NATIONAL BREAST IMPLANT REGISTRY

Physician FAQ

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 will be a prospective, non-interventional, population-based, outcomes and safety surveillance registry and quality improvement initiative. The NBIR will collect 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.

Will data from the NBIR be used for anything else?

The NBIR could be used as the infrastructure for post-market studies. In addition, deidentified NBIR data could also be used for research.

Where can I find more information on the NBIR?

Additional information regarding NBIR can be found by visiting ThePSF.org/NBIR.

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

Yes. You can download a PDF version of all of your completed Case Report Forms (CRFs). You also have access to benchmarking reports that are pulled from the data entered into the NBIR about your practice as well as compared to the entire NBIR dataset.

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.

What kind of information will be collected in the NBIR?

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

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.

Is the NBIR required for all of my patients?

No. The NBIR will be an all-comers, opt-out registry. The design allows physicians and patients to choose whether or not they want to participate in the NBIR, and also give 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.

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How do I sign up to participate?

Visit the portal to sign up for 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. These agreements can be signed online within the Sign-up Portal: psrn.plasticsurgery.org/signup/login.aspx.

How do I enter data?

Visit The Plastic Surgery Registry Network (PSRN) to log in to your account using the following link: psrn.plasticsurgery.org/Dashboard/Login.aspx. Click "add case" to enter data directly into the electronic version of the NBIR Case Report Form (CRF).

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

Visit the PSRN using the following link: 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 psf.support@bot.figmd.com.

Can I have someone else in my practice enter data for me?

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

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 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.

What will I get if I participate?

You will not be compensated for your participation in the NBIR. The data you contribute will provide insight into the safety of breast implants, and also 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.