



Sample Access Policy

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Policy for

Application for, and approval of use of samples (sample access policy)

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Authorised by:

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Document Review History

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1.0 PURPOSE AND SCOPE

This Policy describes the eligibility criteria for access to samples from Breast Cancer Now Tissue Bank (as hereinafter defined).

2.0 DEFINITIONS

- 2.1 The Breast Cancer Now Tissue Bank (BCNTB) shall be referred to as the Tissue Bank.
- 2.2 The Breast Cancer Now Tissue Bank Advisory Council shall be referred to as the Tissue Bank Advisory Council (TBAC).
- 2.3 The Breast Cancer Now Tissue Bank Access Committee shall be referred to as the Access Committee (AC).
- 2.4 The researcher applying to access and use the Materials held in the Tissue Bank shall be referred to as the Applicant.
- 2.5 Material Transfer Agreement shall be referred to as the MTA.
- 2.6 Material refers to any tissue (including cells or their DNA/RNA isolated from tissue) or fluid taken from the human body.
- 2.7 The Request is the submitted application for use of the Material held in the Tissue Bank.

3.0 RESPONSIBILITIES

- 3.1 The Tissue Bank Advisory Council is responsible for:

- 3.1.1 Approving the policy for provision of Material from the Tissue Bank.
 - 3.1.2 Approving new Standard Operating Procedures related to provision of material from the Bank.
 - 3.1.3 Advising on best practice related to biobanking.

3.2 The Access Committee is responsible for:

- 3.2.1 Recommending material release based on the policy for provision of Material from the Tissue Bank.
 - 3.2.2 Reviewing all applications for use of Materials held within the Tissue Bank in order to ensure they are of adequate merit to release material, and that valuable and efficient use is made of the Tissue Bank's contents.

3.3 Breast Cancer Now is responsible for:

- 3.3.1 Assisting and guiding Applicants through the application process.

- 3.3.2 Initiating communication between Applicants and Tissue Bank staff to ensure the most appropriate format of Materials is requested for the research proposed.
- 3.3.3 Checking that adequate funding is in place to do the proposed work with samples, that the work is covered by the BCNTB/individual centre ethics approval and that whether the application severely depletes the Tissue Bank of its stock.
- 3.3.4 Forwarding all relevant information to the Access Committee.
- 3.3.5 Work with Access Committee Chair and Deputy Chairs to aid final decision on Material release where concerns are raised at Executive Committee (EC) or Specialist Group Review.
- 3.3.6 Informing Applicants of the Access Committee's decision.
- 3.3.7 Coordinating the tissue sample preparation and collation prior to being delivered to the Applicant.
- 3.3.8 Preparing, providing and retaining an MTA in respect of each project.
- 3.3.9 Ensuring that the reports on all research undertaken using the Materials are provided to the Tissue Bank bioinformatics personnel at Barts Cancer Institute, Queen Mary University of London, who shall ensure that the information provided is included in the bioinformatic platform of the Tissue Bank.

4.0 **THE ACCESS COMMITTEE**

- 4.1 Due to the nature of material in the Tissue Bank all applications will be assessed and reviewed on the basis of merit by the Access Committee. The scrutiny applied to technical and scientific merit of each application will be dictated by the rarity of the material.
- 4.2 The Access Committee will aim to recommend release of Materials for most applications. In the case of non-rare materials the risk of releasing material to a non-specialist group, with minimal scientific and technical review is accepted.
- 4.3 For rarer materials unless there are serious scientific or technical concerns which cannot be adequately addressed by the applicant, these should also be released.
- 4.3 The Access Committee will consist of a panel of at least 40 individuals covering a range of specialities relevant to breast cancer research.
- 4.4 The EC (a subcommittee of AC) will consist of at least eight scientists/clinicians and 4 patient advocates per three month sitting. For each application 4 scientists/clinicians and 2 patient advocates shall review the

application. At Specialist Group review the panel will consist of 4 experts and 1 patient advocate.

- 4.5 Where an application is for part of a specific collection of Material made available through the Tissue Bank (e.g., SLOANE or POSH studies), a representative for that collection will form part of the Specialist Group reviewing the request.

5.0 **THE TISSUE ACCESS POLICY**

5.1 **Overview of the Tissue Access Policy**

- 5.1.1 The Tissue Bank consists of cancerous and normal tissue and primary cultured cells. All samples are taken from consenting donors for use in basic and translational research projects and stored at Human Tissue Authority (HTA) licenced premises.
- 5.1.2 The contents of the Tissue Bank are open to applications from any researcher seeking to utilise banked Material for legitimate research purposes. The Tissue Bank aims to provide fair access to all in order to maximise public benefit and advance medical knowledge.
- 5.1.3 A searchable online catalogue is available by accessing the website at domain name **www.breastcancertissuebank.org** (the Website). Each sample will have a minimum data set available. There is currently no facility to request data only. The data mining facilities provided through the custom built bioinformatics resource allow rapid analysis and integration of literature data as well as highly efficient and coordinated use of samples, reducing duplication of effort.
- 5.1.4 Applications may be submitted at any time by a research investigator and will be considered in the order in which they are received. For requests for tissue (rather than fluid or cells), the Applicant will be asked to indicate whether they have a named pathologist as a Coapplicant or whether they require support from the Tissue Bank pathologists. It is strongly advised that a pathologist assist in work using tissue; in the case of rare samples, not having pathology support may prevent release of samples after Specialist Group Review. Breast Cancer Now can facilitate links with a pathologist if necessary. All of the details on the form should be completed as any missing information may delay the review process.
- 5.1.5 Applications to obtain Materials from the Tissue Bank should be submitted electronically, via the Website. Submissions should contain sufficient detail regarding intended use, in order to allow the Access Committee to make a full and proper assessment of the scientific and technical merit of the project and the anticipated patient benefit. If and when approval is received for a given project, access to Material from the Tissue Bank is dependent on the Applicant agreeing to the conditions of access and signing an MTA.
- 5.1.6 If the material is in abundance, there is adequate ethics cover, funding is in place and peer review of the project has taken place the EC will review

the application for material. This is a light touch review and reviewers will provide scientific advice to help the applicant.

- 5.1.7 If the material is scarce in the Bank or if there has been no adequate peer review of the project, a Specialist Group review will take place. This group will be matched to the application based on expertise and will scrutinise the application's scientific and technical merit, and the justification of the sample numbers required.
- 5.1.8 The application will go to Specialist Group review if serious concerns raised by EC and these are upheld by the Chair of the Access Committee.
- 5.1.9 Samples are available to academic researchers in the UK and Ireland. Breast Cancer Now will consider applications from the international research community and industry on a case-by-case basis.

5.2 Eligibility for Access

- 5.2.1 Applications are welcome for studies in all areas of basic and translational breast cancer research projects except cosmetic testing and reproductive cloning.
- 5.2.2 Applicants should be employees of a recognised academic institution or NHS organisation with experience in a relevant medical research area. Applications from academic applicants who are associated with a commercial organisation may be considered on a case-by-case basis.
- 5.2.3 Funding for the proposed research must be secured prior to applying for tissue. A letter to indicate that funding in principle has been granted may also be acceptable. Breast Cancer Now requires reassurance that there is funding for the work to take place so that the samples are not wasted.
- 5.2.4 The proposed research must have been approved by a high-quality peer review process prior to applying for tissue.
 - 5.2.4.1 We consider any member of the Association of Medical Research Charities (AMRC) and public funding bodies, such as the Medical Research Council, as having high-quality peer review processes. Other organisations will be considered on a case-by-case basis.
 - 5.2.4.2 Projects receiving faculty funding, or any other funding considered as internal institutional funding will be considered, but the full research proposal, the peer review comments and an outline of the internal peer review procedure must accompany the application for tissue. BCN reserves the right to judge what a high quality peer review process looks like.

5.3 Prioritisation of Access

- 5.3.1 Requests will be assessed on a case-by-case basis and will usually be released in the order the Requests are approved.

- 5.3.2 Where demand for Material exceeds its availability, access will be prioritised based on scientific and technical merit (as judged by the Access Committee).
- 5.3.2.1 As the amount of Material available is limited, Applicants who propose similar studies may be put in touch with each other with a suggestion that they collaborate. If Applicants are not willing to collaborate then both applications will be considered as usual. However, it is very unlikely that access to the Tissue Bank will be granted for two very similar studies; the AC will decide on material use based on merit.
- 5.3.3 In the unlikely event that demand exceeds our ability to review applications in a timely manner a triage system will be used to determine which applications should be prioritised for review based on scientific and technical merit (as judged by the Access Committee Chair and Deputy Chair).

5.4 Ethics approval held by the Tissue Bank

Please contact the Tissue Bank Coordinator regarding ethics approval by email or contact us at tissuebank@breastcancernow.org. Projects must be covered by BCNTB's overarching Research Tissue Bank ethics approval or the individual Tissue Bank centre Research Tissue Bank ethics approval in order for material to be released.

Appendix A - diagram of access process

