



SOP Reference: BCNTB/SOP/009

Standard Operating Procedure for

Principles of consent

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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 and modified to reflect principles of consenting, updated HTA codes of Practice and Standards	Dr. Pamela Reid, Uma Ekbote	December 2016, April 2017

1.0 PURPOSE AND SCOPE

- 1.1 The purpose of this SOP is to describe the principles that guide the approach to patients regarding the possibility of donating surplus tissue and/or blood to the Tissue Bank (defined herein) for the purpose of research.
- 1.2 This SOP is governed by local NHS management and policies.

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 main Institutions are the University of Leeds, University of Nottingham and Barts Cancer Institute Breast Tissue Bank, Queen Mary University of London. Consented samples are also provided by the University of Sheffield and the University of Southampton.
- 2.5 Leeds Research Tissue Bank is referred to as LRTB.
- 2.6 Barts Cancer Institute Breast Tissue Bank is referred to as BCIBTB.
- 2.7 HTA is the Human Tissue Act.

3.0 REFERENCES

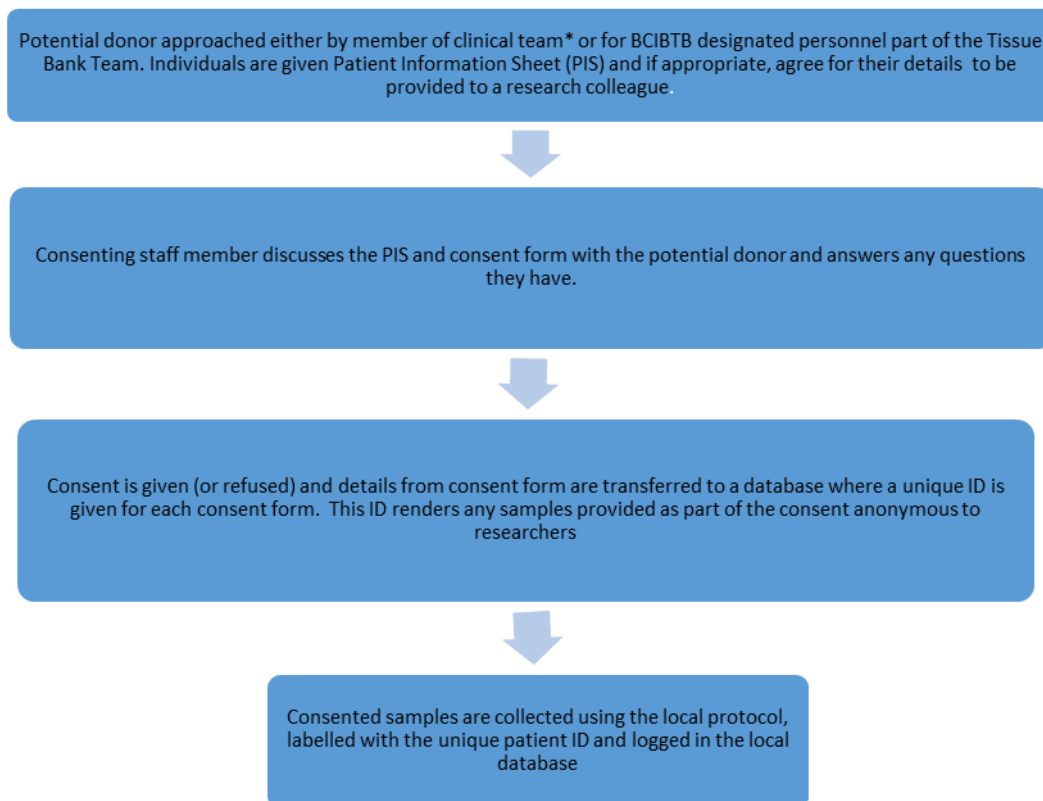
- 3.1 Human Tissue Act 2004
- 3.2 Human Tissue Authority Codes of Practice and Standards, April 2017;
 - 3.2.1 Code A: Guiding principles and the fundamental principle of consent
 - 3.2.2 Code E: Research
- 3.3 BCNTB/SOP/010: Withdrawal of Consent

Informed consent is defined as a process by which a subject voluntarily confirms his or her willingness to participate in a specific clinical trial or research study, after being informed of all aspects of the trial or study that are relevant to the subject's decision to participate.

The HTA is clear that for consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question (Code A: Guiding principles and the fundamental principle of consent).

Each Tissue Bank Centre operates its own local process for consent which is driven by the clinical pathway being followed.

A general schematic for the process is provided below:



*Relevant members are generally the surgeon, qualified medical practitioner, specialist or research nurse. In Nottingham a wider range of individuals can approach for consent. This includes (i) Trained Nottingham Health Science Biobank team members (ii) Trained consultants, registrars, clinical teams and nurses and (iii) Trained patient advocates.

Other relevant issues:

- If a patient is re-consented for any reason the latest form supersedes all previous versions.
- Legally consent is not required for “existing holdings” i.e. material held when the Human Tissue Act came into force on 1 September 2006, but best practice suggests it is best to obtain proof of consent.

All Tissue Bank Centres welcome feedback and have formal processes in place to deal with complaints. Local procedures are followed for the management and escalation of the details provided to the Patient Advice and Liaison Service (PALS).

<http://www.nhs.uk/chq/pages/1082.aspx?CategoryID=68> may also be contacted regarding feedback and complaints.