

SURGEON PARTICIPATION AGREEMENT

The Australian Breast Device Registry is a clinical quality registry aiming to identify and report on possible trends and complications associated with breast device surgery; to track the long-term safety and performance of breast implants; and to identify best surgical practice and optimal patient health outcomes. In accepting to participate in the ABDR I am agreeing to:

- display the ABDR Site Poster in my consulting room(s);
- ensure all patients are given an ABDR Patient Leaflet form prior to surgery to ensure they are aware that their data will be sent to the ABDR;
- complete one Data Collection Form or directly enter patient data into the ABDR database for every surgical procedure pertaining to a breast device, including explants and any procedure requiring return to theatre;
- be available for contact in the event that operation details require clarification;
- be aware that some of your patients may be contacted by the ABDR to complete a short follow up questionnaire (PROMs) at 1, 2, 5 and 10 years post-surgery. Patients may be contacted via text message, phone, email or letter;
- receive periodic reports on procedures that I have undertaken and their outcomes;
- receive periodic electronic correspondence from the ABDR;
- agree for my de-identified data to be used in analysis and reporting;
- agree to follow the guidelines outlined in the Data Access and Publication policy for publication or reproduction of any data provided by the ABDR;
- be named as a contributing surgeon in the ABDR Annual Report (unless I opt-out); and
- where required, act as the primary contact for patients in the event of a hazard alert. To facilitate this, we recommend that you register as a Healthcare Provider in 'My Health Record'.

Monash University's School of Public Health and Preventive Medicine will agree to:

- coordinate the Human Research and Ethics approval process for the site; necessary to implement the 'opt-out' model;
- provide me with all required registry documents, including the ABDR Site Poster and copies of the ABDR Patient Leaflet and ABDR Data Collection Form;
- distribute the ABDR Patient Explanatory Statement to patients following surgery, giving them the option to opt-out of the ABDR (if so desired);
- maintain the privacy of my patients and data contributed;
- provide me with periodic reports on procedures that I have undertaken and their outcomes, and a copy of the ABDR Annual Report; and
- facilitate my registration as a Healthcare Provider in 'My Health Record' (if so desired).

Name:

Preferred contact e-mail address:

Signature:

Date:

Please return form to: abdr@monash.edu or ABDR, Monash University, 553 St Kilda Road, Melbourne VIC 3004

