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 included in this secure 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 in Australia. **Breast implants, breast tissue expanders and acellular dermal matrices are types of breast devices.** Your surgeon has provided information regarding your breast device surgery to the ABDR to assist it to track and monitor the long-term safety of breast devices. This registry 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. 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 primary purpose of the ABDR is to track, monitor and report on the safety and performance 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. No individual is ever identified in any public reports.

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

3. WHY ARE WE ASKING YOU TO BE INCLUDED IN THE ABDR?

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

4. WHAT DOES INCLUSION IN THE ABDR INVOLVE?

You have received this letter because your surgeon has provided the ABDR with information about your breast device surgery. There is nothing further you have to do to be included in this national registry. The information that has been provided by your surgeon includes:

- Device information (serial number, type, etc.);
- Operation information (e.g. type of incision);
- If applicable: details of revision surgery or explant surgery (e.g. device removal or replacement, complications);
- Your Name and Date of Birth so this information can be validated; and
- Your contact details: for ABDR follow up.

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

Information obtained about breast explants is important and assists in understanding reasons for device removal. This helps to track and identify any issues with the device safety and performance. You will not be contacted once we learn that your implants have been removed.

6. WHAT DOES ABDR FOLLOW UP CONTACT INVOLVE?

If you have breast implants, an ABDR team member may contact you at 1, 2, 5 and 10 years after your surgery with a short questionnaire regarding your breast device(s). Contact may be via text message, phone, email or letter. Your response provides valuable insight into long-term device outcomes, and are stored confidential and securely.

7. WHAT ARE THE BENEFITS OF BEING IN THE ABDR?

Your inclusion in the ABDR contributes to long-term monitoring of the safety and performance of implanted breast devices with an aim to safeguard patient health. You will have ongoing access to a record of your breast device details upon request. The registry will enable healthcare providers to access device details of patients with breast devices that have been identified with safety issues.

8. WHAT ARE THE POSSIBLE RISKS?

It is not anticipated there are risks to inclusion in this registry. Only authorised personnel will have access to information provided 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 relevant Human Research Ethics Committee.

9. WHAT WILL HAPPEN TO INFORMATION ABOUT YOU?

Your information is kept in a purpose-built secure database. Monash University employs a multitude of controls to protect the infrastructure and data. These controls are regularly audited to ensure they meet global best practices and are aligned with ISO 27001 security practices. The data collected for ABDR is hosted within Australia using Australian based data centres and IT infrastructure. Data is stored on secure and resilient infrastructure located in Australia that complies with all applicable data protection and privacy obligations.

Personal information, such as your name and contact details, are kept by the registry only to ensure information about your surgery/breast device can be validated. We need these details for verification purposes should you request information about your device, and for sending 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, or for research purposes. Non-identifiable data may also be provided to researchers upon request and following appropriate ethics approval. This data is grouped and all identifiable details including names, date of birth, Medicare and hospital UR numbers are removed.

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 reports arising from the ABDR will not contain any identifiable information about you. Registry data will only be made available to researchers, government agencies or manufactures after all identifiable information has been removed. Any analysis on the data contained 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, (03) 9903.0205 or email abdr@monash.edu

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

The ABDR is an opt-out registry and your inclusion is entirely voluntary. As your surgeon contributes data to the ABDR your device details are automatically included in the registry unless you let us or your surgeon know that you do not want to be included. 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 (03) 9903 0205** or email abdr@monash.edu and state that you wish to opt out providing us the reasons for 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

The ABDR 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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