

# HREC Standard Operating Procedure

## 3.6 Human Stem Cells

### Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 3.2 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring all research involving the collection and use of human stem cells for research purposes are appropriate.

### Definitions

**Stem cells** Stem cells are relatively 'unspecialised' cells that have the unique potential to develop into 'specialised' cell types in the body (for example, blood cells, muscle cells or nerve cells). They occur at all stages of human development, from embryo to adult, and in many (possibly most) tissues of the body.

**Embryonic stem cells** have been derived from human embryos in the first 3-5 days of development, usually after a blastocyst has formed.

**Somatic stem cells** (also known as non-embryonic stem cells or adult stem cells) are derived from the human body after the embryonic stage. They include foetal and umbilical cord stem cells, as well as cells such as mesenchymal and haematopoietic stem cells that have been used in clinical practice for a number of years.

### Procedures

To ensure the appropriate collection and use of human stem cells for research purposes, 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 3.2 and 4.1, to the ethical review of research. Members must also be familiar with the Research Involving Human Embryos Act 2002 and the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines).

Research involving human stem cells must be reviewed and approved by a Human Research Ethics Committee. The only exception to this is research that proposes to use 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), research involving human stem cells must be limited to therapeutic and diagnostic applications. Research cannot not be undertaken at St Vincent's Hospital 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. This specifically prohibits the collection of stem cells from embryonic sources.

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.

The HREC must specifically consider the risks of collecting tissues for the purposes of human stem cell research and whether the collection is prospective or retrospective (from banks, laboratories or pathology), as per procedures 3.2 and 3.4.

Retrospective tissue collection from existing sources which will be used for human stem cell research must be justified within the application and must specify whether consent was initially obtained for the collection and use of the sample as per procedures 2.2, 3.2 and 3.4.

All research which incorporates the collection of stem cells must provide a separate Participant Information and Consent Form for ethical review and approval, to ensure participants comprehend the risks and benefits of the collection and use of this type of tissue.

SVHM prohibits the collection of tissue for research purposes which are intended for commercial sale.

## Associated Procedures/Instructions

Procedure 2.2 – Obtaining and Honouring Consent


Procedure 3.2 – Databanks

Procedure 3.4 – Human Tissue Samples

## 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)
- The Research Involving Human Embryos Act (2002, amended 2022)
- NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines).

**Authorised by:** Dr Megan Robertson, Director of Research



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# 3.6 Human Stem Cells

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