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, patients or donated cord blood units collected using funding provided to cord blood banks from ABMDR ('**Materials**').

Research that ABMDR is involved with is properly governed, ensuring that Materials are only made available for approved research that is non-commercial in nature and conducted according to ethical principles.

ABMDR, as part of its corporate and clinical governance responsibilities, may require advice on ethical issues from a recognised Human Research Ethics Committee (HREC).

2. Scope

This policy covers requests for any Materials for research purposes.

ABMDR research governance comprises:

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

3. Responsibilities

3.1. Ethics Committee:

Research applications involving cord blood units will be reviewed by the Ethics Committee of the relevant Cord Blood Bank.

The Australian Red Cross Lifeblood Ethics Committee (HREC Code EC00206) assess research applications submitted to ABMDR including:

- 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 ethics of research proposals involving ABMDR donors, tissue repository and information and advice 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. Research and Release Governance Committee

- Act as single authority to approve research access to Materials.
- Considering the advice of expert Committees on ethics and scientific advice when approving research applications.
- Responsibility for developing research and release policies.
- Consider cost to ABMDR when approving research applications, particularly if research does not relate to bone marrow transplantation.
- Provide advice on research governance matters.

3.3. Scientific Expert Advisory Committee

- Review research merit and integrity of research proposals, when requested by the Research and Release Governance Committee.

3.4. Chief Executive Officer

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

- Application process for researchers wishing to access Materials
- Referring applications to the Lifeblood Ethics Committee.
- ABMDR requirements and ethical considerations are adequately addressed, in particular ensuring that the Research Governance and Ethics Advice policy is complied with.
- Monitoring research proposals including approval status, reporting and monitoring (where relevant)
- Referring ethical questions, not related to research applications, to the relevant 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
-	Research and Release Governance TOR
-	Scientific Expert Advisory Committee (SEAC) TOR