

Aplastic Anaemia
and other
Bone Marrow Failure
Syndromes Registry



Australian
Marrow
Failure
Biobank

Aplastic Anaemia and other Bone Marrow Failure Syndromes Registry

&

Australian Marrow Failure Biobank

Data Sharing Policy

Version 1.0, 15/10/2025

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1. Introduction

1.1 Preface

Interested parties may request a data extract or an analysis of data for a variety of reasons including academic research, clinical review, project planning, policy review or health technology assessment, or scientific investigation. Applications for data use will be accepted from a wide variety of requestors including participating sites, internal (Monash University) and external researchers, and governmental organisations.

To maintain privacy and confidentiality of the data collected and collated by the Aplastic Anaemia and other Bone Marrow Failure Syndromes Registry (AAR), protocols and procedures are followed in accordance with applicable privacy laws, ethical guidelines, and Monash University policies (see 'References'). Provision of data to the registry is subject to the study protocol, which has been approved by Human Research Ethics Committees (HRECs)/ Institutional Review Boards (IRBs) in each jurisdiction, and the relevant Research Governance Offices of participating sites (a site with ethics and governance approval for registry participation). In particular, specific measures have been put in place to maintain the confidentiality of personal identifying information.

Data requests are subject to the approval of the AAR Management Group and/or AAR Steering Committee and may be subject to conditions in project-related agreements and/or research ethics approvals depending on the nature of the data request.

This policy includes the criteria and conditions for provision of data for research activities and procedures. It also outlines the cases in which fees might be applicable, and highlights associated acknowledgement and publishing responsibilities.

1.2 Project Overview

Aplastic Anaemia (AA) and inherited bone marrow failure syndrome (IBMFS) are rare but serious diseases with significant morbidity and mortality. Currently there is little Australian data on the incidence of aAA, IBMFS or HPHM, the therapies utilised or clinical outcomes. Established in 2013, the AAR is a national registry for all Australian patients with BMFS or HPHM that provides an important community resource to address these issues.

The registry consists of participants who are diagnosed with a BMFS or have a HPHM in any clinical setting, as well as their blood relatives who may (or may not) have a genetic predisposition to a BMFS. Clinical data collection is undertaken by clinicians in specialist units at participating hospitals. Data management and analysis is undertaken by the School of Public Health and Preventive Medicine (SPHPM), Monash University and interpreted with the input of specialist clinicians on the Steering Committee. The registry uses an opt-out model of consent, consistent with comparable registries in Australia. Using this model, the participant's clinical information is provided to the registry unless the participant decides to opt-out.

1.3 Custodianship

All collective registry data and data management systems operate under the custodianship of Monash University. A participating site can access data they contributed to the Registry. Site Investigators/ Study Coordinators/ Data Managers can export a full copy of the dataset for their site.

1.4 Eligible applicants

Researchers, clinicians and pharmaceutical professionals working at research institutions, hospitals and laboratories, private entities, government or other health services are eligible to request access to data held within the registry. All requests for data are noted in the Steering Committee minutes and logged.

1.5 Governance

Data held by the AAR is governed by AAR Management Group and the AAR Steering Committee. When reviewing data requests, the AAR Management Group and Steering Committee will seek to balance the public health interest of the proposed research whilst prioritising the importance of security and information privacy. To support this decision-making process, the 5 Safes model will be consulted. This internationally recognised approach provides a framework that considers the risks associated with data sharing including privacy, security and ethics.

The 5 Safe dimensions to consider are described briefly below.¹

Safe projects	Is this use of the data appropriate?
Safe people	Can the researchers be trusted to use it in an appropriate manner?
Safe data	Is there a disclosure risk in the data itself?
Safe settings	Does the access facility limit unauthorised use?
Safe outputs	Are the statistical results non-disclosive?

1. Ritchie, Felix. (2016). Five Safes: designing data access for research. 10.13140/RG.2.1.3661.1604.

1.6 Fees

The provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements between registry funders/supporters. Fees will be at the discretion of the Steering Committee or Operations/Management Group and will be based on the complexity and estimated time taken to complete the request.

2. Data held by AAR

The data items provided to the AAR include:

- Health at diagnosis
- Demographic details (name, DOB, gender and genetic ethnicity)
- Family history
- Pregnancy history and fertility preservation
- Clinical presentation
- Laboratory and imaging data such as blood test, tissue results, radiological images and reports at initial presentation and diagnosis and at the times during follow-up described above. Genetic testing results for both somatic and inherited genetic changes will also be sought.
- Therapy decisions
- Outcomes including details of any relapse, complications (of therapy or condition), performance status indicators, disease progression, overall survival and QoL measures (using validated questionnaires)

3. Types of data requests

Specific analyses/ study proposals:

Applicants may request AAR to undertake specific analyses of data in which the AAR would provide de-identified aggregate/summary data reports only. Steering Committee approval is required before data is made available.

Applicants may also request de-identified individual unit record data to perform their own analyses for study proposals. These requests require Steering Committee approval, HREC/IRB approval, and a Data-Sharing Agreement or other legal agreement. Approved applicants will be provided restricted access to a de-identified dataset for the permitted purposes only.

Data Linkage Requests:

For projects that require data linkage, a data linkage plan will be developed with the applicant with the overarching requirement that the privacy of individual sites and participants is maintained.

The AAR may require data to be provided for the purpose of conducting the linkage process. A data linkage key, or similar, will be generated to combine the datasets. Before sharing the data with the applicant, participant identifiers will be removed after data linkage is complete.

Steering Committee approval, HREC/IRB approval and a Data-Sharing Agreement or other legal agreement between the custodians of the included datasets will be required.

For data requests requiring linkage to a third-party dataset, applicants may be charged a fee for service to undertake and access the linked data.

Hospital-specific Data If a site, or its representative, makes a specific request for its own performance data, beyond that available on the site Data Report, a request must be submitted to the AAR Project Manager. At the discretion of the Project Manager, depending on the complexity and extent of the request, the request may be further reviewed and require approval by the AAR Management Group.

Biobank data and specimens The Australian Marrow Failure Biobank (AMFB) uses the infrastructure of the AAR to collate the clinical and biospecimen data from participants registered in the AMFB.

The AMFB collects and stores data and biospecimens collected from consented patients. Researchers may access these samples contingent upon the biobank policies and procedures. These samples are available to researchers with appropriate ethics approvals. Biospecimens are linked to clinical data held by the AAR. All requests for biospecimens/data will also require approval by the AMFB Data and Biologicals Access Committee (DBAC). Specific HREC/IRB approval and a material transfer agreement (or similar) are required.

4. Data shared with approved applicants

The AAR is ethically approved to collect personal identifiers to permit longitudinal follow-up of the participants. Methods, such as removing dates and other identifiers, have been adopted to mitigate the risk of identification during analysis, data storage, and presentation and publication of research results. The AAR will release the least sensitive level of data that is practicable for the requirements of the study proposal submitted.

Types of data that may be shared with an applicant include:

1. Aggregate/summary data

Requests for aggregate/summary data are requests where the data may be stratified by non-identifiable data elements, including age (or age group), sex, drug, and diagnosis year(s). The level of aggregation would be sufficiently high to prevent the indirect identification of any individuals. To assist with this, the AAR may suppress any data with few cases.

2. De-identified individual unit record

Requests for de-identified individual unit record information are requests where the dataset would not contain any identifying details. That is, they would not include database registration ID, name, full date of birth, or any data items that either may singly or collectively identify an individual. If a researcher discovers that it is possible to re-identify a participant in the provided dataset, the researcher must immediately notify the AAR Management Group and take the reasonable steps required by the AAR Management Group to mitigate risk or harm to the participants.

Requests for access to individually identifiable data, where the identity of a specific individual can be reasonably ascertained, will not be granted.

5. Conditions of use

1. Requests must be made in accordance with this Data-Sharing Policy and applicants must provide the full project scope including project rationale, research questions and intended use in the request form. The AAR holds the rights to reject or revoke access if the terms of this Policy are not adhered to.
2. Sites contributing data to the AAR may have access to their own patient-level data without charge.
3. Data cannot be provided until all required approvals have been obtained, ethics approval from relevant HRECs/IRBs are in place, and any fees-for-service paid, where required.
4. Data access and usage must comply with all conditions of approval and contractual arrangements where applicable.
5. All acquired data must only be used for the specific research question(s) outlined in the written data request and study proposal, and as approved by the AAR Steering Committee and/or AAR Management Group. Secondary use of the acquired dataset will require additional HREC/IRB and/or AAR Management Group/ AAR Steering Committee approvals.
6. Data provided by the AAR may not be disclosed to any person other than those explicitly listed in the written data request.
7. Applicants should make no attempt to re-identify individuals in the de-identified dataset provided.
8. Applicants are encouraged to complete their research in a timely manner. If there has been no or little progress within 12 months from the data request approval date without valid reason, the AAR Management Group will consider the research as abandoned. Applicants with projects that have exceeded 24 months in duration or exceeded the expected completion timeframe, will not have new projects considered unless sufficient progress in the existing projects has been demonstrated, at the discretion of the AAR Management Group/ AAR Steering Committee.
9. For study proposals, the applicant will be asked to provide an update as to the progress of the study at least every 6 months from the data request approval date or as requested by the AAR.
10. It is a condition of use of AAR data that in publications the registry is recognised as the/a data source and the AAR will be acknowledged in accordance with the AAR authorship and

publication policy in any presentation of the data. A copy of any publication or presentation containing AAR data must be provided to the AAR Management Group for review prior to submission.

6. Requesting Data

6.1. Data Request Form

Prior to seeking HREC/IRB approval for the research project, we encourage applicants to seek conditional approval from the registry steering committee to ensure project feasibility. If the project is deemed feasible, a letter of support from the Steering Committee will be issued to support the applicants HREC/IRB application.

6.2. Documents required to support request for access

The documents required for your submission are:

- Data Request Form (below) outlining the specific categories of data required for analysis
- Where relevant, HREC/IRB application and approval letter

6.3. Review Process

1. Applicants are encouraged to discuss the application with AAR Project Manager/Coordinator before preparing/submitting the Data Request Form and prior to seeking HREC/IRB approval.
2. All requests should include the following information: Study background, aims and objectives, methods and detailed statistical analysis plan, data type and request (see section 3 and 4 above), contact details of the applicants and their supervisors, anticipated timeline, source of funding and proposed publication/presentation plan.
3. All data requests are considered on a case-by-case basis and will undergo an initial review by the AAR Management Group for feasibility, duplication, complexity and scientific merit.
4. Data requests supported by the AAR Management Group (see point 3), will be sent to the AAR Steering Committee for review and approval. The Steering Committee is given 2 weeks to review and provide feedback.
5. If approved, the applicant must submit a copy of the HREC/IRB approval, where required, and subsequent annual HREC progress reports must be provided to the AAR.
6. The AAR Management Group will confirm the anticipated timelines for approved request completion, costing estimate (if needed), feedback from the Steering Committee, and any specific conditions of use including HREC/IRB approval requirements if the request is outside the scope of the ethics approval held by the AAR for its routine operations and purpose. Registry staff will notify the applicant if additional approvals are required.
7. Applicants will be required to complete a progress report every 6 months and/or upon request.

6.4. Terms of release

Registry data are released:

- in accordance with relevant legislation, regulations and guidelines;
- with approval of the relevant data custodians; and
- where applicable, for ethically approved human research projects of scientific merit.

6.5. Prioritisation of data request applications

All requests for AAR data will be processed in a timely manner, but are undertaken in addition to the routine AAR workload.

The following factors may be taken into consideration when prioritising access:

- Data availability,
- Technical feasibility or complexity of project,
- Resource availability, or
- Urgency of request if required for a time-sensitive matter (e.g., conferences).

As a general rule, requests for aggregated data will take 6-8 weeks to complete after approval.

To accommodate data requests for abstract submissions to scientific meetings, the Data Request form must be received no less than 60 days prior to the abstract submission deadline. This timeframe is required to allow a thorough analysis and result discussion for all approved requests.

Where a data request for publication purposes is already the subject of another approved data request, priority will be given to the original request. If deemed appropriate by the AAR Management Group, the AAR may connect both applicants for collaboration.

7. Data storage and sharing

7.1. Monash's Secure File Transfer

In most cases, data will be transferred via Monash University's secure file transfer platform. The de-identified data is encrypted and stored on a server that is accessible only to approved and authenticated researchers.

7.2. Monash Secure e-Research Platform (Monash SeRP)

Where appropriate, access to Monash SeRP may be provided to applicants who wish to conduct their own analysis of unit record data and for data linkage studies.

The Monash SeRP allows a subset of data to be analysed remotely on Monash University servers in a controlled manner and with an appropriate level of security. Individual unit record data may not be removed from this server, only aggregated research outputs can be exported upon approval by the data custodian.

Data will be provided either as labelled .dta files (Stata format) or as .csv files. Within Monash SeRP, researchers can access commonly used statistical software including Stata, SPSS, and R.

7.3. Data security and storage

Recipients of AAR data are responsible for ensuring appropriate security for the storage of any material, confidential or otherwise, held in any format including on computing systems.

No identifiable or **potentially re-identifiable** research data and/or health information should ever be stored on local machines or sent via email or fax or transported on a portable disk or disk drive.

On completion of analysis, users will be required to download their analysis software/code and store as per their local institution guidelines. The de-identified unit record data will be archived for 7 years after the date of publication. For unpublished research, data will be kept for 7 years post the final report.

8. Publishing and dissemination of research results

All data requests for publication purposes must comply with the Acknowledgement and Authorship guidelines outlined in the AAR Publications Policy.

The AAR expends significant time, effort and other resources in collecting, cleaning and preparing the data for research. Because the dataset comprises data from multiple centres, the investigators affiliated with the AAR are also exclusively positioned to take responsibility for the quality and accuracy of the data. For these reasons, consistent with the ICMJE authorship criteria, it is expected that any manuscript arising from AAR research data extract includes an appropriate number of authors from the AAR. The AAR contributors to be named would depend on the actual input to the particular data exercise and should conform to the Australian Code for the Responsible Conduct of Research (http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/r39.pdf), Monash University Research Outputs and Authorship Policy (<http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html>), and the AAR Publication Policy. Applicants are encouraged to discuss the authorship requirements with the Registry Project Manager and will be advised on the appropriate acknowledgement statement.

Any material intended for presentations or publications must be sent to the AAR Management Group at least 4 weeks prior to presentation or submission for review to ensure accurate interpretation of registry data and acknowledgement of the AAR. Approval from the AAR prior to presentation or publication is required. Requests for expedited review may be considered where feasible.

Any material or manuscript to be published using AAR data must contain appropriate acknowledgements of the AAR. Preferred wording for the acknowledgement will be provided with the data. See AAR Publications Policy for more information.

Applicants should seek a template and/or logo from the registry for presentations and they are provided on the condition that individual slides are not altered in any way (including background) prior to use.

AAR maintains a record of all requests for AAR data and its subsequent use as a means of monitoring the value of the project to the wider clinical community.

9. Fees

Requests for data will be considered on a case-by-case basis and may be subject to a fee. If a fee is charged, an agreement in writing from the requesting party must be received prior to data being extracted.

In general, requests for data from contributing clinicians, sites, and academic organisations will either be waived or calculated on a cost recovery basis that is dependent on the complexity and feasibility of the request/study proposal.

10. References

Monash University Research Data Protection and Privacy Collection Statement:

https://www.monash.edu/_data/assets/pdf_file/0010/1595269/Research-Data-Management-and-Privacy-Collection-Statement.pdf

Australian Code for the Responsible Conduct of Research:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

Monash University Research Outputs and Authorship Policy: <http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html>

11. Version History

Date	Document Version	Document Revision History	Author/Reviser
15-10-2025	1.0	Initial draft based on TRU Master Data Access Plan dated 25-06-2025 Includes AMFB Data Access Request Form v2.0 dated 04-07-2025	Laura Sellick

12. DATA ONLY Request Form – Researcher

Please return your completed application to: aar@monash.edu

Part A: Requester Details

Date of Request:			
Type of data request	<input type="checkbox"/> De-identified aggregate/summary data <input type="checkbox"/> De-identified Individual Unit record data		
Short title of data request:			
Principal requester:		Title:	
Other investigators:		Titles:	
Affiliation/organisation:			
Address:			
Telephone/mobile:			
Email:			
Are you a student	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, who has funded the project?			
Was the AAR formally involved in the grant application?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Will the data be used as part of a collaborative project with industry partners?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Does your project require ethics approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No *If NO proceed to PART B		

If YES have you applied for ethics approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES, to which organisation did you submit the application?	
Have you received ethics approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No *If YES, please attach a copy of your approval certificate, a full copy of your application and any other relevant documents such as participant information sheets and consent forms etc.
What is the anticipated date for project completion?	

Part B: Project Details

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Title of project	
Background and rationale for the project (600-word maximum plus key references)	<i>Include possible outcomes and clinical significance of this research</i>
Hypothesis and specific research questions	
Methodology of project (500-word maximum)	
Inclusion and exclusion criteria	
Statistical plan	<i>(Statistical support from the registry can be provided, if required – please indicate this in your response)</i>
Anticipated timeline for completion or important dates for consideration	<i>Include any publication plans and any important dates</i>

13. AMFB DATA and BIOLOGICALS Request Form – Researcher

Access to specimens is managed by the AMFB Data and Biologicals Access Committee (DBAC). As the biological collection is limited, access to AMFB samples will be assessed on scientific merit and sample availability.

Researchers must apply to the DBAC and have their application approved prior to progressing their application with their local HREC. Following DBAC approval, researchers will be required to submit a research plan along with details of credentials and institutional appointments to their HREC. In forming their HREC application, the researcher will work with the AMFB to develop their own Ethically Defensible Plan which adopts the principles of the AMFB EDP. They must also sign a Material Transfer Agreement (MTA).

There are costs involved in accessing and transporting specimens. Charges will be on a cost recovery basis at the discretion of the DBAC in consultation with the AMFB Management Group.

1. RESEARCHER INFORMATION

Name	
Institution	
Address	
Email	
Phone	

2. PROJECT INFORMATION

Title	
Institution	
Project Lead Person	
Other key personnel	
Background	
Aim and objectives	
Study Population	Inclusion criteria: Exclusion criteria:

3. BIOSPECIMEN REQUEST INFORMATION

1. Please specify the number of participants you wish to access samples for and provide justification for this and the number of samples required:

2. Please describe the characteristic(s) of the participants you wish to access samples for (e.g., all female patients, all patients with Fanconi Anaemia etc). It is helpful to be as specific as possible.

3. Please indicate the sample type(s) requested by checking the corresponding boxes in each row below and the volume required.

Type of Sample	Baseline	Follow up	Please specify the amount required.
Extracted DNA from Bone Marrow Aspirate	<input type="checkbox"/>	<input type="checkbox"/>	
Extracted RNA from Bone Marrow Aspirate	<input type="checkbox"/>	<input type="checkbox"/>	
Bone marrow mononuclear cells	<input type="checkbox"/>	<input type="checkbox"/>	
Extracted DNA from Peripheral Blood	<input type="checkbox"/>	<input type="checkbox"/>	
Extracted RNA from Peripheral Blood	<input type="checkbox"/>	<input type="checkbox"/>	
Peripheral Blood (PAXgene)	<input type="checkbox"/>	<input type="checkbox"/>	
Peripheral blood mononuclear cells	<input type="checkbox"/>	<input type="checkbox"/>	
Hair bulb DNA	<input type="checkbox"/>	<input type="checkbox"/>	
Nail clippings DNA	<input type="checkbox"/>	<input type="checkbox"/>	
Oral swab DNA	<input type="checkbox"/>	<input type="checkbox"/>	
Cultured skin fibroblasts (if available)	<input type="checkbox"/>	<input type="checkbox"/>	

4. Please describe any other services / processing you wish the AMFB investigators to provide.
5. Please provide any further information relevant to this application for biospecimens.
6. Are there any other factors that we should be aware of that might influence our ability to deliver service e.g., time constraints? If yes, please give details.
<input type="checkbox"/> Please confirm by checking the box that you have informed / will inform the reviewing Ethics Committee of the source of the samples.

Following in principle approval from the DBAC, please submit your project to an NHMRC approved HREC committee and complete the details below.

4. ETHICS APPROVAL INFORMATION

Name of HREC	
HREC Approval Date	
HREC Ref #	
Research Project Title	
Principal Investigator	
Institution/s where research will be conducted	
Project protocol name, date and version	
Please attach a copy of your HREC approval letter and the approved protocol, a full copy of your application and any other relevant documents such as participant information sheets and consent forms etc.	