

# PROTOCOL

## Establishment of a bariatric surgery clinical quality registry

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Version: 5.2

Date: 19 January 2021

**Data Custodian:**

Monash University

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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 (Updated 2018), the Australian Code for the Responsible Conduct of Research (2018), New Zealand's *National Ethical Standards for Health and Disability Research and Quality Improvement* (2019), Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), ASCSQH Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008), Monash University research policies and procedures, and state and federal laws of Australia and New Zealand governing privacy and confidentiality.

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## 1.0 Glossary of abbreviations & terms

Abbreviation/ Term	Description (using lay language)
ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZGOSA	Australia & New Zealand Gastro Oesophageal Surgery Association
ANZMOSS	Australia & New Zealand Metabolic and Obesity Surgery Society (formerly Obesity Surgery Society of Australia & New Zealand)
AUS	Australia
BSR	Bariatric Surgery Registry
BSR- <i>i</i>	Bariatric Surgery Registry interface
DOS	Day of Surgery
EMR	Electronic Medical Record
HDEC	Health and Disability Ethics Committee
HIS	Health Information Service
HREC	Human Research Ethics Committee
ICD-10-AM	International Classification of Disease 10-Australia Modified
IHI	Individual Healthcare Identifier
legacy participant	participants whose first entry in the Bariatric Surgery Registry is with a revision (or subsequent) bariatric surgical procedure
MBS	Medicare Benefits Schedule
Minor	individual who is not considered to be of age to provide independent informed consent; individuals under the age of 16 years in New Zealand and set at under 18 years in Australia for purposes of this study
National Mutual Acceptance	System under the NHMRC which allows for single ethical review of multi-centre human research studies
NHI	National Health Index
NIHI	National Institute for Health Innovation
NHMRC	National Health and Medical Research Council
NZ	New Zealand
Op	operation

OSSANZ	Obesity Surgery Society of Australia and New Zealand (previous name of the Australia & New Zealand Metabolic and Obesity Surgery Society)
participant	a person who has had a bariatric procedure and has had details about themselves and their procedure submitted to the Registry
patient	individual under the care of a clinician (surgeon or gastroenterologist) and eligible to be included in the research; patients are not considered to be participants unless their information had been entered in the database
PFS	Participant Fact Sheet
PI	Principal Investigator
primary participant	participants whose first entry into the Bariatric Surgery Registry is with their first bariatric surgical procedure
primary procedure	first bariatric surgical procedure undergone by a registry participant
RACS	Royal Australasian College of Surgeons
revision procedure	any subsequent bariatric procedure undergone by a registry participant
SMS	Short Message Service
SFTP	Secure File Transfer Platform
UR	Unit Record

## 2.0 Study sites and ethics committees

The Bariatric Surgery Registry collects information from surgeons and gastroenterologists at public and private hospitals in Australia and New Zealand. As it is made known that bariatric procedures are being undertaken at additional healthcare facilities, those locations will be added as further study sites.

A list of study sites where data may be entered into the registry (dependent on bariatric procedures being performed at the site and/or if data are collected regarding post-operative defined adverse events) is outlined in **Table 1** for Australia and **Table 2** for New Zealand. In addition, the ethics committees which have oversight of the study are listed in Table 3, with the Alfred Hospital HREC as the lead ethics committee for the study under the National Mutual Acceptance (NMA) scheme. The other ethics committees which granted approvals prior to the application under the NMA reviewed those sites are listed in **Table 4**. The Alfred Hospital Human Research Ethics Committee is the lead ethics committee reviewing this protocol.

***Please note the potential involvement of additional sites as stated above.***

**Table 1. List of study sites in Australia**

Site Name	Address	Local Investigator
<b>Albury-Wodonga Private Hospital</b>	West Albury, NSW 2640	Mr Adam Skidmore
<b>Ashford Private Hospital</b>	Ashford, SA 5035	Dr Benjamin Teague
<b>Austin Hospital</b>	Heidelberg, VIC 3084	Mr Ahmad Aly

Site Name	Address	Local Investigator
<b>Baringa Private Hospital</b>	Coffs Harbour, NSW 2540	Dr Andrew Ramsay
<b>Beleura Private Hospital</b>	Mornington, VIC 3931	Mr Ali Andrabi
<b>Belmont Hospital</b>	Belmont, NSW 2280	Dr Timothy Wright
<b>Bethesda Hospital</b>	Claremont, WA 6010	Dr Susan Taylor
<b>Blacktown Hospital</b>	Blacktown, NSW 2148	Prof Michael Edye
<b>Box Hill Hospital</b>	Box Hill, VIC 3128	Miss Salena Ward
<b>Brisbane Private Hospital</b>	Brisbane, QLD 4000	Dr Jacobus Jordaan
<b>Brisbane Waters Private Hospital</b>	Woy Woy, NSW 2256	Dr Kenneth Wong
<b>Buderim Private Hospital</b>	Birtinya, QLD 4575	Dr Ian Baxter
<b>Bunbury Regional Hospital</b>	Bunbury, WA 6230	Dr Senarath Werapitiya
<b>Burnside War Memorial Hospital</b>	Toorak Gardens, SA 5065	Mr Philip Game
<b>Cabrini Hospital Brighton</b>	Brighton, VIC 3186	Mr Paul Burton
<b>Cabrini Hospital Malvern</b>	Malvern, VIC 3144	Mr Paul Burton
<b>Cairns Private Hospital</b>	Cairns, QLD 4870	Dr Harish Kumar
<b>Calvary Adelaide Hospital</b>	Adelaide, SA 5000	Dr Justin Bessell
<b>Calvary Bruce Private Hospital</b>	Bruce, ACT 2617	Dr Charles Mosse
<b>Calvary Central Districts</b>	Elizabeth Vale, SA 5112	Mr Paul Leong
<b>Calvary John James Hospital</b>	Deakin, ACT2600	Dr Charles Mosse
<b>Calvary North Adelaide Hospital</b>	North Adelaide, SA 5006	Assoc Prof Lilian Kow
<b>Calvary Public Hospital Bruce</b>	Bruce, ACT 2617	Dr Charles Mosse
<b>Calvary Riverina Hospital</b>	Wagga Wagga, NSW 2650	Assoc Prof Richard Harrison Dr Nicholas Williams
<b>Calvary St Vincent's Hospital</b>	Launceston, TAS 7250	Mr Stephen Wilkinson
<b>Camden Hospital</b>	Camden, NSW 2570	Assoc Prof Tania Markovic
<b>Campbelltown Private Hospital</b>	Campbelltown, NSW 2560	Dr Govind Krishna
<b>Canberra Hospital</b>	Garran, ACT 2605	Dr Charles Mosse
<b>Concord Repatriation General Hospital</b>	Concord, NSW 2139	Dr David Martin
<b>Darwin Private Hospital</b>	Tiwi, NT 0810	Mr P. John Treacy
<b>Delmar Private Hospital</b>	Dee Why, NSW 2009	Dr Timothy Wright
<b>Dubbo Private Hospital</b>	Dubbo, NSW 2830	Dr James Chau
<b>Dudley Private Hospital</b>	Orange, NSW 2800	Dr Henry Hook
<b>Epworth Eastern</b>	Box Hill, VIC 3128	Mr Patrick Moore
<b>Epworth Freemasons</b>	East Melbourne, VIC 3002	Mr Jason Winnett
<b>Epworth Geelong</b>	Waurin Ponds, VIC 3216	Mr Matthew Leong

Site Name	Address	Local Investigator
<b>Epworth Richmond</b>	Richmond, VIC 3121	Mr Patrick Moore
<b>Fiona Stanley Hospital</b>	Murdoch, WA 6150	Mr Krishna Epari
<b>Flinders Medical Centre</b>	Bedford Park, SA 5042	Assoc Prof Lilian Kow
<b>Flinders Private Hospital</b>	Bedford Park, SA 5042	Assoc Prof Lilian Kow
<b>Footscray Hospital</b>	Footscray, VIC 3011	Miss Ingra Bringmann
<b>Glen Iris Private Hospital</b>	Glen Iris, VIC 3146	Mr Andrew Smith
<b>Glengarry Private Hospital</b>	Dun Craig, WA 6023	Dr Kevin Dolan
<b>Gold Coast Private Hospital</b>	Southport, QLD 4215	Dr Jacobus Jordaan
<b>Gosford Hospital</b>	Gosford, NSW 2250	Dr Kenneth Wong
<b>Gosford Private Hospital</b>	North Gosford, NSW 2250	Dr Kenneth Wong
<b>Greenslopes Private Hospital</b>	Greenslopes, QLD 4120	Dr Michael Hatzifotis
<b>Hamilton Hospital</b>	Hamilton, VIC 3300	Dr Stephen Clifforth
<b>Heidelberg Repatriation Hospital</b>	Heidelberg, VIC 3084	Mr Ahmad Aly
<b>Hillcrest Rockhampton Private Hospital</b>	The Range QLD 4700	Dr Nicole Andrews
<b>Hobart Private Hospital</b>	Hobart, TAS 7000	Mr Stephen Wilkinson
<b>Hollywood Private Hospital</b>	Nedlands, WA 6009	Prof Jeffrey Hamdorf
<b>Holmesglen Private Hospital</b>	Moorabbin, VIC 3189	Mr Adam Skidmore
<b>Holroyd Private Hospital</b>	Guildford, NSW 2161	Dr Fadil Khaleal
<b>Hurstville Private Hospital</b>	Hurstville, NSW 2220	Dr Govind Krishna
<b>Ipswich Hospital</b>	Ipswich, QLD 4305	Dr Phillip Lockie
<b>Jessie McPherson Private Hospital</b>	Clayton, VIC 3168	Mr Zdenek Dubrava
<b>John Fawkner Private Hospital</b>	Coburg, VIC 3058	Mr Ian Michell
<b>John Flynn Private Hospital</b>	Tugun, QLD 4224	Miss Candice Silverman
<b>John Hunter Hospital</b>	Lambton Heights, NSW 2305	Dr Timothy Wright
<b>Joondalup Health Campus</b>	Joondalup, WA 6027	Mr David Yong
<b>Kawana Private Hospital</b>	Birtinya, QLD 4575	Dr Ian Baxter
<b>Kareena Private Hospital</b>	Caringbah, NSW 2229	Dr Ken Loi
<b>Knox Private Hospital</b>	Wantirna, VIC 3152	Mr Geoffrey Kohn
<b>Lake Macquarie Private Hospital</b>	Gateshead, NSW 2290	Dr Timothy Wright
<b>Lakeview Private Hospital</b>	Baulkham Hills, NSW 2153	Dr Roy Brancatisano
<b>Latrobe Regional Hospital</b>	Traralgon, VIC 3844	Mr David Chan
<b>Launceston General Hospital</b>	Launceston, TAS 7250	Mr Stephen Wilkinson
<b>Lingard Private Hospital</b>	Merewether, NSW 2291	Dr Timothy Wright
<b>Macquarie University Hospital</b>	Macquarie Park, NSW 2109	Prof Reginald Lord

Site Name	Address	Local Investigator
<b>Maitland Private Hospital</b>	Ashtonfield, NSW 2323	Dr Mark Gately
<b>Maryvale Private Hospital</b>	Morwell, VIC 3840	Dr David Chan
<b>Mater Hospital</b>	South Brisbane, QLD 4101	Dr Anthony Cheng
<b>Mater Hospital Sydney</b>	North Sydney, NSW 2060	Dr Craig Taylor
<b>Mater Private Hospital (Brisbane)</b>	South Brisbane, QLD 4101	Dr Anthony Cheng
<b>Mater Private Hospital (Redland)</b>	Cleveland, QLD 4163	Dr Anthony Cheng
<b>Mater Private Hospital (Springfield)</b>	Springfield Central, QLD 4300	Dr Anthony Cheng
<b>Mater Private Hospital Mackay</b>	North Mackay, QLD 4740	Dr John Copp
<b>Mater Private Hospital Bundaberg</b>	Bundaberg, QLD 4670	Dr Geoff De Lacy
<b>Mater Private Hospital Rockhampton</b>	Rockhampton, QLD 4700	Dr Andrew Russell
<b>Mater Private Hospital Townsville</b>	Pimlico, QLD 4812	Dr Samuel Baker
<b>Melbourne Private Hospital</b>	Parkville, VIC 3052	Assoc Prof Gary Crosthwaite
<b>Mildura Base Hospital</b>	Mildura, VIC 3500	Mr Salim Chalooob
<b>Mildura Health Private Hospital</b>	Mildura, VIC 3500	Mr Salim Chalooob
<b>Mitcham Private Hospital</b>	Mitcham, VIC	Mr Ahmad Aly
<b>Monash Medical Centre</b>	Clayton, VIC 3168	Mr Zdenek Dubrava
<b>Mount Hospital</b>	Perth, WA 6000	Mr Leon Cohen
<b>Mulgrave Private Hospital</b>	Mulgrave, VIC 3170	Mr Chris Hensman
<b>Nambour Selangor Private Hospital</b>	Nambour, QLD 4560	Mr Michael Donovan
<b>National Capital Private Hospital</b>	Garran, ACT 2605	Dr Charles Mosse
<b>Nepean Hospital</b>	Kingswood, NSW 2747	Dr Michael Devadas
<b>Nepean Private Hospital</b>	Kingswood, NSW 2747	Dr Michael Devadas
<b>Newcastle Private Hospital</b>	Lambton, NSW 2305	Dr Timothy Wright
<b>Nikol Bay Hospital</b>	Karratha, WA 6714	Dr Tony Kierath
<b>Noosa Private Hospital</b>	Noosaville, QLD 4566	Dr Garth McLeod
<b>North Shore Private Hospital</b>	St Leonards, NSW 2065	Assoc Prof Garrett Smith
<b>North West Private Hospital (Brisban</b>	Everton Park, QLD 4053	Dr Philip Lockie
<b>North West Private Hospital (Burnie)</b>	Burnie, TAS 7320	Mr Stephen Wilkinson
<b>Northern Beaches Hospital</b>	Frenchs Forest, NSW 2086	Dr Philip Le Page
<b>Northpark Private Hospital</b>	Bundoora, VIC 3083	Miss Salena Ward
<b>Norwest Private Hospital</b>	Bella Vista, NSW 2153	Dr Michael Devadas
<b>Nowra Private Hospital</b>	Nowra, NSW 2541	Dr Mark Hehir
<b>Orange Health Service</b>	Orange, NSW 2800	Dr Henry Hook



Site Name	Address	Local Investigator
Peel Health Campus	Mandurah, WA 6210	Dr Chris Couch
Peninsula Private Hospital	Frankston, VIC 3199	Mr Geoffrey Draper
Pindara Private Hospital	Benowa, QLD 4217	Dr Jason Free
Port Macquarie Base Hospital	Port Macquarie, NSW 2444	Dr Nigel Peck
Port Macquarie Private Hospital	Port Macquarie, NSW 2444	Dr Nigel Peck
Prince of Wales Private Hospital	Randwick, NSW 2031	Dr David Links
Princess Alexandra Hospital	Woolloongabba, QLD 4102	Assoc Prof Anthony Russe
Queen Elizabeth II Jubilee Hospital	Coopers Plains, QLD 4108	Dr Chung Won
Royal Adelaide Hospital	Adelaide, SA 5000	Dr Shalvin Prasad
Royal Brisbane and Women's Hospital	Herston, QLD 4006	Dr George Hopkins
Royal Hobart Hospital	Hobart, TAS 7000	Mr Stephen Wilkinson
Royal Melbourne Hospital	Parkville, VIC 3050	TBA
Royal North Shore Hospital	St Leonards, NSW 2065	Assoc Prof Garett Smith
Royal Prince Alfred Hospital	Camperdown, NSW 2025	Assoc Prof Tania Markovic
St Andrew's Ipswich Private Hospital	Ipswich, QLD 4305	Dr John Copp
St Andrew's Toowoomba Hospital	Rockville, QLD 4350	Dr Neil Wylie
St Andrew's War Memorial Hospital	Brisbane, QLD 4001	Dr Phillip Lockie
St George Hospital	Kogarah, NSW 2217	Assoc Prof Michael Talbot
St George Private Hospital	Kogarah, NSW 2217	Assoc Prof Michael Talbot
St John of God Ballarat	Ballarat, VIC 3353	Mr Stuart Eaton
St John of God Bendigo	Bendigo, VIC 3550	Dr Janine Arnold
St John of God Berwick	Berwick, VIC 3806	Mr Raymond McHenry
St John of God Bunbury	Bunbury, WA 6230	Dr Senarath Werapitiya
St John of God Geelong	Geelong, VIC 3220	Mr Matthew Leong
St John of God Geraldton	Geraldton, VIC 6530	Dr Jacques Perry
St John of God Mt Lawley	Mount Lawley, WA 6050	Mr Leon Cohen
St John of God Midland	Midland, WA 6056	Mr Siva Gounder
St John of God Murdoch	Murdoch, WA 6150	Dr Harsha Chandraratna
St John of God Subiaco	Subiaco, WA 6008	Mr Leon Cohen
St John of God Warrnambool	Warrnambool, VIC 3280	Mr Phillip Gan
St Luke's Private Hospital	Potts Point, NSW 2011	Dr Clement Tsang
St Stephen's Hospital	Hervey Bay, QLD 4655	Dr Mikhail Mastakov
St Vincent's Hospital Lismore	Lismore, NSW 2480	Miss Candice Silverman

Site Name	Address	Local Investigator
<b>St Vincent's Private Hospital Sydney</b>	Darlinghurst, NSW 2010	Prof Reginald Lord
<b>St Vincent's Private Hospital Northside</b>	Chermside, QLD 4032	Dr George Hopkins
<b>St Vincent's Private Hospital Toowoomba</b>	Toowoomba, QLD 4350	Dr Evan Willingham
<b>St Vincent's Private Hospital</b>	Fitzroy, VIC 3065	Mr Michael Hii
<b>St Vincent's Hospital Melbourne</b>	Fitzroy, VIC 3065	Mr Michael Hii
<b>Shepparton Private Hospital</b>	Shepparton, VIC 3630	Mr David Dalton
<b>Southern Highlands Private Hospital</b>	Bowral, NSW 2576	Dr Shirhan Ho
<b>Sir Charles Gairdner Hospital</b>	Nedlands, WA 6009	Mr Michael Tan
<b>Strathfield Private Hospital</b>	Strathfield, NSW 2135	Dr David Martin
<b>Sunnybank Private Hospital</b>	Sunnybank, QLD 4109	Dr Mark Daoud
<b>Sunshine Hospital</b>	St Albans, VIC 3021	Miss Ingra Bringmann
<b>Sunshine Coast University Private Hospital</b>	Birtinya, QLD 4556	Dr James Askew
<b>Sutherland Hospital</b>	Caringbah, NSW 2229	Dr Ken Loi
<b>Sydney Adventist Hospital</b>	Wahroonga, NSW 2076	Dr Philip Le Page
<b>Sydney Private Hospital</b>	Ashfield, NSW 2131	Assoc Prof Michael Talbot
<b>Sydney Southwest Private Hospital</b>	Liverpool, NSW 2170	Dr Govind Krishna
<b>Tamara Private Hospital</b>	Tamworth, NSW 2340	Dr David Lewis
<b>The Alfred Hospital</b>	Melbourne, VIC 3004	Professor Wendy Brown
<b>The Avenue Hospital</b>	Windsor, VIC 3181	Professor Wendy Brown
<b>The Bays Hospital</b>	Mornington, VIC 3931	Mr Ali Andrabi
<b>The Queen Elizabeth Hospital</b>	Woodville, SA 5011	Mr Markus Trochsler
<b>The Wesley Hospital</b>	Auchenflower, QLD 4066	Dr Reza Adib
<b>Tuggerah Lakes Private Hospital</b>	Kanwal, NSW 2259	Dr Peter Hamer
<b>Wagga Wagga Base Hospital</b>	Wagga Wagga, NSW 2650	Assoc Prof Richard Harris
<b>Waikiki Private Hospital</b>	Waikiki, WA 6169	Dr Chris Couch
<b>Wangaratta Private Hospital</b>	Wangaratta, VIC 3677	Mr Adam Cichowitz
<b>Waratah Private Hospital</b>	Hurstville, NSW 2220	Dr Clement Tsang
<b>Warringal Private Hospital</b>	Heidelberg, VIC 3084	Mr Ahmad Aly
<b>Waverley Private Hospital</b>	Mount Waverley, VIC 3149	TBA
<b>Western Hospital</b>	Henley Beach, SA 5022	Mr Salim Chalooob
<b>Western Private Hospital</b>	Footscray, VIC 3011	Mr Jason Winnett
<b>Westmead Private Hospital</b>	Westmead, NSW 2145	Dr Anthony Brancatisano

Site Name	Address	Local Investigator
Williamstown Hospital	Williamstown, VIC 3016	Miss Ingra Bringmann
Wollongong Private Hospital	Wollongong, NSW 2500	Dr Ulvi Budak

**Table 2. List of study sites in New Zealand**

Site Name	Address	Principal Investigator
Auckland City Hospital	Grafton, Auckland 1023	Mr Grant Beban
Boulcott Hospital Specialist Centre	Lower Hutt 5011	Mr Atul Dhabuwala
Chelsea Hospital Trust	Gisborne 4010	Mr Peter Stiven
Christchurch Hospital	Christchurch Central, Christchurch 4710	Mr Steven Kelly
Gisborne Hospital	Gisborne 4010	Mr Peter Stiven
Grace Hospital	Tauranga 3140	Mr Robert Cable
Hutt Hospital	Hutt 5010	Mr Atul Dhabuwala
Manuka Street Hospital	Nelson 7010	Mr Mark Stewart
Mercy Hospital	Dunedin	Mr Mark Smith
Mercy Ascot Greenlane Hospital	Remuera, Auckland 1050	Mr Jon Morrow
Middlemore Hospital	Otahuhu, Auckland 2104	A/Prof Andrew MacCormick
North Shore Hospital	Takapuna, Auckland 0620	Mr Michael Booth
Ormiston Hospital	Flat Bush, Auckland 2019	A/Prof Andrew MacCormick
Palmerston North Hospital	Palmerston North 4442	Dr Alexandra Gordon
Royston Hospital	Hastings 4122	Mr John Fleischl
St George's Hospital	Christchurch 8014	Mr Steven Kelly
Southern Cross Hospital, Christchurch	Christchurch 8013	Mr Steven Kelly
Southern Cross Hospital, Hamilton	Hamilton 3216	Mr David Schroeder
Southern Cross Hospital, North Harbour	North Harbour	Mr Michael Booth
Southern Cross Hospital, Wellington	Wellington 6021	Mr Simon Bann
Southland Hospital	Kew, Invercargill 9812	Mr Mark Smith
Tauranga Hospital	South Tauranga 3112	Mr Barnaby Smith
Waikato Hospital	Hamilton 3204	Mr Rowan French
Wakefield Hospital	Newtown, Wellington 6021	Mr Simon Bann
Wellington Hospital	Newtown, Wellington, 6021	Mr Simon Bann

**Table 3. Ethics committees with oversight of project**

Name of HREC	Status of Review
The Alfred Hospital HREC (EC00315)	Approved
Calvary Health Care Adelaide HREC (EC00302)	Approved
Calvary Health ACT HREC (EC00105)	Approved

Name of HREC	Status of Review
HREC of Northern Territory Department of Health and Menzies School of Health Research (EC00153)	Yet to submit
Mater Misericordiae Ltd HREC (EC00332)	Approved
Monash University Research Ethics Committee (EC00234)	Approved
St John of God Health Care Ethics Committee (EC00286)	Approved
St Vincent's Health and Aged Care HREC (EC00324)	Approved
South Metropolitan Health Service HREC (EC00265)	Approved
Southern Health and Disability Ethics Committee (NZ)	Approved
Tasmania Health and Medical HREC (EC00337)	Approved

**Table 4. Ethics committees which also reviewed project**

Name of HREC	Status of Review
Austin Health HREC (EC00204)	Approved
Bellberry HREC (EC003721)	Approved
Cabrini Health HREC (EC00239)	Approved
Eastern Health HREC (EC00211)	Approved
Epworth HealthCare HREC (EC00217)	Approved
Gold Coast Hospital and Health Service HREC (EC00160)	Approved
Greenslopes Hospital HREC (EC00161)	Approved
Hollywood Private Hospital HREC (EC00266)	Approved
HREC of the Queen Elizabeth Hospital/Lyell McEwin Hospital/Modbury Hospital (EC00190)	Approved
Joondalup Health Campus HREC (EC00267)	Approved
Mildura Base Hospital HREC (EC00424)	Approved
Monash Health HREC (EC00382)	Approved
North Shore Private Ethics Committee (EC00443)	Approved
Northern Sydney Local Health District (EC00112)	Approved
Royal Brisbane and Women's Hospital HREC (EC00172)	Approved
St Vincent's Hospital (Melbourne) HREC EC00344	Approved
St Vincent's Hospital HREC (EC00140)	Approved
South West Healthcare Multidisciplinary Ethics Committee (EC00257)	Approved
Southern Adelaide Clinical Research Ethics Committee (EC00188)	Approved
Sydney Local Health District Ethics Review Committee (EC00113)	Approved
The Avenue Hospital HREC (EC00242)	Approved
The Adventist HealthCare LTD Ethics Committee (EC00141)	Approved
UnitingCare Health HREC (EC00374)	Approved
Western Health Low Risk Ethics Panel	Approved

**Monash University Research Ethics Committee** and the **Royal Australasian College of Surgeons Ethics Committee** have also given approval for the study. Bariatric Surgery Registry has been granted an Acceptance Status from the New Zealand Ministry of Health for New Zealand personal health information to be stored at Monash University in Melbourne Australia.

## 3.0 Introduction

### 3.1 Lay summary

Obesity is a prevalent disease in Australia and New Zealand. This is a major concern for both countries as obesity is an important risk factor for ill health. Obese persons are more likely to suffer from many other serious health conditions including diabetes, heart disease, liver disease, infertility, stroke and cancer. As a consequence, people who are obese are more likely to have a reduced life expectancy.

Lifestyle interventions have not been found to be effective in providing a long-term solution for the treatment of obesity. When conservative weight loss measures tried by those with obesity are not successful, weight loss or ‘bariatric,’ surgery may be considered.

Bariatric surgical procedures are operations performed with the intention of helping people with obesity achieve and sustain weight loss. Weight loss following bariatric surgery leads to significant improvement in health and well-being. Individuals who have the surgery are known to live longer. However, it is an invasive surgery with known surgical risks and potential side effects, which can be as severe as death. Given people are having this surgery to improve their health, it is critical that the surgery is performed with a minimum of side effects; otherwise, it cannot be justified.

The purpose of the Bariatric Surgery Registry (hereafter, Registry) is to monitor the safety of the surgery and to assess the long-term changes in the health of people who undergo bariatric surgery in Australia and New Zealand.

The Bariatric Surgery Registry collects data, or information, on the operation performed, who performed the operation, where the operation occurred, complications from the surgery, weight at various time points and diabetes status and management. It is necessary for the Registry to keep identifiable participant details, such as their name, date of birth, address and Medicare number (Australia) or National Health Index (NHI) number (New Zealand), in order to track their progress through data linkage to other datasets.

By systematically collecting information on every procedure performed in Australia and New Zealand, the Bariatric Surgery Registry will help to identify when surgeons, gastroenterologists, hospitals and/or procedures are not performing to the expected standard. In time, this Registry should also be able to demonstrate how effectively bariatric surgery results in weight loss and improved health (using diabetes as a marker of health) across the two countries. The Registry aims to collect 95% of the 27,000 (2017) bariatric surgeries performed each year in public and private health care facilities in Australia and New Zealand.

Participants in this study have information related to their bariatric surgery and surgical outcomes provided to the Registry by their surgeon, gastroenterologist or hospital. They may be contacted directly by the Registry staff to see if they suffered any complications and what impact the surgery had on their health (concerning their diabetes status), weight and well-being. The Registry proposes to follow participants up to 10 years after their first bariatric surgery.

The Bariatric Surgery Registry is located at Monash University’s School of Preventive Health and Public Medicine (Melbourne Australia). In New Zealand, the Registry is supported by Auckland UniServices Limited (UniServices), through its business unit, the National Institute for Health Innovation (NIHI).

## 3.2 Background

Obesity poses a major public health challenge for Australia and New Zealand. According to the Australian Health Survey (2014-15), nearly 28% of the adult population are considered obese (defined as a BMI >30 kg/m<sup>2</sup>) compared to 18% in 2004/05.<sup>1,2</sup> Amongst those Indigenous Australians who regularly attend of Indigenous primary health care organisations, 42.9% are obese.<sup>3</sup> In New Zealand, the rate of obesity has been increasing by 1% every year since 1989 and as of the 2016/2017 Health Survey, 32.2% of the adult population (1,234,000 people aged over 15 years) are obese.<sup>4,5</sup> Māori and Pacific Islands peoples have the highest incidence of obesity with rates of 50% and 69%, respectively for adults (aged 15 years and over), and 18% and 29% for children (aged 2-14 years).<sup>5</sup>

Obesity is a major risk factor for many preventable diseases including type 2 diabetes, heart disease, hypertension, stroke, cancer and musculoskeletal disorders. It can also significantly affect quality of life and shorten lifespan.<sup>6-10</sup> As those with obesity may suffer from other chronic medical conditions, the cost of their healthcare is much greater than for those with a healthy weight.<sup>11</sup> In 2010-11, the direct cost of obesity on the Australian economy was estimated to be AUS\$8.6 billion.<sup>12</sup> A New Zealand study approximated the healthcare cost of obesity to be NZ\$722 million; and the cost of lost productivity was estimated to be NZ\$849 million.<sup>13</sup> These figures demonstrate that the management of obesity demands to be a national priority for both countries.

Although lifestyle interventions can be effective in the short term, they are rarely durable in the long-term.<sup>14,15</sup> Maintenance of weight loss for the long term is a challenge for those on lifestyle intervention programmes. For those with class II obesity (BMI>35kg/m<sup>2</sup>), several Randomized Controlled Trials (RCT) and multiple case series suggest that bariatric surgery provides more predictable and durable weight loss than conservative regimes and is generally very safe.<sup>16-21</sup>

Since 2009, New Zealand has annually published 'Clinical Guidelines for Weight Management in New Zealand Adults', which continually review the current evidence and priorities for the prevention and treatment of obesity.<sup>23, 24</sup> These guidelines support the framework set out in the New Zealand Health Strategy and the He Korowai Oranga: Māori Health Strategy which guides health related services to achieve the best health outcomes for Māori.<sup>25, 26</sup> The 2009 Guidelines noted that there was no evidence of bariatric outcome data by ethnicity, demonstrating the public's need for this information.<sup>23</sup>

The New Zealand Ministry of Health guidelines 'Weight Management for Adults' suggests considering bariatric surgery for people with Class II obesity with another significant disease.<sup>27</sup> Public funding for bariatric surgery is available from the Ministry of Health for individuals who meet set criteria. A review of publicly funded bariatric surgery by Rahiri et al (2017)<sup>28</sup> suggested that there may ethnic disparities in the rate of access to public funded procedures.

Bariatric surgery is burgeoning in Australia. The number of separations for bariatric surgery reported by the Australian Institute of Health and Welfare (AIHW) for 2014-15 was 22,713.<sup>29</sup> The Medicare Benefits Schedule (MBS) data for 2017 indicates the number of procedures has grown to over 26,000 procedures per year however, this only reflected approximately 1.4% of the Australian morbidly obese having bariatric surgery as an intervention.<sup>30, 1</sup> The AIHW reported an additional 124,600 bariatric surgery-related procedures were billed to Medicare during the 2014-2015 period, with a total cost estimated at \$62.8 million for all Medicare billed procedures.<sup>30</sup>

In New Zealand, figures show that 889 bariatric procedures were performed for the year ending 2014, representing 0.04% of those with a BMI >40.<sup>31</sup> The Ministry of Health has committed over \$30 million since 2014 for bariatric surgery for individuals who meet set criteria and additional funding has also been made available by local district health boards to support publicly funded procedures.<sup>32</sup> In 2017, approximately 480 people were able to access publicly funded bariatric surgery of amongst at least 210,000 individuals who could be eligible.<sup>5</sup>

As the rate of obesity increases across both Australia and New Zealand, so does the demand for treatments including bariatric surgical procedures. As the rate of procedures increases, there needs to

be a systematic method of ensuring that bariatric surgical procedures continue to be safe and effective for those seeking them. In 2012, the Bariatric Surgery Registry was established with this intention.

### 3.3 Rationale

The Australian Commission on Safety and Quality in Health Care (ACSQHC) promotes clinical quality registries, as they are known to drive change and lead to improved patient care and outcomes.<sup>33, 34</sup> A clinical quality registry is a specific type of registry with data that can be used to:

- benchmark performance;
- determine variations in clinical outcomes; and
- develop guidelines and standards for clinical practice.

A clinical quality registry focusing on bariatric surgery is in the public interest. Such a registry can demonstrate at a population level whether bariatric surgical procedures are safe and if they can effectively treat obesity. Data from a clinical quality registry focused solely on bariatric surgery and its outcomes has the potential to give confidence to persons considering having bariatric surgery, surgeons, gastroenterologists, governments, health funds, hospitals and the wider community that bariatric surgery is safe and improves health outcomes for all persons who undergo a bariatric procedure. A clinical quality registry can also be used to demonstrate disparities amongst the rate of access to publicly bariatric services in New Zealand with the collection of ethnicity data.

With the support of the Australian & New Zealand Metabolic and Obesity Surgery Society (formally Obesity Surgery Society of Australia and New Zealand), the Bariatric Surgery Registry was established in 2012, following specific recommendations from:

- the Georganas Senate Inquiry into Obesity (published as “Weighing it up” May 2009 Recommendation 6)<sup>35</sup>;
- the Australian Commission on Safety and Quality in Healthcare (2008)<sup>33</sup>; and
- the Health Technology Review Report (Review of Health Technology Assessment in Australia, 2009).<sup>36</sup>

Following a successful two-year pilot study from 2012-2014, the shift to a registry properly commenced in Australia in 2014. The Registry launched in New Zealand in mid-2017. The Bariatric Surgery Registry is underpinned by a comprehensive governance structure and funding which ensures an ongoing independent assessment of data quality.

As the Registry collects, uses, and stores identifiable participant information, the project adheres to:

- the *Privacy Act 1988* Cth (2014)<sup>37</sup>;
- the Australian Privacy Principles as set out in the *Act*<sup>37</sup>;
- the NHMRC *Guidelines Approved under Section 95A of the Privacy Act 1988* (2014)<sup>38</sup>;
- NHMRC *National Statement on Ethical Conduct in Human Research 2007* (2018)<sup>38</sup>;
- NHMRC *Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders* (2018)<sup>40</sup>;
- *Privacy Act 1993* (New Zealand)<sup>41</sup>;
- *Health Information Privacy Code 1994* (New Zealand)<sup>42</sup>;
- New Zealand’s *National Ethical Standards for Health and Disability Research and Quality Improvement* (2019)<sup>43</sup>;
- Jurisdictional legislation including:
  - *Health Records Act 2001* (Vic)<sup>44</sup>;
  - *Privacy and Data Protection Act 2014* (Vic)<sup>45</sup>;
  - *Public Health Act 2005* (Qld)<sup>46</sup>;
  - *Information Privacy Act 2009* (Qld)<sup>47</sup>;
  - *Medical Treatment and Planning and Decisions Act 2016* (Vic)<sup>48</sup>;
  - *Privacy and Personal Information Protection Act 1998* (NSW)<sup>49</sup>;

- *Territory Records Act 2002 (ACT)*<sup>50</sup>;
- *Information Act 2017 (NT)*<sup>51</sup>; and
- *Personal Information Protection Act 2004 (Tas)*<sup>52</sup>.

The rights of European data subjects will be considered according to the General Data Protection Regulation (EU) 2016/679 in the event that a resident or citizen of the European Union (including the United Kingdom) is enrolled.<sup>53</sup>

## 4.0 Aims

As a clinical quality registry, the purpose of the Bariatric Surgery Registry is to gather and analyse data in order to monitor and enhance the quality of care received by obese persons undergoing bariatric surgery.

The aims of the Bariatric Surgery Registry are:

- to record the immediate safety of bariatric surgery in Australia and New Zealand;
- to longitudinally study the safety and efficacy of bariatric surgery in Australia and New Zealand assessing procedures, devices, complications and adverse events;
- to track key health changes including weight loss/BMI and diabetes management following bariatric surgery in Australia and New Zealand;
- to report accurate population level data to shape health practices and policy;
- to be a basis for further research into bariatric surgery as a safe and effective treatment for obesity; and
- to allow better analysis of the economic benefits of bariatric surgery as a treatment for obesity related illness.

## 5.0 Outcomes

The establishment of the Bariatric Surgery Registry allows the opportunity to achieve the following important outcomes:

- measure and confirm the outcomes from clinical trials of bariatric surgical procedures at a population level;
- support measurement and understanding of determinants of obesity and disparities in health outcomes for Aboriginals, Torres Strait Islanders, Māori and Pacific Islanders;
- identify variations in care and the reasons for those differences;
- provide an ability to track the long-term effects of bariatric surgery as an intervention for obesity;
- promote evidence-based practice by assessing compliance with best practice;
- inform public health policy and practice;
- provide confidence to clinicians and institutions that they are delivering a high quality service;
- assure the public that bariatric surgical procedures are performed under the oversight of a robust quality assurance program;
- provide bariatric patients with important information about treatment risks and benefits;
- enable further studies and research, including studies evaluating patient reported outcomes (PROMs) recognizing that:
  - the patients' sense of well-being is one of the most important outcomes from this type of surgery
  - it is important to measure, monitor and understand the impact on bariatric patients when losing excess weight; and
- empower patients to make informed decisions about care and treatment options. Benefits will be realised in the short term by producing risk adjusted comparative outcome data based on



currently available treatment and in the longer term by assessing the impact of new technologies and discoveries on outcomes.

## 6.0 Clinical quality indicators

In order to benchmark the standard of care provided to those who undergo bariatric surgery, defined outcomes are measured at established intervals. The Registry will use the following quality indicators to evaluate the safety and quality of care and the subsequent clinical effectiveness of bariatric surgery. The data collected to assess the indicator, the interval during which it is measured, and what the indicator demonstrates are:

### 1. Vital status following bariatric surgery

Data collected:

- mortality following bariatric surgery; and
- likeliness that the death was related to the participant having bariatric surgery

Interval: time of surgery up to 10 years after surgery

Demonstrates: the safety and quality of bariatric surgery

### 2. Incidence of defined adverse events following bariatric surgery

Data collected:

- date participant seen for post-operative review;
- occurrence of defined adverse events (unplanned readmission to hospital, unplanned admission to the intensive care unit, unplanned return to the operating theatre, prolonged length of stay in hospital and/or death);
- reason(s) for any adverse event; and
- cause of death

Interval: time of surgery to 90 days following surgery

Demonstrates: the safety and quality of bariatric surgery

### 3. Re-operation rate

Data collected:

- subsequent bariatric procedures (following a primary bariatric procedure)

Interval: 12 months to 10 years after a primary bariatric procedure

Demonstrates: quality and appropriateness of treatment

### 4. The effect of bariatric surgery on long term weight loss

Data collected:

- participant weight at baseline
- participant height
- participant weight on annual basis (following a primary bariatric procedure)

Interval: 12 months to 10 years after a primary bariatric procedure

Demonstrates: the sustainability of weight loss in the long term

### 5. The effect of bariatric surgery on a participant's diabetes status

Data collected:

- diabetes status at baseline
- diabetes status on an annual basis (following a primary bariatric procedure)

Interval: 12 months to 10 years after a primary bariatric procedure

Demonstrates: clinical effectiveness of bariatric surgery on diabetes status

### 6. The effectiveness of bariatric surgery as treatment for diabetes

Data collected:

- if the participant still requires further treatment for diabetes; and

- if treatment has changed from what was recorded at baseline.
- Interval: 12 months to 10 years following a primary bariatric procedure  
Demonstrates: clinical effectiveness of bariatric surgery on diabetes treatment

## 7.0 Participant terminology

Individuals recruited to participate with their first bariatric procedure are termed as “primary participants”. If they are recruited with a revision bariatric procedure then the term “legacy participants” applies.

## 8.0 Study design

The Bariatric Surgery Registry is a population based, observational and epidemiological quality improvement study of persons with obesity who undergo bariatric surgery. Non-probability sampling is necessary as the Registry aims to capture the entire population.

Surgeons and/or gastroenterologists who are known to perform bariatric procedures are invited to participate in the Registry. Whilst their participation is voluntary, they are asked to sign a participation agreement stating that they have read the protocol and will maintain the responsibility for their patients’ data. All surgeons and gastroenterologists are provided with flyers and a poster for the recruitment of Registry participants using the opt out approach. They are also given **The BSR-i User Manual for Surgeons and Staff** and when requested, paper data forms for submitting their patient and operation information.

Those submitting data directly on the Registry’s web-based interface, the BSR-i, will be given a user ID and temporary password. **The BSR-i User Manual for Surgeons and Staff** contains an authorisation form to record anyone who enters information regarding patients on the behalf of surgeons or gastroenterologists. Data collectors in public hospitals who enter data on the BSR-i are provided with their own account and are able to submit data for each of those hospitals’ surgeons and gastroenterologists that participate in the Registry.

Private and public hospitals in Australia and New Zealand that care for persons who have or had bariatric surgery will be contacted to participate in the Registry. Ethics approval and site or locality approvals are to be sought for each hospital. A Memorandum of Understanding between Monash University and each hospital/hospital group representative should be executed prior to the commencement data collection at the hospital(s). Once these steps have been taken and all approvals has been granted for the hospital’s or hospital group’s participation, Registry staff will contact the person at the hospital responsible for discharge coding. A template will be provided to the coder along with access to a secure file transfer platform to send the coding reports to the Registry.

Principal investigators with credentials for the hospital site will ensure the project is conducted in accordance with the National Statement on Ethical Conduct in Research 2007 (2018) and assist with the ethical and research requirements for the site.<sup>39</sup>

Demographic and operation information for each patient undergoing a bariatric surgical procedure is submitted to the Registry following surgery. Data related to patient outcomes during the 90-day period after the surgery is collected for all participants and annually for primary participants.

The Bariatric Surgery Registry conforms to the Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008) as set out by the ACSQHC.<sup>34</sup> The Registry is expected to be ongoing and data will be retained indefinitely.

## 8.1 Participant eligibility

Anyone who undergoes bariatric surgery as treatment for obesity in Australia or New Zealand is eligible for inclusion for the study (non-probability sampling). The minimum age for eligibility is set at 2 years and a maximum age of 95 years.

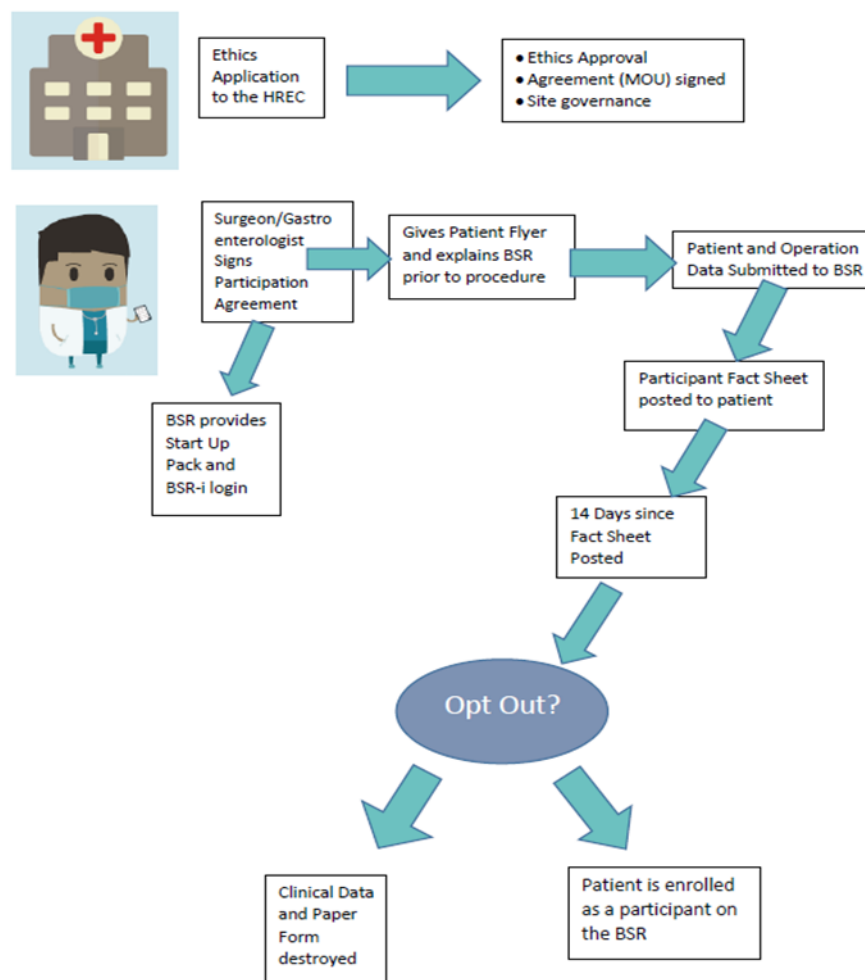
The study population may include:

- children or young persons;
- persons with a cognitive impairment;
- people highly dependent on medical care;
- persons who cannot speak English; and/or
- persons who identify as Aboriginal, Torres Strait Islander peoples, Māori or Pacific Islands peoples.

Pregnant females are not considered for bariatric surgery and are therefore excluded from the study.

**Figure 1** illustrates the overall recruitment process for the participation of hospitals, surgeons, gastroenterologists and bariatric patients in the research.

**Figure 1. Recruitment for the Bariatric Surgery Registry**



## 8.2 Consent

The opt out approach to participation is used in for those individuals who are considered able to provide independent informed consent, due to the scale and significance of the Registry. In New Zealand, the age at which an individual can provide independent informed consent is 16 years. However, the Registry will use the age of 18 years in Australia, as the age when an individual can provide independent consent varies amongst its states and territories. This will ensure consistency amongst Australian participants. Written informed consent will be used for those considered to be 'minors' (those under the age of 16 in New Zealand and under the age of 18 in Australia).

The Bariatric Surgery Registry adheres to the Guidelines Approved under Sec 95A of the *Privacy Act 1988* (2014) and the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), in its rationale for the use of the opt out approach.<sup>38, 39</sup>

Although opt out will be most commonly used, a participant's capacity for consent will need to be considered according to the National Statement.<sup>39</sup> The responsibility for determining capacity of consent will be with the clinician. The concerns and needs of specific groups of participants are discussed in sections **9.1-1.5**.

In accordance with the State and Federal privacy legislation of Australia and New Zealand, the National Statement for Ethical Conduct in Research (AU), and New Zealand's Ethical Guidelines, approval for using the opt out approach will be sought from an ethics committee nominated by the hospital and the Southern Health and Disability Ethics Committee in New Zealand.<sup>39, 43</sup>

## 8.3 Participant recruitment

Eligible participants are recruited (see **Figure 2**) when:

- a surgeon, gastroenterologist or public hospital data collector submits patient details into the BSR-*i* or with an operation form; or
- the Registry receives International Classification of Disease 10-Australia Modified (ICD-10-AM) coding reports (or similar hospital discharge reports) from contributing hospitals or hospital groups (discussed further in section **8.4.2.2**).

### 8.3.1 Recruitment of eligible participants aged 16 or over (NZ) or 18 or over (AU)

Participants aged 16 or over (NZ) or 18 or over (AU) are recruited using the opt out approach according to the requirements set out in Sections 2.3.6-2.3.12 of the National Statement on Ethical Conduct in Research 2007 (2018).<sup>39</sup> Prospective participants must be told that their identifiable health information will be provided to the Bariatric Surgery Registry for medical research that is in the public interest. This is done by surgeons, gastroenterologists and/or public hospital clinic staff who are to provide their bariatric patients with a Registry information flyer and display a poster which states that their practice or clinic participates in the Bariatric Surgery Registry.

In plain English language, both the poster and flyer advise prospective participants that the Registry will contact them after their surgery. The flyer explains:

- that the Bariatric Surgery Registry follows the progress of everyone who has a bariatric procedure in Australia and New Zealand;
- what information is collected by the Registry;
- the voluntary nature of their participation; and
- that they can inform their surgeon or gastroenterologist of their intention for non-participation.

After the surgery is performed, surgeons, gastroenterologists, public hospital data collectors, nurses and hospital information services provide data to the Registry related to the prospective participant's details and their bariatric procedure/s. Data is provided via paper forms or by direct entry on the web

interface, the BSR-*i*. Upon receipt of this data, the Registry posts potential participants a Participant Fact Sheet (PFS), Bariatric Surgery Registry Fact Sheet and a flyer (as a reminder of the one they received prior to surgery). The PFS explains the purpose of the Bariatric Surgery Registry and what their involvement entails. It also advises that their participation is voluntary and how to opt out if they do not want to be involved. General contact information is listed along with details about making a complaint to the relevant ethics committee and a free call number (1 800 in Australia or 0 800 in New Zealand) is also provided.

These steps ensure that prospective participants are fully informed that their sensitive health data will be transmitted to a third party, the Bariatric Surgery Registry at Monash University or Auckland UniServices.

Bariatric patients have three options for participation:

1. **Full participation** – Their data is included on the Registry, and Registry staff may contact the participant for follow-up information. If the bariatric patient wishes to participate, no further action is required by them upon receiving the Participant Fact Sheet. Patient information is systematically included on the Registry after 14 days from when the PFS was posted.
2. **Partial opt out** – Their data is included on the Registry but Registry staff will not contact the participant for follow-up information. The bariatric patient is required to phone the free call 1 800 number (AU) or 0 800 number (NZ) to state their decision to partially opt out.
3. **Opt out** - No clinical data is retained on the Registry. Bariatric patients who choose to opt out are required to phone the free call 1 800 number (AU) or 0 800 number (NZ) listed on the PFS and state their decision not to participate. Participants can choose to opt out at any time.

The Registry will keep the patients' name, date of birth, treating hospital & UR Number/NHI and treating surgeon in a secure "Do Not Contact" file to ensure the patients will not be contacted in the future about that procedure. All information related to their bariatric procedure will be removed from the database and destroyed if in paper form.

Participants who opt out or withdraw will be, upon request, sent a letter confirming their withdrawal or, if they have left a voice message. The decision to opt out is recorded per bariatric procedure. Should the Registry be notified in the future that the patient has undergone a further revision procedure, they will go through the opt out approach again allowing them to re-consider whether they wish to be involved with that subsequent operation.

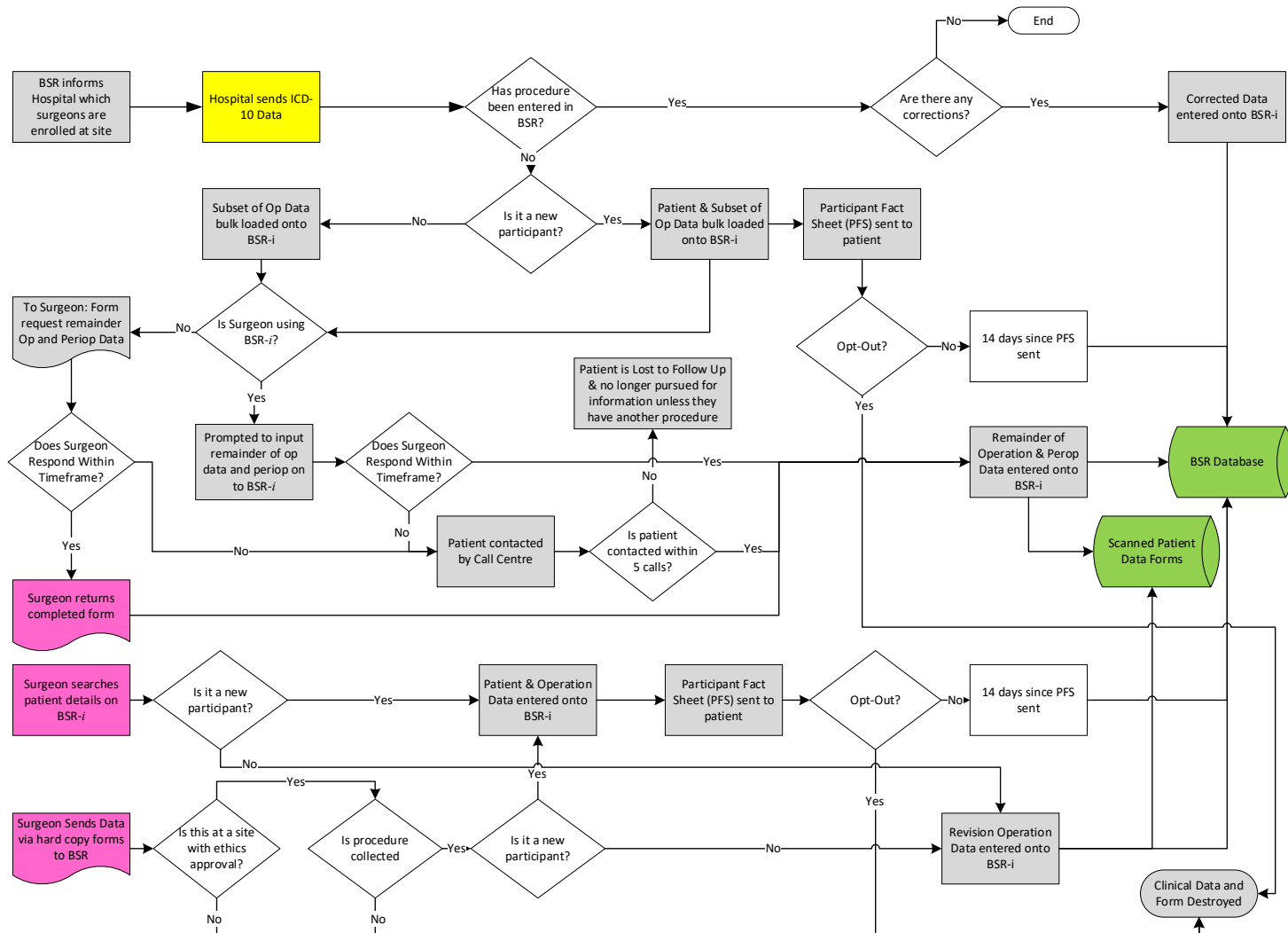
Amongst the participants who choose to opt out are those who request that their details not be kept in any file. These individuals are advised that removing all of their details may result in their being sent another PFS if information related to their procedure is added again. The individual will be advised to contact their surgeon's/gastroenterologist's rooms to have this decision recorded so that any request by the Registry for information related to that procedure will not be submitted.

A secure file is kept of individuals who opt out and this file is strictly accessible to Registry staff only. All health information for those who opt out is deleted and/or destroyed, if in paper form, in accordance with the National Statement for Ethical Conduct in Human Research 2007 (2018).<sup>39</sup> The information kept in the secure file is only that which is needed to ensure the individual will not be contacted again about their procedure, including their name, date of birth, name of the treating surgeon or gastroenterologist and hospital. When individuals contact the Registry to opt out, they will be asked for their verbal consent for this information being kept for this purpose. This retained information validates that the procedure was submitted, ensuring and verifying that surgeons are not selectively enrolling participants. Furthermore, the file allows for accurate reporting of participant opt-out and withdrawal rates, preventing the Registry from reporting a false opt out rate.

If a PFS is returned in the mail, Registry staff will attempt to validate the address used. If a corrected and current address cannot be obtained, all information related to the patient will be deleted and securely destroyed, if in paper form, as the opt out approach is not able to be completed.

**Figure 2** illustrates the typical participant recruitment process as well as recruitment and data verification using the information collected from the hospital discharge reports.

**Figure 2. Participant recruitment aged 16 or over (NZ) or 18 or over (AU)**



### 8.3.2 Recruitment of eligible participants *under* the age of 16 (NZ) or 18 (AU)

When the rooms or clinic is made aware that a minor will be presenting for consultation to discuss surgical bariatric treatment options, the rooms or clinic should contact the Registry to request a consent form in order to potentially recruit the minor patient. The Registry will immediately email the consent forms with instructions. This will ensure that the consent forms are on hand for the patient's appointment.

Consenting a minor to participate in the Registry will follow the Australian Paediatric Research Ethics & Governance Network Guide (2017).<sup>54</sup> Surgeons, gastroenterologists or hospital clinic staff are to discuss the Registry with the minor patients and their parent(s)/legal guardian(s) and give both the patient and parent(s)/guardian(s) a Registry flyer. The rooms or clinic should also have a Registry poster displayed. Further, the Parent(s)/Legal Guardian(s) Informed Consent Form (ICF) will be provided to the parent(s)/legal guardian(s) and the clinician, as an investigator in the study, is to determine the

capacity of the minor participant to understand the research. If the clinician investigator determines that the minor does not have capacity to consent, he/she is to provide information about what their participation will involve in language they understand, using the Information Sheet for Minors. The determination of capacity is to be documented by the clinician in the medical record and a study note should be provided to the Registry.

To protect from the perception of coercion to participate, the consent process should be carried out by a member of staff/the clinic who is not directly involved in the minor's care. The member of staff will verbally go over the consent form in its entirety with the minor and their parent(s)/guardian(s). The staff must clearly state that participation in the Registry is voluntary; that consent can be withdrawn at any time; and that their decision whether or not to participate will not affect the quality of the treatment they will receive. Further, prior to the individual giving consent, the opportunity must be given to consult with another health professional, family member or member of their community.

The form should only be signed when the staff member has been given surety that it is understood by the individual. Three copies of the form are required to be signed by the person giving consent, the person who carried out the consent process and a witness. One copy will be given to the person who gave consent, one is to be kept in the patient's medical record (an electronic copy can be made), and a copy is required to be sent to the Registry. If the consent process is taking place in a hospital clinic, the entire copy of the ICF should be sent to the hospital's Health Information Services (HIS) to be entered in the patient's medical record.

If the minor is mature enough to understand and capable of consenting to participation, they should also be given their own ICF to sign or they can countersign Parent(s)/Legal Guardian(s) ICF.<sup>54</sup> This needs to be witnessed by clinic or room staff who are present at the time of the consent or the patient's parent/guardian. One copy will be given to the patient, one is to be kept in the patient's medical record (an electronic copy can be made), and a copy is required to be sent to the Registry. If the consent process is taking place in a hospital clinic, the entire copy of the ICF should be sent to the hospital's Health Information Services (HIS) to be entered in the patient's medical record.

The Registry will keep a log which will verify that consent was carried out for each minor participant. The log will state: the date(s) when the consent form was requested and sent; the date of consent; and the date the Registry received the signed copy of the consent form. All Registry copies of the consent forms will be securely filed and stored within the Registry.

No minors' data will be held within the Registry prior to receiving a signed consent form.

Consent for participation of the minor can be withdrawn at any time. The 'Form for Withdrawal of Participation-Parent/Guardian' must be completed. Three copies of the form must be signed with one copy given to the parent/guardian, one for the participant's medical record and one provided to the Registry. The Registry will complete the withdrawal in the Consent Log. Once consent has been withdrawn, all health information relating to the participant will be deleted from the database.

#### ***8.3.2.1 Re-negotiating consent when a minor participant reaches 16 years (NZ) or 18 years (AU)***

As part of the Registry's validation processes, it will routinely check the age of Registry participants. The process of doing this routinely will alert the Registry to any 16 year old New Zealand or 18 year old Australian participants. When a 16 year old (NZ) or 18-year-old (AU) participant is identified by the Registry, Registry staff will review the Consent Log to determine who gave consent for treatment. If consent was given by a parent or guardian at the time of the patient being a minor, the participant will be posted a specific Participant Fact Sheet 'Participant Fact Sheet for 16+ (NZ)' or '...18+ (AU)', allowing the opportunity to consider whether or not to continue their participation.

This PFS explains the purpose of the Bariatric Surgery Registry and that they had previously been enrolled at the time of their operation when they were younger. It explains how the reason why they were enrolled and what their continued participation would involve. It also advises that their participation is voluntary and how to opt out if they wish to cease their involvement. General contact information is listed along with details about making a complaint to the relevant ethics committee and a free call number (0 800 in New Zealand or 1 800 in Australia) is also provided. If no contact with the Registry is made within 14 days of posting the PFS, it will be presumed that the participant agrees to their continued participation. All participants are able to opt out at any time.

### **8.3.3 Waiver of consent**

A waiver of consent is required to allow for the opt out approach; for the deceased: for people highly dependent on medical care (in particular instances, only); and for data linkages (including with electronic medical records).

#### **8.3.3.1 Waiver of consent while completing opt out approach**

Patients' data is held prior to the completion of the opt out approach (which includes the mailing of the PFS) twice during the data acquisition process:

- from the time bariatric patient information is submitted to the Registry until the two weeks since posting the PFS has passed; and
- from the time when the Registry receives the discharge coding (ICD-10-AM reports) for bariatric patients whose data was not previously submitted until two weeks since posting the PFS has passed.

The Monash University Office of General Counsel considered this process to be acceptable under the *Privacy Act of 1988* (2014)<sup>37</sup>. The Registry's data acquisition process has had prior review and approval from the ethics committees in Australia and New Zealand listed in **section 2**. The lead ethics committee for the Bariatric Surgery Registry, the Alfred Hospital Human Research Ethics Committee, considered that this process is preferable to the surgeon obtaining direct informed consent at the time of consultation, which holds a risk of power imbalance, coercion and difficult to document that the process had occurred. Ethical considerations are discussed more completely in **section 9**.

#### **8.3.3.2 Waiver of consent for the deceased**

A waiver of consent for the deceased is required in the event that the patient dies following bariatric surgery so as not to burden next of kin. Information related to mortality is essential to determine if the cause of death was related to the bariatric surgery. The Alfred Hospital HREC (Australia), the New Zealand HDEC and all other approving HRECs in **Tables 3** and **4** considered this waiver and approved its use. Having a waiver of consent for this instance implies that the deceased did not need to give previous consent to request or hold their information, nor is consent required from their next of kin to hold the data of the deceased.

#### **8.3.3.3 Waiver of consent for people highly dependent on medical care**

Bariatric patients may become unconscious, receive intensive care, emergency care or end-of-life care as a consequence of having their surgical procedure(s). Information about adverse events leading to patients receiving this type of care or to be in this condition are critically vital to demonstrate the safety and quality of bariatric surgery.

The surgeon, gastroenterologist or hospital should advise the patient's parent, guardian, or other authorised representative of the patient's inclusion in the study and allow them to consider whether their inclusion would be contrary to the patient's interests. However, if no other authority is acting on behalf of the patient, a waiver of consent is required. If such a patient regains capacity for consent, they should be advised as soon as reasonable possible of their inclusion in the Registry and be provided with opportunity to opt out.

#### **8.3.3.4 Waiver of consent for linkage with participants' electronic medical record (EMR)**

Data can be collected directly from a participant's medical record held on the medical practice



software (an electronic medical record or “EMR”) of their surgeon/gastroenterologist/hospital. (Refer to section **8.4.2.1**). In order to link with the software, the Registry needs to disclose participant information to the software provider for the purpose of locating the participant in the medical record. All information disclosed to the software contractor for this purpose is to be deleted after the linkage is completed.

A waiver of consent is needed for the Registry’s disclosure to the software provider to carry out the data linkage.

#### **8.3.3.5 Waiver of consent with data linkages**

The Registry intends to link with other repositories of health information as a means of validating its data as described in **section 8.4.2.4**. Health information about individual participants may be collected who have not completed the opt out approach, just as it may be with the hospital ICD-10-AM reports.

This protocol adheres to the *National Statement for Ethical Conduct in Human Research 2007* (2018) and with New Zealand’s *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (2012).<sup>39, 43</sup> Section 6.47 of the NZ guidelines states, “In the case of audits and related activities it may be ethical to use health information without additional or specific consent, as these activities are sometimes an essential part of high-quality health care delivery, so the activity may be one of the reasons why the data were collected”.<sup>43</sup>

## **8.4 Data**

### **8.4.1 Data collection stages**

#### **i. Operation data collection**

Data is collected about bariatric patients and their procedures after the surgery has taken place.

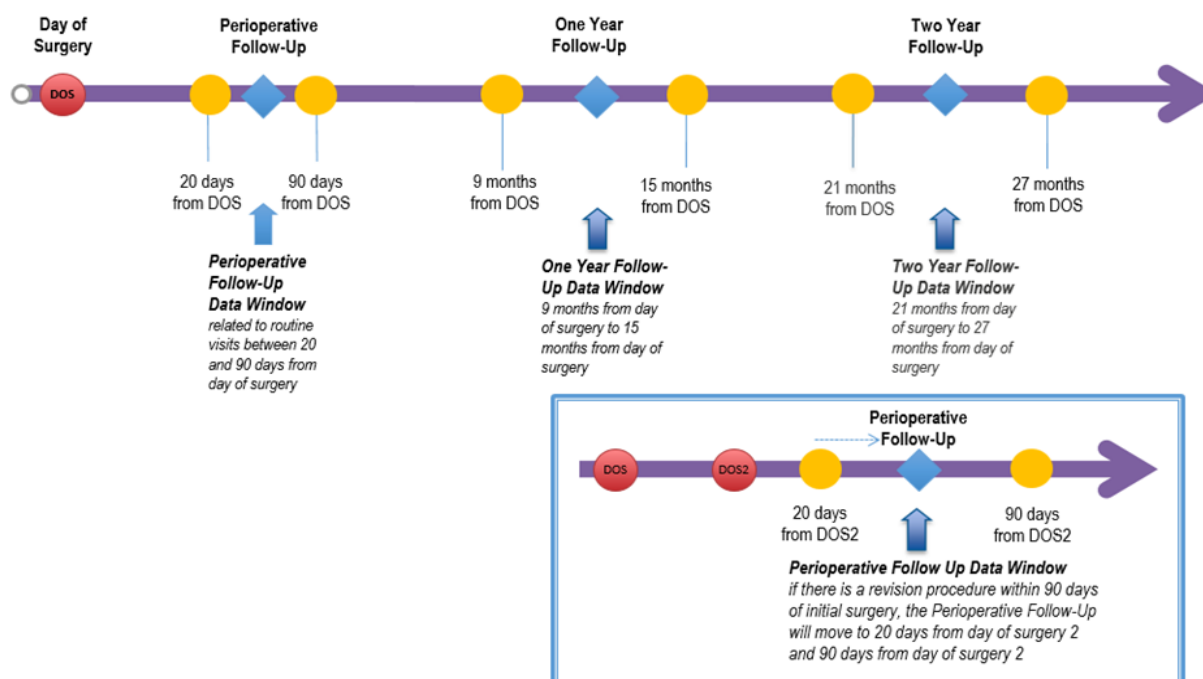
#### **ii. Perioperative follow-up data**

Follow-up data is collected peri-operatively, with regard to the first 90 days after the surgery for all participants. The Registry will not accept routine follow-up data captured prior to 20 days after the surgery. See **Figure 3**.

#### **iii. Annual follow-up data collection**

Follow-up data is collected on an annual basis for primary bariatric procedures only. Acceptable data collecting periods are from 3 months prior to the anniversary of the surgery to 3 months following the anniversary. See **Figure 3**.

Figure 3. Follow up data collection



## 8.4.2 Data collection processes

### 8.4.2.1 Data collected from surgeons, gastroenterologists, and hospital data collectors

The health professionals who performed the procedures (surgeons or gastroenterologists) have the overarching responsibility for submitting data. However, they can delegate submission to their practice staff or hospital data collectors. Data is provided to the Registry:

- in Australia, using:
  - the web browser with secure authorised entry using the Bariatric Surgery Registry Interface (BSR-*i*);
  - paper based data forms securely faxed or posted; or
  - secure electronic record transfer from surgeons' or hospitals' electronic medical record (EMR)
- in New Zealand, using:
  - the web browser with secure authorised entry using the Bariatric Surgery Registry Interface (BSR-*i*); or
  - secure electronic record transfer from surgeons' or hospitals' electronic medical record.

Practitioners who choose to have data collected from their EMR will sign an agreement with their contracted provider to have their patients' records accessed for the purpose of data collection. The Registry would provide an encrypted CSV file on the secure file transfer platform (SFTP) to the software provider. Once the software provider carries out the linkage, the data would be encrypted, converted to an agreed file format, and uploaded to the Monash University SFTP for Registry staff to access.

### 8.4.2.2 Data collected from ICD-10-AM coding reports (or similar hospital discharge reports)

Hospital Information Services (HIS) at each hospital site, or of a private hospital group, are to provide regular ICD-10-AM coding reports (or similar discharge reports) for bariatric procedures performed by surgeons or gastroenterologists who participate in the Registry. The coding reports include patient demographic and procedure information. In Australia, these reports are sent to the Registry using a secure file transfer platform (SFTP). In New Zealand, these reports are sent to UniServices in accordance with the agreed Memorandum of Understanding for each site.

The ICD-10-AM coding (or similar) reports provided by HIS are used to verify data submitted to the Registry. The reports confirm the procedures already submitted and allow Registry staff to identify those which have not. Surgeons, gastroenterologists and hospital data collectors will be asked to provide the remaining clinical information for the patients whose procedures were identified in the coding report:

- device/stapling information;
- whether the operation was a primary or revision;
- height/weight information;
- diabetes status and treatment; and
- perioperative follow-up data is also requested for efficiency.

Patients whose details are obtained from these reports are sent a PFS and the opt-out approach is followed according to the process described in section 8.3. Once the opt out period has passed, if the request for the missing data elements from the surgeon or gastroenterologist was not met, Registry staff will contact the participant to collect the required information.

#### **8.4.2.3 Data collected from participants**

##### **A. Self-reported clinical and follow up data**

When surgeons, gastroenterologists or public data collectors indicate they have not seen the participant and cannot report follow-up, the Registry staff will contact the participant for a brief phone call (using the Call Protocols) to collect the follow-up information related to the perioperative period and/or 12 month interval after surgery. (See **Figure 4**).

If the participant is a minor, the Registry staff member must check the Consent Log to determine if the minor had consented, or a parent/guardian did on their behalf. Registry staff will then speak directly with the individual who provided consent as per the consent form.

Participants (or parent/guardian) may also be asked for any missing data elements about their procedure not previously collected.

As explained in the PFS, participants do not have to agree to this contact but still keep their information on the Registry (partial opt out).

If a participant is to be followed up by the Registry, five attempts will be made to contact the participant before they are allocated to “Lost to Follow-Up”. All information about the participants lost to follow-up status is held by the Registry, as they have been through the opt out approach. These individuals may be captured again if they undergo further bariatric surgery.

An SMS/Secure Portal platform will be developed as another method to obtain follow-up data from Registry participants, through SMS, email and web based links. This platform will invite participants to link to a secure portal at various stages of their post-operative experience. If they do not respond to the request for follow-up, the Registry will call the participants. The SMS/Secure Portal platform will be designed to engage with participants by providing useful information during their post-surgery experience and allow them to give their own data back to the Registry.

##### **B. Participant feedback and quality assurance**

For quality assurance purposes and as a basis for the development of the SMS/Secure Portal platform as described above, participants will be given the opportunity to provide feedback on their experience with the Registry and offer how the Registry could better support their journey as bariatric patients. This feedback may take place during follow-up phone calls made by the Registry’s call centre staff or via an online form on the Bariatric Surgery Registry website that is currently under construction.

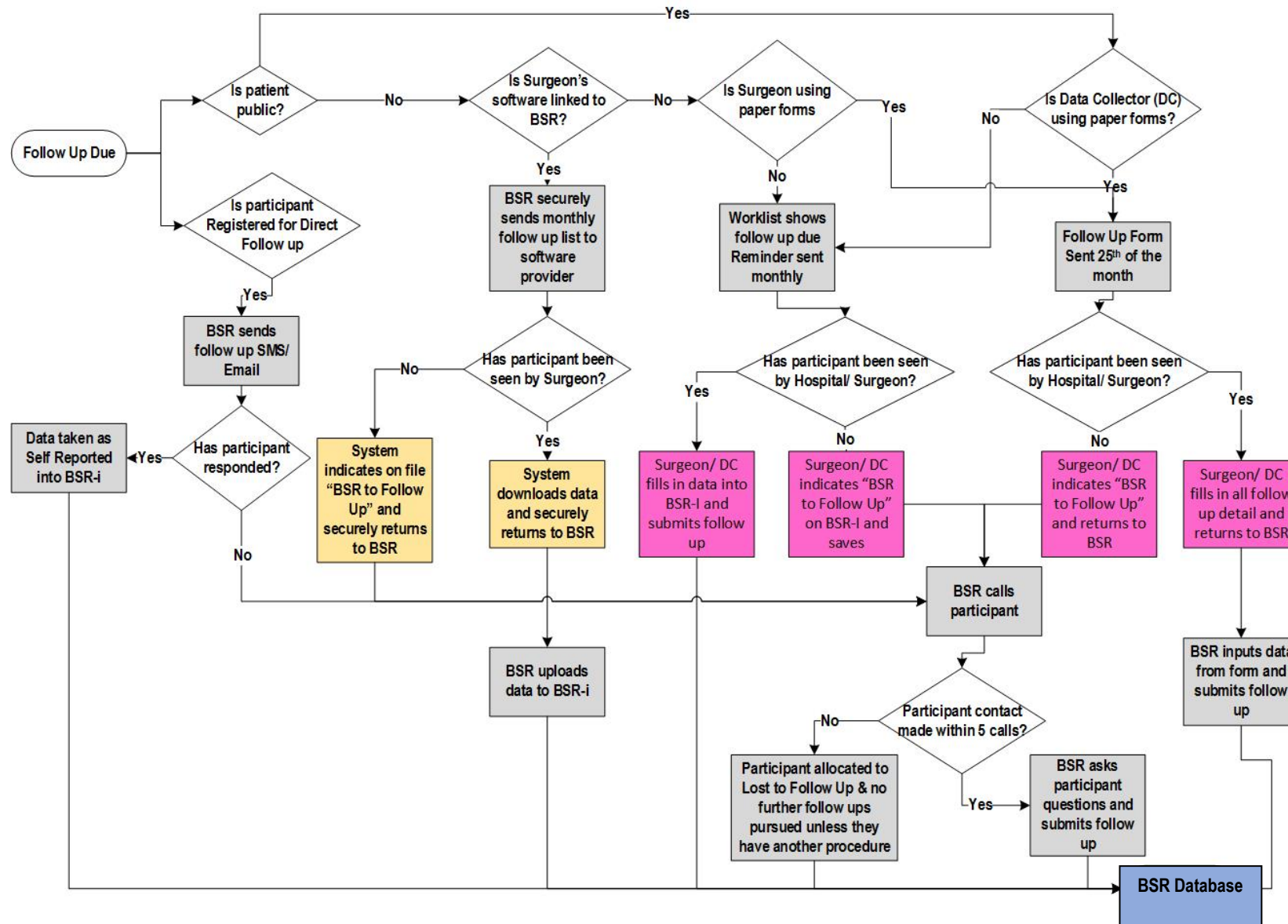
#### **8.4.2.4 Data collected from linkages with other repositories of health information**

Data may be collected with linkages to other repositories, or datasets, of health information for the purpose of verifying critical quality data as explained in the **section 8.4.4**. Any request to link with a data linkage unit will require the necessary ethic approvals.

#### ***8.4.2.5 Data Collected by other interested parties***

More comprehensive data can potentially be collected by interested sub-groups but approval from the Bariatric Surgery Registry Steering Committee and the lead ethics committee, the Alfred Hospital Human Research Ethics Committee, is required.

Figure 4. Follow-up data collection scheme.



### 8.4.3 Data elements

Data elements are defined in the Registry's data dictionary and governed by the Steering Committee, with any changes managed through a data element variation process.

The data elements collected include:

- **Patient data elements:**

*Patient Identifiers:*

- full name;
- address;
- date of birth;
- UR number/hospital (and IHI numbers when available); and
- email address (if supplied by patient)

- **Patient demographic information:**

- Medicare number (Australia only)
- Department of Veterans Affairs (DVA) number;
- NHI number (New Zealand only);
- phone numbers;
- gender; and
- indigenous status (Australia)/ethnicity (New Zealand)

- **Operation data elements:**

*Clinical details:*

- start weight (for primary participants only);
- day-of-surgery (DOS) weight;
- height;
- diabetes status and treatment; and
- concurrent renal and liver transplant

*Procedural information:*

- surgeon name;
- procedure date;
- procedure type;
- surgical approach used (open, laparoscopic, robotic)
- primary/ revision;
- planned or unplanned revision status;
- reason for revision;
- bariatric procedure prior to revision;
- if the procedure was abandoned;
- reason for abandoning procedure;
- length of hospital stay; and
- mortality status including date of death and whether the death was likely to be related to the bariatric procedure

*Device or Staple details:*

- type;
- brand;
- model;
- port fixation method; and
- buttress

- **Follow-up data elements**

*Elements for Perioperative (up to 90 days post-surgery) Data:*

- date participant had a post-operative review
- occurrence of unplanned return to theatre and reason/ complication occurrence of unplanned admission to intensive care and reason/ complication;
- occurrence of unplanned re-admission to hospital and reason/ complication;
- prolonged hospital stay and reason/ complication; and,

- mortality status including date of death and whether the death was likely to be related to the bariatric procedure

*Elements for Subsequent Clinical Data of Primary Participants (collected annually for ten years):*

- weight;
- diabetes status and treatment;
- re-operation and reason; and
- mortality status including date of death and whether the death was likely to be related to the bariatric procedure

#### 8.4.4 Data quality

Data completeness and accuracy are optimised through routine in-built validation and completion checks in the Registry database to minimize data entry error. These include:

- data entry controlled by form logic and limited to feasible data;
- use of built in edit checks to ensure data meets the required formats and range;
- accuracy enhanced by the use of exhaustive drop down lists providing all possible answers to minimize free text entry where applicable;
- use of hide and show mechanisms to guide data entry to required fields;
- use of explanatory texts to assist data entry;
- validation rules applied at the time of submission with alerts to assist with errors and missing data; and,
- the use of a participant management system to list incomplete data and other actions required.

Additional quality checks post data entry includes checking for:

- duplicate data;
- missing data;
- data consistency; and
- data validity.

Data quality and completeness are checked at a number of stages of the data management process. Errors in data quality, when identified, may be referred back to contributing surgeons, gastroenterologists or hospitals for review.

Case ascertainment, as well as both brief and comprehensive audit processes, are performed on site by Monash University Registry staff (Australia only). Registry staff perform regular remote audit checks to verify the accuracy of data received from surgeons and gastroenterologists. This is done during the course of a follow-up phone call from the call centre or by Registry staff directly contacting surgeons' or gastroenterologists' rooms.

Completeness and accuracy of the eligible population captured by the Registry is assessed using hospital ICD-10-AM coding reports (or similar hospital discharge reports) provided by participating hospitals or hospital groups. Cross-checking with these reports allows for complete data capture at each hospital site and provides data validation for each procedure submitted by the surgeon or gastroenterologist. These reports are provided at regular intervals by the organisation's administrator and only contain data of participating surgeons and gastroenterologists.

In Australia, periodic linkages are intended with other repositories, or datasets, of health information that can validate Registry data. The ICD-10-AM discharge report validations and other data linkages will ensure that all eligible patients are included in the Registry and minimise the risk of bias in data entry by contributing surgeons and gastroenterologists. The linkages will also verify critical quality data such as patient mortality, defined adverse events and other outcome measures are completely captured. Requests to link New Zealand Registry data to national data sets will be considered by the Steering Committee on a case-by-case basis. For data linkages in Australia and New Zealand, the necessary approvals from an HREC/HDEC will be sought when required. Examples of repositories, their role in data validation, and what information will be collected and disclosed by the Registry are described in **Table 5**.

#### 8.4.5 Data confidentiality

Only those employed by Monash University and UniServices for the purpose of the project, such as the Registry epidemiologists, data custodian, clinicians involved with the research, research assistants and/or data managers have access to the data which is limited to the extent required to perform their employment duties.

Registry staff involved with data monitoring, analysis or reporting undertake training to ensure that they understand their obligations about data confidentiality and privacy relating to research activities. The Registry researchers and staff are required to complete and submit a Confidentiality Agreement to ensure that they understand the confidentiality and privacy parameters. Registry database users have their own unique username and password to access the interface.

For the purpose of monitoring and/or auditing to determine case ascertainment, accuracy and completion of data, authorised Registry staff may liaise with surgeons and sites to organise access to patient records.

The Privacy Policy of the Bariatric Surgery Registry sets out how and why information is to be collected about individuals in the course of the study and how that information will be used and stored in accordance with Australian and New Zealand Privacy Principles.

#### 8.4.6 Data security

Registry data is secured according Australian *Privacy Act of 1988* (2014), the Australian Privacy Principles (especially APP11), the *Privacy Act 1993* (New Zealand), the *Health Information Privacy Code 1994* and the relevant jurisdictional legislation.<sup>37, 41-2</sup> Registry management and staff will ensure that “reasonable steps” are taken to protect private information as outlined by the Office of the Australian Information Commissioner (2015).<sup>55</sup>

Prior to conversion to electronic files by Registry staff, forms completed in hard copy are stored securely in a locked filing cabinet behind swipe card-only accessible doors. Other electronic files are stored on the Monash University secure shared drive where access to the computers is username and password specific to each user.

The BSR-*i* database is held electronically and stored securely within the Clinical Data Management Unit, Monash University (Melbourne Australia) where other confidential registries are stored and maintained. The Registry database is routinely backed up and encrypted on a secure server (according to ISO27001 standards) in the event of unauthorised data access.

All communication between the users’ browsers and the server (BSR-*i*) occurs on a secure channel, commonly referred to as Secure Sockets Layer (SSL). SSL ensures that a private key on the server encrypts all data before it is sent to the user where it is decrypted by a public key. This ensures the data is not compromised in transit.

All users of the BSR-*i* access the system through a login screen with a pre-figured username and password controlled by administrators of the system.

Disposal of any information will be in accordance with the National Statement on Ethical Conduct in Research Involving Humans 2007 (2018) and New Zealand’s Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012).<sup>39, 43</sup> Archived information will be securely stored for an indefinite period.



**Table 5. Examples of repositories of health information and the Information to be collected and disclosed**

Repository	Data held by	Data validation description	Data collected by BSR	Data disclosed by BSR
<b>ICD-10-AM Extract</b>	Each Hospital	Ascertain cases that are coded to the set of bariatric codes to determine if reported to BSR or omitted	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• Medicare number</li> <li>• treating surgeon/gastroenterologist</li> <li>• length of hospital stay</li> <li>• procedure codes</li> </ul>	Participant name and date of birth
<b>Practice or Hospital Electronic Medical record (EMR)</b>	Medical Practitioner/Hospital software provider	Validate participant and operation information. Linkage is primarily for the purpose of collecting data.	<ul style="list-style-type: none"> <li>• participant weight</li> <li>• diabetes status and treatment</li> <li>• further operation(s) as a consequence of having bariatric surgery</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth,</li> <li>• date of operation</li> <li>• surgeon/gastroenterologist who performed operation</li> <li>• hospital for operation</li> </ul>
<b>Births Deaths &amp; Marriages (Australia)</b>	Each State Jurisdiction	Ascertain death of bariatric patient/registry participant to ensure it is recorded and that no further attempts to collect follow up are made <i>subject to application</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• date of death</li> <li>• cause of death</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth</li> </ul>
<b>Private Health Insurers' Datasets Current: Latrobe Health Service Future: TBA via amendment</b>	Private Insurers	Ascertain if registry participants have returned to hospital (defined adverse event), been admitted to ICU and/ or had a procedure (includes procedures not in the bariatric code set but revision procedures for stapling procedures e.g. stents, lavage, etc.)	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• Medicare number</li> <li>• treating surgeon/gastroenterologist</li> <li>• length of hospital stay</li> <li>• procedure codes</li> <li>• hospital re-admissions</li> </ul>	None
<b>Coronial Court Findings (Australia)</b>	Each State Jurisdiction	Ascertain the likelihood that death was related to bariatric procedure <i>subject to application and ethics committee approval</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• date of death</li> <li>• cause of death</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth</li> </ul>
<b>National Coronal Information System (NCIS)</b>	Commonwealth of Australia	Ascertain the likelihood that death was related to bariatric procedure <i>subject to application and ethics committee approval</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• date of death</li> <li>• cause of death</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth</li> <li>• date of death</li> </ul>
<b>National Death Index</b>	Commonwealth of Australia	Ascertain the likelihood that death was related to bariatric procedure <i>subject to application and ethics committee approval</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• date of death</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth</li> <li>• date of death</li> </ul>

			<ul style="list-style-type: none"> <li>• cause of death</li> </ul>	
<b>New Zealand Collections</b>	New Zealand Ministry of Health	National collections including Mortality Collection that can be linked using NHI number, <i>subject to application</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• NHI number</li> <li>• treating surgeon/gastroenterologist</li> <li>• length of hospital stay</li> <li>• procedure codes</li> <li>• hospital re-admissions</li> <li>• cause of death</li> </ul>	<ul style="list-style-type: none"> <li>• participant name,</li> <li>• date of birth</li> <li>• date of death</li> </ul>
<b>Admission and episodic datasets for each State or Territory:</b> <b>ACT: Admitted Participant Care Collection,</b> <b>NT: In-Participant Activity,</b> <b>NSW: Admitted Participant Data Collection,</b> <b>QLD: Hospital Admitted Participant Data Collection,</b> <b>SA: Integrated South Australia Activity Data Collection,</b> <b>TAS: Public Hospital Admitted Participant Collection,</b> <b>VIC: Victoria Admitted Episodes Dataset</b> <b>WA: Hospital Morbidity Data Collection</b>	Each Jurisdiction	Ascertain if registry participants have returned to hospital (defined adverse event) and/ or if they have had a procedure (includes procedures not in the bariatric code set but revision procedures for stapling procedures e.g. stents, lavage, etc.) <i>subject to application and ethics committee approval</i>	<ul style="list-style-type: none"> <li>• participant name</li> <li>• address</li> <li>• date of birth</li> <li>• Medicare number</li> <li>• treating surgeon/gastroenterologist</li> <li>• length of hospital stay</li> <li>• procedure codes</li> <li>• hospital re-admissions</li> </ul>	None

## 9 Ethical considerations

The Bariatric Surgery Registry was established for the purposes of health research and is considered to be in the public's interest and follows the specific recommendations by the Georganas Inquiry into Obesity in 2009, the Australian Commission on Safety and Quality in Healthcare, and the Health Technology Review Report.<sup>35, 36</sup>

To function as a clinical quality registry, the Bariatric Surgery Registry collects, stores, and uses identifiable, personal and sensitive health information about bariatric patients for research into the quality, safety and effectiveness of bariatric surgery as treatment for obesity. In order to collect longitudinal outcomes of those who underwent bariatric surgery, identifiable information is necessary so that hospitals, surgeons, gastroenterologists and their staff can link back to participants' medical records and provide information on participants' health status following their procedures.

Ordinarily, consent is sought from individuals whose health information is being collected. All quality and safety registries require near total capture of potentially eligible participants to ensure reliable reporting of outcomes. If participation in a quality and safety registry is less than 90%, there is significant risk of bias and underreporting of adverse outcomes. International experience suggests that obtaining prior consent can cause participation rates to drop to around 60%, potentially rendering data unreliable.<sup>56</sup> Obtaining consent, therefore, for a clinical quality registry would 'prejudice [its] scientific value', justifying the use the opt out approach when considering New Zealand's Ethical Guidelines for Observational Studies.<sup>43</sup>

Further, based on the anticipated numbers of participants expected to be recruited for the study, obtaining direct consent would be difficult. Based on the current data, it is estimated that least 27,000 bariatric patients per year will be eligible for recruitment across Australia and New Zealand.<sup>30,31</sup> As such, the scale and significance of the Bariatric Surgery Registry indicates that an opt out approach to participation, rather than informed consent, is necessary.

It is acknowledged, however, that using the opt out approach carries a risk as the Registry stores data without participant consent for the period of time whilst the opt out approach is being undertaken and when discharge coding reveals a patient that a surgeon did not enter into the Registry. This risk is mitigated by participating surgeons, gastroenterologists or hospital clinics providing flyers; displaying the Bariatric Surgery Registry poster; and, advising patients that their information will be provided to the Registry. The Monash Office of General Council, forty ethics committees across Australia and New Zealand's Southern Health and Disability Ethics Committee have considered this to be an adequate process and a waiver of consent was granted allowing for the opt out approach to be used

In Australia, the Registry must comply with the *Privacy Act 1988* Cth (2014) and the Privacy Principles in s14 regarding the collection, use and storage of private and sensitive health information.<sup>37</sup> Jurisdictional legislation and the privacy legislation of New Zealand have similar principles.<sup>41-2, 44-7,49-52</sup> Australian Privacy Principles 3 and 6, respectively, allow for the collection of health information and for stored personal information to be used or disclosed for a secondary purpose without consent of the individual, **if there is a permitted health situation as defined in s16B of the *Privacy Act 1988*.**<sup>37</sup>

Section 16B(2)(d)(iii) allows health information to be collected and s16B(3) allows for the use or disclosure of health information following the Guidelines Approved under Section 95A of the *Privacy Act 1988* (2014).<sup>38</sup> The Bariatric Surgery Registry must comply with the S95A Guidelines, the National Statement, and seek ethics approval from an NHMRC constituted human research ethics committee, as it has been determined that:

- ✓ the health information it collects is necessary for the purposes of research;
- ✓ the research is relevant to public health and safety;
- ✓ it is impractical to obtain consent;
- ✓ identifiable data is necessary; and

- ✓ the opt out approach will be used instead of consent.<sup>38-39</sup>

In New Zealand, the Registry must comply with the *Privacy Act 1993* and the *Health Information Privacy Code 1994*.<sup>41-2</sup>

Any future addition of hospital sites will be submitted for ethical review.

Data from New Zealand is held at Monash University in Melbourne Australia. The Bariatric Surgery Registry has been granted an Acceptance Status from the New Zealand Ministry of Health for personal health information to be stored at Monash University.

## 9.1 Ethical considerations for specific participant groups

With regard to the inclusion of vulnerable individuals, the Registry takes into account the federal and jurisdictional legislation related to consent and decision making.<sup>48, 54, 58-61</sup> In accordance with the Australian Privacy Principles (APP) guidelines (Chapter B. Key concepts B.52-B.55), as surgeons and gastroenterologists are APP entities, they must assess whether patients have the capacity to consent to treatment, and the subsequent capacity to consent to participate in research.<sup>57</sup>

The Registry considers the needs of all participant groups, respecting their rights as prospective participants in this research.

### 9.1.1 Ethical considerations for children or young persons

As bariatric surgery is known to be performed on children and young people, persons under 18 years old are expected to be recruited to participate in the Registry. The collection of their data is essential to reliably report the appropriateness, safety and effectiveness of bariatric surgery as a treatment for obesity in young people.

Children and young persons will not be directly involved in the research as observational data is collected from surgeons, gastroenterologists and hospitals. Their participation in the Registry has a low risk to their safety, emotional and psychological security and well-being.

Written consent will be required for the participation of any minor in the Registry, following the process as set out in section 8.3.2. When a minor participant reaches 18 years, consent for participation will be re-negotiated for those whose participation was consented by a parent or guardian. This allows the individual to decide for his/her self whether or not to continue their involvement with the study. Refer to section 8.3.2.1.

### 9.1.2 Ethical considerations for persons with cognitive impairment

Persons who have a cognitive impairment, intellectual disability or mental illness and undergo a bariatric procedure in Australia or New Zealand are eligible for participation in the Registry. As participants, they would have no direct involvement in the research and their participation has a low risk to their safety, emotional and psychological security and their well-being.

The surgeon or gastroenterologist should assess the degree of cognitive impairment of the patient. For patients capable of consent, the surgeon or gastroenterologist should follow the opt out process for participant recruitment for which he/she is responsible, advise the patient about their details being given to the Registry and give the patient a flyer. The Registry would then send the patient a Participant Fact Sheet (PFS) further advising of the opt out process. The patient can opt out at any time or his/her next of kin or legal guardian can opt out the patient on his/her behalf.

If the surgeon or gastroenterologist is aware that another individual has been authorised to give consent to medical treatment on behalf of the patient, it is the surgeon's or gastroenterologist's responsibility to contact the Registry and advise who should be sent the Participant Fact Sheet. Nonetheless, the participant should always be sent their own PFS and retain the right to decide whether to participate.

The research carries low risk as an observational study, however, vulnerable persons may be distressed when contacting the Registry. The Registry staff are trained to follow the Registry's call protocols to minimise participant discomfort or distress.

### **9.1.3 Ethical Considerations for people highly dependent on medical care**

As a clinical quality registry, the Bariatric Surgery Registry collects outcome measures related to a defined time frame for every bariatric surgical procedure performed. There is the possibility that, as a result of having bariatric surgery, a patient may become unconscious, receive intensive care, emergency care or end-of-life care.

Information about adverse events that occur to people receiving this type of care or in this condition following a bariatric surgical procedure is vital to demonstrate the safety and quality of bariatric surgery. The Registry will use this information to benchmark procedures, outcomes and providers of care (surgeons, gastroenterologists, and hospitals). It will lead to greater understanding about the safety of bariatric surgery, which has the potential to give confidence to patients, surgeons, gastroenterologists, hospitals, governments and the wider community.

As stated in section **8.3.3.3**, if such a patient is to have their information submitted to the Registry, the surgeon, gastroenterologist or hospital should advise the patient's parent or guardian or other authorised representative of the patient's inclusion in the study and be allowed to consider whether it would be contrary to the patient's interests. If no other authority is acting on behalf of the patient, a waiver of consent is required. If such a patient regains capacity for consent, they should be advised as soon as reasonable possible of their inclusion in the Registry and be provided with opportunity to opt out.

### **9.1.4 Ethical considerations for persons who cannot speak English**

Individuals who do not speak English may be recruited to the Registry. To ensure the opt out process can be completed, these patients require an explanation in their own language stating that their information will be submitted to the Registry. The surgeon or gastroenterologist is to give the patient a flyer prior to sending their information to the Registry and ensure that the patient has someone who can translate the flyer for them, such as a support person or translator who attends the surgeons' rooms with the patient. The patient should be advised and understand that after the operation, he/she will receive a letter from Monash University or the University of Auckland with further Registry information.

If the patient indicates that they have no one who can translate the information for them, the surgeon or gastroenterologist will need to contact the Registry to request a translated version of a flyer. The surgeon or gastroenterologist would need to provide the translation to the patient before sending any information to the Registry.

It will be presumed that patients who require a translated flyer will also need a translated Participant Fact Sheet. The Registry has Participant Fact Sheets available in Mandarin and Arabic. If another language is required, the Registry will organise a translation with the Victorian Translation Service or a similar service in New Zealand. Surgeons will need to note that a translated PFS is required and in which language, upon submission of the patient's operation data.

If Registry staff need to contact a participant who cannot speak English for follow-up information and a translator is unavailable, no further attempts to obtain follow-up information from the participant will be made. The participant will automatically be considered "Lost to Follow-Up."

### **9.1.5 Ethical considerations for persons who are Aboriginal, Torres Strait Islander peoples, Māori or Pacific Islands peoples**

The Bariatric Surgery Registry has the potential to identify ethnic disparities for Aboriginal and Torres Strait Islanders in Australia and for New Zealand's Māori and Pacific Islands peoples. The Registry has the capacity to support improving quality outcomes for these groups and it is hoped that these data will enable the development of guidelines for bariatric surgical procedures leading to improved outcomes for all indigenous

participants. The contribution of the first peoples of Australia and New Zealand will be acknowledged in reports and presentations.

This research will involve Māori as participants and will adhere to *Guidelines for Researchers on Health Research Involving Māori v2 2010* and the *Te Mana Rararunga - Māori Data Sovereignty Network Charter*. Māori consultation is sought in New Zealand as part of locality approvals with the district health boards.<sup>62-3</sup> The Waitematā and Auckland District Health Boards Māori Research Committee have reviewed the study and given their approval. In giving its approval the Waitematā Māori Research Committee stated “*While the study does not include the analysis of outcomes by ethnicity, the collection of ethnicity data may provide baseline data for other researchers or Māori communities. Existing research being undertaken with a focus on disparities in Māori bariatric surgery outcomes supports the view that this data may provide valuable information for other studies*” and also advised that the Participant Fact Sheet (PFS) be available in Te Reo Māori (upon request).

The New Zealand version of the Participant Fact Sheet, provided by UniServices, informs prospective participants that they are encouraged to talk to their Whānau in the first instance for Māori cultural support. This PFS also provides the contact numbers for He Kamaka Waiora (Māori Health Team), Māori Research Committee and the Māori Research Advisor.

With a high incidence of obesity amongst Pacific Island peoples, they are also likely to be involved in this research and will be identified by their specific ethnic origin in order to have ethnicity data of high quality. This study will adhere to the *Pacific Health Research Guidelines (2014)*.<sup>64</sup> The researchers will uphold the four Pacific cultural values of communal relationships, reciprocity, holism and respect and will ensure that Pacific peoples’ way of life should not be threatened by this study. Community consultation will be undertaken as required.

In Australia, it is anticipated that members of Aboriginal and Torres Strait Islander community will be recruited to the Registry. An ethics application will be made to the HREC of Northern Territory Department of Health and Menzies School of Health Research, which will further address the ethical considerations of including this community in the study.

*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NHMRC 2018)* and *Keeping Research on Track II (NHMRC 2018)* have been considered and will be regarded in the instances of participation of indigenous persons.<sup>40, 65</sup>

The researchers involved with the Bariatric Surgery Registry aim to uphold the six core values of the Aboriginal and Torres Strait Islander peoples as defined in the guidelines.<sup>40</sup>

**Spirit and Integrity** The investigators and researchers respect the cultural inheritance of the past, present and future generations of Aboriginal and Torres Strait Islander people and are committed ensuring that the Registry is carried out with integrity.

**Cultural continuity** The researchers acknowledge that Aboriginal and Torres Strait Islander peoples may have a negative perception about research and view it as an exploitative process. The conduct of the Registry is not expected to impact upon or erode the social or cultural norms amongst Aboriginal or Torres Strait Islander peoples. Community consultation will be sought as required respecting the role of community in the Aboriginal and Torres Strait Islander culture.

**Equity** The Bariatric Surgery Registry does not target any one single group, culture or ethnicity but rather the entire population of those who have undergone bariatric surgery. The Registry aims to record and follow the quality and safety of bariatric surgery and ultimately improve health outcomes for all patients. It is the researchers' intention that any benefit from the Registry will be shared with stakeholders, investigators and the public, including Aboriginal and Torres Strait Islander peoples.

**Reciprocity** The researchers recognise the contribution of all participants and groups in the study and aim to ensure that all groups and participants will benefit from its conduct. Obesity is particularly prevalent amongst indigenous Australians; hence, the inclusion of Aboriginal and Torres Strait Islanders in the Registry is essential to improving their health outcomes. It is considered of vital importance to include the Aboriginal and Torres Strait Islander community in this research project, not only for the research but also for the wider communities of Australia.

**Respect** The Bariatric Surgery Registry's investigators, researchers and staff are cognisant of the different values, norms, aspirations, expectations and beliefs that individuals, cultures and groups hold, including Aboriginal and Torres Strait Islander peoples. The researchers want to ensure trust amongst the Aboriginal and Torres Strait Islander community and will remain open to the input of their community throughout the conduct of the Registry. The researchers will negotiate a process for individual and community decision making for involvement in the Registry. Participation in the research is voluntary. Only those who are fully informed about the Registry can determine whether or not to participate. The contribution of Aboriginal and Torres Strait Islander peoples will be acknowledged in reports and presentations.

**Responsibility** Investigators, researchers, and all staff are bound by their professional standards to conduct appropriate and ethical research. The Bariatric Surgery Registry is primarily a quality and safety registry aimed at improving the health outcomes of bariatric surgery patients. The study is and will continue to be monitored to ensure it upholds the responsibility of complying with the protocol, that all adverse events are recorded and reviewed. Gaining ethics approval ensures the appropriate ethical oversight of the conduct of the Registry. Publication of annual reports provides feedback and communication to stakeholders, participants, and the public. The Registry maintains its responsibility of communication and reporting for all jurisdictions and among all people, cultures, and groups.

## 10 Participant risk management and safety

The Bariatric Surgery Registry is an observational and epidemiological study collecting data at the time of procedure or from medical records and is unlikely to result in any harm to participants.

Participants who are contacted by telephone for follow-up information may experience minimal discomfort related to anxiety answering personal questions related to their weight, health and medical procedures. The Registry's staff are trained to minimise their distress.

It is not unusual that a participant may not want anyone to know that they have undergone a bariatric surgical procedure and this will be evident if it is made known that they participate in the Bariatric Surgery Registry. This could cause the participant to become upset or aggrieved. The likelihood of harm occurring is perceived to be very low as evidenced by the Registry's low opt out rate which has remained at less than 4% since it began in 2012. Of the participants who have contacted the Registry or ethics committees to complain and/or express their emotional distress when they receive their Participant Fact Sheet, the severity has not been demonstrated to be beyond the level of discomfort. No consequences of any discomfort have been made known to the Registry.

Participants are advised of the low risks associated with participating in the Participant Fact Sheet as well as the indirect benefits of participating in such a registry. Indirect benefits of participating in the research include the monitoring of the quality of care provided by hospitals, surgeons, and gastroenterologists; the delivery of the best possible health service to people undergoing bariatric surgery can be ensured; and, participants can be notified if a significant issue is identified with the medical device or procedure.

## 11 Data analysis

### 11.1 Process of data analysis

Non-identifiable data is provided to an independent biostatistician by secure file transfer for review on a 6 monthly basis.

The results are provided to the Registry's Programme Manager. Only Monash University Registry staff, who are non-clinical, have access to identifiable data. All data used in reports and/or publications is cleaned, de-identified and verified prior to analysis. Routine re-analysis of data is undertaken by the Programme Manager to ensure findings are reproducible.

### 11.2 Case-mix (risk) adjustment

Operative outcomes for each individual surgeon or gastroenterologist need to be interpreted with great care as the case-mix of surgical practice can vary. For example, some surgeons may only take on patients needing more difficult revision surgery while others may operate predominantly on higher risk patients having primary surgery. As a result, the comparison of outcomes must carefully consider the patient characteristics that are beyond the control of the surgeons or gastroenterologists. This typically will involve taking account of a participant's age, sex, body mass index (BMI) and the existence of any other co-morbidity.

Other confounders to be considered are the socioeconomic status (SES), demographic location and complexity of the surgery. In cases where clear exceptions exist, as identified by validated bio-statistical means, individuals may be excluded from sample data to ensure results are not misleading. Documentation of decisions to remove cases from samples for data analysis purposes is maintained by the Registry's Data Manager. The number and percent of such observations will be reported to the Steering Committee.

It is expected that this information will eventually be used for the development of a policy, which will be able to identify potential outliers.

## 12 Monitoring of outcomes

The Steering Committee will review the risk adjustment model and its performance characteristics until such time that Registry data has matured to allow for a policy to be developed to identify potential outliers. The Bariatric Surgery Registry aims to one day provide information which can minimise patient harm should a device, procedure, surgeon, gastroenterologist or hospital prove to be deficient. The Registry can also be a useful tool in contacting participants should a device recall ever be necessary.

## 13 Reporting

The Bariatric Surgery Registry issues regular reports to deliver data that is valuable to key stakeholders. A range of reports is prepared for various stakeholders, as described below.

All data related to participant information is presented in aggregate and is not identifiable to protect participant privacy. No data from patients who have declined to participate will be included in any data analysis or reporting, as their clinical information is securely destroyed. The percentage of participant opt outs is to be reported to demonstrate the level of participation amongst those recruited.



Information related to individual surgeons or gastroenterologists is also reported in aggregate and are non-identifiable. Contributing hospitals are listed in reports but data related to the procedures and outcomes from those sites are not reported publicly or to other parties without prior consent.

### 13.1 Publicly available reports

As required by the 2008 ACSQHC Operating Principles<sup>34</sup>, the Registry produces regular publicly available reports. **Annual reports** comprehensively review the data held on the Registry's database, analysing the safety and quality of bariatric surgical procedures and the effect on participants' clinical outcomes (diabetes management and total and excess weight loss maintained following surgery). These aggregate reports are available on the Bariatric Surgery Registry website and are sent directly to contributing surgeons, gastroenterologists, hospital executives, hospital group executives, ethics committees, state and federal health departments, medical device manufacturers, third party private insurers and other professional organisations with a vested interest in the outcomes of bariatric surgery. **A semi-annual brief update** is also made available by the same channels.

Annual reports are published as at June 30 each year and are released in the September of the same year. The semi-annual update is published as at 31 December each year and is released in the following March.

### 13.2 Individual reports

Contributing surgeons and gastroenterologists can receive benchmarked reports once they have submitted sufficient data to the Registry to allow for comparison. These reports compare the non-identifiable data for that surgeon or gastroenterologist against the Registry as a whole and include information on their case mix demographics of their participating patients, follow-up rates and the safety and clinical outcomes. These are published as at 30 September each year and are confidentially released to each of the surgeons or gastroenterologists in the December of that year.

Other key stakeholders including hospital groups and device manufacturers receive benchmarked annual reports. All information presented in their reports is based on aggregate data and no identifiable participant, surgeon or gastroenterologist information is disclosed.

Progress reports for the Registry are also prepared and delivered annually for each contributing hospital and the ethics committee providing oversight for project and to relevant research governance offices. These reports generally detail participant recruitment, withdrawal figures, and disclose serious adverse events and mortality figures.

Bi-annual progress reports are also delivered to the Commonwealth's Department of Health in line with the Registry's funding agreement. These progress reports provide an oversight of the current status of the Registry and detail participant recruitment, withdrawal figures, and disclose serious adverse events and mortality figures. However, these reports do not contain any identifiable information with regard to participants, surgeons or hospitals.

### 13.3 Data access for research purposes and ad hoc reports

Governments, institutions, organisations and researchers may seek access to data or request analysis of data. Such ad-hoc reports may be prepared following data requests approved in accordance with the Bariatric Surgery Registry Data Access Policy. These requests need to be reviewed by the Registry's Steering Committee and may also require ethics review.

Where a request for data for research purposes utilises only non-identifiable existing Registry data, ethics approval for the project may be sought from the Alfred Hospital HREC in Australia or the Southern Health and Disability Ethics Committee in New Zealand.

## 14 Registry organisation

The Bariatric Surgery Registry is a multi-centred, investigator driven endeavour. Each site is to have a local principal investigator (PI), responsible for ensuring that research activities undertaken at their site are conducted in accordance with the Registry protocol, site Registry agreements and related policy documentation. To contribute to the Registry, all surgeons and gastroenterologists are asked to sign a participation form outlining their responsibilities.

Each Australian hospital site is required to have ethics approval from an NHMRC constituted human research ethics committee and grant governance for the Registry project. A Memorandum of Understanding (MoU) will be executed between the site or private hospital group outlining the roles and responsibilities of the respective site or hospital group and Monash University. The MoU will also document the agreement of the relevant site to make the necessary resources and reports available for the Registry. Data will only be collected from hospital sites once these necessary steps are taken.

In New Zealand, a Memorandum of Understanding (MoU) will be executed between each approved site and UniServices outlining the roles and responsibilities of the respective site, surgeon(s)/ gastroenterologist(s), Monash University and UniServices. The MoU will also document the agreement of the relevant site to make the necessary resources and reports available for the Registry. Ethics and governance approval, including locality, will be obtained prior to the collection of data at any hospital site where bariatric surgical procedures are performed.

The School of Public Health and Preventive Medicine within Monash University is the data custodian. Custodianship responsibilities of Monash University entail accountability for the information held within the Registry. Day to day project management is undertaken at Monash University. While Registry staff at Monash University oversee all project related activities; contributing surgeons, gastroenterologists, and hospitals are ultimately responsible for ensuring timely and accurate data collection (where central data collection is not used). This is supervised by the Programme Manager and Data Manager at Monash who report and provide feedback on data completion and quality to sites and the Bariatric Surgery Registry Steering Committee, the governing body of the Registry.

Support for the free call number in New Zealand will be provided by trained staff located at the National Institute for Health Innovation, UniServices, in conjunction with Monash University. UniServices will also provide support with implementations of MoU with new sites and the on boarding and training of surgeons and gastroenterologists. Monash University retains overall responsibility for project management of the Bariatric Surgery Registry in New Zealand and for ensuring that the protocol is updated and ethics approvals are maintained for the duration of the study.

### 14.1 Registry governance

The governance structure is in keeping with the operating principles established by the ACSQHC and the Terms of Reference for the Bariatric Surgery Registry Steering Committee are written to comply with such principles.<sup>34</sup> The Steering Committee oversees the governance of the Registry, provides strategic direction, and ensures the agreed outcomes of the registry are achieved. This Committee meets formally at least two (2) times a year.

A diverse range of key stakeholders has been engaged to formally join the Steering Committee. The membership currently represents the bariatric surgical profession (through ANZMOSS), the broader surgical profession (through RACS and ANZGOSA), Monash University (as data custodian), the Commonwealth (as a

major funder and key user of bariatric surgery services), the medical technology industry (as providers of devices used in bariatric procedures) and a community advocate. The Chair is an independent obesity expert, who is not a surgeon or gastroenterologist, to maintain impartiality across the Registry's processes. The Steering Committee also nominates a Clinical Lead from Australia and a Clinical Lead from New Zealand.

The Steering Committee is to:

- provide oversight of the Registry, including the Executive Management Committee;
- provide ongoing review of the objectives of the Registry and its effectiveness in meeting them;
- establish policies to address issues of clinical interest or significance that may arise;
- facilitate policy support for issues identified by the Executive Management Committee;
- provide advice on the Registry's management, organisation, scope, development and funding;
- monitor the Registry's data quality management processes and timeliness of reporting;
- develop and monitor policies for access to data and responses to quality of care issues identified;
- review and advise on outputs from the Registry;
- review all research and data requests for identifiable data;
- review publications arising from the Registry; and
- review and advise communication strategies, including communication with the media and consumers.

## 14.2 Funding

Commonwealth funding up to \$850,000 per year for the period 1 July 2017 to 30 September 2022 has been secured to support Australian implementation, quality control, data collection and reporting of the Registry. A proposed business case for continued Commonwealth funding will be prepared in 2021 for beyond this current funding period.

A broad-based funding model engaging those within the profession, insurers, medical technology industry, federal, state and territory governments and medical defense organisations, is being developed to secure at least 20 stakeholders as funders. It is proposed that these stakeholders will initially contribute \$20,000 per annum then increase to \$50,000 per annum towards the Registry. These funds will be used in conjunction with the Commonwealth funding until 2022.

Funding for the New Zealand launch of the Registry was provided by the medical technology industry and future funding will be sought from additional sources to support the on-going operations there.

## 14.3 Quality assurance

As part of the funding agreement with the Commonwealth Government, Registry management will undertake quality assurance activities with its stakeholders including persons who have bariatric surgery, surgeons, gastroenterologists, hospitals, medical technology industry, health services and the Jurisdictions. These activities may be undertaken as online surveys, focus groups, forums and/or other related self-audit endeavours designed to gain understanding of the service the Registry provides. These activities will also help the Registry align its practices with this evolving medical field as well as remain current and relevant as a clinical quality registry.

# 15 Significance

Establishing a bariatric surgery clinical quality registry allows for community wide comparisons of the safety of care provided by procedures, devices, surgeons, gastroenterologists and hospitals. This provides surety for patients and payers that the delivered services are of the highest quality. Importantly, the Bariatric Surgery Registry provides the opportunity for early recognition of a problem device, procedure, surgeon,

gastroenterologist, or hospital, allowing for rapid intervention to prevent patient harm. The Registry has the potential to identify ethnic disparities for Aboriginal, Torres Strait Islander, Māori and Pacific Islander peoples and can support improving quality outcomes for these groups. In the future, it is hoped that Registry data will enable the development of guidelines for bariatric surgical procedures leading to improved outcomes for all patients. This research will provide longitudinal, long term community data on the outcomes of bariatric surgery including weight loss, change in diabetes, and need for reoperation. At an **individual level**, these data will give patients a more accurate view of what to expect from a bariatric procedure and will enable more valid informed consent for surgery. At a **community level**, this data will allow for the assessment of the economic and societal benefits that bariatric surgery potentially holds when offered as a treatment for obesity.

## 16 Other documents to be used in conjunction with the protocol

- ✓ **Bariatric Surgery Registry Poster**
- ✓ **Bariatric Surgery Registry Flyer**
- ✓ **Bariatric Surgery Registry Fact Sheet**
- ✓ **Participant Fact Sheets (AUS and NZ versions)**
- ✓ **Parent(s)/Legal Guardian(s) Informed Consent Form (and Withdrawal of Consent)**
- ✓ **Information Sheet for Minor Participants**
- ✓ **Data Forms (Australian sites only)**
- ✓ **BSR-*i* User Manual for Surgeons and Staff (AUS and NZ versions)**
- ✓ **Call Protocols**
- ✓ **Data Access Policy**
- ✓ **Privacy Policy**
- ✓ **Grievance and Complaint Policy**
- ✓ **Data Dictionary**
- ✓ **Steering Committee Terms of Reference**

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