

# Criteria for ABS Registration of Innovation Projects Evaluating Novel Technologies in Breast Surgery

## Purpose

The Association of Breast Surgery (ABS), through its Academic and Research Committee (ARC), recognises the importance of supporting innovation, and aims to embrace a culture of 'No innovation without evaluation'. High-quality evaluation, including post-market surveillance that evaluates novel technologies, devices, applications or procedures used in breast surgery is an ABS priority.

The ABS aims to have oversight of the development and assessment of innovations across the UK, fostering a collaborative culture of innovation and technique development through shared learning, with patient safety as the underpinning priority.

The purpose of ABS Innovation Registration is to provide formal recognition, expert peer review, and visibility for projects that evaluate patient safety, surgical outcomes, and the evidence base for innovative surgical practice, allowing collaborative shared learning and maximising the engagement and inclusivity of all innovators across the ABS membership.

## Scope

Multicentre collaboration is encouraged, but single sites are acceptable. Endorsement may be granted to **audits, service evaluations, or QI projects** that:

- Evaluate novel or emerging surgical devices, techniques or applications (e.g. localisation technologies, imaging adjuncts, surgical instruments, reconstructive materials, digital platforms).
- Involve meaningful participation by breast surgeons or ABS members.
- Aim to generate clinically relevant data on safety, feasibility, and performance in real-world NHS settings.
- Align with the strategic aims of the ABS and its A&R Committee in promoting safe innovation, shared learning, evidence-based practice, and national collaboration.

Themes may include, but the list is not intended to be exhaustive: enhanced surgical planning, minimally invasive approaches (including endoscopic & robotic), intraoperative navigation & margins, tissue engineering (implants/meshes), surgical instruments, digital health and wearables, AI and machine learning.

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During Project Development: ABS ARC support can be provided to early-stage projects at any phase in development. Proposals for Registration of Innovation Projects may be presented to the A&R Committee. Feedback will be provided by committee members to guide study design, governance, and methodology. Written feedback may be referenced in funding or ethics submissions as evidence of independent peer review.

Formal inclusion to the ABS Innovation Registry: Following Project Development, endorsement of Registration of Innovation Project may be granted once the project protocol is finalised and all necessary governance arrangements are in place.

Inclusion in the ABS Innovation Registry reflects ABS support for the project's aims, methodology, and collaborative value but does not imply governance responsibility for project delivery or oversight.

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## Criteria for ABS Innovation Registration

Projects will be considered for Innovation Registration by the Academic and Research Committee if they meet **all** of the following criteria. Collaboration and inclusivity between sites is strongly encouraged to facilitate shared learning and prevent duplication of projects:

### 1. Scientific and Clinical Merit

- The study addresses a relevant question in breast surgery, particularly relating to the evaluation or implementation of novel technology, devices, procedures, or applications.
- The aims, methods, and outcomes are clearly defined and appropriate for an audit or QI framework.

### 2. Feasibility and Funding

- The project is feasible within participating centres and is supported by appropriate resources or local audit/QI governance structures.
- Any necessary external or institutional funding is secured.

### 3. Governance and Ethics

- The project team has confirmed that appropriate local governance and data protection measures are in place.
- Ethical approval is sought where applicable (e.g. when identifiable or sensitive data are collected).

#### 4. **Breast Surgical Involvement**

- Breast surgeons, ideally ABS members, are integral to project design, delivery, and analysis.
- The Project Management Group, Steering Committee, or equivalent includes ABS members as co-applicants or investigators.

#### 5. **Alignment with ABS Objectives**

- The project supports the strategic goals of the ABS in advancing patient care, safety, and research excellence.
- It facilitates collaboration and engagement across the UK breast surgical community, including trainees and multidisciplinary partners.

#### 6. **Dissemination and Impact**

- The project includes a clear plan for dissemination of results through peer-reviewed publication, presentation at ABS or related conferences, or integration into national guidance.
- Commitment is made to acknowledge ABS Innovation Registration in all study materials and outputs.

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## **Application for Innovation Registration**

Applicants seeking ABS Innovation Registration should submit the [Innovation Registration Form \(Appendix 1\)](#) to [lnasebova@absgbi.org.uk](mailto:lnasebova@absgbi.org.uk) at least four weeks before the next scheduled A&R Committee meeting.

Applications will be reviewed by committee members, and outcomes will be communicated formally following the meeting.

Please label all relevant attachments with study name and document name eg ALMANAC\_Ethic; ALMANAC\_protocol v3 etc

Please provide the study protocol (or draft protocol)

Please address all the following points individually, either below or as a separate attachment.

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