

HREC Standard Operating Procedure

3.5 Human Genetics

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 3.3 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring the collection and use of samples for protocols involving genetic analyses are appropriate.

Definitions

Genetic Analysis is defined as is the study of the structure, location, function, expression, interaction, abnormalities and effects of the genes or genetic material and their products, including but not limited to studies of the structure of the nucleic acids and other molecules that make up the genetic material.

Procedures

To ensure the appropriate assessment of genetic analysis for the purposes of research, 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 3.3, to the ethical review of research.

All research involving human genetics must be reviewed and approved by a HREC. The only exception to this is research that involves the use of retrospectively collected non-identifiable data that incurs; negligible risk.

To ensure adherence to the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001), genetic research must be limited to therapeutic and diagnostic applications. Genetic research cannot not be undertaken at SVHM if the purpose is to change either the fundamental human nature or the unique identity of an individual person, or if the technique involves the asexual creation or reproduction of human embryos or other eventualities that are contrary to respect for human life or human dignity (including the collection of stem cells from embryonic sources).

Where research may discover or generate information of potential importance to the future health of participants or their relatives, researchers must provide a comprehensive management protocol for the disclosure or withholding of information within the application form. This must include the potential existing contractual duties to disclose the results to third parties including insurance companies, employers, financial and educational institutions.

Participants may be asked to decided whether they wish to access such information or not, but in the latter circumstance, this must again be confirmed if potentially important information is discovered. Where potentially important information is discovered and disclosed to participants or their relatives, genetic counselling must be offered by an

appropriately qualified and experienced professional. This information must be included within the Participant Information and Consent Form (PICF).

Researchers must also incorporate rigorous measures to ensure the privacy and confidentiality of participant is protected, to ensure any resultant genetic material cannot be used to unfairly identify, discriminate against or stigmatise individuals.


All research protocols which incorporate the collection of tissues for genetic analysis must provide a separate PICF for ethical review and approval prior to use.

Particular attention must be paid to the risks of collecting tissues for the purposes of research, whether this is prospective or retrospective (from banks, laboratories or pathology). Retrospective tissue collection from existing sources must be justified in writing at the time of application, and must address the process of initial consent including the future use, coding and/or disposal of samples as per procedures 3.2 and 3.4.

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)

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3.5 Human Genetics

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