

## **Breast Cancer Now Tissue Bank Tissue Access Committee Terms of Reference**

### **1. Purpose**

The Tissue Access Committee (TAC) shall operate as a virtual Committee and be responsible for the review of requests to access clinical material in the Breast Cancer Now Tissue Bank (BCNTB), to enable the release of as many patient samples (with their associated data) as quickly as possible to the research community.

### **2. Responsibilities**

**2.1** The TAC will be responsible for:

- Reviewing the merit of applications to acquire biological materials from the BCNTB to facilitate biological material based breast cancer research.
- Agreeing and implementing the policy for the provision of material from the Tissue Bank.
- Reviewing all proposals assigned to them within the deadlines set and to maintain dialogue with the BCN research resources team regarding periods when they are unavailable.

**2.2** Applicants to the BCNTB will be responsible for:

- Making sure they have consulted with the necessary advisers, such as pathologists, clinicians or statisticians. The BCNTB can facilitate links for applicants who do not have these connections.
- If less experienced in the cancer field or in the use of human tissue samples, ensuring that a more experienced scientist/clinician is listed as a co-applicant, to assist in development of the research proposal.

**2.3** Breast Cancer Now will be responsible for:

- Offering all applicants, the opportunity to consult with a BCNTB PI prior to submitting their request, to advise the applicant on the details of the request.
- Providing full guidance notes to applicants so they include the right information in their application.
- Ensuring ethical cover is in place.
- Ensuring that appropriate peer review by an AMRC-registered organisation, public funder or equivalent has taken place.
- Ensuring that funding is in place and if there is ample sample supply in the BCNTB to fulfil the application.
- Ensuring a Material Transfer Agreement (MTA) and Data Sharing Agreement (DSA) are signed prior to material release. The MTA and DSA will ensure that the following are addressed:
  - Acknowledgement of BCNTB is made in publications.
  - Protections are in place with regards to patient data/anonymity and future data processing.
  - BCN will receive a profit share in relation to any commercialisation due to released material.
  - Cost recovery is applied in line with the BCN's cost recovery model.
- Ensuring timely release of the requested samples to the applicant
- Providing the TAC with a quarterly newsletter with details of BCNTB activity and requests

### 3. Membership

#### 3.1 The TAC will comprise:

- Independent members, appointed by the tissue access representative from the Tissue Bank Advisory Council, in consultation with the Director of Research and the Research Directorate, to ensure that the TAC representation includes (but is not exhaustive to) expertise from the following areas: breast cancer research; pathology, biobanking; biobanking governance; surgery and (bio)informatics. This is to include a balance of clinical and non-clinical members.
- A minimum of four lay members, two of which should have experience of breast cancer as a patient and another two with experience as either a patient, relative or carer.
- PIs in receipt of a BCNTB grant.
- Representatives of 'special collections' that have been donated to/acquired by the Tissue Bank.
- Members will be appointed for an initial term of three years, renewable by mutual agreement for a second term of three years and membership managed to ensure efficient rotation of members. Members will be scientifically diverse and reflective of the protected characteristics recognised in equality principles.

### 4. Review Process

**4.1** Subject to initial checks by BCN, TAC members will be selected to review requests based on their expertise.

**4.2** Three TAC reviewers will be selected for each request (two experts and one lay), plus the TBAC tissue access representative.

**4.3** The selected TAC reviewers will be contacted by email and asked to review the request in line with the following questions:

- Does the research have the potential to benefit breast cancer patients?
- Are there any significant risks to releasing the samples?

**4.4** Reviews must be submitted within five working days from receipt of the request to review.

**4.5** For most requests, where there are sufficient samples in the bank to honour the request, we would expect the TAC reviewers to respond in the following way:

- Accept (no comments)
- Accept with scientific advice to be mailed anonymously via the review system to the applicant. The approval is not dependent on advice being accepted.
- Request further information:
  - If a TAC reviewer requires further information before approving a request, they will need to email [eleonor.garrattsmith@breastcancer.org](mailto:eleonor.garrattsmith@breastcancer.org) detailing the information required.
  - The request will be forwarded (anonymously) to the applicant
  - The applicant will have five working days to respond
  - The TAC reviewers will be notified once the requested information has been made available and will have a further five working days to approve or reject the request.
- In exceptional circumstances, if a reviewer wants to reject a request then they select this response. They will then need to email [eleonor.garrattsmith@breastcancer.org](mailto:eleonor.garrattsmith@breastcancer.org) detailing the reason for rejection.

**4.6** The final decision to approve or reject a request will be based on the majority decision of the TAC reviewers.

**4.7** The TBAC tissue access representative and BCN's Director of Research reserve the right to review concerns raised by TAC reviewers and override these if the risk of the material being released is deemed low.

### 5. Conflicts of Interest

- 5.1 Members will be asked to declare their conflicts of interest on an annual basis and on receipt of details of any tissue requests.
- 5.2 The Tissue Bank Co-ordinator will record members' interests and deal with any conflicts of interest. Where conflicts of interest arise, or in dispute, the Chair of TBAC and the TBAC tissue access representative will work with the Director of Research to make a decision.
- 5.3 Further details surrounding the management of conflicts of interest are detailed in the Conflicts of Interest Policy made available to all members.

## 6. Additional expectations of TAC members

- 6.1 TAC members may be asked to provide advice to Breast Cancer Now staff as required.
- 6.2 TAC members will be expected to represent and promote Breast Cancer Now's work amongst the worldwide breast cancer research community.

### **Date of Approval by the TBAC:**

**These Terms of Reference should be reviewed before:** 01 March 2021