Patient Explanatory Statement

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This Patient Explanatory Statement advises you about the role of the **Australian Breast Device Registry (ABDR).** Please read this explanatory statement; it provides information about the ABDR to help you to decide whether you would like to have your information contained in this registry.

1. WHAT IS THE AUSTRALIAN BREAST DEVICE REGISTRY?

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

The ABDR uses this information to securely track and monitor 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. This is the first registry in the world to have the full support of all surgical groups that specialise in breast device surgery. The ABDR is 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 track, monitor and report on the safety, performance and quality of breast devices to health authorities, such as the Therapeutic Goods Administration (TGA). The registry also aims to identify best surgical techniques and provide feedback on quality of care and patient outcomes to surgeons, health service providers, government and on the safety of devices to manufacturers.

The ABDR provides you with an indefinite record of your device and surgery details should you ever need them in the future.

3. WHY ARE WE ASKING YOU TO PARTICIPATE?

Information about your device, including revision or its removal, makes an important contribution that helps the registry successfully monitor the safety of breast devices.

4. WHAT DOES PARTICIPATION IN THIS PROJECT INVOLVE?

Participation involves the ABDR storing this information, which has been provided by your surgeon:

- Device details (serial number, type, etc.);
- Operation notes (e.g. type of incision);
- If applicable: details of the revision surgery (device removal or replacement);
- Your Name, Date of Birth to make sure we have the right person; and
- Your contact details: In the event health authorities determine you should be contacted about your breast device in the future and for ABDR follow up.

5. WHY ARE WE INCLUDING PEOPLE WHO HAVE HAD THEIR BREAST DEVICES REMOVED WITHOUT REPLACEMENT?

Information obtained about this procedure is important and assists in understanding reasons for device removal.

6. WHAT DOES ABDR FOLLOW UP CONTACT INVOLVE?

You may be contacted by an ABDR team member at 1 year, 2 years, 5 years, and 10 years after your surgery and asked to complete a short questionnaire (5 questions) about the look and feel of your breast device. Contact may be via text message, phone, email or letter using the contact details that were provided. . Your response provides valuable insight into long-term patient well-being and will help the registry to understand possible trends or complications associated with the

device or the surgery. Your responses are confidential and stored securely.

7. WHAT ARE THE BENEFITS OF PARTICIPATION?

Your participation in the ABDR contributes to long-term monitoring of the safety and performance of implanted breast devices with an aim to safeguard patient health. Participating in the ABDR may provide peace of mind that the safety of your breast device is being tracked and monitored. You will have ongoing access to a record of your breast device details upon request (ordinarily, medical records only need to be kept for seven years). The registry will enable healthcare providers to be made aware and access device details, of patients with breast devices that have been identified with safety issues in significantly shorter timeframes.

8. WHAT ARE THE POSSIBLE RISKS?

It is not anticipated that there are risks to participation in this registry. Only authorised registry staff will have access to health information provided to us by your surgeon. The ABDR takes privacy and confidentiality very seriously and enforces strict policies and procedures covering privacy, data access, and governance to protect confidentiality. The ABDR complies with State and Commonwealth privacy laws and is overseen by the Human Research Ethics Committee.

9. WHAT WILL HAPPEN TO INFORMATION ABOUT YOU?

Your information is kept in a purpose-built secure database. The database is housed within Monash University's "red zone" which is compliant with ISO27001 standards with access restricted to select ABDR personnel.

Personal information, such as your name and contact details, are kept by the registry only to ensure information about your surgery/breast device is correct. We need these details to provide information to you at your request, to assist health providers to notify you in the event of an issue with a breast device, and to possibly send you a short follow up questionnaire. We do not release any personal information other than to your surgeon or your healthcare facility. In the future your details may be linked with state/national health and death registries to ensure the information we hold is accurate and complete.

Only data about your surgery and breast device are 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 not contain any identifiable information about you. Registry data will be made available to external researchers only after all identifiable information has been removed. Any analysis on the data in the registry requires approval by a Human Research Ethics Committee.

10. CAN YOU ACCESS YOUR INFORMATION?

Yes, you can access your information but we will need to confirm your identity before providing this to you. You may need information about your breast device if you are seeing a new surgeon, or last saw your surgeon more than seven years ago. To access information about your surgery or to notify the registry of a change of your contact details, please contact the ABDR on 1800 998 722 or email abdr@monash.edu.

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

This is an opt-out registry and your participation is entirely voluntary. Because your surgeon contributes to the ABDR, your details are automatically included in the registry unless you let us or your surgeon know that you do not want to participate. Should you decide to take part but later change your mind, you are free to withdraw at any time.

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

Please contact us within 2 weeks of receiving this letter if you do not want us to retain your information.

12. WHERE TO GET MORE INFORMATION?

To speak to a member of our team - T: 1800 998 722 or (03) 9903 0205 E: abdr@monash.edu or visit www.abdr.org.au

This study has been approved by the <xxxx> Ethics Committee. If you have any concerns about any aspect of the project, the way it is being conducted or any questions about being a 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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