BREAST ACCESS POLICY

About BREAST

Breast Screen Reader Assessment Strategy (BREAST) is an education tool and a resource for research in cancer detection through screen reading digital mammography (DM) and digital breast tomosynthesis (DBT) that was developed by the University of Sydney and BreastScreen NSW. BREAST is used by clinicians (radiologists, radiology registrars, breast physicians, etc.) for training and quality assurance. Researchers use BREAST as a resource for DM/DBT cases, screen-reader data, and access to image display equipment. BREAST is currently funded by the Australian Commonwealth and Cancer Institute NSW (previous funders include the National Breast Cancer Foundation, New Zealand Ministry of Health and the Royal Australian and New Zealand College of Radiologists).

The clinicians who use BREAST for training within BreastScreen Australia and New Zealand are registered through their breast screening services. Clinicians outside of these organisations and regions participate in the test sets through BREAST workshops at various radiology meetings and by special request to the BREAST team. The data that clinicians enter into the system are de-identified and stored for use in reporting and research.

What resources are available?

Researchers are invited to apply for access to:

1. DM or DBT cases known as **"test sets"** and associated truth locations and lesion type descriptions.
2. Screen reader data in the form of -
   a) **"form data"** referring to readers' responses to a survey/questionnaire on individual attributes and clinical experience
   b) **"scores"** referring to the results in a test set (consists of sensitivity, lesion sensitivity, specificity, ROC and JAFROC FOM)
   c) **"raw data"** referring to all selections and markings placed in the scoring software in a test set
3. Access to the "**equipment"** in the BREAST Mobile Imaging Platform that is housed at the Cumberland Campus, consisting of DM/DBT PACS workstation units.

Who can access the resources of BREAST?

The resources of BREAST are open to researchers from a range of institutions such as Universities, medical research institutes, and commercial research groups such as DM/DBT equipment and PACS companies, subject to conditions outlined in this Access Policy. Applications from international research groups will be considered.

Each research project applying for access to this data must have approval from a duly constituted Human Research Ethics Committee (HREC) or appropriate equivalent. Applications from researchers outside of Australia must demonstrate approval from a HREC or equivalent that is recognised by the Access and Management

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Committee as applying similarly rigorous standards of review. BREAST participants understand that their data used in research are de-identified.

A key issue for Access and Management Committee review is to ensure that the research supported by this resource fits within the boundaries of informed consent provided by BREAST participants.

Further information about the nature of the resource can be obtained by contacting Chief Operation Officer of BREAST. Contact details are on page 4 of this document.

Ethical Approval

The images used in BREAST test sets are from the BreastScreen NSW Digital Image Library with ethics approval from the NSW Population & Health Services Research Ethics Committee (until 2015), the institutional approval from 2016 onwards via a Memorandum of Understanding between Cancer Institute NSW and The University of Sydney (Version 1.5, 29 March 2016) and the institutional ethics approval for Databank of BREAST from The University of Sydney (to 2023)

Researchers wishing to access the BREAST resource must show the Access and Management Committee that their application is both ethically and scientifically appropriate. Researchers must also demonstrate that their project has local HREC approval before any data is released.

Approval Process

1. Expression of Interest	Brief summary to be supplied by email to the Chief Operation Officer. Informal discussion with BREAST project staff to determine how the resource can meet the needs of research project.
2. Stage 1 review	Formal submission of application for review by BREAST team. Further information of clarification may be requested from the researcher.
3. Stage 2 review	Application referred to BREAST Access and Management Committee (BAMC) for review with recommendations and comments from Management.
4. Data / Images / Access to equipment supplied to researcher	Cost recovery fees may apply.

Expression of Interest (EOI)

The purpose of the EOI is to ensure that the request is within the scope of the BREAST resources and could reasonably be supplied. The EOI will provide a broad outline of the nature of the project and the scope of the data request. The EOI should be no more than 1 page in length and sent via email to the Chief Operation Officer. The EOI can be drafted in dot-point form, containing the project aim, project design, a description of the BREAST data required and a list of the project investigators.

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The EOI will then be distributed by email to the BREAST team. A response will be received within 10 working days in most instances. Included in the response will be a request for full application submission and an approximate quote for any relevant cost recovery charges.

Stage 1 Review for consideration of the Manager and Directors

Applicants must provide in the full application form a detailed scientific proposal including aims, project design, and relevant background information. A detailed research plan should be provided including methods, references and a timeline for their work.

The application must be completed and signed by the Chief Investigator or the most senior researcher in the team.

The application should provide a detailed justification for any data request.

The application should include details of existing funding and any prior scientific and ethical review.

Stage 2 Review for consideration of the BAMC

All application documents provided by the applicant will progress to Stage 2 Review along with the recommendations of the BREAST team.

Amendments to existing projects

In the event that existing projects using BREAST resources need to make changes to the project design, applicants are required to notify the Chief Operation Officer by email and submit the original application form with track changes containing the amended information. This amended form will be subject to Stage 1 review, and if necessary, will progress to Stage 2 Review. If the amendments are approved by Management in Stage 1, the applicant will be advised by email and no further review will be required.

Cost Recovery Fees

BREAST may levy charges which aim to recover some of the costs associated with collecting images, preparing and collating data, and access to equipment such as storage systems, postage and freight, and equipment peripherals.

Responsibilities of Investigators using BREAST data

- BREAST data must only be used for the purposes described in the approved research proposal and cannot be passed on to any third party without the permission of the BREAST Management.
- Any publications, reports or presentations arising from the use of BREAST data must acknowledge the BREAST project and its funder(s). Suggested wording for this acknowledgement will be provided by BREAST, e.g. This project is supported by The BreastScreen Reader Assessment Strategy (BREAST), which is finally supported by Department of Health and Cancer Institute New South Wales in Australia

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- A copy of any publication/document that result from this collaboration must be lodged to BREAST within three months after completion.
- Following publications, BREAST requests that researchers submit the raw data generated using BREAST resources back to BREAST. This may be made available for future use by other researchers and will
- Investigators must agree to their research project summary being published on the BREAST website.
- All changes and amendments to the research project must be reported to the Chief Operation Officer.
- In the case of access to other data that correspond with but is not within the scope of BREAST, such as additional individual attributes of readers, clinical audit data, and other such records, investigators must seek separate consent from clinicians subject to the project ethical approval. BREAST can mediate this process subject to approval by the BAMC.

Dispute Resolution

The Chairs of the BAMC will deliberate over disputed access issues.

Contact Details

BREAST Chief Operation Officer can be contacted via email t.li@sydney.edu.au

For further information visit the website http://sydney.edu.au/health-sciences/breastaustralia

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