HREC Standard Operating Procedure

5.1 Low risk research

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5.1 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring 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.

Procedures

All members of the SVHM HREC must be familiar with the National Statement on Ethical Conduct in Human Research (2023), and in particular, Section 5.1.

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

This pathway involves out of session review by the HREC. A minimum of two reviewers selected by their level of expertise to participate in the expedited review process (National Statement 5.1.14) will be selected (including at least one lay member), and asked to review the Low Risk Research Application. All 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 review 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 Human Research (2023)
- 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

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

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5.1 Low risk research

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