

# HREC Procedure

## Handling Conflicts of Interest in Ethical Review of Research

### Purpose:

The purpose of this procedure is to advise researchers and HREC members on matters related to potential, perceived or actual/real conflicts of interest to ensure the integrity of research activities is not compromised.

### Scope:

This procedure applies to all approved research personnel on Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (HREC) approved projects.

It also applies to HREC members and any advisors to the HREC.

It applies to all pathways of review conducted by the HREC.

### Procedure / Method:

A conflict of interest, in the context of research, may exist where the interests of an individual (whether his or her own or in his or her institutional role) have the potential to influence the way that he or she carries out his or her research or vice versa. A conflict may relate to financial interests and/or private, professional or institutional benefits that depend significantly on the research outcome.

Conflicts must be recognised and then avoided or managed so as not to compromise the decision making of the HREC and must not compromise or be seen to have compromised any aspect of the research itself.

In identifying and managing potential, perceived or actual conflicts of interest, the key principles which should guide individuals are:

- disclosure;
- avoidance of perceived or actual conflict of interest; and
- management of perceived or actual conflict of interest where avoidance is not possible.

At the time of proposing research, through to reporting research findings, researchers have a responsibility to disclose any actual, perceived or potential conflict of interest that may influence or be seen to influence any aspect of the conduct of the research. This responsibility extends to matters related to research including investigations, publication, media reports, ethics and compliance applications, grant applications and applications for appointment or promotion.

The processes for managing disclosures are as follows:

#### 1. Researchers

Researchers shall disclose the potential conflict of interest to their Head of Department (HoD)/Unit in which they work via their Manager. If a HoD may have/has a conflict of interest related to research activities, the Executive Director Medical Services (EDMS) will be responsible for determining the appropriate management. If the EDMS has a conflict of interest related to research activities, the Chief Executive Officer (CEO) will be responsible for determining the appropriate management.

The HoD/ EDMS/ CEO shall make a determination as to whether the matters disclosed constitute a conflict of interest requiring action and what that action should be as follows:

- the officer in receipt of the disclosure, must discuss the matter with the staff member concerned and together they should develop a conflict of interest management or elimination plan;
- the plan must be recorded, the staff member advised in writing and a copy of the agreement held in the Research Office (RO). The RO will notify the HREC Chair;
- where relevant, conflicts of interest should be disclosed to research participants in the Participant Information and Consent Form; and
- in the event that a researcher, or staff of a researcher, identifies an affiliation or financial involvement with any organisation with a direct commercial interest in the research, a report must be forwarded in writing to the EDMS/CMO, on an annual basis. The Hospital's Declaration of Interest Form should be used and details of any benefits

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should be included.

### 2. HREC members

In addition to financial interests in research, HREC members may have potential conflicts of interest for research projects in which they have personal involvement. Conflicts can also exist in respect of competing research projects. The process for the disclosure and handling of potential conflicts of interest of HREC members is as follows:

- all members of and advisers to the HREC will sign the HREC conflict of interest declaration at the time of their appointment and annually thereafter;
- HREC members are asked to declare any conflicts that do not relate to a specific project to the HREC Chair as they arise during their appointment period or between annual declarations;
- conflicts of interest that relate to specific research projects will be identified when the Chair calls for members to declare such at the beginning of each HREC meeting. For new project discussions and project amendment discussions, the affected HREC member will be asked to leave the meeting for the duration of discussion on the matter for which the conflict exists. For all other project post-approval discussions (reports for HREC to note), the affected HREC member may be asked to leave the meeting. If an unforeseen conflict becomes evident, as soon as practicable during the meeting, the Chair must be informed and the member may be asked to leave the room to avoid the conflict. The minutes should reflect how the conflict has been dealt with in each case;
- if the HREC Chair has a conflict of interest, then the Chair will leave the room with responsibilities delegated to the Deputy Chair to lead the discussion of the project;
- written reviews/comments from (absent) members or HREC advisors are to include a full disclosure of any potential conflict of interest, financial or otherwise, in a project or other related matter(s) under consideration by the HREC. The HREC Chair will determine whether the conflict of interest renders the review/comments inadmissible;
- HREC meeting minutes will record all conflict of interest declarations, how the conflicts of interest were managed and the absence of member(s) during the consideration of project;
- when a potential conflict of interest related to an institution is identified by the HREC, the institution involved will be notified via the RO; and
- depending on the nature of the conflict of interest, the HREC may recommend that the conflicts of interest are disclosed to research participants in the patient information consent form (PICF) and/or in publications arising from the research. The HREC may also recommend that the researcher with a conflict of interest plays a limited role in the research, or the research not be conducted.

#### Enquiries concerning conflicts of interest:

Any enquiries regarding the handling of conflicts of interest should be directed as outlined below:

For Researcher enquiries:                      Researchers own Head of Department/Unit in which they are based

or

Executive Director Medical Services  
Via the Research Office  
Telephone: 61 3 9929 8525 Email: [ethics@eyeandear.org.au](mailto:ethics@eyeandear.org.au)

For HREC Member enquiries:                      Dr Marc Sarossy  
Chair, Human Research Ethics Committee  
Royal Victorian Eye and Ear Hospital  
Telephone: 61 3 9929 8525 Email: [ethics@eyeandear.org.au](mailto:ethics@eyeandear.org.au)

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### **Outcome:**

To ensure that research conducted at the Eye and Ear is not compromised or brought into question on conflict of interest grounds.

### **Definitions:**

**Conflict of Interest** A situation where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.

### **Standards:**

NHMRC National Statement on Ethical Conduct in Human Research (2007 and as amended)

NHMRC Australian Code for the Responsible Conduct of Research (2007 and as amended)

NSQHS National Standard 1 - Governance

### **Linked Policy & Procedure:**

Research Policy

Code of Conduct Sept 2015

### **Approval / Committees:**

Executive Director Medical Services

Chair, Human Research Ethics Committee

### **Responsible Executive:**

Executive Director Medical Services

### **Evaluation:**

This procedure will be evaluated through analysis of research applications, HREC minutes and review of the organisations Research Policy and associated procedures.

### **Procedure Review:**

This procedure will be reviewed triennially or earlier if NHMRC guidance or procedures change.

### **Key Words for Search:**

HREC, research, conflict of interest

## HREC Procedure Handling Conflicts of Interest in Ethical Review of Research

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### Policy / Procedure Details:

Details		
Policy / Procedure Number:	RS1.0	
Section:	Research	
NSQHS Standards	Governance 1.1	
Legislation Section:	E – Patient’s Rights F – Privacy	
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