NBIR
NATIONAL BREAST IMPLANT REGISTRY

Physician FAQ

General:

What is the National Breast Implant Registry?

In collaboration with the U.S. Food and Drug Administration (FDA) and breast implant device manufacturers, The Plastic Surgery Foundation (PSF) has developed the National Breast Implant Registry (NBIR) for the purpose of strengthening national surveillance for breast implant devices in the United States. The NBIR is a prospective, non-interventional, population-based, outcomes and safety surveillance registry and quality improvement initiative. The NBIR collects clinical, procedural and outcomes data at the time of operation and any subsequent reoperations. Data collection is anticipated to continue as long as breast implants are being manufactured.

Why should I participate in the NBIR?

Participating in the NBIR can help you:

- Satisfy your Practice Improvement Activity of Continuous Certification (instead of your 10 tracer cases) for the American Board of Plastic Surgery (ABPS)
- Replace the Device Tracking Form for most manufacturers, leading to less duplication of work
- Collect accurate and meaningful data on your own practice, such as rates of reoperation, implant failure and your most common complications leading to reoperation
- Contribute to patient safety for your own patients and for others across the country
- Be recognized for your commitment to patient safety, with public-facing recognition on ASPS Find A Surgeon

Will data from the NBIR be used for anything else?

The NBIR provides an infrastructure for breast implant manufacturers to facilitate the post-implant component of their federally-mandated device tracking data collection. The NBIR can also be used as an infrastructure for post-market studies and de-identified NBIR data can be used for research.

Who can participate in the NBIR?

The NBIR is currently only open to physicians practicing in the United States. We will let you know if/when the NBIR is available to physicians outside of the U.S.

Do I have to submit to an IRB in order to participate?

The PSF has received an IRB exemption determination for the NBIR. This means that a central IRB has determined that this does not require IRB review, however, it is up to your institution to determine what your IRB process will need to be. If you have a local IRB of record, they may want to review the registry protocol prior to beginning data collection. If you have any questions, please contact research@plasticsurgery.org.

Will it cost me money to participate in the NBIR?

NBIR participation is free of charge. However, if your site requires an IRB review, you will be responsible for this expense.

Is the NBIR required for all of my patients?

No. The NBIR is an all comers, opt-out registry. Patient consent is not required in order to contribute your patient's data to the registry. The design allows physicians and patients to choose whether or not they want to participate in the NBIR, and it also gives them the opportunity to withdraw from the NBIR at any time. Patients that choose to withdraw from the NBIR once they have been registered are able to discontinue future registry data collection. However, the data included prior to withdrawal will remain in the NBIR.

What will I get if I participate?

You will not be compensated for your participation in the NBIR, however, you will be recognized for your commitment to patient safety via public-facing recognition on the Find A Surgeon feature on the ASPS website (https://find.plasticsurgery.org/). Also, the data you contribute will provide insight into the safety of breast implants and can help address any concerns raised by the FDA or other agencies. By participating, you will have access through your data entry dashboard to reports about your practice, compared to the NBIR totals.

Device Tracking:

How can I use the NBIR to submit device tracking data to the breast implant manufacturers?

The NBIR case report form (CRF) was designed to capture data that is required for the purposes of device tracking. By submitting the NBIR case report form (CRF), you can simultaneously submit device tracking data to Allergan, Mentor, and Sientra.

If I use the NBIR for device tracking, does that mean I no longer have to complete the manufacturer-specific device tracking form?

If your patient agrees to participate in the NBIR, you can use the registry to submit device tracking data to the breast implant manufacturers by completing the NBIR CRF. If your patient does not want to participate in the NBIR, you cannot use the registry for device tracking and will need to use the paper device tracking form that is in the implant box.

Data Collection:

What kind of information is collected in the NBIR?

The NBIR captures patient demographic, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants.

Is my patient's social security (SSN) number collected in the NBIR?

Yes. SSN is collected for the purpose of linking reoperation procedures to the initial implant procedure to help us better understand common reasons for needing a reoperation. However, we recognize the sensitivities around providing SSN, so we allow the user to check if/when this is unavailable. In this instance, the system will link using last name and birthdate.

Can I contribute data for all of my patients who allow me to?

The NBIR is open to all women who undergo breast implant procedures in the United States.

Registration:

How do I sign up to participate?

Visit the PSRN Sign-up Portal to register to participate in the NBIR using the following link: psrn.plasticsurgery.org/signup/login.aspx.

Do I have to sign any agreements to participate in the NBIR?

Each physician must sign a Business Associate Agreement (BAA) and Data Warehousing Agreement with our registry vendor, FIGmd, as well as a Registry Participation agreement with The PSF, in order to participate in the NBIR. Participants will also have to acknowledge that they reviewed the NBIR Exhibit. These agreements can be signed online within the Sign-up Portal: psrn.plasticsurgery.org/signup/login.aspx.

Can I create an account for someone else at my practice to help me with data entry?

Yes. You may add "designated users" to enter data on your behalf when you register to participate in the NBIR.

Data Entry:

How do I enter data?

Visit the Plastic Surgery Registries Network (PSRN) to log in to your account using the following link: https://psrn.plasticsurgery.org/Dashboard/Login.aspx. Click "add case" to enter data directly into the NBIR case report form (CRF).

Is the NBIR Barcode Scanner App required for data entry?

No. The NBIR Barcode Scanner App is available to assist you with auto-populating data pertaining to the implanted device. If you do not wish to use the app, you may enter this data manually.

Can I manually enter data if I have no longer have the Unique Device Identifier (UDI) barcode/QR code?

Yes. If UDI is unavailable, you can manually enter the implant serial number and other data points related to the implanted device that are required to submit the case to the registry.

Can I retrospectively enter my breast implant procedures into the NBIR?

You can retrospectively enter data for breast implant procedures that occurred at the time the registry launched (October 2018) to present. Any procedures that occurred before the registry launched should not be entered into the registry.

I forgot my username and password to log in to my account. How should I proceed?

Visit the PSRN Dashboard using the following link: https://psrn.plasticsurgery.org/Dashboard/Login.aspx. In the white login box, click "I forgot my password". You will be prompted to enter the email address that is associated with your account. Once you provide this, an email will be sent to you with a link to reset your password. If you do not receive an email within 15 minutes, please check your junk folder and/or contact research@plasticsurgery.org.

Will I have access to the data I entered into the NBIR?

Yes. All of your data entered will appear in your "My Cases" table within your dashboard. You can export all of your cases to Excel or download a PDF version of each individual case if needed. You also have access to a report that you can submit to the ABPS to satisfy your practice improvement activity of continuous certification. In addition, there are 8 graphs that capture data you entered into the NBIR that you can review to learn more about your practice. These reports can also be exported to PDF and Excel.

NBIR Barcode Scanner App & Scanning Process:

Is the NBIR Barcode Scanner App HIPAA-Compliant?

Yes. The NBIR Barcode Scanner App was determined to be HIPAA-Compliant during a third-party risk assessment. Documentation of this assessment can be found within the app.

Where are all of the UDI barcode/QR codes located for each manufacturer?

- Allergan – implant box and packaging
- Mentor – implant box
- Sientra – implant sticker
- Ideal – implant box

What do I do if I scanned the wrong barcode for a particular case?

If your case is in an 'in progress' status, you can reset the data that auto-populated using the app. For detailed instructions, please refer to the NBIR Barcode Scanner App User Manual. If the case is submitted, please contact our Support Team (email: psf.support@bot.figmd.com; phone: 773.672.3155 ext: 2106) who will assist you with this request.

Resources:

Can someone from The PSF help me with registration and/or data entry?

YES! The NBIR Team is more than happy to help your site participate in the NBIR. Please visit ThePSF.org/NBIR to complete a Demo Request Form.

Where can I find more information and resources for the NBIR?

Additional information regarding the NBIR can be found by visiting ThePSF.org/NBIR. On this page, you can find various resources for both physicians and patients.

Do you have any NBIR resources that I can give to my patients?

Yes. Visit ThePSF.org/NBIR for all up to date resources available for patients.