Patient Explanatory Statement

Chief Investigator: Dr Ingrid Hopper
Principal Researchers: Prof Rodney Cooter, A/Prof Colin Moore, A/Prof Elisabeth Elder
Site Investigator: <to be updated>
Registry Coordinator: Catherine Mulvany

This Patient Explanatory Statement follows on from information provided to you by your surgeon about the **Australian Breast Device Registry (ABDR).** Please read this explanatory statement; it provides more in depth information about the ABDR to help you to decide whether you want to take part. If you have further questions, speak to your surgeon or feel free to contact us.

1. WHAT IS THE AUSTRALIAN BREAST DEVICE REGISTRY?

The Australian Breast Device Registry (ABDR) is a public health registry that records information about breast device surgery in Australia. Your surgeon has chosen to submit details of device surgery, such as the insertion and/or removal of breast implants, tissue expanders and acellular dermal matrices to the registry.

Upon receiving information about the surgery, the ABDR securely tracks and monitors the long-term safety of breast devices. The ABDR is funded by the Commonwealth Department of Health, and managed by an independent academic research organisation, Monash University, School of Public Health and Preventive Medicine. We are the only registry in the world to have the full support of all surgical groups that specialise in breast device surgery. The ABDR has been approved by the Human Research Ethics Committee at <insert site name> and is provided at **no cost** to you, the patient.

2. WHAT IS THE PURPOSE OF THE ABDR?

The purpose of the ABDR is to monitor the long-term safety of breast devices and record their impact on the health and wellbeing of patients. It also aims to identify best surgical techniques and provide feedback on quality of care to surgeons, health providers and device manufacturers. No personal details are ever published in public reports.

The ABDR also provides a long-term record of your device and surgery details should you ever need them.

3. WHY ARE WE ASKING YOU TO PARTICIPATE?

Your information makes an important contribution to the ABDR. To successfully reflect the safety of breast device surgery in Australia, the registry needs to gather as much information as possible on all related surgeries performed in Australia.

4. WHAT DOES PARTICIPATION IN THIS PROJECT INVOLVE?

By allowing us to keep information relevant to your surgery in the ABDR, you are participating. Your surgeon has provided this information:

- Device details (serial number, type, etc.);
- Operation notes (e.g. type of incision);
- If applicable: revision details (device removal or replacement);
- Name, Date of Birth (to make sure we have the right person and in case we need to contact you); and
- Address and contact details (required for follow up questionnaire and in the case of device recall).

You may be contacted by an ABDR team member at 1 year, 2 years, 5 years, and 10 years post-surgery and asked to complete a few questions about the look and feel of your device. Your response to these questions provides valuable insight into long-term patient well-being and will help the Registry to predict trends or complications associated with the device (implant) or the surgery.

5. WHY ARE WE INCLUDING PEOPLE WHO HAVE HAD THEIR BREAST IMPLANTS REMOVED?

The purpose of the ABDR is to track and monitor all breast devices. Information from this procedure is important and will help researchers better understand reasons for their removal and your wellbeing following their removal.

6. WHAT ARE THE BENEFITS OF PARTICIPATION?

Your participation in the ABDR contributes to long term safety monitoring of implanted breast devices with an aim to improve patient safety. Participating in the ABDR will provide peace of mind that the safety of your implants and devices are being tracked and monitored. You will have ongoing access to a record of your surgery details upon request (medical records only need to be kept for seven years). The registry will enable you and/or your surgeon to be made aware of identified safety issues in significantly shorter timeframes than previously.

7. WHAT WILL HAPPEN TO INFORMATION ABOUT YOU?

Your information is kept in a purpose-built electronic database. The database is housed within Monash University's "red zone" which is compliant with ISO27001 standards (bank level security) with access restricted to ABDR personnel only. All ABDR personnel must comply with very strict privacy principles.

Personal information, such as your name and contact details, are kept by the registry only to ensure information about your surgery/device is correct. We need these details to provide information to you at your request, to assist notifying you in the event of an issue with a device or recall, and to send you a short follow up questionnaire. No identifiable information is included in data analysis. We will not release any personal information other than to your surgeon and state/national death registries in order to ensure that information we hold is accurate and complete.

Information about your surgery and device will be included in an analysis on the safety and quality of care relating to breast devices. Data analysis and public reports arising from the ABDR will contain no identifiable information about you. Registry data will be made available to external researchers only after all identifiable information has been removed. Any research analysis on the data in the registry will be approved by a Human Research Ethics Committee.

The ABDR takes privacy and confidentiality very seriously and enforces policies and procedures covering privacy, data access, and governance to safeguard your confidentiality. The ABDR complies with State and Commonwealth Privacy Laws and is overseen by a Human Research Ethics Committee.

8. CAN YOU ACCESS YOUR INFORMATION?

Yes, you can access your information but we will need to confirm your identity before providing any information. You may need this information if you are seeing a new surgeon, or your previous visit took place more than seven years ago (medical records are only required to be stored for seven years). To apply for access to information about your surgery or to notify the registry of a change of your contact details, please contact the ABDR Coordinator.

9. DO YOU HAVE TO TAKE PART IN THE ABDR?

We understand that not everyone is comfortable being in a registry. Participation is entirely voluntary and your involvement will not change or impact your relationship with your surgeon or care you receive. Should you decide to take part but later change your mind, you are free to withdraw at any time. It is important to note that this is an opt-out registry; your details will automatically be included in the registry unless you let us know that you do not want to participate.

If you do not wish to have your data included on the registry – contact the registry on **1800 998 722**
or email abdr@monash.edu and state that you wish to opt out.

If you do not contact us within 2 weeks we will assume that you are happy for us to retain this information.

10. WHO CAN YOU CONTACT FOR MORE INFORMATION?

For any questions relating to the ABDR or to opt-out please call 1800 998 722 or email abdr@monash.edu

To request access to your data or for general information, please call the ABDR Coordinator: 1800 998 722 or (03) 9903 0205 or email abdr@monash.edu or visit the website http://www.abdr.org.au/

This study has been approved by the <xxxx> Ethics Committee. 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 <Research Governance Officer> at <Name of Site> on (xx) xxxx xxxx. You will need to quote the following project number: <project number>.

The Australian Breast Device Registry is supported by funding from the Australian Government Department of Health