

HREC Standard Operating Procedure

4.1 Ethical Considerations Specific to Participants

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 4 of the National Statement on Ethical Conduct in Human Research (2023) 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 peoples and people in other countries.

Procedures

To ensure the appropriate design and conduct of research involving participants of particular vulnerability, all members of the SVHM HREC must be familiar with, and apply the principles of the National Statement on Ethical Conduct in Human Research (2023), 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 (PICF), where appropriate. Furthermore, a PICF 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 HREC 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 HREC, except where that research uses collections of non-identifiable data and involves negligible risk.

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

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)



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- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2018)

Authorised by: Dr Megan Robertson, Director of Research

A handwritten signature in black ink, appearing to read 'Megan Robertson', positioned above a horizontal line.

Megan ROBERTSON (Jul 1, 2024 09:47 GMT+10)

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