NOCA National Office of Clinical Audit

IBIR Irish Breast Implant Registry

Statement of Purpose:

Irish Breast Implant Registry

National Office of Clinical Audit

Document Name	Statement of purpose for Irish Breast Implant Registry
Document No	ST 10
Version No	2
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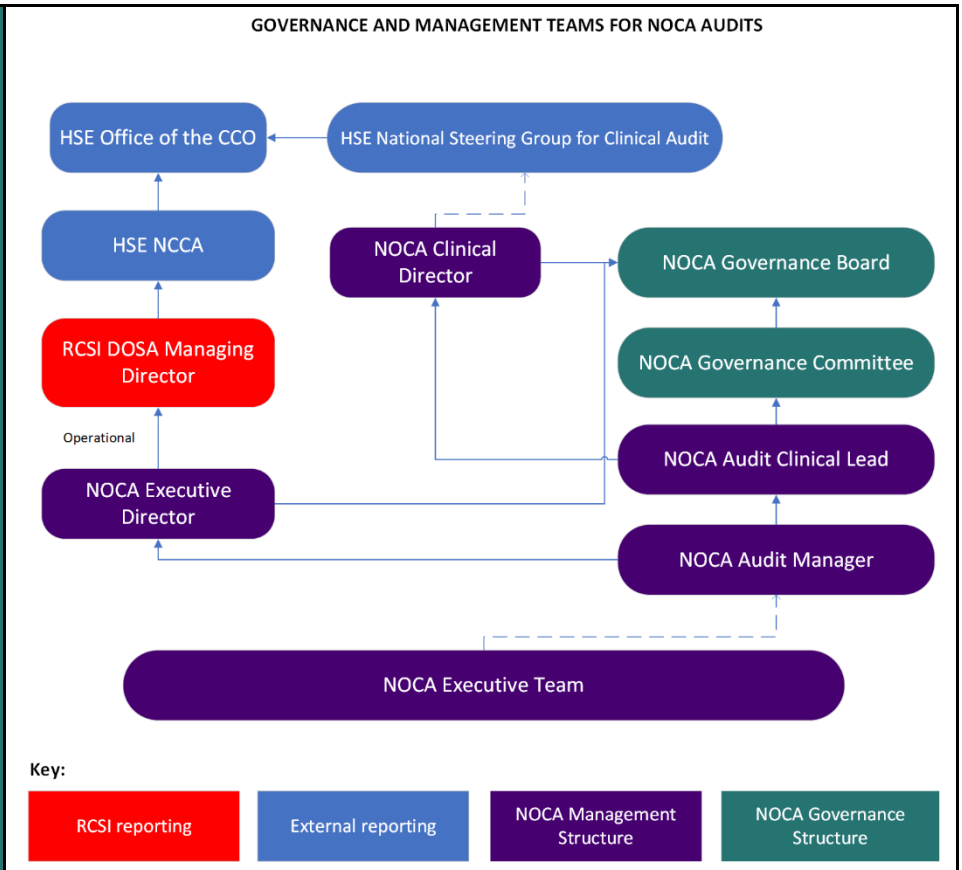
Title	Irish Breast Implant Registry (IBIR)
Year established	2023
Web address	https://www.noca.ie
Managing Organisation	National Office of Clinical Audit (NOCA)
Aim	The IBIR aims to improve patient safety and quality of care by monitoring and identifying trends and complications associated with operative techniques, breast implants and devices. The registry aims to assure patients, surgeons and their organisations of an independent early warning system for recorded breast implants and devices.
Objectives	The objectives of IBIR are to; • provide for both short and long-term monitoring of breast implants and devices to inform patient safety. • improve adherence to best practice standards by providing insights from reported data. • improve awareness for the public of the national registry for breast implants and devices. • collaborate with international breast implant registries within the International Collaboration of Breast Registration Activities (ICOBRA) to contribute towards research for greater understanding of risk factors associated with breast implants and devices.
Overall function & Purpose	IBIR will collect and record prospective data on breast implant and device surgeries, including tissue expanders and meshes, implant replacements, implant exchanges and implants that have been removed. The purpose of IBIR is to: • Develop an IBIR dataset, data validation and reporting process. • Carry out and report from a pilot of the IBIR development project. • Develop a consent model for IBIR. • Make recommendations for an implant catalogue for IBIR. • Develop an approach for the reporting of field safety notices and product recall notices. • Make recommendations for the management of patients on IBIR who have breast implant and device procedures outside the Irish healthcare system. • Make recommendations on how PROMs will be collected and reported in IBIR. • Make recommendations for national implementation for IBIR. This project work is currently in development.
Target population	Patients having procedures for both breast reconstruction and cosmetic augmentation. This includes implantation, revision and explantation procedures. Patients undergoing breast implant and device procedures in Public Hospitals, Private Hospitals and Cosmetic Clinics will be included.
Data providers	The registry is currently under development. Health Service Organisations who will provide data to NOCA will be identified as the project progresses.

Governance and Managing Structure	
Legal basis	Service arrangements: 1. Section 39 Health Act 2004 between Health Service Executive and the Royal College of Surgeons in Ireland (RCSI): This sets out the administrative and operational management of NOCA including costs and deliverables per audit. 2. Development work in progress regarding participating sites legal basis.
National Legislation & Standards	The National Clinical Audit complies with the following national legislation and standards; • Data Protection Act (2018) • HIQA National Standards for Information Management in Health and Social Care (2024) • HSE National Consent Policy (2024) • Patient Safety Act (2023) • Medical Devices Regulation (EU) 2017/745 IBIR quality indicators are under development: • In accordance with the position paper *Surgical Antibiotic Prophylaxis Duration* produced following collaboration between AMRIC, the National Clinical Programme in Surgery (NCPS), the Royal College of Surgeons (RCSI), NCP for Anaesthesia, Institute of Obstetrics and Gynaecologists, National Women and Infants Health Programme, NCP in Trauma and Orthopaedics, National Heart Programme, College of Anaesthesiologists and the HSE Antimicrobial Stewardship Advisory Group (2021).

International Legislation & Standards	IBIR complies with the following: • European Union General Data Protection Regulation 'GDPR' (2018) IBIR quality indicators are under development: • In accordance with the international consensus within ICOBRA (International Collaboration of Breast Device Registry Activities). • Begum H, Vishwanath S, Merenda M et al (2019). Defining Quality Indicators for Breast Device Surgery: Using Registries for Global Benchmarking.
Source of funding	NOCA is funded by HSE through the Office of the Chief Clinical Officer (CCO) and the National Centre for Clinical Audit (NCCA).
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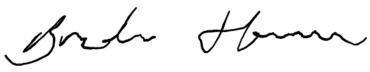
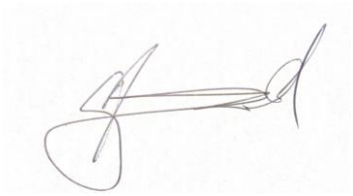
Signatures of responsible parties:	 **NOCA Head of Communications, Operations & Quality Assurance: Aisling Connolly**
	 **NOCA IBIR Project Manager: Breda Horan**
	 **IBIR Clinical Lead: Ms Éilís Fitzgerald**

Reference

Begum H, Vishwanath S, Merenda M et al (2019). *Defining Quality Indicators for Breast Device Surgery: Using Registries for Global Benchmarking*. Plastic and Reconstructive Surgery. Global open. Wolters Kluwer Health. doi: 10.1097/GOX.0000000000002348.

HSE (2021) A joint position statement on surgical antibiotic prophylaxis duration (AMRIC and NCPS) Available at: https://assets.hse.ie/media/documents/Surgical_antibiotic_prophylaxis_duration_position_statement.pdf (Accessed 13.02.2026)