BCT GUIDELINES FOR TRANSLATIONAL RESEARCH APPLICATIONS

WI-T-10

Version 1.0, 20th April 2021

Revision History:

Version Number	Version Date	Summary of Revisions Made
1.0	20 APRIL 2021	Original version

1. BCT TISSUE BANK

Breast Cancer Trials (BCT) maintains a Tissue Bank of specimens collected from participants who take part in clinical trials conducted by the Group.

The material collected is, in principle, regarded as donated by the participants for research; BCT therefore has custodianship of the samples. Participant consent for future unspecified research on tissue samples is determined at the time of participant entry to the clinical trial and is recorded by BCT.

Specimens held in the BCT Tissue Bank are intended for use in projects that are likely to translate into improved outcomes for patients with breast cancer, either directly, or via future projects. Collaboration with commercial companies is not excluded, but no material or data resulting from translational research will be sold for profit. Where intellectual property may arise from research, intellectual property rights will remain with BCT and any financial gain will be reinvested in BCT research.

Researchers who receive tissue specimens to conduct approved research projects must adhere to the same ethical standards as BCT.

2. AVAILABILITY OF SPECIMENS FOR TRANSLATIONAL RESEARCH

Stored tissue specimens may be released for translational research projects proposed by BCT Members or non-members; for all projects approved for ongoing development, researchers must become BCT members.

Translational Research Applications may be submitted to BCT at any time, however tissue collected for a specific trial will not generally be released until after planned protocol analyses are completed. The tissue specimens are intended for use in projects that are likely to translate into improved outcomes for patients with breast cancer, either directly, or via future projects.

Collaboration with commercial companies is not excluded, but no material or data resulting from translational research will be sold for profit. BCT Members/institutions who receive tissue specimens to conduct approved research projects must adhere to the same ethical standards as BCT.

Where intellectual property may arise from research, intellectual property rights will remain with BCT and any financial gain will be reinvested in BCT research.

The BCT Tissue Bank is managed under the direction of the BCT Board of Directors and the BCT Scientific Advisory Committee (SAC).

3. REVIEW OF APPLICATIONS

The BCT Operational Executive (Director of Research (or designee), SAC Chair, SAC Deputy Chair, Chief Executive Officer, Chief Operating Officer - Research) will appraise the scientific value and the priority of proposed research projects and determine the proper use of material. BCT will check the availability of tissue for the proposed project and will report to the Operational Executive.

The Operational Executive will nominate peer reviewers to review the research application, who will provide a recommendation to the SAC via the BCT Translational Research Review Form. SAC will endorse the research.

3.1. ETHICS AND PEER REVIEW

Applications must include a commitment to obtain appropriate Human Research Ethics Committee approval for research on material released from BCT Tissue Bank.

Applications that have been peer reviewed by major scientific bodies (including the NHMRC, NIH, CINSW, NBCF, etc.) will be subject to minimal scientific review.

4. PILOT PROJECTS

Researchers may request permission to conduct a pilot project before submission of a full application. In general, a pilot project involves a limited number of specimens e.g. 5 x frozen tissue; <15 FFPE blocks. The same processes and decision criteria will be required, as well as a full application, although the need for peer review may be waived. Pilot projects will only be approved for one year. The decision to assess an application as a pilot or full project rests with BCT. It is expected that pilot projects will have potential for development into larger projects funded by peer reviewed grants.

5. BCT MATERIAL TRANSFER AGREEMENT

The Chief Investigator(s) of the proposed research project and/or head of any research facility to which tissue material, or any derivatives thereof, is shipped for a specific project must sign a BCT Material Transfer Agreement stating the use of the material and the rules applicable for surplus material.

Surplus material must be shipped back to the BCT Tissue Bank.

All publications arising from Translational Research projects from BCT material will follow the BCT Policy on Publications.

<u>The Chief Investigator(s) of the project must</u>:

- Sign the Material Transfer Agreement and agree not to distribute the material or data to investigators or institutions who are not named in the approved application.
- Ensure BCT is acknowledged in any resulting publications, in addition to any BCT members who fulfil authorship criteria for the project.
- Submit an annual report on the project for the Operational Executive.
- Meet costs involved in preparing and shipping biological specimens and in extracting data from the clinical trial database, if required.
- Notify BCT of project completion.
- Submit a copy of published data to BCT, if requested.
- Return unused material to BCT.
- Obtain a Material Transfer Agreement from any collaborator to whom they wish to pass on material for use in the approved project. This must be notified to BCT with a request that BCT consider the addition of a collaborator to the project.