

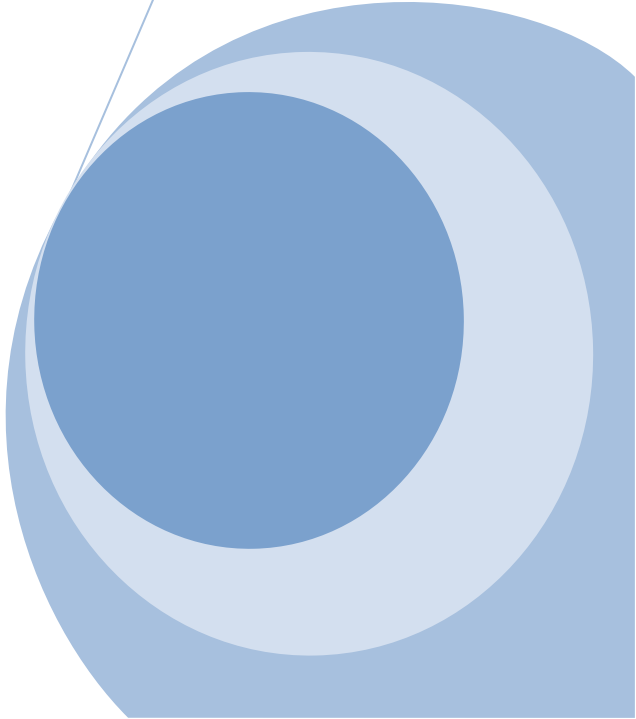


Bariatric Surgery Clinical Quality Registry

Data Access and Reporting Policy



An initiative of the Obesity Surgical
Society of Australia and New Zealand
in collaboration with Monash University,
School of Public Health & Preventive
Medicine



Data Access and Reporting Policy

The Bariatric Surgery Registry (BSR) encourages the use of its data for a variety of purposes such as quality improvement projects, research and clinical planning. This **Data Access and Reporting Policy** sets out a framework of co-operation between participating Researchers/Hospitals and the Data Custodian of the Bariatric Surgery Registry (BSR) to facilitate data access and reporting.

A. Access to Bariatric Surgery Registry data

1. Data collected for the Bariatric Surgery clinical quality Registry (BSR) is held by Monash University as Custodian, and OSSANZ (Obesity Surgery Society of Australia and New Zealand).
2. Aggregate data may be made available to third parties (collaborating researchers) where there is formal Ethics Approval in addition to a written request to the Bariatric Surgery Registry Steering Committee.
3. Requests to access BSR data are reviewed by the BSR Steering Committee. If the request is approved, data is provided for the analysis described in the request, including any reasonable amendments and additions that arise during the course of the proposed work. Approval is current for 12 months; HREC approval should reasonably dictate the duration of the project. Extensions beyond 12 months to access BSR data can be obtained by submitting HREC amendment, in addition to a review by the Steering Committee who can deem that work is progressing reasonably.
 - i. The BSR Project Officer must be notified of any HREC amendments to the nature of the analysis, the topic addressed, or the datasets requested (including amendments to study protocol) – send copy of HREC Amendment Request and Approval (and amended study protocol, if applicable).
 - ii. Minor changes (eg. changes to study personnel) should also be advised to the BSR Project Officer - send copy of HREC Changes to Research Personnel Form and Approval.
4. A **Data Access and Reporting Policy** must be signed by the Lead applicant for the project, listing the names of other collaborators who are potentially associated with the project, including those who present results or whose name appears on any publication associated with the project.
5. BSR data will be provided once a signed **Data Access and Reporting Policy** has been returned to the BSR Project Officer by the collaborator(s).
 - i. Mode of access to data will depend on the complexity of the data requested and will be determined by the BSR Steering Committee.
6. By signing this Policy, the project contact person (BSR Project Officer) acknowledges responsibility for ensuring the availability of adequate facilities to enable the project to progress in a reasonable manner and to completion.
7. Full acknowledgement of the source of the data must be provided in any publications that arise from access to and the use of BSR data (as set out in Section D.4)
8. Publications must use the most up-to-date information available and should include the date and source of all data used in the publication.

B. Guidelines for storing and maintaining the privacy of de-identified Bariatric Surgery Registry data

Please note, only de-identified aggregate data will be made available to collaborators.

1. Any data files obtained through the BSR dataset must only be used for research purposes.
2. Only members of the investigator team (as listed on the Release of Data Application Form) are permitted to have access to the data files.
3. Data files must be copied onto a password-protected area on the project leader's computer or network that is not accessible to those who are not members of the investigator team. It is highly recommended that you store data files on networked drives that are managed by professional IT staff centrally or within a specified faculty, academic unit or institutional department.
 - i. Copies of the data files must not be made except for the purpose of creating a backup.
4. The Project lead applicant must inform the BSR Project Officer when data analysis has been completed.

i. Upon completion of the project, data files must be retained in accordance with the relevant HREC Approval with which the application has been lodged. For further guidance on the retention of research data and primary materials, please refer to the current NHMRC Australian Code for the Responsible Conduct of Research 2007 - www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

5. Collaborators must provide the BSR Project Officer with details of where and how data files will be stored, in accordance with University regulations.

C. Guidelines for the analysis of Bariatric Surgery Registry data

1. Data analysis must be conducted according to recognised standards. Collaborators should familiarise themselves with the BSR dataset and the BSR Data Dictionary.

D. Guidelines for reporting using Bariatric Surgery Registry data

1. Collaborators should follow their institution's guidelines and the Vancouver guidelines regarding authorship of publications and conference presentations. The Vancouver Group has evolved into the International Committee of Medical Journal Editors (ICMJE) and current guidelines (Nov 2003) are available at - www.icmje.org

2. Persons who are listed as authors must have participated substantially in the conception, execution, and/or interpretation of the research that is described in the publication.

3. All publications should include the following acknowledgement: "The research described in this publication is based on data collected for the Bariatric Surgery Registry, an initiative of OSSANZ, Monash University (as Custodian) and the Federal Government."

4. Persons who have provided comments, advice, support, or other input into the publication and who are not already listed as authors must be acknowledged. Permission should be sought from these persons before inclusion.

5. Publication of multiple papers based on the same set(s) of data is not permitted unless full cross-referencing occurs within the papers, for example, by reference to a preliminary publication at the time of the complete work which grew from it.

6. Project leaders have overall responsibility for publications arising from the use of BSR data. Proposed publications and journal submissions (including conference abstracts and posters) must be reviewed by the BSR Steering Committee before submission to a journal, editor, or conference.

i. The BSR Steering Committee will have 30 working days from the date of receipt to review proposed publication submissions.

7. Collaborators must provide copies of manuscripts/reports/abstracts when these have finally been accepted. An electronic copy (pdf format) of the published manuscript should also be provided.

8. Collaborators must provide all details of conference presentations to the BSR Project Officer. An electronic copy of the abstract and final poster/slide presentation should also be provided.

Release of Data Application Form

Each request for release of data must be accompanied by this completed form. Please type or print clearly.
Please return this completed form to the Project Officer:

BSR Registry - Project Officer

School of Public Health and Preventive Medicine
Monash University
Level 6, The Alfred Centre
99 Commercial Road
Melbourne VIC 3004

Tel: +61 3 9903 0721
Fax: +61 3 9903 0717

SECTION 1: LEAD APPLICANT'S DETAILS

All correspondence regarding this application should be directed to:

Lead Applicant's name	
Affiliation	
Address	
Telephone	
Fax	
E-mail	
Co-ordinating Principal Investigator	
Affiliation	
Address	
Telephone	
Fax	
E-mail	
Requesting party:	
<input type="checkbox"/> Research/Academic Institution	<input type="checkbox"/> Government Department
<input type="checkbox"/> Registry	<input type="checkbox"/> Treating physician
<input type="checkbox"/> Industry: Please specify	
<input type="checkbox"/> Other: Please specify	

List names of other collaborators for this study:

Name
Name
Name
Name

SECTION 2: PURPOSE OF THE DATA REQUEST

- Research Clinical Planning Business
- Other, specify: _____

SECTION 3: PROPOSED RESEARCH PLAN

Short title of data request:

Project plan:

Please attach a description of your project, this must include:

- *Background*
- *Objectives*
- *Methods*
- *Data analysis plan*
- *Person responsible for data analysis*
- *How potential results will be displayed*
- *Proposed output from the project: include scientific journal/s to which the completed manuscript will be submitted, detail of conference/forum where data will be discussed*
- *References*

What data fields are you requesting from the BSR? Attach additional pages as required.

How will this project be resourced?

SECTION 4: ETHICS APPROVAL

Have you received Ethics Approval to access the BSR? <input type="checkbox"/> Yes <input type="checkbox"/> No
Sites approving the ethical conduct of the research:
Sites yet to approve the project and anticipated approval date (if applicable):
If No Ethics application has been lodged, please explain why:

SECTION 5: PROCESSING FEE

Individual researcher without funding	No charge
Individual researcher with funding	Negotiable
Industry group	\$500 per hour

SECTION 6: CERTIFICATION

I certify that I have read the BSR Data Access & Reporting Policy and agree to the terms outlined in the Policy	
Applicant's signature	
Lead Investigator/ Supervisor signature	

Notes:

FOR OFFICE USE ONLY

Date received	
Documentation checked	
Researcher contacted	
Outcome provided to researcher	
BSR Responsible Person	
Processing fee	