ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House
Cambridge House
DePaul House

ASSESSMENT OF RISKS AND BENEFITS

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 2 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) by ensuring an appropriate assessment of the risks and benefits involved in all research protocols, with such risks and benefits appropriately communicated to participants.

Definitions

Risk is defined as the potential for harm, discomfort, or inconvenience and is qualified in terms of the likelihood of harm occurring, and the severity of the harm, including its consequences.

Low risk research is defined as research in which the only foreseeable risk is one of reasonable discomfort. Research in which the risk for participants is more serious than discomfort cannot be defined as low risk.

Negligible risk research is defined as research in which there is no foreseeable risk of harm or discomfort greater than what is considered reasonable inconvenience.

Procedure

Section 1 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) requires that the risks of harm to research participants, investigators, the institutions involved and others, be assessed. Research can only be ethically acceptable if the potential benefits outweigh and justify the risks involved in the research.

To ensure an appropriate assessment of risk is undertaken, the St Vincent's Hospital Human Research Ethics Committee must comply with the minimum requirements as stipulated within the National Statement. Furthermore, all members of the St Vincent's Hospital Human Research Ethics Committee must be familiar with, and apply the principles of The National Statement on Ethical Conduct in Human Research (2007, updated 2018), and in particular, Sections 2.1.1 to 2.1.8 to the ethical review of research.

If a project places participants at a greater risk relative to the proposed benefits, the risk must be comprehensively justified. The HREC must specifically determine the appropriateness of the project based on the justification provided to ensure that ethical standards are maintained.

Any risks and benefits of a research project must also be appropriately communicated to participants to ensure that a person's decision to participate is entirely voluntary, and based

on sufficient information. This communication must occur through the use of a "Participant Information and Consent Form" which conforms to the National Statement guidelines (2.2.6 (a) – (m)) and standard requirements of the institution. The Participant Information and Consent Form must be reviewed by the HREC in an individualised manner to ensure the needs of the specific participant cohort are considered.

To ensure a detailed assessment of risk and benefit, full HREC review will be supplemented by allocating a Professional Spokesperson and a Lay Spokesperson to undertake and present a specialised review of each protocol. The purpose of this specialised review is to lead the full committee discussion by providing two separate opinions from the perspective of a clinical/scientific member and a lay member regarding the ethical acceptability of the study. These reviews are guided by a "Review Checklist" in keeping with the National Statement.

In the event further expertise is required, the HREC Committee, HREC Chair or Research Governance Unit may co-opt individuals both internally, and externally to obtain this expert opinion, at any time. All expert opinions must occur as per procedure 5.10 – Expert Opinion.

Associated Procedures/Instructions
Procedure 1.1 – Application of Values and Ethical Conduct
Procedure 5.10 – Expert Opinion

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 (Cth) – Updated 2018
- Australian Code for the Responsible Conduct of Research (2018)

Authorized by:

Dr Megan Robertson
Director of Research

Author: Dr Tam Nguyen, Deputy Director of Research	
Date Issued: 2011	**Next Review:** 2023
Date Revised: 2020	**Filepath:**