



SOP Reference: BCNTB/SOP/010

Standard Operating Procedure for

Withdrawal of consent

Version number: 2

Date effective: final date of approval

Date of last review: December 2016

Date of next review: annual

Authorised by:

	Name	Designation	Signature	Date approved
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Document review history			
Version Number	Revision History	Name of Reviewer/Author	Review date
1.0	1 st Issue	Uma Ekbote	January 2012
2.0	Admin edits, changes to participating centres, removed local policy links, updated HTA codes of Practice and Standards	Dr. Pamela Reid	December 2016, April 2017

1.0 PURPOSE AND SCOPE

- 1.1 This SOP outlines how patients and donors who no longer wish any tissue and/or blood or other samples that they have donated to the Tissue Bank (defined herein after) to be used for medical research purposes can withdraw their consent.
- 1.2 This SOP is governed by local NHS hospital management and policies.

2.0 DEFINITIONS

- 2.1 The Breast Cancer Now Tissue Bank shall be referred to as the Tissue Bank.
- 2.2 The researcher applying to access and use the Materials held in the Tissue Bank shall be referred to as the Applicant.
- 2.3 Material refers to any Tissue within the Tissue Bank.
- 2.4 Tissue refers to any tissue or fluid taken from the human body.
- 2.5 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.
- 2.6 Leeds Research Tissue Bank is referred to as LRTB.
- 2.7 Barts Cancer Institute Breast Tissue Bank is referred to as BCIBTB.

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 fundamental principle of consent- includes Withdrawal of consent-section Two, reference points 51-52
 - 3.2.2 Code E: Research- includes Disposal reference points 127-129
- 3.3 BCNTB/SOP/012: Disposal of Tissues

4.0 OVERVIEW AND RESPONSIBILITIES

The following two points are adapted from the HTA Codes of Practice and Standards- Code A.

- 4.1 Consent may be withdrawn at any time and should be discussed at the time consent is being sought. There is no need for an explanation of the reasons for withdrawal of the consent to be provided and patients should be reassured that this will not affect their clinical care or treatment now or in the future. It is important that

patients understand that withdrawal of consent cannot apply to tissue that has already been used for a scheduled purpose (e.g. research).

4.2 If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled purpose (e.g. research), this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent has been withdrawn. In addition, if someone withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

The above paragraph does not apply for BCIBTB where partial consent is treated as a refusal of all consent.

4.3 Procedures for withdrawal of consent are in place at each of the Tissue Bank Centres and are governed by local practices for annotation and deletion of relevant records. In addition to following the local practice, the Institution will notify the Tissue Bank Coordinator of withdrawal of consent plus the details of the relevant samples so the central Breast Cancer Now database can be updated.

4.4 The Tissue Bank Coordinator will then inform any Applicants of the relevant sample using the unique identifier number and ask them to dispose of unused samples and certify that they have done so, or return them to the Tissue Bank Coordinator for disposal (Code E: Research, Disposal reference points 127-129).

4.4.1 Results obtained from samples that have already been used for research need not be destroyed.

4.4.2 If the data has already been published or submitted for publication the linkage data held by the core site will be destroyed but the Applicant(s) may continue to use the anonymised data in their study.

4.4.3 Any existing samples within the Tissue Bank will be disposed as per (BCNTB/SOP/012).