



## BreastSurgANZ Quality Audit (BQA)

### Data Release Policy

#### Preamble

Breast Surgeons of Australia and New Zealand (BreastSurgANZ) is a specialty society for surgeons that treat breast cancer. A key purpose of the society is to provide quality assurance for its members, which is achieved through participation in the BreastSurgANZ Quality Audit (BQA).

To promote excellence in the care and management of early and locally advanced breast cancer, BreastSurgANZ encourages collaborative research based on the use of BQA data. The purpose of this document is to describe the data release process and conditions placed upon requests for data.

Most requests for data release are assessed by the BQA Committee, under the direction of the Chair. The BQA Committee is under no obligation to approve any proposal. In addition, the BreastSurgANZ Executive have absolute discretion to vary any part of the data release process on a case-by-case basis.

All research conducted using BQA data will be done so in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007. Where a research project presents more than low or negligible risk, evidence of Human Research Ethics Committee (HREC) review and approval will be required.

#### Overview

The BQA, formerly the National Breast Cancer Audit, has been in operation since 1998. When the BreastSurgANZ Society formed in 2010 participation in the BQA became mandatory for BreastSurgANZ Society members. Over 10,000 cases are entered into the BQA database each year, and the audit recorded its 200,000<sup>th</sup> episode on 6 December 2017. Participants either submit their data directly using online portals, or indirectly via an upload program. An upload program is used to transfer data from a closely matching institutional dataset at the request of a surgeon. Following data entry or upload, surgeons can only view their own patient records in the BQA.

The usefulness of the BQA is premised on the careful collection of accurate data, robust analysis, and the application of a full cycle of clinical audit. The BQA is uniquely positioned to evaluate trends in the management of breast cancer and the uptake of best-practice guidelines.

The BQA is operated by the Royal Australasian College of Surgeons under contract with the Breast Surgeons of Australia and New Zealand. The College employs staff who operate the audit under direction from the BreastSurgANZ Quality Audit Committee.

## Privacy & Qualified Privilege

There is a small possibility that BQA data, whether supplied directly by surgeons or via institutional upload, may enable patient identification; however, no information will be released for research purposes that could identify patients. The audit's status as a Quality Assurance Activity (protected by national legislation in both Australia and New Zealand) prohibits the disclosure of any information that could identify an individual participant beyond the agreed parameters of the activity. Data that might identify an individual surgeon or group of surgeons cannot be released without written consent from each surgeon involved.

## Informal and formal requests for data

Participants can freely and informally access their own data, and audit staff will assist in the extraction and analysis of such data. For descriptive statistics analysis to a surgeon's own data there is no requirement for a formal request using the BQA Data Release Form. For more complex analysis, or any requests requiring data belonging to other surgeons, the procedure to make a formal request (as outlined below) must be followed. Any external researcher who wishes to access selected BQA data but is not a participating member of the BreastSurgANZ Society must request data using the formal process.

## Process for requesting data

Formal requests to access selected BQA data, or to have data analysed by audit staff, must use the [BQA Data Request Form](#). Information that must be supplied includes the requestor's contact details, institution where the research is being conducted (i.e. university, surgeon, government), data required, timeframe, type of analysis to be performed, and how the data will be securely stored and destroyed on completion of the research. Requests for research purposes must be accompanied by a *curriculum vitae* of the requestor, HREC approval letter and all documents study documents which were reviewed and approved by the HREC.

If the request requires surgeon identification or, if the subset of data is so small that there is a risk of such identification, signatures from all identifiable surgeons are required as consent from participants.

Formal requests should be emailed to [breast.audit@surgeons.org](mailto:breast.audit@surgeons.org) for review by the BQA Committee.

## Role of BQA Committee

The role of the BQA Committee includes reviewing requests for audit data and providing a timely response. They may, if necessary, request further information from the requestor.

The Committee will consider:

- The scientific merit of the research
- The importance of the research to existing public health issues
- Any potentially negative political, workforce or other impacts
- The intended purpose of the research
- Whether the request will result in a duplication of research
- Whether the data requested is available.

An important consideration for the Committee is to ensure that there are no potential breaches of the obligations and commitments given to national agencies which seek to protect the privacy of

individuals under 'qualified privilege' arrangements (specifically the protections afforded to audit participants under the Australian Commonwealth Qualified Privilege Scheme and the New Zealand Protected Quality Assurance Activities provisions).

If concerns are raised, the request may be referred to the BreastSurgANZ Council and/or the BreastSurgANZ Executive for further consideration. The BQA Committee will ensure that the least sensitive level of data practicable is released to fulfil the requirements of the research proposal.

The BQA Committee may recommend that the data be analysed in-house, without the release of raw data to the requestor. In this situation, the cost of data analysis will need to be agreed by the requestor prior to any analysis proceeding.

Once a final decision has been made by the BQA Committee, audit staff will inform the requestor of the decision in writing.

## Ethics approval

The BQA Committee requires evidence of ethics approval from a Human Research Ethics Committee (HREC) where proposed research demonstrates higher than low or negligible risk. If the research has been reviewed and approved by a HREC a copy of the ethics approval and approved study documents will need to be provided to the BQA Committee. Ethics approval is not required by the BQA Committee if the data request is not for research purposes. It is suggested that the requestor discuss their project with their institution's Research Governance Officer, or equivalent, prior to making a request for data, as the institution may have its own requirements for staff conducting research.

## Charging for data requests

The BQA Committee may decide that a request can be approved, but that some financial contribution must be made.

Fees are calculated based on the following factors and applied at the discretion of the BQA Committee:

- Number of hours required
- Complexity of data analysis
- Level of expertise required
- Whether external consultation is necessary
- Costing will take into consideration the 'accumulated value' of the BQA data. This will factor in the number of data fields required and the number of years of data requested. This is to reflect the previous costs in accruing and storing the data and the database structure
- Members will be charged at a lower rate than external academic bodies, and these rates will be lower again than those charged to commercial entities.

An estimate of cost will be provided prior to the commencement of any work.

## Release and use of BQA data

Released data is confidential and remains the property of BreastSurgANZ.

The requestor must acknowledge and agree to the terms of data release. Terms will include compliance with national privacy laws and 'qualified privilege' provisions in Australia and New

Zealand. The requestor remains liable to BreastSurgANZ for any breaches of these provisions and the Society retains the right to revoke access to data if the requestor does not abide by the terms of data release.

The provision of data will depend on the available resources at the time of request. Requestors will be given a password protected file. Larger files, and those that include potentially identifying information, will be transferred using secure online file-sharing software.

Data may only be used for the purpose approved by the BQA Committee. That is, the purpose stated on the [BQA Data Request Form](#) and associated study documents provided for the BQA Committee's review, or a negotiated purpose subsequently approved by the Committee.

Released data must not be disclosed to third parties, combined with other data sets, or linked with other data without specific prior approval by the BQA Committee. The released data set must only be used for the purpose stipulated in the contract of release.

The successful applicant will have the use of selected data up to the proposed completion date, and six-monthly progress reports must be made to the BQA committee. When the approval period has lapsed, the requestor will be asked to submit an amendment release to extend the data release approval or cease using the data provided. Data must be kept for a minimum of five years post publication, if the data is published.

After the approval period (or post-publication period) has ended, the applicant will be asked to provide written confirmation that the provided data has been destroyed.

## BQA involvement in reporting of results

The BQA Committee may choose to release data on the condition that audit staff and/or one or more contributing BreastSurgANZ members participate in the data analysis process and reporting. In such cases, the staff member and/or BreastSurgANZ member would be a co-author in any arising reports or publications. This will be made clear to the requestor in writing prior to the release of any data.

BreastSurgANZ must be provided with a copy of all resulting reports, manuscripts or presentations, 14 days prior to publication or presentation. BreastSurgANZ may provide comments and/or reasonable amendments to the publication within 14 days of receipt. If no such comments or amendments are provided within those 14 days, the researcher can publish.

## Acknowledgements

The BQA must be acknowledged as the source of data in any report, publication or presentation.

When external researchers prepare a manuscript primarily based on BQA data, the 'BreastSurgANZ Quality Audit' must be acknowledged, regardless of whether any audit staff or BreastSurgANZ members were involved in the preparation of the manuscript.

When the BQA data forms part, but not the sole focus of the research, 'BreastSurgANZ Quality Audit' must be explicitly acknowledged as a source in the 'Acknowledgements' section.

The following acknowledgement is required in either situation:

The authors acknowledge the data reported here has been supplied by the Breast Surgeons of Australia and New Zealand from the BreastSurgANZ Quality Audit. The interpretation and reporting of these data are the responsibility of the authors and should not be seen as an official interpretation by the BreastSurgANZ Quality Audit or Breast Surgeons of Australia and New Zealand.

The source and treatment of the data should also be made clear in the 'Methods' section of any manuscript. Preferably the abstract should include the phrase 'BreastSurgANZ Quality Audit (BQA)' to allow for searching of audit publications.

BreastSurgANZ reserves the right to publicize with acknowledgement any arising publication on their website, in their Newsletter or in the form of a general media release.

## Data sharing / data availability for publications

Many journals now require a data availability statement upon submission of a manuscript. Data from the BQA must not be shared by uploading to publisher's websites or data repositories. Where such a statement is required by the publisher, we recommend the following:

*The data that support the findings of this study were obtained from the BreastSurgANZ Quality Audit (bqa.org.au) under approved data release 202X-X. Restrictions apply to the availability of these data. To gain access, requestors will need to submit a data request form to the BQA quoting the release number and have their request approved.*

## Consumer summaries

BreastSurgANZ has a valuable relationship with consumers and seeks to ensure that current developments in research are readily accessible.

It is a condition of data release that any resulting publications or presentations are accompanied by a draft consumer summary authored by the requestor or delegate. A final approved summary will be released after general agreement is reached between authors, the BQA consumer representative, and the Chair of the BQA Committee.