ST VINCENT'S HEALTH AUSTRALIA

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ST. VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE

SITE SPECIFIC ASSESSMENT FORM

Site-Specific Assessment (SSA) is a key component of research governance and involves assessment of the suitability of the site and the Investigator(s) for the proposed research. The SSA is the mechanism for professional, legal and financial accountability and transparency and is consistent with the NHMRC's "Australian Code for the Responsible Conduct of Research" 2007 (the Code).

The SSA process considers the following elements of Research Governance:

- Ethical Approval
- Compliance with legislation, regulations, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, biosafety, radiation safety and professional standards.
- Financial management and site-specific requirements (adequate resources - financial, human, equipment and infrastructure) for the research to proceed at the site
- Legal and Insurance – consent, indemnity and contracts
- Researchers have the necessary expertise and experience; if not relevant training is planned before carrying out their research study
- Monitoring of research throughout the life of the project

Instructions for the Principal Investigator:

- This form must be completed by the Principal Investigator (PI) responsible for the research project at this site.
- Applicants should begin negotiations with relevant SVHA Health Services personnel responsible for resources that will be required for the study, e.g. Heads of Departments or Managing Accountant, as early as possible.
- The completed form must be submitted to the SVHA Research, Ethics & Governance Officer for review prior to final Authorisation by the facility Chief Executive Officer or delegate, before the research can begin.
- Items 1 to 10 (and Sections MR, CT, and IN, if applicable) of the form are to be completed and the required associated documents attached.

1. General Details

Date:	Click here to enter a date.
HREC Ref	Click here to enter text.
SVHA Site(s)	☐ St Vincent's Private Hospital Brisbane (SVPHB) ☐ Holy Spirit Northside Private Hospital (HSNPH) ☐ St Vincent's Private Hospital Toowoomba (SVPHT) ☐ St. Vincent's Care Services
Study Title	Click here to enter text.
Principal Investigator	Click here to enter text.
SVHA Main Contact For Study	Click here to enter text.

2. Research Team

2.1 Are all research personnel listed on the HREA/LNR Application Form accompanying this submission?
☐ Yes ☐ No
2.2 Clinical staff only: Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator's participation in this study?
☐ Yes ☐ No ☐ N/A
2.3 Will non-SVHA researchers be accessing the SVHA site/s for purposes of this research?
☐ Yes ☐ No
If yes, please provide details:
Click here to enter text.
2.4 Will non-SVHA researchers be approaching SVHA participants for purposes of this research (e.g. providing project-related information, undertaking informed consent procedures)?
☐ Yes ☐ No
If yes, please provide details:
Click here to enter text.

3. Training

3.1 Will any of the researchers at SVHA require extra training to enable their participation in this project?
☐ Yes ☐ No
If yes, please provide details:
Click here to enter text.
If No, please provide an explanation:
Click here to enter text.

3.2 Are any members of the research team certified in Good Clinical Practice (GCP)?		
☐ Yes ☐ No		
If yes, please complete table below		
Researcher	**Level of GCP training (e.g. Online course, half-day course, 2-day course etc.)**	**Year training was undertaken?**
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

4. Access to Confidential Information

If researchers require access to confidential information (e.g. patient records, databases, departmental records) to conduct their research then approval must be obtained from relevant SVHA facility Privacy Officer. This is to determine whether the project complies with all Privacy Laws and that the data required for the study is collected and accessible for the research project. Please contact the Research, Ethics and Governance Officer for further details.

4.1 Does this project require access to confidential information held by the specified SVHA site?
☐ Yes ☐ No
If yes, please complete section MR: Access to Medical Records

5. Recruitment

5.1 What is the proposed number of participants to be recruited at the SVHA sites?
Click here to enter text.
5.2 Does this project use existing collections of retrospective clinical data?
☐ Yes ☐ No
5.3 If yes, what is the planned number of SVHA site/s patient records to be reviewed?
Click here to enter text.
5.4 What process will be used to identify potential participants at the SVHA site/s?
Click here to enter text.
5.5 How will initial contact be made with potential participants at the SVHA site/s?
Click here to enter text.

6. Compliance with requirements of a Catholic organisation

6.1 Does the research comply with requirements of the Catholic Health Australia "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" 2001, particularly regarding the following types of research? **(i) Use of embryos in human research** **(ii) Clinical trials where pregnancy must be avoided**
☐ Yes ☐ No
If No, please provide an explanation:
Click here to enter text.
For further information regarding acceptable wording in participant information and consent forms (PICF) suggested by SVHA, please refer to the PICF guidelines (provided by the Research, Ethics and Governance Officer on request.

7. Resource and budget information

SVHA may incur costs in providing support for your research over and above those costs associated with standard care. Any additional routine care costs to be met by SVHA are to be clearly identified and detailed. This includes both the 'actual monetary' costs and 'in kind' support.

Funding source/s

Type of funding	Name of funding organisation/source	Amount for this site (either $/year or $/participant)	Sought or Approved
Business (commercially sponsored)	Click here to enter text.	Click here to enter text.	Choose an item.
Private Non-profit Organisations (e.g. collaborative groups)	Click here to enter text.	Click here to enter text.	Choose an item.
Australian Government (e.g. NHMRC, ARC)	Click here to enter text.	Click here to enter text.	Choose an item.
Joint Business/ Government	Click here to enter text.	Click here to enter text.	Choose an item.
Non QLD state/ local government	Click here to enter text.	Click here to enter text.	Choose an item.
University	Click here to enter text.	Click here to enter text.	Choose an item.
Institutional Competitive Research Grants	Click here to enter text.	Click here to enter text.	Choose an item.
Internal Department Funds	Click here to enter text.	Click here to enter text.	Choose an item.
Other Australian Sources	Click here to enter text.	Click here to enter text.	Choose an item.
Other (e.g. Researcher Self-Funded)	Click here to enter text.	Click here to enter text.	Choose an item.

Project Funding/ Support (site-specific)

- Document only those items which are above the usual standard care and are particular to the research study, e.g. extra documentation, extra tests.
- If actual monetary costs are involved, dollar values are to be supplied. If seeking in-kind support, please provide details of resources required, e.g. SVHA investigator time, time of any other SVHA staff involved (e.g. as participants), use of infrastructure, administrative support.
- The monetary costs need to be covered by a funds source /s which may be an existing source or new funds.

If a detailed budget worksheet has already been prepared for the SVHA site, this may be attached to the application instead of completing Section 9.3. If the budget is provided as an attachment, please ensure that any requested 'in kind' support is listed below.

7.1 If costs are not covered by the sponsor or funding body please explain how the costs will be covered or explain how SVHA will benefit from this research?
Click here to enter text.

8. Clinical trials information

8.1 Is the study a clinical trial?
☐ Yes ☐ No
If yes, please complete Sections CT: Clinical Trial and IN: Indemnity and Insurance.

9. Indemnity and Insurance

9.1 Will non-SVHA investigators access the SVHA site for the purposes of this research?
☐ Yes ☐ No
If yes, please complete Section I: Indemnity and Insurance.

10. Declarations

Declaration by the 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 responsibility for the conduct of the study at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the SVHA Human 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 the Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and Catholic Health Australia "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" (2001).
4. I agree 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 agree 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 if 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 data 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 on file and in the research databases of the SVHA HREC. This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Print Name	Signature	Date
Role in Project:		
Print Name	Signature	Date
Role in Project:		

Section MR: Access to Medical Records

Every non-SVHAC researcher wishing to access medical records for the purpose of research at any SVHA Queensland facility must have approval by the facility General Manager and Privacy Officer having signed the Privacy Declaration below. This approval is only valid for the project specified on this form.

All applications must be accompanied by:

- A current signed patient consent to access records (<12 months)
- A copy of the study protocol
- Evidence of ethics approval. For example, ethics approval letter by approving HREC.

Person that will need access to the medical records (if > 1 person, all must sign a declaration):

Name	Click here to enter text.
Profession	Click here to enter text.
Organisation	Click here to enter text.
Aust Health Practitioner Regulation Agency (AHPRA) Registration	☐ Yes ☐ No AHPRA Reg No.: Click here to enter text. If no, has appropriate training been arranged with the Manager, Health Information Services relating to privacy and confidentiality? ☐ Yes ☐ No

Information required:

Number of records	Click here to enter text.
List of variables sought	Click here to enter text.

Privacy Declaration

1. I agree to abide by St Vincent's Aged and Shared Services Privacy Policy and at all times comply with the relevant Australian Privacy Principles (APPs) under the Commonwealth Privacy Act (1988) and the Australian code for the responsible conduct of research (2007) whilst accessing medical records for research purposes.
2. I agree that if given access to confidential information, confidentiality must be maintained. Information must only be used for the purpose for which it was requested and with relevant consent obtained.
3. I also agree to keep confidential any information concerning persons or events that comes to my attention at St Vincent's Health & Aged Care Facilities. Such information includes anything relating to the research above, and any other information which I hear, see or read during my time at the hospital.

Print Name	Signature	Date
Role in Project:		
Print Name	Signature	Date
Role in Project:		

OFFICE USE ONLY

Principal Investigator	Click here to enter text.
Study Title	Click here to enter text.
HREC Ref	Click here to enter text.
Expiry of ethical approval	Click here to enter a date.

Approval granted to access medical records for the purpose of the research project outlined above:	
☐ Yes ☐ No	
Privacy Officer:	**Date:**
Facility General Manager:	**Date:**

Section CT: Clinical Trial

CT.1 Select the study phase
Choose an item.

CT.2 Clinical trials registry

Section 19 of the Declaration of Helsinki (2008) states:
"*Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.*"
In addition, it is an essential criterion for publication of a trial in journals of the International Committee of Medical Journal Editors (ICMJE) that the details of a trial should be publicly available in a clinical trials registry.

a) Is the clinical trial registered on a publicly accessible clinical trials registry database?

☐Yes ☐No

b) If yes, please provide detail (name of registry, registry number).

If no, please explain why the study is not registered on a publicly accessible clinical trials registry database

Click here to enter text.

CT.3 Industry Sponsored/Contract Research Organisation (CRO) trials
If the study is not industry sponsored, please proceed to Section CT.4.

SPONSOR DETAILS

Organisation name:	Click here to enter text.
Contact person:	Click here to enter text.
Full Name:	Click here to enter text.
Position:	Click here to enter text.
Business phone no.:	Click here to enter text.
Email address:	Click here to enter text.
Account details:	Click here to enter text.
ABN:	Click here to enter text.

CONTRACT RESEARCH ORGANISATION (CRO) DETAILS

Organisation name:	Click here to enter text.
Contact person:	Click here to enter text.
Full Name:	Click here to enter text.
Position:	Click here to enter text.
Business phone no.:	Click here to enter text.
Email address:	Click here to enter text.
Account details:	Click here to enter text.
ABN:	Click here to enter text.

CT.4 Invoicing details for Research Governance review fees The SVHA Research Governance Office has established a schedule of fees for SSA submissions. Refer to the schedule of fees located on the SVHA HREC website. Please note that these fees are in line with other hospitals and universities in Brisbane. Advised which entity should be invoiced for Research Ethics and Governance review fees:
Click here to enter text.
CT.5 Is the fully executed Medicines Australia Standard Indemnity Form attached? Please liaise with the Research, Ethics and Governance Officer regarding signing of this form.
☐ Yes ☐ No ☐ N/A
If No or N/A please give an explanation:
Click here to enter text.
CT.6 Clinical trial agreement A copy of the fully executed Clinical Trial Agreement (CTA) must be supplied to the SVHA Research Governance office when available. SVHA Research Governance Authorisation cannot occur until all agreement requirements are in place.
a) Is the Medicines Australia Standard CTA attached?
☐Yes ☐No

Please complete Section I: Indemnity and Insurance

Section IN: Indemnity and Insurance

If the research project is a clinical trial or if non-SVHA investigators are accessing the SVHA site for the purposes of this research, evidence of insurance is required (e.g. Certificates of Currency for Clinical Trial Insurance and/or Product and Public Liability and/or Professional Indemnity).

IN.1 Is evidence of adequate insurance cover attached?
☐Yes ☐ No ☐ N/A
IN.2 If no or N/A please give an explanation:
Click here to enter text.

For internal use only

Not to be completed by the researcher. For full SSA (more than low or negligible risk).

Recommendation by the Research Chair

HREC application 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).

SSA Authorisation is:

☐ Recommended

☐ Not recommended

☐ Requires Chief Executive/delegate consideration

Authorisation by Chief Executive Officer/Delegate

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

Name of Chief Executive Officer: .....

Name of Organisation: .....

Signature ..... Date .....