

Policy: Research governance

Approved by ABMDR Board 23 September 2015

1. Research governance

ABMDR supports research by providing data, information or tissue samples that may originate from donors, donated cord blood units or patients. 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 and is conducted according to ethical principles.

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.

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.

3. Responsibilities

3.1. 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.
- Take into consideration the broader aspects of the research on the primary purposes of the ABMDR, such as likely impacts in the media, government and on donor trust.
- 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.

3.2. Ethics Committee

- Assess whether research proposal meets ethical standards.

3.3. Scientific Expert Advisory Committee

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

3.4. Cord Blood National Management Committee

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

3.5. Staff

- Implement research governance policy.

4. Approval of research proposals

Applications to access ABMDR donors, cord blood units, samples and data must be submitted to the ABMDR Research Secretariat.

The committee with responsibility for approving access for research is the Research Governance Committee.

In approving research, the Research Governance Committee must ensure that the research application has been approved by the ABMDR Ethics Committee.

In approving research to access to cord blood units from the National Cord Blood Collection Network inventory, the Research Governance Committee must take into consideration any advice received from the Cord Blood National Management Committee.

Criteria for approving research applications to access ABMDR material for research:

1. Meets ABMDR operational and governance requirements:
 - a) The research chief investigator must provide the following documentation before ABMDR can initiate process to approve research proposal:
 - the scientific proposal with peer review of scientific, ethical and practical aspects of proposed project
 - participant information and consent completed form, if applicable
 - copies of the ethics approvals or reports from other ethics / scientific committees
 - clinical trial notification form is available, if required.

- b) Impact to ABMDR primary purposes is negligible (donor trust, community respect, government relationships etc.).
- c) Impact to ABMDR operations are manageable (resourcing, risk, privacy, quality and safety implications etc.).
- d) Can meet requirements specified by Research Governance Committee including appropriate cost recovery.

2. Meets ethical standards as assessed by Scientific Review Committee and Ethics Committee and any requirements.
3. Incorporates advice from Cord Blood National Management Committee for access to cord blood.

5. Fees and cost recovery

The Research governance committee has the responsibility for developing policies and identifying opportunities for resourcing and cost recovery of research activity..

Appendix 1. Research approval process

The process for a researcher applying to access materials from ABMDR for research is described below. The Cord Blood National Management Committee would need to approve requests to access to cord blood in addition to this process.

