



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

Ethical Considerations Specific to Participants

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 4 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) by ensuring that all research involving participants of particular vulnerability is appropriately designed and conducted. This includes (but is not limited to) pregnant women, those highly dependent on medical care, those unable to provide informed consent, those with a cognitive impairment, an intellectual disability or mental illness, those who may be involved in illegal activities, Aboriginal and Torres Strait Islander people and people in other countries.

Definitions

Nil

Procedure

To ensure the appropriate design and conduct of research involving participants of particular vulnerability, 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, Section 4, to the ethical review of research.

Particular attention must be paid to the process of obtaining informed consent, and the review of the Participant Information and Consent Form, where appropriate. Furthermore, a Participant Information and Consent Form may also be required for the participant's legal guardian, or next of kin. Circumstances for which a legal guardian or next of kin is required, must be guided by the Guardianship Act (1986).

The Committee retains the right to request additional consent processes all times. In the event further expertise is required, the Committee, Chair or Research Governance Unit may co-opt individuals both internally, and externally to obtain this expert opinion, at any time.

Research involving vulnerable groups must be reviewed and approved by a Human Research Ethics Committee, except where that research uses collections of non-identifiable data and involves negligible risk.

Additional review involving Aboriginal and / or Torres Strait Islander people must also be reviewed by a specialist Aboriginal Ethics Committee or receive specialist advice from an appropriate person/s who is able to represent the target group in accordance with the research conforming to the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018).

Associated Procedures/Instructions

Nil

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 (2007)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)

Authorized by:



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