SOP Reference: BCNTB/SOP/001

Standard Operating Procedure for

Specimen collection

Version number: 2
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Document review history

<table>
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<tr>
<th>Version Number</th>
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<td>Uma Ekbote</td>
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<td>Admin edits, change in participating centres and sample processing, updated HTA codes of practise and standards reference</td>
<td>Rosie Robertson, Angie Berwick, Dr Fabricio Barros, Sameena Iqbal, Uma Ekbote</td>
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1.0 PURPOSE AND SCOPE

1.1 This SOP provides the protocol for collection of specimens from patients who have given consent for their tissues to be stored in Breast Cancer Now Tissue bank to be used for research purposes.

2.0 DEFINITIONS

2.1 The Breast Cancer Now Tissue Bank shall be referred to as the Tissue Bank.
2.2 Material refers to any Tissue within the Tissue Bank.
2.3 Tissue refers to any tissue or fluid taken from the human body.
2.4 The Institutions are the, University of Leeds, University of Nottingham, Barts Cancer Institute, Queen Mary University of London, University of Sheffield and University of Southampton.
2.5 Bart Cancer Institute Breast Tissue Bank is referred to as BCIBTB.
2.6 Formalin Fixed Paraffin Embedded is referred to as FFPE.

3.0 REFERENCES

3.1 Human Tissue Act 2004
3.2 Human Tissue Authority, Codes of Practice and Standards, April 2017;
   3.2.1 Code A : Guiding principles and the fundamental principle of consent
   3.2.2 Code E: Research and Standards
3.3 BCNTB/SOP/002: Tissue Processing for Paraffin Wax Embedding
3.4 BCNTB/SOP/003: Snap Freezing Fresh Tissue
3.5 BCNTB/SOP/009: Approach to Consent
3.6 BCNTB/SOP/024: Data Collection
3.7 BCNTB/SOP/034: Preparation of Human Breast Tissue for Generation of Organoids

4.0 HAZARDS AND PRECAUTIONS

4.1 Vaccination:

   All staff involved in tissue collection should have Hepatitis B vaccination under the guidance of their local Occupational Health Service.

4.2 Fresh Tissue

   Unfixed tissue poses increased risk of infection. Gloves should be worn and standard laboratory practices followed.
4.3 Consent

Consent forms should be checked and any inconsistencies noted on the sample report form to ensure swift correction of errors and evidence of due diligence.

5.0 NOTES

*Procedure should be carried out by suitable individual and all laboratory Control of Substances Hazardous to Health (COSHH) and risk assessments should be up to date and followed.*

5.1 A list should be obtained from the Tissue Bank Nurse or relevant personnel, summarising the number of patients scheduled for surgery. Note that this list may be the subject to change.

5.2 Vials where applicable or possible should be pre-labelled for each sample. Where handwritten, labelling should be legible and in permanent ink.

5.3 If transport is required, before processing, between surgery (applicable to London & Leeds), histopathology and laboratory, a polystyrene/propylene Igloo box or sample carrier with ice packs must be used to transport the samples back to the laboratory.

5.4 Prior to transferring processed samples to -80 °C (if applicable), ensure that the temperature of the snap frozen samples is maintained by either transporting the vials on dry ice or in liquid N₂.

6.0 PROCEDURE

When specimen is received at routine histopathology cut-up, the time must be noted and recorded in accordance with local procedure and guidelines

Short-term storage details and transit times if applicable to any specific site are to be noted

Relevant Tissue Bank staff notified, in accordance with local procedure and guidelines

Samples checked against consent form and then assessed by pathologist or biomedical scientist (BMS)

Check consent and ensure it has been filled in appropriately; any inconsistencies should be noted and later recorded in the incident log.

After the tissue has been taken for diagnostic analysis, any surplus tumour or surrounding tissue samples are banked for freezing and tissue culture.
N.B: Site-specific sample worksheet (refer BCNTB/SOP/003, appendix A) and incident log will be available upon request.