

RESEARCH GOVERNANCE AND ETHICS ADVICE

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1. Purpose

ABMDR supports research by providing data, information or tissue samples that may originate from donors, donated cord blood units or patients. The organisation, as part of its corporate and clinical governance responsibilities, may require advice on ethical issues from a recognised Human Research Ethics Committee (HREC).

Research that ABMDR is involved with needs to be properly governed checking that research materials are only made available for research that meet ABMDR operational and governance requirements, is non-commercial in nature and is conducted according to ethical principles.

2. Scope

This policy covers requests for any material from ABMDR for research purposes including data, donor information, donor samples, tissue repository samples and cord blood.

Elements of research governance at ABMDR are:

- operational management
- policies and procedures
- ethical approval
- compliance with legislation, regulations, guidelines and codes of practice
- complaints management

3. Responsibilities

3.1. Ethics Committee:

The ABMDR National Management Board appointed Australian Red Cross Blood Service Ethics Committee (HREC Code EC00206) as the ABMDR's Ethics Committee.

The responsibilities of the Ethics Committee are to:

- Provide advice on the applicable regulatory frameworks, guidelines and policies for research, including policies of the Australian Health Ethics Committee (AHEC) and National Health and Medical Research Council standards and guidelines for Human Research Ethics Committees.
- Evaluate the research ethics of research proposals involving ABMDR donors, tissue repository and information and advise the Board whether the proposal is acceptable from a human research ethics perspective.
- Assist the ABMDR in meeting applicable reporting requirements of the Australian Health Ethics Committee (AHEC).
- Monitor and provide appropriate ethics governance oversight of approved research projects.
- Receive, assess and advise on complaints and adverse events relating to ethics and research projects.

3.2. Scientific Expert Advisory Committee

- Appoint a scientific research review panel to review research merit and integrity of research proposals.

3.3. Cord Blood National Management Committee

- Review and approve requests for access to cord blood units from the National Cord Blood Collection Network inventory.

3.4. Research Governance Committee

- Act as single authority to approve access to ABMDR research materials for research, but must also seek approval and advice of appropriate Committees such as Ethics Committee, Scientific Review Committee and Cord Blood National Management Committee.
- Responsibility for developing policies.
- Consider cost to the organisation when approving research applications, particularly if research does not relate to bone marrow transplant.
- Advise the Board on research governance matters.

3.5. Chief Executive Officer

The National Executive Officer must ensure that the procedures cover the following points:

- The application process for researchers wishing to access the ABMDR.
- The process for referring applications to the Blood Service Ethics Committee.
- The process for ensuring that ABMDR considerations in addition to ethical considerations are adequately addressed, in particular ensuring that the Research Governance policy is complied with.
- Reporting to the Board on research proposals, their approval status and monitoring (where relevant).
- The process for referring ethical questions that are not related to research applications to the Blood Service Ethics Committee.

Appendix A. References and Associated Documents

Document Number	Title
ABMDR-STD-EQM-1	ABMDR Organisation
ABMDR-SOP-OPS-1	Research Application Submission and Assessment
ABMDR-TOR-EQM-1	Research Governance TOR
ABMDR-TOR-EQM-3	Cord Blood National Management Committee Terms of Reference
ABMDR-TOR-EQM-4	Scientific Expert Advisory Committee (SEAC) TOR