve?**Please detail all aims, hypotheses, objectives, and research questions of the study/project.

**2.1.3 Is there a possibility of significant new Intellectual Property being developed from this study?**

Yes  No

If yes, please provide details of legal agreement stating arrangements for the use of existing Intellectual Property and the party's rights in relation to ownership.

**2.1.4 Does the research comply with site-specific requirements as outlined in the AHCL Research Policy (found here:** [**https://www.sah.org.au/research-ethical-review/**](https://www.sah.org.au/research-ethical-review/)**)?**

Yes  No

**2.2 Study Type**

**Investigator-Initiated Research**

Investigator-initiated research has the following characteristics:

* The research is initiated by an investigator at an AHCL facility and addresses relevant clinical questions and not industry needs
* A pharmaceutical/device company is not acting as the Sponsor for the purposes of the CTN Scheme application
* A pharmaceutical/device company is not directly funding the study or making payments to the investigator or institution
* The Principal Investigator or institution is the primary author and custodian of the study protocol

**Co-operative/Collaborative Research**

Co-operative/collaborative research has the following characteristics:

* The research addresses clinical questions and not industry or commercial needs
* The co-operative group must declare the nature of any sponsorship from a pharmaceutical entity or other entity that may directly benefit commercially from the research outcomes
* The co-operative group must be the primary author and custodian of the clinical trial protocol

**Commercially Sponsored Research**

Commercially sponsored research has the following characteristics:

* The research is initiated by a pharmaceutical/device company or other commercial entity and not by an investigator at an AHCL facility
* The research is conducted to investigate a medication/device for commercial exploitation by its manufacturer/sponsor
* The study protocol has been developed and is the responsibility of a pharmaceutical/device company of other commercial entity

**2.2.1 The project involves (choose as many answers as applicable):**

Observational research

Interventional research

Retrospective Data Analysis

Research using qualitative methods

Research using quantitative methods, population level data or databanks, e.g. health data stored in registries, survey research, and epidemiological research

Research involving the collection and/or use of human bio specimens (e.g. establishing a registry)

Genetic testing

Any of the following specific population groups:

Women who are pregnant and the human fetus

Children and young people

People in dependent or unequal relationships

People highly dependent on medical care who may be unable to give consent

People with a cognitive impairment, an intellectual disability, or a mental illness

People who may be involved in illegal activities

Aboriginal and Torres Strait Islander peoples

People in other countries

Research involving ionising radiation (*if yes, please provide a Site specific Radiation Safety Report*)

The administration of a drug/medicine

The use of a medical device

Other (please define below):

**2.2.2 How is the study/project being funded?**

Every research study involves cost, regardless of risk and whether there is any formal source of funding. This includes unfunded in-kind support, such as the time that research personnel are required to devote to the study. An explanation of how the research will be funded at the site **must be provided** to ensure adequate financial arrangements are planned. To assess the financial impact of the research, any costs incurred by the research project needs to be provided.

Commercial Sponsor  
Amount [include currency, e.g. USD, AUD, EURO]:

Other/non-commercial sponsor

Donation(s)  
Amount [include currency, e.g. USD, AUD, EURO]:

Scholarship  
Amount [include currency, e.g. USD, AUD, EURO]:

Grant  
Amount [include currency, e.g. USD, AUD, EURO]:

In-kind support e.g. research performed within existing work hours.  
Please provide details of the organisation, person, department or service that provides in-kind support and include an estimation of hours provided per week:

**2.2.3 Which organisation will receive/manage this funding and/or will be the Administering Organisation?**

**Organisation name:**

**Details of contact person:**

|  |  |
| --- | --- |
| **Title, First Name, Surname:** |  |
| **Phone / Mobile Number:** |  |
| **Email address:** |  |

**2.2.4 Insert account number(s) / cost centre details into which funds are to be deposited:**

**2.3 Data Security**

**2.3.1** **The research-related information collected by the research team (AHCL site) about participants will be in the following format:** (Tick more than one if applicable and explain further)

Non-identifiable

(Data that has never contained any identifiable information, eg: DOB, names, address, phone number)

Re-identifiable

(Data from which identifiers were removed and replaced with a code; the key to the code is kept separate from the data but can be easily accessed and used to re-identify data)

De-identified data

(Identifiers are permanently deleted or data is coded and only the CPI/PI can access the key to the code)

Individually identifiable

(Data contains personal information that can, in combination or on its own, identify a person, eg: name, DOB, address, phone number, etc)

**Details:**

**2.3.2 In what format will the data be stored, e.g. REDcap, other cloud based storage, computer, portable storage device, software provided by the commercial sponsor (e.g. Pharmaceutical company) or hardcopies:**

**2.3.3 Specify the measures to be taken to ensure the security of information from misuse, loss, unauthorised access while stored, collated, and analysed during and after the project.**

Please include details on when data is coded (if applicable), whether computers are in an institutional network that regularly creates data back-ups, whether files and/or computers are password protected/encrypted; how hardcopies are stored safely for the required period of time. If data is collected on behalf of a commercial sponsor (i.e. pharmaceutical company or medical device company) under a research agreement, please state this (no further details required in that case).

**2.3.4 Is the project a clinical trial as defined by the WHO?** (<https://www.australianclinicaltrials.gov.au/what-clinical-trial>)

Yes  No

**Yes** – please complete the **‘Clinical Trials Information’** section below.

**No** – is the drug or device registered with the ARTG?

**Yes** Please include listing on Australian Register of Therapeutic Goods registration (for example screen clips of results of an [online search of the ARTG](https://www.tga.gov.au/resources/artg))

**No** Please select the pathway:

Special Access Scheme – please follow the instructions on the [TGA’s website](https://www.tga.gov.au/form/special-access-scheme) and provide proof of approval by the TGA

Authorised Prescriber – please submit documentation in line with the [AHCL Governance Office’s process](https://www.sah.org.au/authorised-prescriber)

**2.4 Clinical Trials Information**

(Complete if the project is a clinical trial as identified in the previous section)

**2.4.1 Please provide the Trial Registration Number (if available):**

**2.4.2 Is this a Phase 1 trial?**

Yes  No

**2.4.3 Does the trial involve the use of a device?**

Yes  No

If yes, is the device currently used or registered at the hospital?  Yes  No

If no, please contact the Research Office for a copy of the *Clinical Product Presentation Form* for review by the Medical Procedures Prosthetics and Devices Committee (MPPD).

**2.4.4 Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes?**

YesIf yes, confirmation needs to be submitted to the Research Office within 4 weeks of granting site specific authorisation

No Please attach the ARTG listing

**2.4.5 Is the Standard Indemnity Form (Medicines Australia or MTAA) attached, signed by the sponsor and the Principal Investigator?**

Yes  No  N/A

**If N/A please state reason:**

**2.4.6 Is the Clinical Trial Research Agreement (Medicines Australia) or Clinical Investigation Research Agreement (MTAA) attached, signed by the sponsor and Principal Investigator?**

Yes  No  N/A

**If N/A please state reason:**

**2.4.7 Is the study budget attached to or included in the CTRA or CIRA?**

Yes  No

**2.4.8 Has the following statement been included in the payment schedule of the CTRA or CIRA?**

“Fees for Research Governance (RGO) review are fixed, non-cancellable, non-refundable costs payable on receipt of a valid tax invoice. RGO fees are charged in accordance with our most current fee schedule. The sponsor (CRG) agrees to pay the applicable RGO fees for the initial site-specific assessment of the project and for all subsequently submitted amendments within 30 days of CRG’s receipt of a valid invoice. The sponsor acknowledges that Research Governance Fees are reviewed annually and are subject to change.”

Yes  No– **please explain why not below:**

**2.4.9 Please confirm that no changes have been made to the body of the CTRA or CIRA template, and that all intended changes have been added to the section for Special Conditions?**

Yes  No– **please explain why not below:**

*If any changes are requested to the* ***Special Conditions*** *section of the CTRA or CIRA, these should be sent to the Research Office for review as early as possible before the agreement is signed by any party so that any issues can be identified and worked through without delaying the entire submission.*

**2.5 Research Personnel**

Provide details of **ALL investigators at AHCL sites** including qualifications, expertise/skills and experience in areas related to the research. If there are several Associate Investigators, please copy and repeat this section as many times as required.

**2.5.1 Principal Investigator (PI)**

|  |  |
| --- | --- |
| **Title, First Name, Surname:** |  |
| **Mailing Address:** |  |
| **Organisation Name, Department & Position:** |  |
| **Phone / Mobile Number:** |  |
| **Email address:** |  |

***Only one person can assume this role****. Students cannot be PI. A full list of investigator responsibilities can be found in the “IHC Guideline for Good Clinical Practice” or ISO 14155:2011 “Clinical investigation of medical devices for human subjects — Good clinical practice”*

Is this the **contact person** for this project?

Yes  No

Is this also the **Coordinating Principal Investigator** (for multi-centre studies only)?

Yes  No

Briefly describe the qualifications, expertise and experience of the Principal Investigator relevant to this project (i.e. qualifications, expertise, and experience)

Briefly describe the research activities that will be undertaken by the Principal Investigator in this project

**2.5.2 Study Co-ordinator(s) or Administrative Support***If the coordinator changes during the lifetime of a project, this must be communicated to the Research Office.*

|  |  |
| --- | --- |
| **Title, First Name, Surname:** |  |
| **Mailing Address:** |  |
| **Organisation Name, Department & Position:** |  |
| **Phone / Mobile Number:** |  |
| **Email address:** |  |

Is this the **contact person** for this project?

Yes  No

**2.5.3 Associate Investigator(s) (AI)***Copy and repeat this section if more than one AI*.

|  |  |
| --- | --- |
| **Title, First Name, Surname:** |  |
| **Mailing Address:** |  |
| **Organisation Name, Department & Position:** |  |
| **Phone / Mobile Number:** |  |
| **Email address:** |  |

Is this the **contact person** for this project?

Yes  No

Briefly describe the qualifications, expertise and experience of the Associate Investigator relevant to this project (i.e. qualifications, expertise, and experience)

Briefly describe the research activities that will be undertaken by the Associate Investigator in this project

**2.6 Site Resources and Support**

**2.6.1 Project sites to which this SSA applies (i.e. where are study activities to be conducted)**If your site is not listed please contact the Research Office.

Sydney Adventist Hospital including hospital facilities, San Radiology & Nuclear Medicine (SRNM), Sydney Adventist Hospital Pharmacy, Australasian Research Institute (ARI) and San Clinical Trials Unit (San CTU)

San Day Surgery Hornsby

San Clinics – specify which VMO rooms:

NHOG

Australian Clinical Trials

Other – please specify:

**2.6.2 Access to / support from AHCL staff and practitioners required for the study/project:**

Patients

Allied Health (Physiotherapy / Dietetics)

Nursing staff

Pharmacists

Medical Doctors (employed by AHCL)

Medical Doctors (VMOs)

Volunteers

Information Services (IS) Department

Other – please specify:

**2.6.3 Do you need access to AHCL records or electronic databases?**

SanCare

Radiology

ICIMS

Other Data – please specify:

**2.6.4 Will the research physically be conducted at any of the following AHCL Departments and Facilities?**

San Radiology – if yes, which of the following will be required?

Diagnostic equipment

Medical records

Other – please specify:

San Pathology (\*DHM entity) – if yes, which of the following will be required?

Phlebotomy only

Specimen testing (please provide us with the applicable pathology request form)

Specimen storage

***\*Please note:*** *projects conducted exclusively at San Pathology need to be approved by the governance office of Douglass Hanly Moir (DHM).*

Information Services (IS) Department

**Please specify the type of service and/or number of hours required:**

Has the requirement for these services already been discussed with the Director Information Services?

Yes  No

San Pharmacy

**Please specify the type of service and/or number of hours required:**

Operating Theatres

**Please specify the type of service and/or number of hours required:**

Other departments –

**Please specify name, type or service and / or number of hours required:**

**2.7 Participants**

**2.7.1 Does the study involve planned admissions to SAH for overnight stays of participants?**

Yes (for how long: XX nights on XX occasions (per participant); Ward(s) \_\_)

No

**2.7.2 Overall number of participants to be recruited in this study (all sites together):**

**2.7.3 Proposed number of participants to be recruited at this site:**

**2.7.4 Briefly describe how you are going to recruit and consent participants**Include details on where participants will be recruited, who is recruiting the participants and how (e.g. GPs at the next consultation; study coordinator contacting potential participants on the phone, etc)

**2.7.5 Is it proposed to screen or assess the suitability of the potential participants for the study?**

No   
 Yes: How will this be done?

**2.7.6 For Clinical Trials:**

Please confirm that appropriate persons involved in the project (research nurses, study coordinators, investigators) can be contacted in medical emergencies and/or that a process is in place providing the participants with 24/7 emergency treatment, should such become necessary as a result of study participation.

Yes

No – provide details of how participants are provided with 24-hour medical support for health issues or severe side effects resulting from study participation.

**2.7.7 Has this trial been registered?**

Clinical trials which are initiated in Australia or New Zealand must be registered with the [Australian New Zealand Clinical Trials Registry (ANZCTR)](http://www.anzctr.org.au/), prior to recruitment of patients into the trial. Other NHMRC-funded trials which are part of an existing study or which are being conducted overseas must be registered on ANZCTR or an equivalent clinical trials registry such as the US National Institutes of Health [ClinicalTrials.gov](https://clinicaltrials.gov/) or a primary registry on the World Health Organisation’s [International Clinical Trials Registry Platform (ICTRP)](http://www.who.int/ictrp/en/), prior to the recruitment of patients into the trial.

Yes  No

**2.8 Biosafety, Chemical and Radiation Safety**

It may be necessary for research organisations to complete notification, registration or licence requirement for research involving biosafety, regulatory issues and/or radiation. If so evidence of this is required.

*If any of the points below are marked ‘****Yes****’, then the appropriate documentation or approval must be attached or forwarded to the Research Governance Office when available.*

**2.8.1 Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required?**

Yes  No

**2.8.2 Is committee approval of chemical safety required (drugs/pharmacy Committee)?**

Yes  No

**2.8.3 Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment?**

Yes  No

**2.8.4 Will the project require application for a licence to the NHMRC Licencing Committee to conduct embryo research?**

Yes  No

**2.8.5 For projects where Australian Radiation Prot4ection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required?**

Yes  No

**2.8.6 Will data in this study be linked with state or federal databases (e.g.** [**https://www.aihw.gov.au/our-services/data-linkage**](https://www.aihw.gov.au/our-services/data-linkage)**)?**

Yes  No

**2.9 Compliance with Section 95A of the Privacy Act 1988**

If this project has been granted a Waiver of Consent by the approving HREC, please complete below sections to confirm that the study documentation contains the below required information.

**Note**: if you have been granted a Waiver of Consent **at least one section** (A.2.6 or B3.6) of *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024)* applies to your study.

**A2.6:** In the proposal to collect health information for the **purpose of research relevant to public health or public safety**, the collector(s) should state:

1. the aims or purpose of the collection
2. the credentials and technical competence of the collector(s) of the data
3. the data needed
4. the study period
5. the target population
6. the reasons why de-identified information cannot achieve the relevant purpose of the research activity
7. the reasons why it is impracticable to seek consent from the individual for the collection of health information
8. the estimated time of retention of the health information
9. the identity of the custodian(s) of the health information collected
10. the security standards to be applied to the health information. Standards must be in accordance with APP 11 (security of personal information) [Note: In particular, health information should be retained in accordance with guidance set out in the *Australian Code for the Responsible Conduct of Research*, as in force or existing from time to time and in a form that is at least as secure as it was in the sources from which the health information was obtained unless more stringent legislative or contractual provisions apply]
11. a list of personnel within the collecting organisation or organisations with access to the health information collected
12. the level of protection that will be applied by the collector(s) to protect health information disclosed to the collector(s) by the disclosing organisation. These should include:
13. terms of any release agreement between the disclosing organisation and the collector(s) to govern limits on the use and disclosure of collected health information [See: paragraph A.2.9 of *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024)*]
14. proposed methods of disposal of the health information on the completion of the research activity, as required by APP 11.2 (security of personal information).
15. any proposal to send data overseas for the purpose of the research project including the names of the countries to which it is proposed the data be sent and how the research project will comply with APP 8 (crossborder disclosure of personal information) of the Privacy Act.

Confirmed  Not applicable

**B3.6:** In the proposal to collect health information for the **purpose of the compilation or analysis of statistics, relevant to public health or public safety,** the user or discloser should state:

1. the aims or purpose of the use or disclosure
2. the credentials and technical competence of those seeking to use or disclose the data
3. the data needed
4. the study period
5. the target population
6. the reasons why de-identified information cannot achieve the relevant purpose of the compilation or analysis of statistics activity
7. the reasons why it is impracticable to seek consent from the individual(s) for the use or disclosure of health information
8. the specific uses or disclosures that will be applied to the health information during the study
9. the proposed method of publication of results of the research, including a statement that health information will not be published unless in de-identified form
10. the estimated time of retention of the health information
11. the identity of the custodian(s) of the health information used or disclosed collected
12. the security standards to be applied to the health information. Standards must be in accordance with APP 11 (security of personal information). [Note: In particular, health information should be retained in accordance with the *Australian Code for the Responsible Conduct of Research*, as in force or existing from time to time, and in a form that is at the least as secure as it was in the sources from which the health information was obtained unless more stringent legislative or contractual provisions apply. The Code is principles-based; there is further guidance in the associated guides.]
13. a list of personnel within an organisation or organisations with access to the health information to be use or disclosed
14. any proposal to send data overseas for the purpose of the research project including the names of the countries to which it is proposed the data be sent and how the research project will comply with APP 8 (crossborder disclosure of personal information)
15. the level of protection that will be applied by those seeking to use or disclose health information to protect that health information. These should include:
16. the terms of any disclosure agreement between the organisation that holds the health information and the user or discloser, to govern limits on the use and disclosure of the health information [See: paragraph B.3.10 of *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024)*]
17. the proposed methods of disposal of the health information on the completion of the statistical compilation or analysis activity, as required by APP 11.2 (security of personal information)
18. the level of protection that will be applied to protect the privacy of health information where it is made available to others if that is proposed.

Confirmed  Not applicable

**A3.8:** If those seeking to use or disclose health information propose to **use or disclose that information to contact a person**, the user or discloser of that information must inform the person:

1. that his or her health information is being used or disclosed in accordance with the Privacy Act 1988 and these guidelines
2. how his or her health information will be used or disclosed
3. that he or she is free at any time to withdraw consent for further involvement in the research activity; [See: NHMRC *National Statement on Ethical Conduct in Human Research (2023)* Chapter 2.2 General requirements for consent]
4. of the standards that will apply to protect the privacy of that individual; and of existing complaint mechanisms to HRECs, the Commissioner [See: paragraph A3.6(l) of *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024*)]
5. of the complaint mechanisms in section G of *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2024*)

Confirmed  Not applicable

**2.10 Declarations**

1. **Declaration by the Principal Investigator**

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Health Research Ethics Committee (HREC).
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC *National Statement on Ethical Conduct in Human Research (2023).*
4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research is the authorising authority withdraws authorisation at the site where I am Principal Investigator.
10. I understand and agree that study files and documents and research records and date may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC and the research governance officer. This information will be sued for reporting purposes and managed according to the principles in the Privacy Act 1988 (Cth) and relevant laws in NSW and Territories of Australia.

**If the research is not a commercially sponsored clinical trial the following needs to be confirmed by the Principal Investigator. Please tick boxes to confirm**

This research will be conducted in compliance with all applicable laws (Australian federal and state laws) and Governmental Regulations including but not limited to the Australian Privacy Principles, the NSW Health Privacy Principles, the Privacy Act 1988 (Commonwealth), and the Health Records and Information Privacy Act 2002 (NSW);

If cross border disclosure of personal information forms part of this project, I confirm there are processes in place to ensure the overseas recipient does not breach the Australian Privacy Principles in relation to the information (APP 8.1);

I am aware that I am accountable for any acts or practices of the overseas recipient in relation to the information that would breach the APPs (S16C) when disclosing personal information to an overseas recipient, and have taken reasonable measures to ensure compliance of the overseas recipient.

Signature of Principal Investigator:

Print Name: Date:

1. **Declaration by the Associate Investigator(s)**

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Health Research Ethics Committee (HREC).
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC *National Statement on Ethical Conduct in Human Research (2023).*
4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Associate Investigator. I will discontinue the research is the authorising authority withdraws authorisation at the site where I am Associate Investigator.
10. I understand and agree that study files and documents and research records and date may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC and the research governance officer. This information will be sued for reporting purposes and managed according to the principles in the Privacy Act 1988 (Cth) and relevant laws in NSW and Territories of Australia.

Signature of Associate Investigator:

Print Name: Date:

Signature of Associate Investigator:

Print Name: Date:

Signature of Associate Investigator:

Print Name: Date:

1. **Declaration by Head of Department \*(or Divisional Director / other authority) where the Principal Investigator will conduct the research.**

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

1. I certify that I have read the research project application named above
2. I certify that I have discussed the project and the resource implications for the Department with the Principal Investigator
3. I certify that all researcher/students from my Department involved in the research project have the skills, training and experience necessary to undertake their role.
4. I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
5. My signature indicates that I support this research project being carried out using such resources.

Name of Head of Department

(or appropriate person):

Name of Department

(or relevant section):

Signature:

Print Name: Date:

***\*Where an investigator is also Head of Department, please contact the Research Office for further advice.***

**(d) Declaration by Head of Supporting Department**

This form is to be completed by the Head of any Department that is providing support services to the research project, but which does not have any member(s) on the research team.

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

I have discussed this project with the Principal Investigator, within the present resources of the Department.

I am: *(tick whichever applies)*

Able to perform the investigations/services indicated, within the present resources of the Department

Able to perform investigations/services indicated, if the following financial assistance is provided:

Unable to undertake the investigations/services indicated, on the following grounds:

Signature:

Print Name: Date:

Department:

**(e) Declaration by the Authority for Data Provision**

This form is to be completed by the person authorised to provide data services for research projects.

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required.

The Department is: *(tick whichever applies)*

Able to confirm that the data services indicated will be provided, within the present resources

Able to confirm that the data services indicated will be provided, if the following financial assistance is provided:

Unable to provide data services indicated, on the following grounds:

I certify that I will give due regard to any ethical conditions imposed by the approving HREC when deciding whether, and in what form, I will release data to the investigator.

Signature:

Print Name: Date:

Position:

Department:

**(f) Declaration by the Patient Services / Finance Departments (as required)**

This form is to be completed by the person authorised to provide financial advice or approval for research projects.

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

I/We have considered this proposal and consulted the appropriate personnel and confirm that all relevant documents required have been reviewed.

The Department/s are: *(tick whichever applies)*

Able to confirm that the study is approved to proceed from a financial perspective (budget is approved, payment processes for sponsor reimbursements are in place etc)

Able to confirm that the study could be approved to proceed from a financial perspective AFTER the following information is provided / work is completed:

Unable to provide approval to proceed on the following grounds:

Signature:

Print Name: Date:

Position:

Department:

Signature:

Print Name: Date:

Position:

Department:

**(g) Declaration by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

This form is to be completed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

I/We have considered this proposal and consulted the appropriate personnel and confirm that all relevant documents required have been reviewed.

The Department/s are: *(tick whichever applies)*

Able to confirm that the study is approved to proceed

Able to confirm that the study could be approved to proceed AFTER the following information is provided / work is completed

Unable to provide approval to proceed on the following grounds:

Signature:

Print Name: Date:

Position:

Department:

**(h) Declaration by the Research Governance Office**

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

**RGO to confirm that the following criteria have been addressed:**

Section 95A confirmation by approving HREC (if applicable)

Ensure appropriate level of HREC review according to population groups, as follows:

HREC review required (full HREC) if study participants are from any of these specific population groups: Women who are pregnant and the human fetus, People highly dependent on medical care who may be unable to give consent, People with a cognitive impairment, an intellectual disability, or a mental illness, People who may be involved in illegal activities, Aboriginal and Torres Strait Islander peoples, People in other countries.

Ethics review body acceptable (HREC Sub-Committee) if study participants are from any of these specific population groups: Children and young people, People in dependent or unequal relationships.

SSA Authorisation is:

Recommended

Not recommended *(please specify reasons why)*

Signature:

Research

Governance

Officer Name

(or equivalent): Date:

Position:

**(i) Authorisation by Chief Executive (or delegate)**

|  |  |
| --- | --- |
| **HREC Reference No:** |  |
| **Project Title (in full):** |  |
| **Principal Investigator:** |  |

This research is:

Authorised

Not authorised

**Conditions applied to authorisation / or reasons for not authorising:**

My signature indicates that I authorise/do not authorise this research project to commence at this site.

Name of Chief Executive

(or delegate): Date:

Signature: