ST. VINCENT'S HEALTH AND AGED CARE

EVALUATION FOR LOW AND NEGLIGIBLE RISK RESEARCH

St Vincent's Health & Aged Care (SVHAC)Human Research Ethics Committee (HREC) is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2007 (National Statement). It facilitates the review and oversight of human research to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards of human research in facilities governed by St Vincent's Health & Aged Care.

The SVHAC HREC reviews research submissions via different processes depending on whether the research poses low/negligible or high risk. A low/ negligible risk submission may undergo expedited review outside of the scheduled HREC meeting times. In order for the Expedited Review Panel of the HREC to consider whether research meets the low/negligible risk criteria, researchers must complete this form to accompany their submission.

Researchers will be updated by the SVHAC HREC Research Governance Officer as to the outcome of their submission.

Please complete the form below to determine if your research is low/negligible risk and include it with your research submission

Principal Researcher	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Fax:	Click here to enter text.
Email	Click here to enter text.

Project Title
Click here to enter text.

ADVICE REGARDING NEGLIGIBLE AND LOW RISK REVIEW PROCESSES

The National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research" (2007) ("The National Statement") recognises that human research involves a wide range of activities that have variable risks and potential benefits. The "National Statement" establishes different levels of ethical review, based on the degree of risk involved.
There are three levels of risk:

1. Harm
2. Discomfort
3. Inconvenience

Researchers and HRECs are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity. The National Statement, sections 2.1.6 – 2.1.7 holds that:

> "**2.1.6** *Research is "Low Risk" where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk;*
>
> **2.1.7** *Research is "negligible risk" where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk*."

Research that involves the risk of harm or the likelihood of harm, must be reviewed by a fully constituted HREC. For research involving only the risk of inconvenience, the National Statement allows Institutions to choose to grant exemption from HREC review. For Research that involves only the risk of discomfort, Institutions may establish other levels of ethical review processes other than a fully constituted HREC. However, for research involving certain groups, methodologies or procedures only full HREC review is allowable, irrespective of the level of the risk (see checklist and processes below). A full HREC application must be prepared using the NEAF.

Researchers are encouraged to complete the checklist first and consult with the local HREC office to gain an independent assessment of whether the project satisfies the criteria for alternative review to that by a full HREC. Time constraint is not an acceptable reason for seeking review through this process where projects carry risks greater than discomfort

CHECKLIST FOR LOW RISK RESEARCH PROJECTS

NHMRC "National Statement on Ethical Conduct in Human Research"
Sections 2.1.6, 5.1.6, 5.1.7, 5.1.18 – 5.1.21

The "National Statement on Ethical Conduct in Human Research" 2007 describes low risk as not more than discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Participants would normally (but not always) be competent and independent adults.

If the project includes the following types of research and/or participants it will require review by a Human Research Ethics Committee and will **not be eligible for low risk review**. Projects that are not deemed eligible for low risk review are forwarded to the Human Research Ethics Committee for consideration and approval in the usual way. A full HREC application must be prepared using the HREA.

- Interventions and therapies, including clinical and non-clinical trials and innovations;
- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus;
- People who are highly dependent on medical care who may be unable to give consent;
- People with a cognitive impairment;
- People with an intellectual disability or a mental illness;
- Aboriginal or Torres Strait Islanders;
- People who may be involved in illegal activities

If a project does **NOT** include any of the above, complete the detailed checklist below:

1. ARE ANY OF THE FOLLOWING TOPICS COVERED IN PART OR IN WHOLE?					
Sensitive cultural issues	Yes☐	No ☐	Suicide risks	Yes☐	No ☐
Explorations of grief, death or traumatic loss	Yes☐	No ☐	Gender identity	Yes☐	No ☐
Mental Disorders	Yes☐	No ☐	Fertility	Yes☐	No ☐
Self-report of criminal behaviour	Yes☐	No ☐	Substance abuse	Yes☐	No ☐
Termination of pregnancy	Yes☐	No ☐	Race or ethnic identity	Yes☐	No ☐

2. ARE ANY OF THE FOLLOWING PROCEDURES TO BE EMPLOYED?		
Use of personal data obtained from Commonwealth or State Government Department/Agency	Yes☐	No ☐
Deception of participants; Covert observation (or minimal disclosure)	Yes☐	No ☐
Audio or visual recording without consent	Yes☐	No ☐
Recruitment of a third party or agency	Yes☐	No ☐
Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching)	Yes☐	No ☐
Use of medical records where participants can be identified or linked	Yes☐	No ☐
3. OTHER RISKS		
Are there risks to the researcher (for example, research conducted in unsafe environments)?	Yes ☐	No ☐

Are there risks to non-participants in the research such as participant's family members and social community? (for example, effects of biography on family and friends or infectious disease risk to the community).	Yes ☐	No ☐

4. SELECT THE CATEGORIES THAT ARE <u>TARGETED OR LIKELY TO BE INCLUDED</u> AS PARTICIPANTS IN THIS RESEARCH PROJECT		
Children and/or young people	Yes☐	No ☐
Resident of a custodial institution	Yes☐	No ☐
English as a second language	Yes☐	No ☐
Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities	Yes☐	No ☐
Those in a dependent relationship with the researchers (for example, lecturer/student, doctor/patient, teacher/pupil & professional/client)	Yes☐	No ☐
Participant information is potentially identifiable	Yes☐	No ☐
Research findings are expected to be published in a peer reviewed Journal	Yes☐	No ☐

If "Yes" has been answered to any item in the checklist, the project may not be eligible for low risk review.

However, because of the particular nature of the project and participants involved, the project may be deemed low risk if the following considerations are reasonably justified with the provision of detailed information in the following application:

- The likelihood and severity of the risks (any risk greater than discomfort, even if unlikely, is not low risk);
- Identification of whom (participants and/or others) the risk may affect:
- The means taken to minimise the risk;
- The potential benefits of the research;
- To whom the benefits are likely to accrue

APPLICLATION FOR REVIEW OF LOW AND NEGLIGIBLE RISK RESEARCH
About this form:
Following completion of the *St Vincent's and Aged Care Evaluation for low and negligible risk research* form, the *Application for review of low risk research* form must be completed.
Attachments:
Before submitting your application, please check that you have attached the completed and copies of all required supplementary documentation (for example, Participant Information Sheet and Consent Forms)
Authorisations:
Please check that you have obtained all required signatures before submitting the application

Do not commence research until written approval has been received from the SVHAC HREC

SECTION 1.0 RESEARCHERS AND SITE INFORMATION	
Principal Researcher	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Email	Click here to enter text.
Other Researcher (1)	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Email	Click here to enter text.
Other Researcher (2)	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Email	Click here to enter text.
Other Researcher (3)	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Email	Click here to enter text.
Other Researcher (4)	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.
Email	Click here to enter text.
Other Researcher (5)	
Title:	Choose an item.
Name:	Click here to enter text.
Phone:	Click here to enter text.

Email	Click here to enter text.

Researcher/s Qualification, Experience and Skills:
List academic qualifications and outline experience and skills relevant to project that researcher/s and any supporting staff have in carrying out the research. (100 words max)

Click here to enter text.

SITE SPONSOR/ CONTACT	
Facility/s	Click here to enter text.
Contact Name:	Click here to enter text.
Email	Click here to enter text.

SECTION 2: PROJECT DETAILS

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Section 1}**

PROJECT TITLE
Click here to enter text.

LAY DESCRIPTION (Briefly outline in simple terms the project's aim (s), justification, participant group(s), method and possible outcomes). 150 words max.
Click here to enter text.

RESEARCH METHODS (Outline the proposed method, including data collection, techniques, tasks participants will be asked to complete, estimated time commitment required of them and how data will be analysed. Give a justification of your proposed sample size including details of statistical power of the sample where appropriate)
Click here to enter text.

RESEARCH AIMS AND SIGNIFICANCE

(State the aims, research objectives, key research questions and significance of the project. Where relevant, state the specific hypothesis to be tested. Also please provide a description of the relevance of your proposed project to current research, a justification as to why your research should proceed and an explanation of any expected benefits to the community. Comment on any potential to contribute to existing knowledge, treatment, disease prevention, health promotion or social improvement) 600 words max.

Click here to enter text.

SECTION 3: FUNDING AND FINANCE (DECLARATION OF CONFLICT OF INTEREST)

Researchers should include any source of funding (for example, departmental, commercial, non-commercial, government)

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Chapter 5.4}**

Has this project received research funding?
Click here to enter text.
If yes to above, describe the source of funding and what the funding is for?
Click here to enter text.
Will the researcher receive any remuneration and/or in kind funding to perform this research?
Click here to enter text.
Will the participants receive any payment or expenses for participant in the research? **If Yes, please give details.**
Click here to enter text.

SECTION 4: OTHER APPROVALS

The Principal Researcher is responsible for informing each HREC of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research project; of any previous decisions regarding the research made by another HREC; and informing each HREC of whether the protocol is presently before another HREC

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Chapter 5.3}**

Is This protocol being submitted or has it previously been submitted to another Human Research and Ethics Committee
Yes☐ No ☐ If Yes; please attach documentation or provide details below from other HRECs involved
Click here to enter text.

SECTION 5: RECRUITMENT OF PARTICIPANTS

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Chapter 2.2}**

PARTICIPANT DETAILS

Provide number, age range and source of participants. This explanation should also include how potential participants will be identified and how initial contact will be made.

Click here to enter text.

What is the proposed method of recruitment of participants?

Click here to enter text.

SECTION 6: CONSENT

The potential participant must be provided with information **at their level of comprehension** about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results)

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Chapter 2.2; 2.3}**

Will the research involve informed consent of participants?

Yes☐ No ☐

If yes, how will informed consent be obtained/recorded?

Click here to enter text.

If no, please justify why consent will not be obtained?
Click here to enter text.

SECTION 7: INFORMATION PROTECTION (CONFIDENTIALITY, DATA STORAGE AND SECURITY)

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Section 2}**

CONFIDENTIALITY Explain what methods will be used to guarantee confidentiality/ anonymity of participant data.
Click here to enter text.

DATA STORAGE AND SECURITY Explain how and where data will be held, including any arrangement for data security during?
Click here to enter text.
Please explain how long the data will be kept?
Click here to enter text.
How will data be disposed of?
Click here to enter text.

SECTION 8: DISSEMINATION OF RESULTS

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council **{Section 4}**

Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the findings or outcomes of the project

Click here to enter text.

SECTION 9: DECLARATION - Signatures and Undertakings:

Applicant/ Principal Investigator/ Additional Researchers (including Students and Supervisors where permitted)

I/we certify that:

- All information is correct and complete as possible;
- I/we have had access to and read the NHMRC *"National Statement on Ethical Conduct in Human Research" (2007) updated May 2015)*
- The research will be conducted in accordance with the National Statement;
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these;
- I/we will immediately report to the HREC review body anything which might warrant review of the ethical approval of the research, including:
    - Serious or unexpected adverse effects on participants;
    - Proposed changes in the protocol; and
    - Unforeseen events that might affect continued ethical acceptability of the project;
- I/we have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants;
- I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC review body, including;
    - Conditions of approval stipulated by the HREC review body;
    - Cooperate with monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC review body;

I/we have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;

Signatures over page

Principal Researcher	
	(Print Name in block letters)
Signature (Principal Researcher)	**Date:** Click here to enter a date.
Other Researcher (1)	
	(Print Name in block letters)
Signature (Other Researcher 1)	**Date:** Click here to enter a date.
Other Researcher (2)	
	(Print Name in block letters)
Signature (Other Researcher 2)	**Date:** Click here to enter a date.
Other Researcher (3)	
	(Print Name in block letters)
Signature (Other Researcher 3)	**Date:** Click here to enter a date.
Other Researcher (4)	
	(Print Name in block letters)
Signature (Other Researcher 4)	**Date:** Click here to enter a date.

SITE SPONSOR

I certify that:

- I am familiar with this project and endorse its undertaking:
- The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

Site Sponsor	
Title:	Choose an item.
Name:	Click here to enter text.
Position	Click here to enter text.
Facility/ Organisation	Click here to enter text.
Email	Email Address
Phone:	Click here to enter text.
	Signature (and date)