Patient Explanatory Statement

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This Patient Explanatory Statement outlines information about the **Australian Breast Device Registry (ABDR)** and will help you to decide whether you want to take part. Please read this information carefully and direct questions to either your surgeon or the contacts listed at the end of this sheet. **If you do not wish to participate in the ABDR please call 1800 998 722.**

1. WHAT IS THE AUSTRALIAN BREAST DEVICE REGISTRY?

The ABDR is a very secure repository for information on surgical procedures involving a breast device; either a breast implant or a tissue expander. 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. WHO IS MANAGING THE REGISTRY?

The ABDR is a Commonwealth Government initiative managed by Monash University's School of Public Health and Preventive Medicine in collaboration with the Australian Society of Plastic Surgeons (ASPS), Australasian College of Cosmetic Surgery (ACCS) and Breast Surgeons of Australian & New Zealand Inc. (BreastSurgANZ). Monash University houses several of Australia's largest clinical quality registries within their Department of Epidemiology and Preventive Medicine (DEPM), and employ experts in the field of quality assurance activities in health care.

3. WHAT IS THE PURPOSE OF THE ABDR?

The purpose of the ABDR is to monitor the safety of breast devices and record their impact on the health and wellbeing of patients. It also aims to identify optimal surgical techniques and provide feedback on quality of care to surgeons and device manufacturers. The ABDR will contribute to our understanding of the long term safety of implanted breast devices and help to improve patient safety.

The ABDR can be thought of as an information 'safe-keep' for patients' device details and the details of their surgery. It provides a communication link between breast device manufacturers and device recipients, facilitating direct notification of device-related complications and/or device re-calls.

4. WHAT DOES PARTICIPATION IN THIS PROJECT INVOLVE?

If you choose to participate, the following information will be collected by your surgeon and sent to the registry:

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

You may be contacted by the ABDR staff at four time points - 1 year, 2 years, 5 years, and 10 years post-surgery. At each stage you will be asked to complete a short survey to help us understand how satisfied you are with your surgery and the reasons for satisfaction/dissatisfaction.

5. WHAT ARE THE BENEFITS OF PARTICIPATION?

The ABDR provides a direct line of communication between you and the device manufacturers/regulators. This is important in case your device is found to be unsafe and requires a re-call. In the past, re-call of a defective device has occurred and the existing registry was used to contact the recipients who had received that device.

The ABDR is able to provide you with access to your surgery details. This information may be useful should you require a revision or experience complications, or where either you are not returning to the surgeon who performed the initial surgery or your previous visit took place more than seven years ago (medical records are only required to be stored for seven years). In addition, you can contact the ABDR to report any complications you may experience.

6. WHAT ARE THE POSSIBLE RISKS?

ABDR personnel will have access to information about your surgery (or surgeries). To ensure that this information is safeguarded, and thereby maintain your confidentiality, all ABDR personnel must comply with very strict privacy principles. They will not release your identifiable information to any person or organisation, other than to state/national death registries and government databases containing details on operations performed in hospitals, in order to ensure that information on the registry is accurate and complete. Reports arising from the registry will not contain any identifiable information about you and information used in analyses will be coded ('re-identifiable').

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

Participation is entirely voluntary and your involvement will not change or impact your relationship with your surgeon or service. 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. There are three options available:

1. **Allow your data to be included on the Registry** – you are not required to do anything and you are free to withdraw your data at any time.
2. **Do not allow your data to be included on the Registry but agree to be contacted again in the event of future surgeries** – contact the Registry on **1800 998 722** or email abdr@monash.edu and state this. Your data will be completely deleted from the database.
3. **Do not allow your data to be included on the Registry and do not agree to be contacted again in the event of future surgeries** – contact the Registry on **1800 998 722** or email abdr@monash.edu and state that you wish to opt off completely. Your name and contact details will be retained in the database to ensure we do not contact you again.

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

8. WHAT WILL HAPPEN TO INFORMATION ABOUT YOU?

Your data will be held in an identifiable format so that you can be contacted if required - for completion of the follow-up survey, to provide information at your request or in the unlikely case of device recall. It will be safeguarded through State and Commonwealth privacy laws and stored securely with access restricted to ABDR personnel only. Your identifiable information will not be released to any person or organisation, other than for the purpose of ensuring that information on the registry is accurate and complete (state/national death registries and government 'admitted episode' databases).

By taking part in the ABDR you will be agreeing to have your information used for research evaluating quality of care issues relating to breast device surgery. All research undertaken will require approval by an ethics committee and analyses and reports arising from the ABDR will contain no identifiable information about you. Registry data will be made available to external researchers but only after all identifiable patient information has been removed.

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

9. CAN YOU ACCESS YOUR INFORMATION?

Yes, you have the right to access your information. To apply for access or to notify the registry of a change of your contact details, please contact the ABDR Co-ordinator.

10. WHO CAN YOU CONTACT?

To opt-out: 1800 998 722 or abdr@monash.edu

To request access to your data, report any complications, or for general information, please call the ABDR Co-ordinator: 1800 998 722 or (03) 9903 0205 or email catherine.mulvany@monash.edu or consult 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>.

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