ST VINCENT'S HEALTH AND AGED CARE
EVALUATION FOR LOW AND NEGLIGIBLE RISK RESEARCH

St Vincent's Health & Aged Care Human Research Ethics Committee (SVHAC 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.

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 governance officer or HREC secretariat as to the outcome of their submission. All complete submissions must be emailed to the secretariat of the HREC prior to the meeting cut off date

Email details: svhac.hrec@svha.org.au

For a list of definitions, please refer to the 'Glossary' section of the NHMRC National Statement: http://www.nhmrc.gov.au/guidelines/publications/e72

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

Principal Researcher:

Title: Name: Phone: Fax: Email:

Project Title:

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:

- Harm
- Discomfort
- 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 (contact: svhac.hrec@svha.org.au). Time constraint is not an acceptable reason for seeking review through this process where projects carry risks greater than discomfort.

Office Use Only

Accepted for Low Risk Review Not Accepted for Low Risk Review

HREC Number:……..

Allocated to:

Expedited review Panel (Designated Committee members):

1……
2……

Date sent to ERP: …….

Outcome of ERP:

- Application approved:
- Application approved "subject to"
- Application not approved

Secretariat advised and outcome for noting at next HREC meeting. Date……

Advice sent to Principal Investigator. Date …….

Checklist for Research that is Exempt from HREC review

NHMRC "National Statement on Ethical Conduct in Human Research"
Sections 2.1.7, 5.1.18 – 5.1.23

A Research project might be exempt from HREC review if both of the following can be answered 'yes':

It only involves negligible risk where there is no foreseeable risks of harm or discomfort and any foreseeable risk is no more than inconvenience to the participants. The National Statement describes inconvenience as the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research	Yes ☐	No ☐
The project involves the use of existing collections of data, or records that already contain only non-identifiable data about human participants	Yes ☐	No ☐

In addition, research which involves the following cannot be considered exempt, from HREC review and all answers must be "no":

Participants are identifiable or re-identifiable	Yes ☐	No ☐
Some form of deception is involved	Yes ☐	No ☐
Participants are aged less than 18 years	Yes ☐	No ☐
Participants are cognitively or emotionally impaired	Yes ☐	No ☐
Participants belong to the Aboriginal or Torres Strait Islander background or minority	Yes ☐	No ☐
The procedure involves any experimental manipulation or include the presentation of any stimulus other than question-asking;	Yes ☐	No ☐
The questions asked include sensitive personal and/or cultural issues	Yes ☐	No ☐
There is any power-dependency relationship between researcher(s) and participants(s)	Yes ☐	No ☐

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 NEAF.

- 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 to ascertain whether the proposed research is eligible for consideration for low risk review by the institution's low risk review processes.

1. Are any of the following topics covered in part or in whole?

Research investigating sensitive cultural issues	Yes ☐	No ☐
Explorations of grief, death or serious/traumatic loss	Yes ☐	No ☐
Mental Disorders e.g. Depression, mood states, anxiety	Yes ☐	No ☐
Gambling	Yes ☐	No ☐
Eating disorders	Yes ☐	No ☐
Illicit drug use	Yes ☐	No ☐
Substance abuse (prescribe or over the counter)	Yes ☐	No ☐
Self-report of criminal behaviour	Yes ☐	No ☐
Any psychological disorder	Yes ☐	No ☐
Suicide risks	Yes ☐	No ☐
Gender identity	Yes ☐	No ☐
Sexuality	Yes ☐	No ☐

Race or ethnic identity	Yes ☐	No ☐
Any disease or health problem	Yes ☐	No ☐
Fertility	Yes ☐	No ☐
Termination of pregnancy	Yes ☐	No ☐

2. <u>Are any of the following procedures to be employed?</u>

Use of personal data obtained from Commonwealth or State Government Department/Agency with participant consent	Yes ☐	No ☐
Deception of participants	Yes ☐	No ☐
Concealing the purposes of research	Yes ☐	No ☐
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 ☐
Psychological interventions or treatments	Yes ☐	No ☐
Application of physical stimulus	Yes ☐	No ☐
Invasive physical procedures	Yes ☐	No ☐
Infliction of pain	Yes ☐	No ☐
Administration of drugs	Yes ☐	No ☐
Administration of other substances or devices	Yes ☐	No ☐
Exposure to ionising radiation	Yes ☐	No ☐
Tissue sampling or blood for pathological or genetic testing	Yes ☐	No ☐
Collecting body fluid (e.g. saliva)	Yes ☐	No ☐
Use of medical records where participants can be identified or linked	Yes ☐	No ☐

3. <u>Other Risks</u>

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. <u>Select the categories that are targeted or likely to be included as participants in this research project</u>

Suffers from a psychiatric or psychological disorder	Yes ☐	No ☐
Suffering a physical disability or medical condition	Yes ☐	No ☐
Children and/or young people without parental or guardian consent	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 ☐
Participants are identifiable in final report when specific consent for release has not been given	Yes ☐	No ☐
Research findings are expected to be published in a peer reviewed Journal	Yes ☐	No ☐

If "No" has been answered to all questions, the project is eligible for review as a low/negligible risk process.

If "Yes" has been answered to any item in the checklist, the project would normally **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:

- 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

Application for Review of low 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: RESEARCHERS

Principal Researcher:

Title:

Name:

Phone:

Fax:

Email:

Student/Other Researcher/s:

Title:	**Title:**	**Title:**
Name:	**Name:**	**Name:**
Phone:	**Phone:**	**Phone:**

Fax:	**Fax:**	**Fax:**
Email:	**Email:**	**Email:**

Site Sponsor (if Researcher/s not employee of St Vincent's Health and Aged Care):

Title:

Name:

Phone:

Fax:

Email:

Departmental/Faculty Head (undertaking work in the hospital) Title:

Name:

Phone:

Fax:

Email:

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)

SECTION 2: Project Details:

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1)

Project Title:

Lay Description:
Briefly outline in simple terms the project's aim(s), justification, participant group(s), method and possible outcomes. (150 words max.)

Research Methodology:
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. (300 words max)

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 brief 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 and it potential to contribute to existing knowledge, treatment, disease prevention, health promotion or social improvement. (600 words max.)

SECTION 3: Funding and Finance

Researchers should include any source of funding (for example, departmental, commercial, non-commercial, government).
(NHMRC "National Statement on Ethical Conduct in Human Research 2007" Chapter 5.4)

Has this protocol received research funding or is this submission being made as part of an application for research funding?

What is the source of funding and has the funding been approved?

Will the researcher receive any remuneration and/or in kind funding to perform this research?

Will participants receive any payment or expenses for participation in the research? If yes, give details.

SECTION 4: Other Approvals?

(NHMRC "National Statement on Ethical Conduct in Human Research", Chapter 5.3)

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.

Is this protocol being submitted or has it been previously submitted to another ethics committee?

Yes ☐ No ☐

If yes, give details of other centres involved; the approval status of the study at each centre; and details of any required amendments.

Other External Approvals/Reviews?

If your research has undergone peer review, review from a funding body or involves participants from other organisations, copies of letters of approval or reviews must be attached to this application (if pending at the time the application is submitted, forward to HREC/low risk review Committee when available). In some cases, institutions/authorities may decline to provide approval letters until ethics approval has been granted. In such cases, you should submit your application to the HREC for provisional approval pending receipt of the documentation.

Has the research undergone peer review, review from a funding body or does it involve participants from other organisations?

Yes ☐ No ☐

If yes, please specify from whom and attach a copy:

SECTION 5: Recruitment of Participants

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", 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.

What is the proposed method of recruitment of participants?

SECTION 6: Consent

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", Chapter 2.2, 2.3)

Informing Participants: Participant Information Sheet and Consent Form

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).

Will the research involve informed consent of participants?

Yes ☐ No ☐

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

If no, please justify why consent will not be obtained?

SECTION 7: Information Protection (Confidentiality, Data Storage and Security)

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1 and NHMRC, Universities Australia "Australian Code for the Responsible Conduct of Research 2007", Section 2)

Confidentiality:

Explain what methods will be used to guarantee confidentiality/anonymity of participant data.

Data Storage and Security:

Explain how and where data will be held, including any arrangements for data security during?

Please explain how long the data will be kept?

How will data be disposed of?

SECTION 8: Dissemination of Results

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1 and NHMRC, Universities Australia "Australian Code for the Responsible Conduct of Research 2007", 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.

SECTION 9: Declarations

Signatures and undertakings:

Applicant/Principal 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)

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;

…… ……
(Principal Researcher)

…… ……
(Other Researcher)

…… ……
(Print Name in block letters)

…… ……
(Print Name in block letters)

Date: / /

Date: / /

Site Sponsor (if required):

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.

Title:

Name:

Position:

Organisation Name:

Signature:

Date:

General Manager/Director of Medical Services/Director of Clinical Services (choose most appropriate):

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- The resources required to undertake this project are available;
- The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

Title:

Name:

Position:

Organisation Name:

Signature:

Date: