

# HREC Standard Operating Procedure

## 5.10 Expert Opinion

### 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 accessing independent, external opinion/s as required to assist the ethical review of research.

### Definitions

**External** is defined as a person or person/s with little to no affiliation with the institution at which the research is proposed to be undertaken.

**Independent** is defined as a person or person/s with little to no affiliation with the research in question (including the Investigators), and who have little to no conflict of interest in providing such an opinion.

### Procedures

The HREC may access professional expertise as necessary to enable it to address any ethical issues arising from any research under consideration. This may necessitate going outside the current membership, and / or outside the institution. Expert opinion may also be sought from other HRECs whom have reviewed the application in question.

This decision (including the reviewer to be approached) will be made at the discretion of the HREC and/or Chair at any time, and will be communicated in writing to the Investigator prior to expert review. Preference will be given to the pool of experts included within database of the Victorian Department of Health Coordinating Office for Clinical Trial Research.

In the event an external opinion is sought, an Expert Opinion Agreement should accompany the request, accompanied by a formal covering letter reiterating the requirement to maintain confidentiality and declare conflicts of interest. A request for the return of all confidential documents must also be included.

A formal declaration must also be signed by reviewers approached for Expert Opinion (termed the "Expert Opinion Agreement"), to confirm they understand their responsibilities in terms of declaring conflicts of interest. If a conflict of interest is identified, the reviewer must not provide an expert opinion, and an alternative must be found.

The recommendations detailed within the expert review will be formally communicated to the HREC before a formal decision is made. Such discussions will also be formally documented within the minutes.

If the expert is external to the institution, evidence of an appropriate level of professional indemnity must be obtained prior to providing an opinion, in line with the Victorian Managed Insurance Authority Clinical Trial Guidelines.

All reviews must be formally recorded within the Research Governance Unit database for accountability. The external opinion will be requested in writing, and filed appropriately post review.


## Associated Procedures/Instructions

Procedure 5.7 – Documentation and Record Management

## Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research (2018)

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



Megan ROBERTSON (Jul 1, 2024 09:52 GMT+10)

**Author:** Alexandra Braun, HREC Executive Officer

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# 5.10 Expert Opinion

Final Audit Report

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