CAN MY INFORMATION BE USED FOR HEALTHCARE RESEARCH?

Health care research can also help to improve care. Subject to your consent, NOCA may allow health care researchers to access your data. Before this happens, the research must be approved by a research ethics committee.

Most research will use pseudonymised data. Pseudonymised means that information that could identify you, such as your name, address or date of birth, will NOT be given to a researcher and is replaced with a code. This means the data can be used for learning and improving care, but the people analysing the data cannot see who you are. You can decide whether you wish to participate in research or not. You have the right to say no and this will not affect your treatment in any way. You can also withdraw your consent at any time.

Research for IBIR will usually include looking at factors that influence the outcome of surgery, whereby researchers investigate questions that are patient, surgery or implant related.

IBIR AND OTHER HEALTH INFORMATION

This anonymous and unidentifiable information can be used to compare performance across international breast implant registries and provide a worldwide early warning if an implant needs to be recalled.

HOW DOES NOCA KEEP MY INFORMATION CONFIDENTIAL?

It is our duty to keep your information confidential. We will do this by:

- Training staff in data protection, handling information and knowing their responsibilities
- Keeping all your information in a secure purpose-built database
- Ensuring it is only viewed by authorised staff approved by NOCA
- Ensuring compliance with data protection obligations under the General Data Protection Regulations (GDPR) 2018, Data Protection Act 2018 and Health Research Regulations 2018 and other relevant legislation.

WHAT IS THE NATIONAL OFFICE OF CLINICAL AUDIT (NOCA)?

NOCA was set up in 2012 to support national clinical audits of healthcare in Ireland. National clinical audits regularly look at different areas of care to see how well services are working and where improvements can be made. National clinical audits look at:

- how healthcare services are organised
- how care is provided
- the outcomes experienced by patients

NOCA works with healthcare providers to help them understand and use this information so they can learn from it and improve patient care over time.

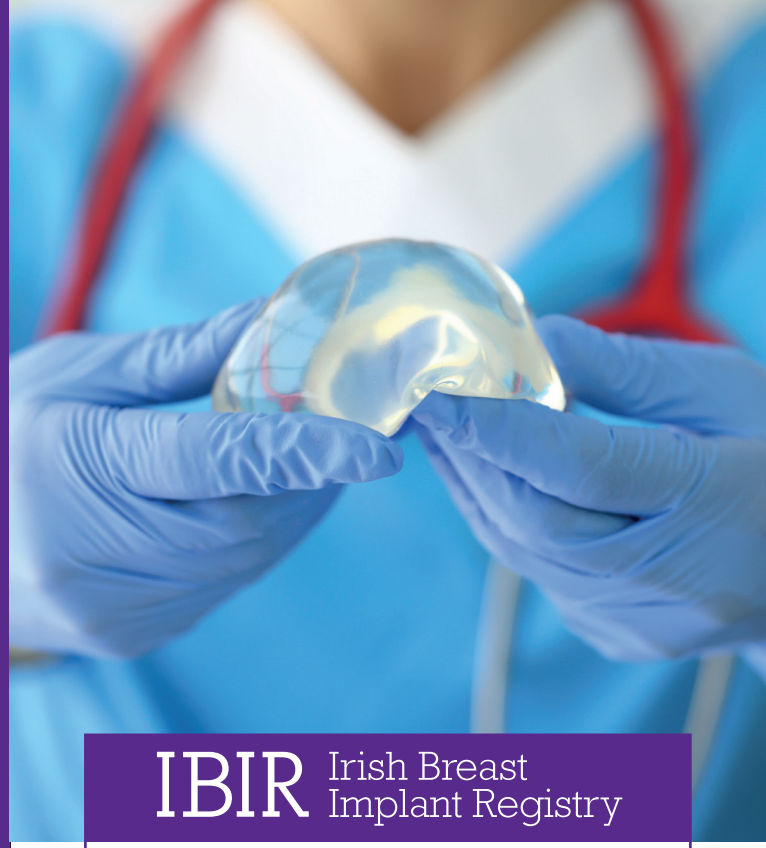
You can contact the National Office of Clinical Audit at:

4th Floor, 118 St Stephen's Green, Dublin 2, D02 X0N1.
Telephone: +353 1 4028577
Email: ibir@noca.ie Website: www.noca.ie

NOCA National Office of Clinical Audit

NOCA IBIR-PL01 v1.0 - Effective date July 2026





IBIR Irish Breast Implant Registry

PATIENT INFORMATION

YOUR QUESTIONS ANSWERED

NOCA National Office of Clinical Audit

NOCA National Office of Clinical Audit

WHAT IS THE IRISH BREAST IMPLANT REGISTRY?

The Irish Breast Implant Registry (IBIR) is a national register that collects information about breast implant surgeries performed in Ireland. This includes surgery to insert, replace or remove a breast implant. The register also collects information about tissue expanders and other devices used during breast implant surgery, including acellular dermal matrices and meshes. In this leaflet, the term breast implant refers to all of these implants, tissue expanders and devices. The IBIR is managed by the National Office of Clinical Audit (NOCA) and has been commissioned by the Health Service Executive and the Department of Health.

WHAT ARE THE BENEFITS OF IBIR?

IBIR helps monitor the safety of breast implants over time. If there is a recall of breast implants because of a safety concern, the register can help hospitals and clinics identify patients who may be affected.

WHAT INFORMATION IS COLLECTED FOR IBIR?

IBIR collects personal information and clinical data about breast implant surgeries.

- Personal information includes name, address, date of birth, sex and hospital/clinic number.

The clinical data collected by IBIR is based on a standard set of questions agreed by international breast implant registries (International Collaboration of Breast Registry Activities - (ICOBRA)). This includes questions such as:

- details of your surgery, including the type of surgery and the name of your surgeon
- surgical techniques used, including the incision site and position of the implant
- whether antibiotics and/or antiseptics were used
- details of the implant, including the manufacturer, reference number and serial number
- if an implant is changed or removed, information about any problems or complications, such as pain, infection or tightening of scar tissue around the implant (capsular contracture).

DO I HAVE TO CONSENT?

No. It is your decision to allow your personal information to be included on the register. IBIR needs your consent to record these details. You can change your consent at any time. To do this, contact the hospital or clinic where you had your surgery or write to NOCA. Contact details are provided on the back of this leaflet.

Your hospital or clinic will provide you with a patient information leaflet and consent form before your surgery. You can speak with your surgeon if you would like to ask questions and understand more about the register. You will be asked to sign the consent form before your surgery.

WHAT HAPPENS IF I DO NOT CONSENT?

If you do not give your consent, it will not affect the care or service you receive. If you say NO to consent, your personal data will not be shared with NOCA but will be available to the staff in your hospital or clinic where you are receiving care and treatment. However, details about your surgery, such as the date of surgery, hospital or clinic name, and implant information will be recorded in a pseudonymised format on the register. This means you cannot be identified from this information.



IBIR Irish Breast Implant Registry

HOW WILL THE IBIR BE CARRIED OUT?

A staff member in each hospital or clinic enters your breast implant surgery information into a secure web-based form. You will be assigned a unique IBIR identification number, which will be linked on the register to the breast implant you receive. This information is securely stored on the register computer system and accessed in the event of a safety concern.

NOCA analyses the information and sends a report back to your hospital or clinic and surgeon.

WHAT WILL HAPPEN TO MY INFORMATION?

IBIR uses your information to monitor the safety of your breast implant, identifying areas for improvement in patient care and supporting hospitals and clinics should an implant recall occur. This information is important if your surgeon or health service provider needs to contact you.

HOW IS THE INFORMATION USED?

NOCA analyses information from IBIR and produces reports for participating hospitals and clinics, as well as national reports. Hospital or clinic reports are produced four times a year and national reports are published annually. These reports will not contain any personal information about you. Only data about your surgery and breast implant are included in an analysis on the safety and quality of care relating to breast implants. The report includes information that was collected such as the types of implants inserted or removed, reason for an implant being changed and antibiotics use. National reports are made available on the NOCA website www.noca.ie.

WHO CAN SEE MY RECORDS?

NOCA and the clinical staff in the hospital or clinic where you had your surgery will have access to your register information. If you attend another hospital or clinic in Ireland participating in IBIR for another breast implant surgery, your surgeon and clinical staff directly involved in your care can use IBIR to view summary information about your previous surgery. If your surgeon needs more information, they will have to contact you or the hospital or clinic that performed your previous surgery.