

# Patient Explanatory Statement



{Insert your hospital logo here}

## Participant Explanatory Statement

**Full Project Title:** Establishment of a bariatric surgery clinical quality registry

**Project Number:** [insert project number here]

**Co-ordinating  
Principal Investigator:** Professor Wendy Brown

**Principal Investigator:** [insert surgeon here]

**Associate Investigator(s):** [insert surgeon here]

### 1. Introduction

We are establishing a Bariatric Surgery Registry to improve the quality of care provided to people undergoing bariatric surgery. The registry has been established with support from the Obesity Surgery Society of Australia and New Zealand (OSSANZ). We will be collecting data on the care provided to patients who have undergone Bariatric Surgery at a number of private and public hospitals across Australia.

This Participant Information Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

### 2. What is the purpose of this research project?

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

We will collect information on:-

- Your name, date of birth, address, contact details, indigenous status and medicare information;
- The name of your surgeon and the hospital where you had your surgery;
- Clinical information related to assessing your condition and procedures or treatment provided;
- The date/s when treatment was provided or commenced.
- Some information about your general state of health and well being including your weight and diabetes status.

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This registry has been piloted across a number of hospitals in Australia from February 2012 and is now being rolled out across Australia. Once completely rolled out, we expect to have approximately 16,000 registrations per year.

We will also periodically access information from State Registries to update our files.

### 3. What does participation in this research project involve?

We record data on your treatment and outcomes from your hospital medical record, from the medical record in your Consultant Surgeon's rooms, information from other medical databases such as those held by state and territory governments as well as from other Commonwealth and State Registries. We may contact you for a 5 minute phone call at 30 days and 12 month intervals after your surgery to see how you are doing; however, you do NOT have to agree to this. It is also possible to have your data included on the Registry but NOT be contacted during your follow-up care.

### 4. What are the possible benefits?

You will receive no direct benefit from contributing to this registry.

You will, however, benefit indirectly from findings obtained from the registry. Specifically, a major benefit from the registry will be the ability to monitor quality of care across sites to ensure the delivery of the best possible health service to people undergoing bariatric surgery. We will notify you if a significant issue is identified with the medical device or procedure you have received.

### 5. What are the possible risks?

Researchers directly involved in collection of data will have access to your medical record. These researchers will be independent of the doctors involved in the research. To ensure that your private information is safeguarded registry staff must comply with very strict privacy principles.

Researchers will not release your identifiable information to any person or organisation outside the registry, except to those bodies with which the Registry will periodically link to obtain important clinical information and check the accuracy of the data. Those bodies may include the State Department of Health and other Registries. No report will contain any identifying information about you.

### 6. Do I have to take part in this research project?

You do not need to take part in this research project. Participation in any research project is voluntary. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with your treating surgeon or hospital and your doctor will be unaware of whether you participate or not.

You have three options for participation:

1. You can **allow your data to be included on the Registry** and also **allow the Registry to contact you during your follow-up care** – which requires you to do nothing; you may still decline further contact (opt off) on receiving your follow-up phone call.
2. You can **allow your data to be included on the Registry**; however, **not agree to any follow-up contact in regards to your care** – which requires you to call the 1800 number below and state this.

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3. You can **fully opt out** of your data being included on the Registry **by calling the 1800 number below**.

This is an opt-off registry. That means that your details will automatically be included on the registry unless you let us know that you don't want to participate.

**If your preference is to OPT OFF the Registry, please state:**

- **Complete OPT OFF** (no data included, no follow-up contact)
- **Partial OPT OFF** (data included, no follow-up contact)

**You, or your next of kin on your behalf, can opt off the registry at any time by contacting us on freecall 1800 998 722**

If you do not contact us within two weeks on the freecall number, we will assume that you are happy for us to collect this information. If you choose to opt off the project at any time, we will not include your clinical information. We will retain your full name and date of birth, name of treating hospital and name of treating surgeon to ensure we do not contact you in the future.

### **7. What will happen to information about me?**

Data within the registry will be identifiable. It will be safeguarded through State and Commonwealth privacy laws. Information will be stored securely, with access restricted only to registry officers.

In consenting to having this information collected, you will be agreeing to having your information used for research which aims to investigate quality of care issues relating to bariatric surgery. Research may be undertaken using only de-identified registry data. Any research undertaken will need to be approved by an ethics committee. Should you wish to see a copy of any research arising from this study, you may contact Professor Wendy Brown (see below for contact details).

As this is an ongoing registry, data will be kept indefinitely in a secure environment.

### **8. Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

Further, in accordance with regulatory guidelines, the information collected in this research project will be kept indefinitely.

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### 9. Is this research project approved?

The ethical aspects of this research project have been approved by [insert name of the hospital's nominated Human Research Ethics Committee].

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

### 10. Who can I contact?

If you want any further information concerning this project you can contact

- Professor Wendy Brown (Co-ordinating Principal Investigator) on 9903 0625,  
or
- [insert Principal Investigator's name] (Principal Investigator) on (xxx)
- Ms Catherine Pound (Administrative Assistant) on 03 9903 0891

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact

- [insert name of the hospital's nominated Executive contact or governance officer],  
[hospital name or HREC committee] on [phone number]