PROTOCOL

Establishment of a bariatric surgery clinical quality registry

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Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
BSR	Bariatric Surgery Registry
PES	Patient Explanatory Statement
BSR-*i*	Bariatric Surgery Registry Interface

2. STUDY SITES FROM PILOT PHASE

Site	Address	Contact	Contact details
The Alfred Hospital (Vic)	Melbourne VIC 3004		
The Avenue Private Hospital (Vic)	Windsor VIC 3181		
SJOG Warrnambool, (Vic)	Warrnambool VIC 3280		
Box Hill Hospital (Vic)	Box Hill VIC 3128		

3. INTRODUCTION/BACKGROUND INFORMATION

3.1. LAY SUMMARY

A bariatric registry, or collection of patient demographic and bariatric surgical data, will be used to track those patients who have undergone bariatric surgery, and the long term impact of bariatric surgery on diabetes. The Registry will also provide an alert over device flaws, and surgeons with elevated complication rates.

The Registry is located at Monash University and is expected to include data from 95% of the 16,000 bariatric surgeries performed in Australia and New Zealand annually. It is anticipated to reach out to all public and private health care facilities in both Australia and New Zealand where bariatric surgery is performed. The primary aim of the Registry is to measure the safety of bariatric surgery and the outcomes for patients - the key reason for operating for obesity is for a healthier outcome in the longer term, so we need to be sure that the operations are both safe and are delivering sustained weight loss to patients.

3.2 BACKGROUND INFORMATION

Obesity is one of the most important public health issues facing Australia in the 21st century. It has proved difficult to prevent and according to the latest Australian Health Survey, 28.3% of Australians are now obese, up from 19% in 1995. Lifestyle interventions can be effective in the short term, however, are rarely durable in the long term [1,2]. However, for those with severe obesity (BMI>35kg/m2) there are several Randomized Controlled Trials (RCT)[3-6] and multiple case series[7] which suggest that bariatric surgery provides more predictable and durable weight loss than conservative regimes and is generally very safe [8,9].

On the basis of these data, bariatric surgery is burgeoning in Australia. There has been a 300% increase in the number of procedures performed over the last 5 years. In 2013 there have been more than 12,000 such procedures performed in Australia at a direct cost of $200 million. Yet there are no evidence based guidelines directing who should be offered this surgery, nor is there any long-term community data documenting the efficacy and safety of the procedures in Australia.

The Bariatric Surgery Registry (BSR) has been primarily established to measure quality and safety of bariatric surgery. The Registry tracks the performance of hospitals, surgeons and devices. The BSR has been underway since 2012 including a 2 year pilot subsequently adding 1500 patients to the Registry. We have transitioned to Registry proper as of mid-2014 and continue to roll-out nationally.

The ability to track longitudinally all persons undergoing bariatric procedures offers an unprecedented opportunity to:

1. Confirm the outcomes from clinical trials on bariatric surgery at a population level;
2. Measure health outcomes from bariatric surgery at a population level;
3. Translate these efficacy and health outcomes into practice guidelines;
4. Utilise the Registry as a resource for future research projects

The Registry provides confidence to surgeons, funders, hospitals and the wider community that bariatric surgery is safe and is achieving improvement in health outcomes to patients at a population level. It is in line with the recommendations of the Australian Commission on Safety and Quality in Healthcare (2008)[10] and the Health Technology Review report (Review of health technology assessment in Australia, 2009). There have now been two specific federal recommendations for the establishment of a bariatric surgical registry: Georganas senate inquiry in to obesity published as "Weighing it up" (released May 2009) recommendation 6); Medical Benefits Reviews Task Group, 2011.

4. STUDY OBJECTIVES

4.1 STUDY AIMS

The Bariatric Surgery Registry is predominantly a quality and safety registry, which gathers and analyses information so as to monitor and enhance the quality of care patients receive. The stated aims are to:

- Record the immediate safety of bariatric surgery in Australia and NZ
  - Surgical safety
  - Surgical quality
- Study longitudinally the safety and efficacy of bariatric surgery in Australia and NZ
  - Procedure
  - Devices
  - Complications
  - Re-operations
- Track key health changes following bariatric surgery in Australia and NZ
  - Weight change
  - Diabetes

4.2 OUTCOME MEASURES

A registry should provide useful and high quality information which is respected by clinicians and therefore capable of driving change. It must be underpinned by a comprehensive governance structure and provided with adequate funds to ensure that independent assessment of data quality occurs on an ongoing basis. Critical to the success of a surgical registry is engagement of surgeons to ensure near complete data capture. When enrolment drops below 95% the ability to report on quality outcomes is compromised[11].
More comprehensive data can potentially be collected by interested sub-groups, with the approval of the Steering Committee.

Outcome measures include:

- Weight loss status
- Diabetes status
- Comorbidity status
- Re-operation rate
- Complication (defined adverse event) status and frequency
- Mortality status and if related to bariatric procedure

4.3 STRATEGY FOR ETHICAL REVIEW

Any research undertaken needs to be approved by an Ethics Committee. This is also stated in the Patient Explanatory Statement. As bariatric surgeons express their wish to participate in the Registry, they are asked to indicate where they perform bariatric surgery in order that the ethical review process may commence.
New ethical review submissions are prepared for all new sites. Dependent upon the assessment of the reviewing body, this may be full ethical review or low & negligible risk ethical review.

5. STUDY DESIGN

5.1 STUDY DESIGN & METHODOLOGY

5.1.1 DATA CAPTURE AND TRANSMISSION

Options:

- Web browser with secure authorised entry – the Bariatric Surgery Registry Interface (BSR-*i)* has been developed in conjunction with Monash University and is used for data collection and reporting.
- Paper based data collection, faxed or posted – 24% of our members do not use a system of electronic medical records.
- Electronic record transfer – there are currently 5 providers of electronic medical records that are used by the membership of OSSANZ (Obesity Surgery Society of Australia & New Zealand), with two dominant providers.

We elected to start with a paper based system for the pilot as this enabled us to make modifications more easily than in a web-based model. Throughout the progress of the pilot study (an earlier phase of the project), our data-set and data dictionary have been confirmed, and we have now moved to a web-based system, BSR-*i*, which is our preferred method of data collection and reporting. The second phase of our web-based development will enable the BSR-*i* to further reduce surgeon workflow through smarter data capture such as potentially interfacing with software providers.

5.1.2 RECRUITMENT PROCEDURE

Identification process:

Recruitment to the Registry will originate with the surgeon and be generated by:

- surgeon discussion of the Registry in consultation with the patient (initial pre-operative assessment clinic appointment or private rooms)
- display of BSR Poster (clinic or private rooms) aligning surgeons with the Registry
- provision of a leaflet to the patient by their treating surgeon which outlines the goals of the Registry, informing them that their data will be submitted

to the Registry by their surgeon and that they will be sent a formal explanatory statement after their operation and they will have the opportunity to opt off if they do not want their information included. This leaflet also provides a contact number at the Registry if they require further information.

- inputting patient details into the BSR-*i* or completion of a BSR Operation form, and
- receipt of hospital-generated ICD-10 coding reports received periodically from each participating site

This process allows for the best chance of complete data capture.

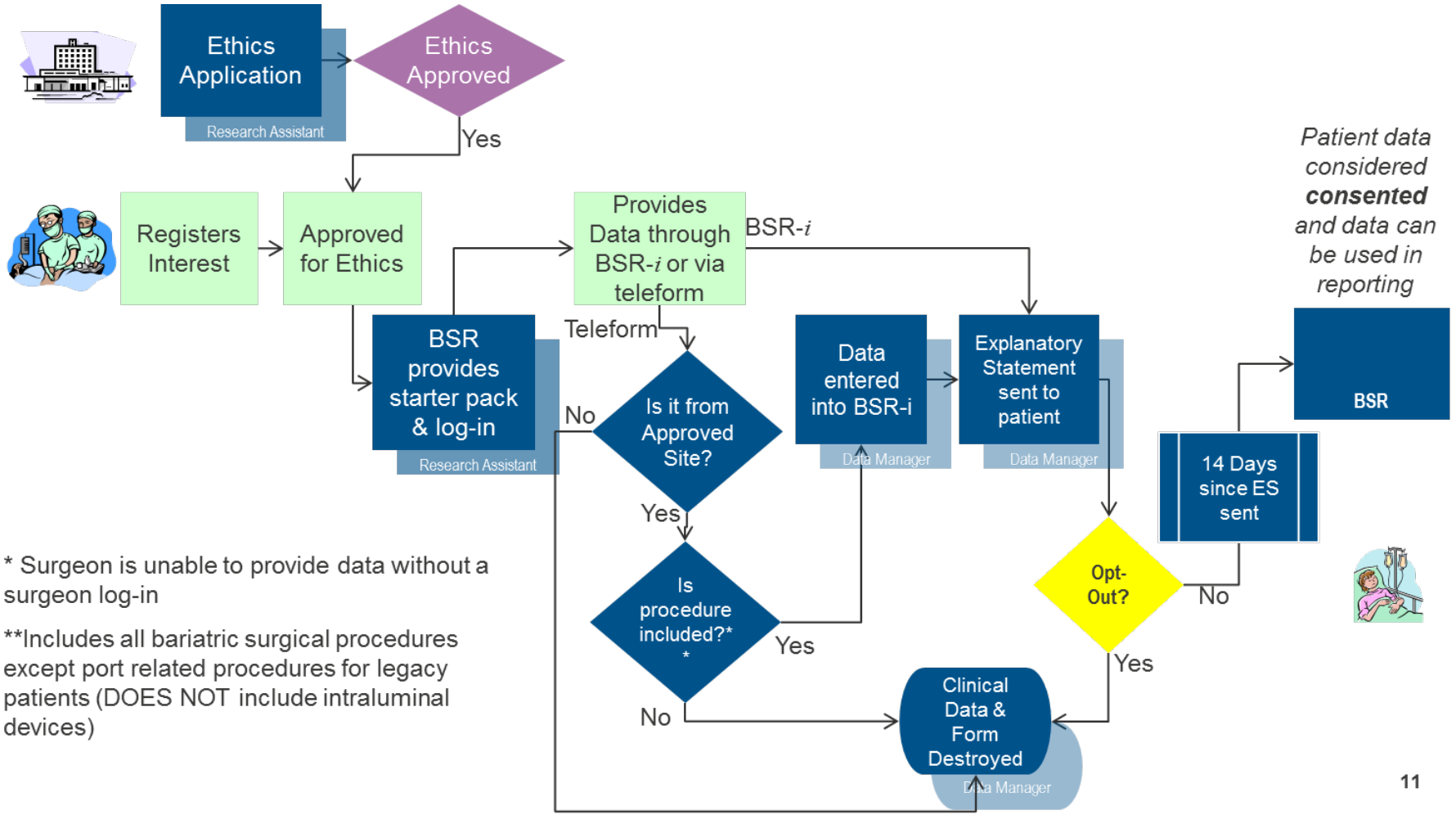
Invitation process:

Patients are made aware of the BSR through discussion with their surgeon, posters advertising the BSR in the rooms as well as being given a leaflet at the time of their first appointment in surgeon's rooms. This leaflet outlines the goals of the Registry, informs them that their data will be submitted to the Registry by their surgeon and tells them that they will be sent a formal explanatory statement after their operation and they will have the opportunity to opt off if they do not want their information included. This leaflet also provides a contact number at the Registry if they require further information.

Operation details will be directly entered on to the BSR-*i* by the surgeon or their delegate, or alternatively, a BSR Operation form will be completed and faxed (or posted) to the Registry office. Patients are then sent a Patient Explanatory Statement (with treating hospital logo) and a Flyer in the mail, further explaining the Registry and the voluntary nature of participation and the Opt Off process.

For those patients who have been identified via the ICD-10 coding reports (where the surgeon has **not** entered the procedure on to the BSR-*i* or a BSR Operation form has **not** been received), Operation forms are filled in by Registry staff with patient demographic data obtained from the coding report. The Operation form is sent to the treating bariatric surgeon for confirmation, and completion of Operation data. Only on receipt of this completed BSR Operation form from the treating surgeon are these patients similarly invited to participate in the Registry (as above).

figure 1. Data Collection Process



5.1.3 *ENGAGING SURGEONS TO CONTRIBUTE TO THE REGISTRY*

Engaging surgeons to participate in the Registry poses a challenge to both operators of the Registry and funders.

Two approaches exist—a mandatory or voluntary system. We have found the voluntary approach to be very effective. Registry participation is currently voluntary with surgeon participation stemming from those who are members of OSSANZ. The BSR maintains a presence through the OSSANZ website as well as their annual conference in order to inform surgeons of the importance of the Registry. Non-OSSANZ members are also eligible to participate in the Registry. Mechanisms for information sharing include ongoing updates through the BSR website as well as distributing our public reports and newsletters to all stakeholders.

- Surgeons can now achieve Continuing Medical Education (CME) points through the Royal Australasian College of Surgeons (RACS) as a Level 1 Audit Activity.
- An incentive for hospitals might be that contributing to such a registry would provide evidence of benchmarking and therefore of operating at a higher level for accreditation purposes.

5.1.4 *DATA*

The Registry consists of three data collection forms and screens within the BSR-*i*:

1 Patient Information and Operation Form (pink form),
2 Perioperative Follow-Up (blue form) and
3 Annual Follow-Up Form (blue form)

Data capture must be simple – our forms have been designed to "stick" and "tick."

Operative data collection comprises:

- patient identifiers (name, address, Medicare or DVA number, date of birth, phone numbers, gender & indigenous status NB: there is a capacity to collect IHI numbers when they become available))
- clinical details (hospital and surgeon name, Hospital UR number, weight, height, diabetes status & treatment, concurrent renal and liver transplant)
- procedural information (procedure date, procedure type & status, whether the procedure was planned or unplanned, and device details)

Follow-up data collection comprises:

- outcome data at:
  - 20-90 days post-surgery (weight, defined adverse event & reason as well as mortality status and if related to bariatric procedure)
  - annually (weight, diabetes status, re-operation & reason as well as mortality status and if related to bariatric procedure)

Follow up data is acceptable within certain windows (see figure 2):

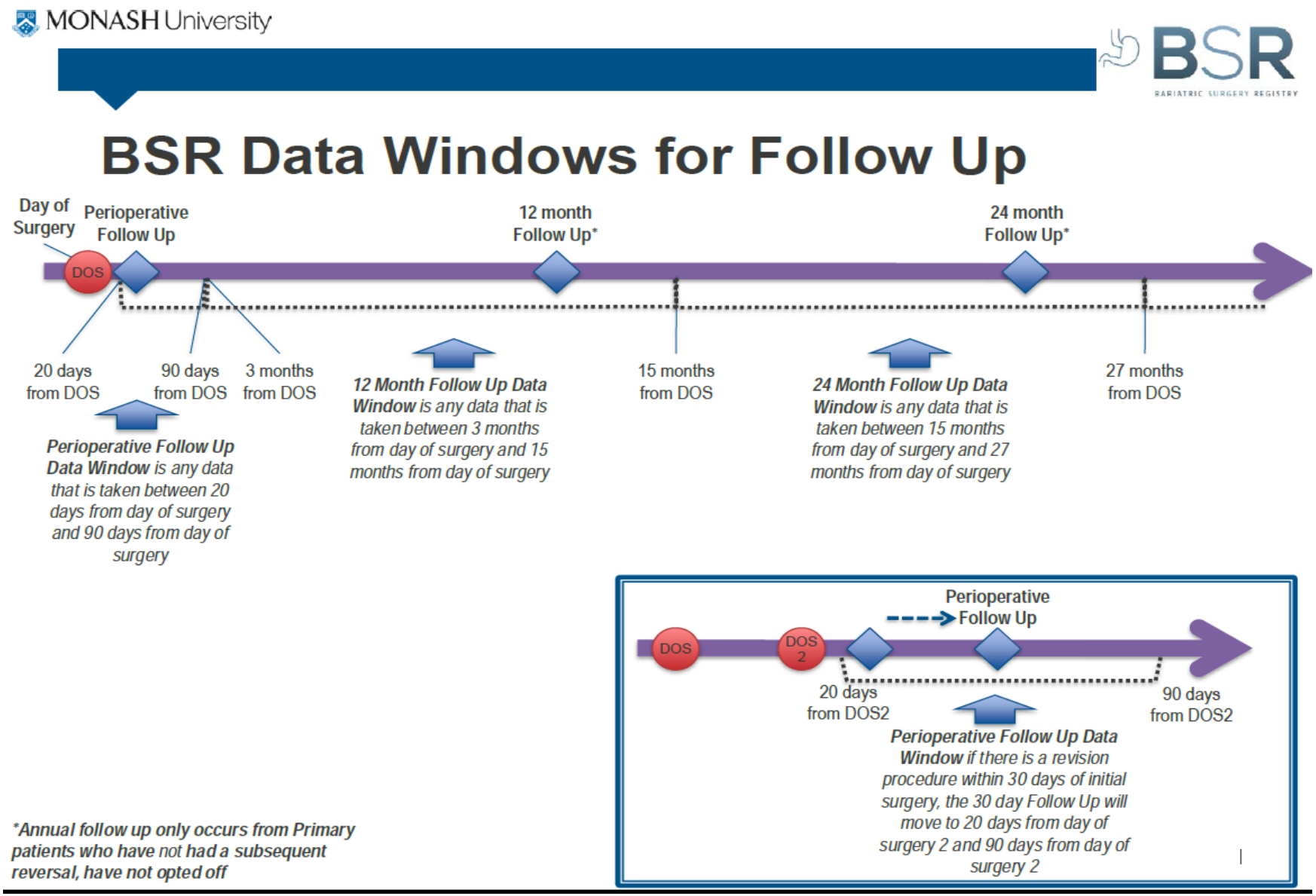
- Perioperative follow up can be any data taken between 20-90 days post-surgery
- Annual follow up can be any data taken between 9 months prior to annual anniversary or 3 months post.

The Registry has a strong desire to collect longer term outcome data on primary patients (ie those whose first inclusion on the BSR is through a primary procedure) who have had bariatric surgery. The challenge in obtaining this information is to reduce loss to follow up after 12 months.
During the pilot phase of the project, strategies to overcome this challenge at 12 months, 24 months and beyond have been investigated.

An email is sent to the surgeon or follow-up data collection forms are sent to the various surgeons` rooms. In the event that follow up is not entered or the data forms are not returned within an acceptable timeframe, measures have been approved to allow for a more representative follow-up dataset from the population of patients undergoing bariatric surgery.

- Where follow-up data collection forms are received, data is entered into the database.
- Where follow-up data collection forms are not received, Registry staff will contact the patient for a brief 5 minute phone call (using set Registry Protocols) at 20-90 days and/or 12 month intervals after surgery. This is explained in the Patient Explanatory Statement - patients do not have to agree to this contact, and can Opt Off the Registry at this (or any) point.

figure 2. BSR Data Windows for Follow Up



5.2 INCLUSION/EXCLUSION CRITERIA

All patients who undergo bariatric surgery will be eligible for inclusion in the study. An opt-out approach will be used as recommended by the National Guidelines[10].

Patients aged less than 18 years will be asked to participate in the Registry - there are fewer than 50 procedures around Australia being performed annually on those under 18 years. A Patient Explanatory Statement will be addressed to the participant as well as a separate copy to the participant's parents (or legal guardian) If the participant's parents (or legal guardian) choose to opt the patient off the registry, they will do this on behalf of the patient following the opt-off approach, by calling the Freecall 1800 998 722 number. Patients retain the right to opt-off the Registry at any time.

People whose primary language is other than English (LOTE) will be asked to participate in the Registry - if the admission forms, or the treating surgeon, indicate that they require a translator, we will send the appropriate language form to the patient, as well as the English version. We have arranged interpretation of the PES into 5 commonly spoken languages.

5.3 CONSENT

The Bariatric Surgery Registry is an Opt Off Registry. This is a necessary step to ensure that sufficient patients are captured to provide reliable outcome reporting. Previous data suggests that less than 2% of patients opt off registries.

Patients are made fully aware they do not need to take part in the Registry (on receiving the Patient Explanatory Statement and Registry Flyer) - participation in any research project is voluntary. The patient's decision to participate in the Registry, or to participate and then opt off the Registry, will not affect their relationship with the treating surgeon or the hospital, and their doctor will be unaware of their participation status.

Patient details will be included on the Registry unless they have notified Registry staff via the Freecall 1800 telephone number.

Patients have three options for participation:

1. **Data is included** on the Registry, and Registry staff may contact the patient during follow-up care – patient is required to do nothing on receiving the Patient Explanatory Statement.

   The patient may still decline contact (opt off) on receiving the follow-up telephone call.

2. **Data is included** on the Registry; Registry staff will not contact the patient during the follow-up period - patient is required to phone the Freecall 1800 number and state this (patient has partially opted off).

3. **No clinical data is included** on the Registry (the patient has fully opted off) - patient is required to phone the Freecall 1800 number and state this. The Registry will retain the patient's name, date of birth, treating hospital and treating surgeon to ensure the patient will not be contacted in the future.

A waiver of consent will only be required in the event that the patient dies following bariatric surgery. We do not wish to burden next of kin with details of the Registry at this time. We need to collect this information to ensure that the death was not the impact of the bariatric surgery.

6. DATA SECURITY & HANDLING

The BSR is an ongoing project, and Registry data will be stored according to privacy principles. Bariatric surgery hard copy data will be stored securely in a locked filing cabinet, behind locked and swipe card-only accessible doors.

Electronic data will be stored securely on the BSR-*i* within the Clinical Informatics and Data Management Unit, Monash University – where other confidential registries are stored and maintained. This data is backed up and encrypted (according to ISO2700 level of accredited standards specifically reserved for information security matters in Australia) in the event of unauthorised data access.

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

7. DATA MONITORING AND REPORTING

7.1 DATA LINKAGE

As a fundamental part of Registry processes, it is required that each hospital site submits an ICD-10 coding extract to the BSR. Cross-checking with ICD-10 codes allows for complete data capture at each hospital site and provides data validation for each procedure submitted by the surgeon. It is intended that the Registry will periodically link to each State's Births, Deaths & Marriages registry. Again, this allows the Registry to ensure complete and accurate data capture on all patients within the Registry.

7.2 STRATEGY FOR MONITORING AND REPORTING

The primary role of the BSR is to ensure the safety and quality of bariatric surgery in Australia. It does this by providing high-quality, robust clinical data. It is anticipated that outliers will be rarely detected and that a regular reporting cycle will help to drive up clinical quality. Where outliers are found, the BSR team will seek to provide additional help to providers wanting to review data entry and quality.

De-identified data will be provided to an independent biostatistician employed by the Monash University, Department of Epidemiology and Preventive Medicine by secure file transfer for review on a 6 monthly basis.

The results will be provided to the Project Manager. Only Registry staff, who are non-clinical will have access to identifiable data. All data to be used in reports or publications are to be cleaned and verified prior to analyses. Routine, re-analysis of data will be undertaken by the Project Manager of the BSR to ensure findings are reproducible.

The steering committee will work on an "early warning model" that will have the provision of opportunity to review the factors (data not being sent in a timely manner, or the case-mix of the surgeon) which may have contributed to being an outlier with all stakeholders including surgeons, device manufacturers and hospitals. The Registry will provide information that should minimise patient harm should a device prove to be deficient. The Registry could also provide a resource to assist with patient contact should a recall be necessary.

7.3 Potential Outliers

BSR will compare a surgeon's/ device's performance (unplanned readmission to hospital, unplanned ICU admission, unplanned reoperation, need for reoperation, weight loss, change in diabetes status) against all other surgeons or devices in the same class after case-mix.

If the value of a performance indicator is more than a specified number of standard deviations (SD) from the expected performance level, over a specified period of time, it will be considered an outlier. For instance, those surgeons or providers who fall between 2 SD and 3 SD from the expected level of performance will be considered as an 'alert'. If in subsequent two reporting periods the surgeon or the provider falls beyond 3 SD from the expected level of performance, will be flagged as an outlier.

The outlier policy is in line with the recommendations of the Australian Commission for Quality and Safety in Healthcare recommendations for the correct functioning of clinical quality registries.

The following table indicates the three stages that will be followed in managing a potential outlier, the actions that need to be taken, the people involved and the maximum time scales. It aims to be feasible and fair to providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information.

	Level 1 alert	Level 2 alert	Level 3 alert
Definition	Two standard deviations below the mean; OR Statistically significant deterioration in outcomes between reporting period (annual reports)	Three standard deviations below the mean; OR Two reporting period at two standard deviations below the mean, OR if a patient dies during or as a consequence of the bariatric surgical procedure.	Two reporting periods at three standard deviations below the mean OR continued performance at two standard deviations below the mean despite corrective measures
Action by BSR	Surgeon, device or hospital flagged as level 1 alert will not be subject to the review process. This is because this size of difference from the	Data will be checked for major errors e.g. validate against hospital records and devices, ensure data entry are correct.	Chair of steering committee convenes investigation committee. New data checked and old data re-checked for

	Level 1 alert	Level 2 alert	Level 3 alert
	national average may occur simply from random variation alone.	Data checked for accuracy, major shift (case-mix) and other potential confounders. Assess whether there are case-mix factors peculiar to this situation that may explain the observed variations. Check with the Surgeon/hospital whether the submitted data is correct. If not request correct data.	accuracy, major shift (case-mix) and other potential confounders.
Expected Outcome		• <u>No case to answer:</u> Submitted data in BSR revised, updated results show provider is not an outlier • <u>Case to answer:</u> data in BSR records revisited, reanalysis shows potential outlier status persists	• <u>No case to answer:</u> Submitted data in BSR revised, updated results show provider is not an outlier • <u>Case to answer:</u> Appropriate pathway decided by Investigation Committee including reporting to appropriate body
Reporting	To support regular local review of data submissions and clinical practice, the BSR will notify surgeons of their "alert" status.	The surgeon and the hospital where he is practicing should be notified of the finding Support will be offered to surgeons. If a device is raises a level 2 alert, the	If performance is persistently at the level 3 stage and the Investigation Committee is satisfied with the validity of the data, reporting to the

	Level 1 alert	Level 2 alert	Level 3 alert
		device manufacturer should be notified of the finding.	appropriate regulatory body by the Chair of the Steering Committee will be mandated. For example – • A **device** will be notified to the Therapeutic Goods Authority (TGA) • A **surgeon** will be reported to the Royal Australasian College of Surgeons (RACS) • A **hospital** will be reported to The Department of Health or the regulator in each state

To view a copy of our current Outlier Policy in full, please visit our website: http://www.med.monash.edu.au/sphpm/depts-centres-units/bariatric/policies-procedures.html

8. FUNDING & FUTURE FUNDING STRATEGIES

We currently have sufficient secure Commonwealth funding to support Australian implementation, quality control, data collection and reporting to cover the period from 2013-2017. The Commonwealth have promised up to $1,000,000 per year for the four year period.

Alongside this we have been developing a broad-based funding model engaging other stakeholders including the profession, insurers, industry, state and territory governments and medical defence organisations. Our plan is to secure at least 20 stakeholders who will be funders, each contributing initially $20,000 per annum then increasing to $50,000 per annum towards the Registry when the Commonwealth funding ceases. This model should ensure that the Registry is not vulnerable to the funding capacity of one major funder. We have identified 25 potential stakeholders, and at this time have secured funding from 6 of them.

With regards to New Zealand, we will require a project officer in that country to ensure that the data collection and collation is of the highest quality. We are not able to use Australian Commonwealth funding for this purpose, so are currently looking to secure funding from the New Zealand Government as well as local industry. Whilst we have had a strong expression of interest from New Zealand surgeons, we will not commence in that country until sufficient funding is secured.

9. REFERENCES

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