



MONASH University
Medicine, Nursing and Health Sciences

Bariatric Surgery Registry Privacy Policy

Revision History

Version	Date	Author	Reason for version change	Sections modified
1.0	26/11/2014	B. Smith	First Release	
1.1	4/8/2016	D. Brown	Change in protocol around period & data collected Aligning security of data section with protocol	3.2, 3.3, 3.4.1

Amendments in this release

Section Title	Section Number	Amendment Summary

1. Preface

The following policy defines how the Bariatric Surgery Registry (BSR) implements privacy practices into its everyday operations and specifically, how relevant privacy principles are addressed in common registry practice. The BSR is housed within Monash University's School of Public Health and Preventive Medicine. Monash University has ongoing practices and policies in place to ensure that personal information is managed in an open and transparent way and relevant privacy principles are upheld. The University Privacy Compliance Framework is available at: <http://www.privacy.monash.edu.au/>.

The BSR complies with Monash University policies and procedures.

Further to Monash's commitment, the BSR is committed to ensuring the security, privacy and confidentiality of all information collected and housed within the registry in addition to the handling of stakeholder information outside the registry's database. All patients' and stakeholder information will be handled in accordance with the Commonwealth Privacy Act (1988) including The Privacy Amendment (Enhancing Privacy Protection) Act 2012 and other relevant state and territory laws and regulations relating to the collection, storage and dissemination of such information. All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC).

2. Project Information

2.1 Purpose of the Bariatric Surgery Registry

The primary aim of the BSR is to measure outcomes for patients undergoing bariatric surgery across surgical practices in Australia and is predominantly a quality and safety registry. BSR will report outcomes back to stakeholders. These reports will provide hospitals, device manufacturers, government bodies and insurers with a greater understanding of the outcomes of bariatric surgery patients. It will provide a valuable resource to better understand and reduce factors associated with sub-optimal outcomes.

2.2 Project Overview

We propose to monitor a population of people who have been treated with bariatric surgery to reduce obesity. This initiative has the support of the Obesity Surgery Society of Australia & New Zealand (OSSANZ), which regards the registry establishment as an important step forward in monitoring and evaluating patient outcomes across Australia.

The registry collects patient demographic, risk factor, procedural, health outcome and adverse event data. It provides a tool for quality assurance and for determining the efficacy of bariatric surgery in Australia. Data collection is standardised and of high quality. Outcomes are risk adjusted to take into effect important factors not within the control of the treating surgeon, and data will be returned to stakeholders in an appropriate and timely manner to drive quality improvement.

3. Information and Privacy

3.1 What is personal information?

Personal information is information or an opinion about an identified individual, or an individual who is reasonably identifiable, whether or not the information or opinion is true or not; and whether the information or opinion is recorded in a material form or not.

Sensitive information is a subset of personal information and includes information or opinion about an individual's racial or ethnic origin, political opinions and political associations, religious beliefs or affiliations, philosophical beliefs, membership of a professional or trade association, membership of a trade union, sexual preferences or practices, criminal record, health information, genetic information or biometric information.

3.2 What information is collected in the Bariatric Surgery Registry (BSR)?

Sensitive and personal information will only be collected where reasonably necessary to conduct essential registry functions, or other activities as approved by a Human Research Ethics Committee (HREC). The BSR collects information about patients and their health status during and after a hospital admission for relevant bariatric procedures. The following information is collected on the day of operation:

- Name
- Date of Birth
- Gender
- Address
- Phone Numbers
- Medicare & DVA Information
- Hospital UR number
- Name of Hospital & State
- Name of Surgeon & Operation Date
- Aboriginal/Torres Strait Islander status
- Patient Height
- Start and Pre-op weight
- Diabetes Status
- Treatment of diabetes if any
- Procedure Status
- Type of Procedure *if procedure is unplanned revision*, Reason/ Complication that caused it
- Concurrent renal or liver transplant

The additional following information is collected perioperatively for all patients:

- Date of Follow up
- Mortality if any
- *If mortality has occurred;*
 - Date of death
 - Cause of death (if known)
 - Details of whether Death is related to procedure

- Defined Adverse Events
 - Unplanned Return to Theatre
 - Unplanned Admission to ICU
 - Unplanned Re-admission to Hospital
- *If there is a Defined Adverse Event*, the Reason/ complication that caused it

The additional following information is collected Annually for Primary patients only:

- Date of Follow up
- Mortality if any
- *If mortality has occurred;*
 - Date of death
 - Cause of death (if known)
 - Details of whether Death is related to procedure
- Follow Up Weight (if self-reported or not)
- Diabetes status
- Treatment of diabetes (if any)
- If a Reoperation has occurred in last 12 months
- *If there was a Reoperation*, the Reason/ complication that caused it

In order to achieve the primary function of BSR, other personal information may be collected, held and disclosed to support the registry's day to day operations. This includes collecting contact information about stakeholders, other researchers, hospitals and health services, service providers and other individuals or groups who may be involved or correspond with the BSR in order for the registry to function effectively

3.3 How is information collected?

Every patient who undergoes a relevant procedure in a participating Registry hospital will have their data collected by the participating surgeon, theatre staff or administrative staff member. Data is collected via a one-page hard copy data form or via a web-based form on the day of procedure, perioperatively (20-90 days post surgery), and annually (for primary patients only). If a paper copy is used, the completed data form will be sent to the registry and will be entered into the secure database by BSR staff.

BSR will also collect Health Coding reports from the nominated hospital to ensure complete data capture for all patients who have received a bariatric procedure. Registry staff may contact patients or their doctor directly to follow-up on patients' health status after discharge.

Follow-up (perioperative and annual) data will be collected directly from the participating surgeon or their administrative staff via a hard-copy form, a web-based form or from a direct download from the surgeon's patient management system. If the patient is no longer in contact with the participating surgeon, they will be contacted via telephone by Registry staff.

The registry employs an opt-out approach to consent, where all patients included in the registry are afforded the right to not have their information recorded. Patients will receive a Patient Explanatory Statement (PES) via post after their procedure. The PES explains the function of the registry and explains the process for opting out of the registry which can be done using a freecall number.

More general information about the registry, the data collection procedure and opting off the registry can also be found on the BSR website at: <http://www.med.monash.edu.au/sphpm/depts-centres-units/bariatric/>.

It is important to note that the only time personal information may be collected from a patient outside the usual function of the registry data collection is when a patient decides not to participate in the Registry. We will retain the patient's name and date of birth as well as the treating surgeon and hospital to ensure they are not contacted again in the future. Patients may request for their names to be removed from this list but may be contacted again in the future if they have a subsequent revision procedure.

3.3.1 Why collect identifiable, personal information?

It is important that the BSR collects identifiable, personal information about bariatric patients. Having this information allows hospital staff to link back to the patient's medical records and to follow-up on the patients' health status following their procedure (where appropriate). Information collected in the registry may also be used for further research relating to the standard of care provided to patients undergoing bariatric procedures in Australia.

To protect patient's privacy, all linkage or further research activities using BSR data are bound by privacy legislation and must meet specific privacy and security conditions before ethical approval is granted.

No research or data linkage activity will occur without approval from an NHMRC approved Human Research Ethics Committee. Any research undertaken with BSR data will be bound by the same guidelines and legislation.

3.4 Security of personal information

3.4.1 How will the privacy of patients be protected?

All information collected about patients is treated as confidential. Identifying information is protected by privacy legislation and would only be disclosed with the patient's permission, or in compliance with the law. All data is safeguarded by State and Commonwealth privacy laws. No identifiable information will be shared. Any additional researchers or registry staff involved with data monitoring, analysis or reporting will be required to complete a Confidentiality Agreement. No personal information about patients will ever be disclosed in any publication or report.

Information will be stored in line with Privacy Principles. Data will be kept in a secure location behind locked and swipe card only accessible doors, password protected, backed up on disk, securely encrypted (according to ISO2700 level of accredited standards specifically reserved for information security matters in Australia.) Only the researchers and those employed for the purpose of the project such as registry epidemiologists, data custodian, clinicians involved with the research, research assistants and data managers will have access to the data. Any researchers or registry staff involved with data monitoring, analysis or reporting will be required to complete a Confidentiality Agreement.

Disposal of any information will be in accordance with the National Statement of Ethical Conduct in Research Involving Humans (March 28, 2007) Archived information will be stored in a secure location within Monash University.

3.4.2 How will BSR information be shared?

BSR will use aggregate data to produce general reports on bariatric outcomes for public, government, clinical, industry and academic audiences. It is anticipated that these publications will help to inform the community about common trends and/or gaps that may exist in service provision. No publication or report will ever contain any identifying information about patients nor will patients ever be referred to directly.

Researchers may use unidentified, aggregate group data for future research projects. Information collected in the registry, may be used for further research relating to the standard of care provided to patients undergoing bariatric procedures in Australia. This may include ongoing linkage to other Clinical Quality Registries as well as the various States' Department of Births, Death or Marriages for monitoring any instances of patient mortality. To protect the privacy of patients, all linkage activities are bound by privacy legislation and must meet specific privacy and security conditions before ethical approval is granted. Any further research undertaken using BSR data will require approval by a Human Research Ethics Committee.

4. Access to Information

4.1 Accessing information in BSR

Patients do have the right to request access to personal information stored in BSR. Individuals may request a copy of their personal information at any time by contacting the Principal Investigator listed on their Patient Explanatory Statement that was sent to the patient via post. Individuals that request information must identify themselves and be able to provide sufficient proof of identity. This includes providing five points of identification over the phone. For example, patients would be asked to provide their full name, date of birth, Medicare number or postcode, the date of their procedure and/or at which hospital the procedure was performed. The provision of this information will assist BSR staff in identifying patient's data correctly within the registry and ensure that information is not disclosed in error. Upon confirming the patient's identification, copies of the requested information will be sent via traceable post within a reasonable timeframe, negotiated with the patient at the time of their request. This information cannot be sent electronically.

Obviously, this identification process precludes patients from using a pseudonym and/or from being anonymous in communication with the Registry for these types of requests. Information will not be released until Registry staff are satisfied that sufficient identification has been provided.

Patients are free to contact BSR if they become aware that any information is inaccurate and/or incomplete (refer to section 6 for BSR contact details). The Data Manager will take reasonable steps to either correct the information, or, if necessary discuss alternative action with the patient. BSR would also recommend that patients contact the participating hospital to ensure that their records are up to date with their treating health service (all data in BSR comes directly from patient medical records).

5. Addressing concerns

5.1 General concerns

If patients or stakeholders have any questions or concerns about general project operations, they can contact the BSR Clinical Lead (refer to section 6 for BSR contact details).

Alternatively, please refer to BSR website for additional information: <http://www.med.monash.edu.au/sphpm/depts-centres-units/bariatric/>

5.2 Ethical concerns

If patients or other stakeholders have any ethical concerns about this project, participant rights, or would like to make a complaint about research conduct, enquiries should be directed to the approving Human Research Ethics Committee (HREC) for the relevant hospital or health service. These details can be found on the Patient Explanatory Statement which is sent to the patient via post approximately 2 weeks after their bariatric procedure. If these details are still unclear, please contact the BSR on the details below in Section 6.

5.3 Complaints handling

A complaint can be made by any stakeholder, partner organisation, community or individual with whom BSR has an established relationship, in addition to any member of the public whether an individual, organisation or other entity. BSR takes privacy and data management obligations seriously and welcomes any feedback in order to improve the quality of our work. Complaints will be handled in the timely and sensitive manner protecting the privacy of respective parties.

BSR will request that any complaint or concern be submitted in writing (via email, fax or post: refer to section 6 for contact details). A member of the BSR will acknowledge all correspondences within one week of receipt. BSR will attempt to resolve any complaint within 15 working days, however, if this is not possible, BSR will contact the complainant to advise of the status of the matter. The BSR Data Manager and Clinical Lead will be notified of all complaints and issues will be escalated accordingly. HREC committees will be notified of any complaints and/or adverse events as per the conditions of each HREC approval.

If patients or other stakeholders are unsatisfied with the outcome of complaints relating to privacy or confidentiality, BSR will advise further options including, if appropriate, review by the Office of the Australian Information Commissioner.

6. Contacting BSR

Registry staff members can be contacted on the details below:

*Bariatric Surgery Registry
Level 6, The Alfred Centre
99 Commercial Rd, Melbourne VIC 3004
Email: med_bsr@monash.edu
Office Telephone: +61 3 9903 0725
Office Facsimile: +61 3 9903 0717*

7. Changes to BSR privacy policy

This Privacy Policy was ratified by the BSR Steering Committee on 2nd September 2016 and published 12th September 2016. BSR reserves the right to update the policy at any time, as long as it complies with the Privacy Act and other relevant state and commonwealth legislation. The most up to date

version of all BSR policies are publicly available on the BSR website
at: <http://www.med.monash.edu.au/sphpm/depts-centres-units/bariatric/>