

## **POLICYI022      GOVERNANCE OF THE REVIEW OF RESEARCH**

---

<b>Manual:</b> Policies	<b>Document ID:</b> PI022	<b>Date Created:</b> Jan 10
<b>Section:</b> Investigator	<b>No. Pages:</b> 2	<b>Review Date:</b> Sep 16
		<b>Future Review Date:</b> Sep 18

---

### **PURPOSE**

To outline the requirements for governance of the review of research by the Bellberry Human Research Ethics Committees in line with the National Statement on Ethical Conduct in Human Research (2007) Chapter 5 and the Australian Code for the Responsible Conduct of Research 2007.

1. Scientific and Ethical Review:

The Bellberry Human Research Ethics Committee are constituted as per the National Statement, and relevant expertise is available to ensure all research is scientifically and ethically reviewed.

**SOPC001      Conduct of Business**

2. Conflict of Interest:

The following policies apply to ensure any conflict of interest is declared from Investigators and/or Committee members.

**PolicyI003      Conflicts of Interest**

**SOPC002      Chairs and Members Section 3 and section 7**

3. Monitoring of Approved Research:

The following policy applies to the ongoing oversight of research that has been approved by the Bellberry HREC's.

**SOPC006      Site Monitoring**

**Policy I009      Monitoring of Approved Trials**

**Policy I009a      Site Monitoring**

**Policy I010      Monitoring – Progress reports**

**Policy I019      Monitoring – Protocol violations**

4. Handling Complaints:

The following policies apply to the management of complaints.

**PolicyI005      Complaints related to conduct of research project**

**PolicyI006      Complaints relating to the review process**

5. Site Approval Form:

A completed Site Approval Form if relevant. This form is required where studies are to be carried out within a hospital or institution. For studies being conducted within hospital/institutions, Bellberry will forward its completed review and relevant documentation to the investigator for forwarding to the Chief Executive or delegate. This will allow the hospital/institution to review its own governance matters relating to the study and provide final sign off prior to commencement.

6. Insurance /Indemnity requirements:

The following insurance/ indemnity arrangements are required prior to final approval being given.

i. Completed and signed Indemnity Forms (Medicines Australia Forms of Indemnity are accepted)

- Indemnity cover between the local sponsor and Bellberry HREC

- Indemnity cover between the local sponsor and the Principal Investigator

- Personal indemnity cover for the Principal Investigator

- ii. Insurance to the minimum amount of AUD\$10 million for any one occurrence and in the annual aggregate;
  - Certificate of Currency from Sponsor
- iii. A copy of the Principal Investigator's medical registration and personal medical insurance cover where applicable (on an annual basis only).
- iv. Ordinarily research without appropriate insurance will not normally be approved. Some exceptions may be made.

### **SOPA002 Insurance/Indemnity Requirements**

7. Investigator requirements:

Refer to **Policy I015 Investigator Qualifications**

8. Committee Members:

Bellberry has Professional Indemnity cover, Directors and Officers Insurance cover and building and contents insurance.

Bellberry Limited accepts legal responsibility for the decisions and advice of the Committee and indemnifies Committee Members against any costs, charges, losses, damages, expenses, penalties and liabilities of any kind including, in particular, legal costs incurred in defending any proceedings (whether criminal, civil, administrative or judicial) or appearing before any court, tribunal, government authority or other body, that may arise out of the conduct of the Company's business or the discharge of duties by a Committee member.

The Company through its professional insurance policy continues to provide financial support for the indemnity.