



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

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## LOW RISK RESEARCH

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### Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 5 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) to ensure that the review of low and negligible risk research activities are expedited, and that such research receives appropriate research governance at all times.

### Definitions

**Low Risk Research** is defined as research in which the only foreseeable risk is one of discomfort.

**Negligible Risk Research** is defined as research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

**Research Governance** is defined as the regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality.

### Procedure

All members of the St Vincent's Hospital Human Research Ethics Committee must be familiar with The National Statement on Ethical Conduct in Human Research (2007, updated 2018), and in particular, Section 5.19.

To maximise efficiency and reduce resource expenditure, an expedited approval pathway is offered to low and negligible risk research.

This pathway involves review by a Low Risk Research Subcommittee. The Subcommittee is comprised of members from the HREC who are selected by their level of expertise to participate in an online review process. A minimum of two reviewers will be selected (including at least one lay member), and asked to review the Low Risk Research Application. All Subcommittee members must be afforded the opportunity to formally comment on the Low Risk Research Application and any comments by other reviewers prior to its approval.

Once comments are received, the Research Governance Unit will provide the Principal Investigator with formal written correspondence approving the application, requesting additional information/clarification or rejecting the application. The Subcommittee retains the right to refer any project to review by the full HREC meeting, but must justify this to the Principal Investigator in a timely manner.

All comments from the Low Risk Research Subcommittee will be documented and filed within the Research Governance Unit. All decisions of the Subcommittee must be formally noted at the next available HREC meeting and formally documented within the minutes.

A governance review (if applicable) will also be undertaken by the Research Governance Unit.

To be considered via the Low Risk Research pathway, the research must **not** include:

- Women who are pregnant
- Children or young people under the age of 18
- Persons with an intellectual disability or mental impairment of any kind
- Persons incompetent to provide informed consent
- People involved in illegal activities
- Prisoners or people on parole
- Research specifically recruiting Aboriginal and / or Torres Strait Islander people
- Persons not usually considered to be vulnerable but would be considered vulnerable in the context of this research project
- Establishment of a databank for research purposes
- Interventions and therapies including clinical and non-clinical trials and innovations
- Human genetic research or gene technology
- Derivation or use of human stem cells
- Deception of participants, concealment or covert observation
- Radioactive substances / ionizing radiation e.g. X-rays, DEXA
- Assisted reproductive technology (ART)
- Xenotransplantation
- Toxins / mutagens / teratogens / carcinogens

### **Associated Procedures/Instructions**

Procedure 2.1 – Assessment of Risks and Benefits

Procedure 2.2 – Obtaining and Honouring Consent

Procedure 2.3 – Qualifying or waiving conditions for consent

### **Reference Documents**

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