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# Data Access Policy

Version 2.0  
15 November 2024

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## Revision History

Version Number	Author	Date	Summary of changes
1.1	Not recorded	21 May 2014	Version history not previously recorded
2.0	Jennifer Holland	June 2024	See below

### Amendments release version 2.0, approved 15 November 2024

Section Title	Section Number	Amendment Summary
Policy title	Title page	Title changed from Data Access and Reporting Policy to Data Access Policy
Various sections		Policy rewrite. Guidelines for storing data, analysis of data and reporting of data removed. Added purpose & scope, data access principles, request process overview. Reporting Policy no longer in scope of this policy and Data Access Request Form changed to stand alone document. Updated scope to cover research and non-research requests. Data access widened to include provision for requests for non-aggregate data that has been deidentified and provision for identifiable data to be released for data linkage with accredited data linkage agency only.

## Document Control

Version	
Bariatric Surgery Registry, Data Access Policy	
Version Number: 2.0	Author(s): Executive Officer
Date Approved: 15 November 2024 Year	Document status: Approved
Effective Date: 15 November 2024	Approved by: BSR Steering Committee
Superseded Version: v1.1	Date of Next Review: November 2026 (maximum 2 years)

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### Acknowledgement

The Bariatric Surgery Registry acknowledges the Australian Dementia Network (ADNeT) Registry for sharing their Third-Party Data Access Policy, v1.0. Parts of this policy have been adapted from the ADNeT Registry policy.

## 1. Purpose and Scope

This Data Access policy applies to the provision of data by the Bariatric Surgery Registry (BSR) to a third party. Requests for data access are considered to be either a research request or non-research request.

For the purposes of this policy, third party data requests refer to those by:

- Researchers (including students) external to the Bariatric Surgery Registry team
- Professional organisations or agencies, government departments and industry
- Health services or surgeons who are participating in the Registry
- Health services not participating in the Registry
- Registry participants requesting a copy of their own data

The types of Registry data that may be requested by a third party include:

- Aggregate or summary data that is available in publicly accessible Registry reports
- Aggregate or summary data that is not publicly accessible
- Participant-level, health-service level and surgeon-level data that has undergone deidentification for use in research
- Individual participant record level data (if a participant requests a copy of their Registry record).
- Identifiable participant-level data (if a participating health service or surgeon requests a copy of the data they have contributed to the Registry).

## 2. Principles and conditions of data access

### General

- 2.1 Requests for **aggregate or summary data that is publicly available in** Registry reports does not require approval. For these requests, the Registry asks that there is acknowledgement of the source of the data and encourages the third party to report back their use to the Registry to assist the Registry in tracking use of Registry data.
- 2.2 Requests for **aggregate or summary Registry data that is not publicly accessible** can be approved by the Steering Committee Chair or Deputy Chair and may be referred to the Steering Committee for formal review at the Chair/Deputy Chair's discretion.
- 2.3 **Participant-level, surgeon-level or hospital-level data that has undergone deidentification** may only be accessed for research studies with ethics approval and BSR Steering Committee approval. This data type of data will only be released if the Steering Committee is assured that reasonable steps have been taken to minimise the risk of reidentification of the data and that level of risk is deemed acceptable.
- 2.4 **Identifiable participant, surgeon or hospital-level data** may not be released to third parties except in case of providing a participating surgeon or health service with data they have contributed to the Registry, providing a participant with a copy of their Registry data, or for the purposes of data linkage.
- 2.5 The Registry will not release participant names or contact details to third parties. Projects that require direct contact with individual Registry participants for study recruitment, even if that contact is to be initiated through the Registry on behalf of researchers, will not be approved.

- 2.6 The Registry will only release data that is cleaned and deemed to be of sufficient quality for the intended use.
- 2.7 Third parties requesting data should familiarise themselves with the current version of Registry Data Dictionary.
- 2.8 A fee may be charged for data requests by third parties. The fee will be determined on a case-by-case basis and an indicative quote will be provided by the Registry.
- 2.9 Mode of access to data will depend on the complexity of the data requested and will be determined by the Steering Committee. It may be a condition of data access that the researcher uses a safe haven (e.g. Monash SERP) for data access and analysis.
- 2.10 Full acknowledgement of the source of the data must be provided in any publications that arise from access to and the use of Registry data. Suggested wording of acknowledgement:
- The research described in this publication is based on data collected for the Australia and New Zealand Bariatric Surgery Registry, an initiative of Australian and New Zealand Metabolic and Obesity Surgery Society (ANZMOSS), Monash University (as Custodian) and the Australian Government.*
- 2.11 Data sovereignty principles in relation to the release and reporting of data about Māori, Aboriginal and/or Torres Strait Islander peoples will be considered in reviewing data access requests.

### Research requests

- 2.12 All research requests for **participant-level, surgeon-level or hospital-level data that has undergone deidentification** need to be approved by the Bariatric Surgery Registry Steering Committee and have ethics approval. At the discretion of the BSR Steering Committee, it may be a condition of approval that a formal Data Sharing Agreement be signed by all parties before data access will be granted.
- 2.13 Research requests for **aggregate data that is not publicly available** will require ethics approval and approval from the Steering Committee.
- 2.14 Research requests for **aggregate data that is publicly available** do not require Steering Committee approval.
- 2.15 Regardless of whether the research project has ethics approval, the Steering Committee may not approve the request for data access if the application is deemed to include insufficient detail about project aims, methodology, justification for each data item requested, the statistical analysis plan and data management plan in the data access request and/or research protocol.
- 2.16 Data access may not be granted if the research is deemed to significantly overlap with the Registry's core business or an existing study using Registry data.
- 2.17 Only research team members specified in the approved Data Access Request may have access to the shared Registry data.
- 2.18 The third party agrees that the data that is shared will only be used for the purposes stated in the approved Data Access Request.
- 2.19 Any amendments to the study's protocol, including changes to associated documentation and to the use of Registry data need to be re-approved by the Registry. Amendments may be approved by the Steering Committee Chair or delegate and more substantive changes may require re-review by the Steering Committee.
- 2.20 Approval for data access may include conditions specified by the Steering Committee or delegate.
- 2.21 It may be a condition of data access that any proposed publications and journal submissions (including conference abstracts and posters) arising from the research be reviewed by a member/s of the Steering Committee or Steering Committee before submission to a journal, editor, or conference. In such cases, this will be specified as a condition in the data access request approval. The Registry will have 30 working days from the date of receipt to review the proposed publication or journal submission.

- 2.22 Copies of the data files must not be made except for the purpose of creating a secure backup
- 2.23 Researchers are required to provide copies of any published works to the Registry.
- 2.24 Data requests relating to PhD projects should be co-signed by the student and their primary supervisor.

### Non-research requests

#### *Requests from Registry participants*

- 2.25 The Registry will undertake an identity check prior to releasing data to a participant requesting a copy of their own Registry data. The participant will not be provided with any notes from their BSR record that are considered to be administrative in nature rather than part of the participant's personal and health information. It may be necessary for the Registry to redact information in a participant's record that identifies another person or health service. A Data Access Request Form is not required for this type of data request.

#### *Requests from industry*

- 2.26 The Registry will not provide any data to industry that could be considered to provide a competitive advantage or where it is not deemed to be within the public good. Patient-level or health-service level data will not be shared with industry.

#### *Other requests*

- 2.27 In the case of requests from a health service or surgeon who is participating in the Registry, if the third party is requesting data that does not directly pertain to their respective site or bariatric procedures, the request will be reviewed as research data access request and require BSR Steering Committee approval. For example, if the requested data includes outcome data for participants that have had subsequent procedures or interventions with another health service or surgeon, or includes patient-reported data.

## 3. Request Process Overview

### Step 1 -Initial enquiry

Before making contact with the Registry it is recommend that the third party familiarise themselves with this Data Access Policy and the Registry's Data Access Form and Data Dictionary. These documents are accessible on the Registry website. When a third party makes initial contact with the Registry about data access request, in the first instance the request will typically be managed by the Registry's Executive Officer. The third party is strongly encouraged to arrange a time with the Executive Officer to further discuss their request and the data access process prior to completing the Data Access Request Form. The Executive Officer will advise the requestor if a formal data access request is required.

### Step 2 -Submission of Data Access Request form (where applicable)

A Data Access Request form is not required for publicly available aggregate data, participating surgeons or health services requesting copy of their own data, or a registry participant requesting a copy of their Registry record.

All other requests require submission of the Data Access Request form. Once the request is submitted it will be screened by the Registry Office to ensure all required information or associated documents are included. Incomplete applications will be need to be resubmitted and may delay the approval process.

### Step 3 -Review & approval phase

The review process will differ depending on the type of data requested, proposed use of data and the level of approval required. A Data Access Request requiring approval will either go to the Chair or Deputy Chair of the Steering Committee for review or it will be reviewed by the Steering Committee. All requests for participant, health service or surgeon level data that is identifiable or has been undergone deidentification must be reviewed by the Steering Committee.

### Step 4 -Notification of review outcome (where applicable)

The Executive Officer is responsible for notifying the third party of the outcome of the review and providing a copy of the Data Access Form signed by the Registry Steering Committee Chair or delegate. The outcome of the review will be one of the following:

- **Approved** (subject to acceptance of any additional conditions specified)
- **Provisionally approved** (subject to amended data request addressing the specified queries from the review)  
This means the Steering Committee agrees in principle with the request but more detail or specified amendments are needed before data access will be granted.
- **Not approved**

The Registry can provide an estimate of any applicable fees prior to submission of a formal Data Access Request. Fees will be confirmed after formal review by the Registry Steering Committee.

### Step 5 -Data access provided

The mode of access to data will vary depending on the type of data to be released:

- **Identifiable data** being provided back to the contributing surgeon or health service will be shared digitally through secure means.
- **Participant-level data** requested by an individual participant requesting a copy of their own BSR data will be sent in hard copy through registered post.
- **Aggregate data** may be provided to the researcher via email
- **Participant-level and hospital-level data** that has undergone deidentification will be accessible through the Monash University safe haven (Monash SERP), or an equivalent safe haven.
- **Identifiable data** for a data linkage project will only be released to authorised data linkage providers through secure means.

## 4. Related documents

Document Name
Bariatric Surgery Registry Data Access Request Form
Bariatric Surgery Registry Data Dictionary