#

**Australian and New Zealand**

 **Myeloma and Related Diseases Registry (ANZ MRDR)**

**DATA ACCESS AND PUBLICATION POLICY**

**Version 2.1 dated 10 July 2019**

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## Preface

The ANZ MRDR encourages the use of its data for purposes including quality improvement, research and clinical planning. This data access policy defines how data from the ANZ MRDR and the M1000 Biobank may be accessed, including the criteria and conditions for provision of data for research activities, and procedures for data request applications. It also outlines situations in which fees for access might be applicable, and any associated acknowledgement and publishing responsibilities.

The aims of the ANZ MRDR are to monitor access to care and trends in incidence and survival; benchmark outcomes; explore variation in practice and outcomes; and to act as a resource for clinical trials. The ANZ MRDR has a blood biobank substudy, the Myeloma 1000 Project (M1000). The aim of this substudy is to collect specimens from 1000 patients with multiple myeloma (MM) and 1000 patients with monoclonal gammopathy of undetermined significance (MGUS) which will allow assessment of biomarkers that predict treatment response, patients at risk of developing myeloma, and patients at risk of accelerated disease progression. Requests for both ANZ MRDR data and M1000 bio-specimen access are included in this document.

Data and biospecimens collected and collated by the ANZ MRDR and M1000 are guided by strict protocols and procedures to ensure the security, privacy and confidentiality of information collected and stored in the registry. Patient and stakeholder information will be handled in accordance with the *Commonwealth Privacy Act (1988)*, the *Privacy and Data Protection Act 2014 (Vic)*, the *Health Records Act 2001 (Vic)*, the *European Union General Data Protection Regulation 2016/679* (as applicable), and any code of practice or guidelines made under these Acts. In addition, all research subject to Human Research Ethics Committee (HREC) review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).  Regarding Myeloma 1000 requests, an ethically defensible plan to disclose or withold findings (National statement 3.1.64-65) is a HREC requirement for studies involving the use of biospecimens.

Registry activities have been approved by several Australian National Health and Medical Research Council (NHMRC) approved Human Research Ethics Committees (HRECs), a New Zealand Health and Disability Ethics Committee (HDEC) and Monash University HREC.

## Data access summary

The following points summarise the principles that guide access to data requested from the ANZ MRDR and their use in routine reports and scientific publications. The guidelines are explained in detail in Section 4.

* Requesting data for research is encouraged and considered important to further the body of information that will lead to improved outcomes for patients diagnosed with multiple myeloma or a related disease.
* All contributing hospitals have unrestricted access to their own registry data and routine reports are generated using this data without charge.
* Identifiable patient registry data will not be made available to third parties.
* Data where institutions may be identifiable will only be provided to researchers where permission from the Local Investigator and/or Institution has been obtained.
* All requests for biospecimen data will require approval by the M1000 Research Committee and ethics committee approval
* Research-related requests for registry data will require specific ethics committee approval if the researcher is not directly affiliated with the ANZ MRDR and/or the request is outside the scope of the ethics approval held by the ANZ MRDR for its routine operations and purpose.
* Any abstract, presentation or manuscript resulting from use of data requested from ANZ MRDR or M1000 Biobank, will be reviewed by the ANZ MRDR Management Team (and M1000 Research Committee if relevant) before presentation or submission for publication and must comply with the ANZ MRDR Publication Policy.
* Requests for Asia-Pacific (APAC) and ANZ MRDR registry data will require the approval from both the APAC MRDR and the ANZ MRDR Steering Committees. Conditions of use outlined in the APAC MRDR Data Access Policy must also be adhered to.

## Conditions of use

1. All use of data from ANZ MRDR, in whatever context, must receive prior approval from the ANZ MRDR Management Team and/or the ANZ MRDR Steering Committee. Biospecimen data requires additional approval from the M1000 Research Committee.

- Specific hospital Ethics Committee approval may also be required for registry data if the researcher is not directly affiliated with the ANZ MRDR and/or the request is outside the scope of the ethics approval held by the ANZ MRDR for its routine operations and purpose.

1. Identifiable patient data will not be made available to third parties.
2. Only limited authorised Monash staff have direct access to the ANZ MRDR database.
3. Data access may be subject to conditions in agreements or research ethics approvals. A caveat and conditions of use statement will be provided with the data.
4. Data provided to researchers must be securely stored and may not be released to other parties not explicitly mentioned in the written data request, nor used for purposes other than that specified in the data request, without the permission of the ANZ MRDR (and the M1000 Research Committee if relevant).
5. Where a request for data for publication purposes is already the subject of another approved data request, priority will be given to the original request. ANZ MRDR or the M1000 Research Committee will endeavour to put both research groups in touch with each other.
6. The provision of data / additional specimen processing may be subject to a fee-for-service. Refer to ‘ANZ MRDR Fees for Provision of Data’ and the biospecimen access request table D below for further information.
7. All requests for access to ANZ MRDR registry data / M1000 biospecimens must take appropriate timelines into account as these requests will need to be scheduled along with routine ANZ MRDR tasks. Generally, simple requests for data will take 2-4 weeks to complete. Requests should be made to the ANZ MRDR Project Manager/ M1000 Research Committee who will table the request at the next Steering Committee meeting (held quarterly). If required, the data request will be sent for consideration out of session via email. Data cannot be extracted until approval is given and relevant ethics approval is in place.
8. All data requests must be formally lodged, using the Data Request Form in this document, via email ( sphpm-mrdr@monash.edu ).

## ANZ MRDR Access Guidelines

The ANZ MRDR Access Guidelines are listed by type of data request:

|  |  |
| --- | --- |
| **Summary Data:** | Where summary registry data only (i.e. total number of patients) is requested, the information can be provided by ANZ MRDR staff. Such provision of data does not require Steering Committee approval but ANZ MRDR will require a formal request in writing and will keep a record of such requests. The ANZ MRDR Steering Committee will be provided with a summary of such requests on an annual basis.  |
|  |  |
| **Specific Analyses (Aggregate Data):** | ANZ MRDR investigators and Third parties may request ANZ MRDR to undertake specific analyses of data. In all cases, the receiving party would subsequently be provided with resulting aggregate data only. A formal written request should be made to ANZ MRDR for approval from the Steering Committee. Data access may be subject to conditions in agreements or research ethics/IRB approvals. |
|  |  |
| **Individual Record Data**: | Individual record data will not be provided to a third party. If a third party researcher or student requires individual record data for linkage studies or their own analyses, access to Monash University’s Data Safe Haven may be provided. The Data Safe Haven allows a subset of data to be analysed on Monash University servers in a controlled manner and with an appropriate level of security. Data may not be removed from this server, only the non-identifying results of any analyses. For linkage studies, it may be possible for the third party to provide their data to ANZ MRDR and for ANZ MRDR to provide non-identified data or aggregate data summaries based on the linked data. The above projects will require separate ethics committee approval from relevant Ethics Committees. A formal written request should be made to ANZ MRDR for approval from the Steering Committee. This also applies to the comparison of external data sets with data maintained by ANZ MRDR. In all cases, privacy and other relevant legislation must be complied with. |
|  |   |
| **Hospital-specific Data (Third party requests)**: | If a researcher requires data from a particular hospital or hospitals in the registry that the researcher is not affiliated with, approval from an Ethics Committee will be required before data is made available.  |
| **Own Hospital’s Performance Data**: | If a hospital or its representative makes a specific request for its own performance data, beyond that available on the Hospital Data Report, this will be provided by ANZ MRDR. No data that could specifically identify a patient will be provided. All requests for this category data should be made in writing to the ANZ MRDR Project Manager. Whilst such data requests do not require Steering Committee approval, the Project Manager will notify the Steering Committee of the requests.  |

## ANZ MRDR Fees for Provision of Data

1. The provision of data may be subject to a fee-for-service on a cost recovery basis unless there are existing funding agreements in place or MOUs between the registry and funders/supporters. Research collaboration with investigators associated with the registry will not incur a fee. Fees will be at the discretion of the ANZ MRDR Management Team and will be based on the complexity and estimated time taken to complete the request as well as current ANZ MRDR routine workload.
2. Upon receipt of a data analysis request, ANZ MRDR will provide a cost estimate for the work. This will normally be within 2 weeks of receipt of the request. Those requesting data must agree to these costs (in writing) before any analyses are performed.
3. GST (10%) is also payable.

## Acknowledgement and Authorship Policy

* Any data provided is on the condition that ANZ MRDR is acknowledged as the source of the data. The suggested citation is: *The data was provided by the Australian and New Zealand Myeloma and Related Diseases Registry.* If the data is the primary source for a report or publication, an additional statement that the analysis and interpretation are those of the author, not the registry must be included. The publication must be submitted to the ANZ MRDR Management Team / M1000 Research Committee for feedback prior to submission. The decision to publish remains with the authors.
* Where the interpretation of ANZ MRDR data is central to the data request, it is expected that at least one ANZ MRDR member is named as a co-author on any publication arising from use of requested data. The actual ANZ MRDR contributor/s 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>) and Monash University Research Outputs and Authorship Policy (<http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html>).
* PowerPoint Slides from ANZ MRDR for presentations are provided on the condition that individual slides are not altered in any way (including background) prior to use.
* ANZ MRDR requires that a copy of any document or presentation using ANZ MRDR data, figures, or PowerPoint slides be provided to the ANZ MRDR Project Manager via email ( sphpm-mrdr@monash.edu ). ANZ MRDR maintains a record of all requests for ANZ MRDR data and its subsequent use as a means of monitoring the value of the project to the wider clinical community.

## Data request form

**Please return your application to the address below:**

|  |  |
| --- | --- |
| *ANZ MRDR Project Manager**533 St Kilda Rd, Melbourne 3004*  | *EMAIL: sphpm-myeloma@monash.edu**PH: +61 3 9903 0355* |

### Part A: Requester Details

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Request:** |  | **Date required by:** |  |
| **Type of data request** |  |
| **Short title of data request:** |  |
| **Principal Requester:** |  | **Title:** |  |
| **Name and contact details of Prinicipal Investigator :** | For PI on HREC approval if different to above | **Title:** |  |
| **Other Investigators:** |  | **Titles:** |  |
| **Affiliation/Organisation:** |  |
| **Address:** |  |
| **Telephone:** |  | **Mobile:** |  |
| **Email:** |  |
| **Are you a student** | [ ]  Yes [ ]  No |
| **If YES, what degree are you working towards?** |  |
| **Name and contact details of your supervisor** |  |
| **Is this a funded research project?** | [ ]  Yes [ ]  No  |
| **If YES, who has funded project?** |  |
| **Was the MRDR formally involved in the grant application?** | [ ]  Yes [ ]  No  |
| **Does your project require Human Research Ethics committee (HREC) approval?** | [ ]  Yes [ ]  No  | \* If NO proceed to PART B |
| **If YES have you applied for HREC approval?**  | [ ]  Yes [ ]  No |
| **If YES which organisation’s HREC did you apply to?** |  |
| **Have you received HREC approval?** | [ ]  Yes [ ]  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. |

### 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**(500 word maximum plus key references) |  |
| **Hypothesis and specific research questions** |  |
| **Possible outcomes and clinical significance of this research** **(**250 word maximum) |  |
| **Methodology of project**(500 word maximum) |  |
| **Inclusion and Exclusion criteria** |  |
| **Proposed method of publication / presentation of results** |  |

###

### Part C: Data fields required

Please contact the ANZ MRDR for a list of data collected. MRDRis required to maintain patient privacy. No data will be released that could potentially identify patients.

|  |  |
| --- | --- |
| **Data item required** | **Justification** |
|  |  |
|  |  |
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|  |  |
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If Myeloma 1000 bio-specimens are required for this project, please complete part D below.

If not skip to Part E.

### Part D: Request for Myeloma 1000 project bio-specimen access

|  |
| --- |
| **Myeloma 1000 bio-specimen access** |
|   | **Bio-specimens**The fields below indicate which bio-specimens you wish to access. Samples are limited and access to samples will depend on scientific rationale and sample availability. **NOTE:** There are costs involved in accessing and transporting bio-specimens. Charges will be on a cost recovery basis at the discretion of the Myeloma 1000 Project Research Committee (see Myeloma 1000 Project protocol) in consultation with the MRDR management team. |
| **i)**  | **Are you requesting access to bio-specimens for analysis?**[ ]  Yes [ ]  No  ⮡ (you do not need to complete this section) |
| If Yes, please specify the number of participants you wish to access samples for and provide justification for this and the number of samples required: |
| **ii)** |  Please describe the characteristic(s) of the participants you wish to access samples for (e.g. all female pts, all patients with multiple myeloma etc). It is helpful to be as specific as possible. |
| **iii)** | **Please indicate the sample type(s) requested by checking (**[x] **) the corresponding boxes in each row below and the volume required.**Samples from multiple myeloma (MM) patients were taken before treatment. SMM = Smouldering MM |
| **Type of Sample****Samples kept at -80°C** | **MM** | **SMM** | **MGUS** | **Please specify the volume required in *µL (microlitres)*.**Note: samples are stored in 500µL aliquots*.* |
| EDTA Plasma | [ ]  | [ ]  | [ ]  |  |
| Serum  | [ ]  | [ ]  | [ ]  |  |
| Streck DNA plasma | [ ]  | [ ]  | [ ]  |  |
| Streck RNA plasma | [ ]  | [ ]  | [ ]  |  |
| **iv)** | Please describe any other services / processing you wish the Myeloma 1000 investigators to provide.  |
| **v)** | Please provide any further information relevant to this application for biospecimens |
| **vi)** | [ ]  Please confirm by checking the box that you have informed / will inform the reviewing Ethics Committee of the source of the samples. |
| **vii)** | 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. |

|  |  |
| --- | --- |
| **x)** | The biobank reports on areas of research that we support. Please help us by ticking all areas that apply to your project. |
| **Category** | **% of project** | **Category** | **% of project** | **Category** | **% of project** |
| [ ]  Translational research |  | [ ]  Biomarker discovery |  | [ ]  Genomic research |  |
| [ ]  Proteomic research |  | [ ]  Diagnostics development |  | [ ]  Clinical trial support |  |
| [ ]  Cancer-related biology |  | [ ]  Other (specify) |

### Part E: Applicant’s signature

*I certify that I have read and understood the ANZ MRDR data access policy. I agree to comply with that policy.*

*I agree to undertake all activities described in this request in accordance with the research proposal, research approval of the reviewing human research ethics committee (HREC) and all relevant privacy legislation relating to patient information and health records.*

*I agree to adhere to all the conditions placed on use and storage of the data as outlined in any ANZ MRDR data access approval that will be provided to me prior to commencement of any research activity or data analysis.*

*I agree that the information provided by me to the ANZ MRDR is true, accurate, complete and without material omission.*

*I agree that the information provided to me by the ANZ MRDR whether in the form of data, reports, models, samples and regardless of how communicated or recorded, is confidential and confidentiality of all information and communications will be maintained unless otherwise agreed by both parties.*

*Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**OFFICE USE ONLY:**

|  |
| --- |
| **Short Title of Data Request:** |
| ANZ MRDR Steering Committee decision | [ ]  approved[ ]  approved subject to amendment[ ]  declined  |
| If approved, subject to amendment, list required changes |  |
| Approved by ANZ MRDRSteering Committee Chairperson:Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of approval: |   |

*History of changes to the Data Access policy for the Myeloma & Related Diseases Registry*

|  |  |  |  |
| --- | --- | --- | --- |
| Version  | Date  | Author  | Summary of Revisions  |
| 1.0  | 5/5/2012 | Ms Naomi AokiDr Ieva Ozolins  | Data Access Policy created  |
| 1.1 | 20/9/2012 | Naomi Aoki | Amended Page 1, Clause 3: All uses of MRDR data will require specific hospital ethics committee approval.  |
| 2.0 | 10/11/2018 | Elizabeth Moore | Changes to provide clarity about data access, assessing needs for new study proposals, and to incorporate Myeloma 1000 biobank requests. |
| 2.1 | 10 /7/2019 | Elizabeth Moore | Changes to Part D to ensure compliance with biobank ethical responsibilities and completeness of information collected. Change to Part E to cover any applicable privacy legislation. Other minor changes to improve document. |