SOP Reference: BCNTB/SOP/009

Standard Operating Procedure for

Approach to consent

Version number: 1  Date created: 4th Sept 2010
Date of last review: Not applicable  Date of next review: annual
Author: Uma Ekbote

Authorised by:

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Document review history

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1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe how to approach 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. The site specific SOPs are attached as following appendices.

Appendix A: Dundee TTB SOP CC001.R00
Appendix B: Leeds LRTB_SOP_D01
Appendix C: Barts BCITB/SOP01
Appendix D: Nottingham This SOP is awaiting local management approval.

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 Dundee, University of Leeds, University of Nottingham and Barts Cancer Institute, Queen Mary University of London.

2.5 Tayside Tissue Bank is referred to as TTB

2.6 Leeds Research Tissue Bank is referred to as LRTB

2.7 Barts Cancer Institute Tissue Bank is referred to as BCITB

3.0 REFERENCES

3.1 Human Tissue Act 2004

3.2 Human Tissue Authority, Codes of Practice 2009

3.2.1 Code of practice 1- Consent

3.2.2 Code of practice 9- Research

3.3 BCNTB/SOP/010: Withdrawal of Consent
1.0 PURPOSE

1.1 The purpose of this SOP is to describe how patients should be approached regarding the possibility of donating surplus tissue to the Tayside Tissue Bank (TTB) to ensure any consent obtained is freely given and fully authorised by competent patients. Importantly, it describes the measures taken to verify that patients are aware of their entitlement to refuse or withdraw consent without any impact on their care or treatment.

2.0 REFERENCES

2.1 SOPs

2.1.1 TTB SOP PL003: Governing policies of the Tayside Tissue Bank
2.1.2 TTB SOP CC003: Withdrawal of Consent.

2.2 Relevant Scientific Literature or Background Information

2.2.1 Human Tissue Act (HTA) Code of Practice 1: Consent (Sept 2009)
3.0 RESPONSIBILITIES

3.1 It is the responsibility of the management of Tayside Tissue Bank (TTB) to ensure that consent procedures are ethical, updated as appropriate and adhered to at all times.

3.2 It is the responsibility of the Research Nurses or other clinical professional seeking consent to ensure that the proper procedure for obtaining consent is followed for each patient.

4.0 DEFINITIONS

4.1 TTB = Tayside Tissue Bank

4.2 HTA = Human Tissue Authority

4.3 MDT = Multi disciplinary team

5.0 GOVERNING POLICIES

5.1 See TTB SOP PL003: Governing policies of Tayside Tissue Bank

6.0 SAFETY

6.1 Normal precautions for entering and leaving wards and lab areas should be taken (e.g. thorough and regular hand washing, appropriate PPE)

7.0 PROCEDURE

7.1 Background

Approaching patients regarding the possibility of donating tissue or blood or other samples to the Tissue Bank should always be done sensitively and respectfully and with no sense of pressure or obligation. Patients about to undergo surgery or recently diagnosed with a potentially serious illness are inevitably anxious and may have much to concern themselves. They will often have other forms, consents and documents to consider and complete and so any approach by the Tissue Bank should be seen in this context. Patient’s responses will inevitably range from unquestioning eagerness to contribute to those who are very cautious and distrustful. Each person’s standpoint must be respected. They must be provided with an explanation of why any surplus tissue or other material is being requested, the purposes to which it could be put and a clear understanding that a decision to give their consent, or to withhold their consent, will not affect their treatment or care in any way. If time for reflection or discussion with their family or friends is requested this should be encouraged.
7.2 Identifying patients to approach for consent

Consenting nurses or clinicians should:

- Check theatre lists and be advised by the clinical team as to the suitability of patients for approach
- Ensure that only adults capable of giving informed consent are approached
- Ensure the patient fully understands the information provided before consenting
- Ensure the patient is given a copy of the Patient Information Sheet and Consent Form and provided with details on how they, or their relatives, might obtain further information regarding the use to which their tissue may be put (e.g. website address).
- Ensure relevant theatre and pathology staff are alerted to collect and receive any tissue donation
- Ensure each patient’s consent is documented, that a hardcopy is retained on file and the information is recorded on the Tayside Tissue Bank database (and patient’s notes if available).
- Ensure the consenting pathways are kept current by reporting any necessary change in procedure
- Document any deviation to sample procurement protocols

7.3 Topics to cover with potential donors during the consenting process

- Provide a personal introduction, your role as consenter and how you may be contacted.
- Explanation that tissue for donation is surplus to diagnostic and therapeutic requirements.
- Seek consent that blood samples as well as tissue may be collected where appropriate.
- Confirm no aspect of the patient’s treatment is affected by donation or non-donation.
- Donation is not obligatory.
- Consent to donate is confidential (as is non-donation).
- Donated tissue is anonymised. There will be no direct contact from the researchers.
- Relevant anonymised medical information may be passed onto recipients of tissue and stored in our database.
- There is no financial inducement to patient or surgeon or pathologist.
- Tissue is not sold but storage and administration costs may be recovered.
- Users of the tissue may apply for patents and could potentially make a profit.
- Benefits to the patient include:
  - Humanitarian reasons
  - Improved resources for e.g. cancer research

The Patient should initial, sign and date two copies of the consent form and retain one for information. A copy of the Patient Information Sheet should be provided, the topics raised discussed and any questions the patient may have should be addressed.

7.4 Consent Pathway

The Tayside Tissue Bank collects samples and data from patients having, or who have had, surgery to remove tissue where cancer or other illness is a possible diagnosis.

It is recognised that the consent pathway can vary in order to minimise disruption to clinical procedure and to fit in with a given clinic and/or admissions protocol. Different tumour sites will also generate differences in pathways. A typical consent pathway is shown below and where there are variations due either to tumour type or local practice, specific pathways should be documented.

**Tissue Consent Pathway**

1. Patient identified by Tayside Tissue Bank Nurse or highlighted by clinician

2. With the acknowledgement of relevant clinical staff the patient is approached by a Tayside Tissue Bank Research Nurse who explains the reasons for requesting surplus tissue and seeks the patients consent

3. Following receipt of consent from patient the Tayside Tissue Bank Nurse informs surgeon’s secretary or relevant clinical staff that the patient has been approached.
4. The Tayside Tissue Bank Nurse liaises with the ward and theatres on day of surgery to confirm if and when patient has undergone surgery and availability of any donation.

5. Research Nurse collects the tissue following surgery and immediately takes it to pathology for examination and for any surplus tumour and/or normal tissue to be retrieved.

**Breast Research Studies**

Consent Pathway for Tissue and Peri-operative Blood Collection
(Breast Cancer – Dundee)

1. Patient identified at MDT

2. Patient arrives on ward for surgical operation. Approached by Tayside Tissue Bank Nurse who explains the reasons for requesting blood/surplus tissue. Provides Patient Information Sheet (PIS) or matched blood PIS and seeks patient’s consent.

3. Following receipt of consent from the patient, Research Nurse informs Surgeon’s secretary or other clinical staff as appropriate that TTB consent (for tissue and blood) has been obtained from the patient.

4. Porter collects the tissue following surgery and immediately takes it to Pathology for examination and for any surplus tumour and/or normal tissue to be retrieved.

**Breast Research Studies (cont)**

Consent Pathway for Matched Blood Collection

1. Tissue Bank Research Nurse obtains clinic list (maximum of 6 weeks before clinic) Enters CHI numbers into TTB database to identify patients with tumour but no blood in bank
2. Research Nurse creates list of patients requiring matched blood (using NHS PC to ascertain patient identity). Liases with Charge Nurse & Surgeons regarding patients sought.

3. Patient arrives at clinic. Approached by Research Nurse who explains the reasons for requesting blood sample. Patient is provided with ‘matched blood Patient Information Sheet’ and their consent to donate a blood sample is sought.

4. Research Nurse collects the blood sample and returns to Tissue Bank to process, log and store the samples received.

8.0 ATTACHMENTS/APPENDICES

8.1 Tissue Consent Form

9.0 SUMMARY OF REVISIONS

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APPENDIX 1
Tissue Consent Form

I agree that any surplus tissue removed in the course of my procedure as a necessary part of my diagnosis or treatment may be used for research after all tests necessary for my care have been performed on the understanding that the following conditions apply:

Please initial each box:

1. I have read the information below, received a copy of the Patient Information Sheet (Version 2, 5 March 2010) and had an opportunity to ask any questions.

2. Supplementary blood sample (up to 20 ml) may be collected as part of my participation.

3. Samples of tissue will be anonymised and kept securely. They will not be directly traceable to me or my family by researchers.

4. Data relating to my clinical record will be stored and made available to researchers but not my identity.

5. Tissue and relevant anonymised clinical data will be shared but will be provided on a non-commercial basis to researchers within the University of Dundee, NHS and medical research companies.

6. Tissue samples may undergo analysis on an anonymised basis to help find out whether genetic make up has any connection with disease.

7. Tissue donation will not result in any payment to me, even if my tissue is involved in research that leads to a new treatment or medical tool.

8. My tissue will only be used for research approved by a Review Panel made up of Doctors and Scientists and which has Medical Research Ethics Committee oversight.

If you do not wish to give consent this will not adversely affect your treatment or care. You may choose to withdraw your consent at any time (See Patient Information Sheet for details).

Signed: ____________________________ Date: ____________

I have explained the request for tissue for research purposes and answered any questions that the patient has asked.

Signed: ____________________________ Name: ____________________________ Date: ____________

Medical Practitioner, hospital letter:

For tissue bank use only:

Patient Name: ____________________________ Date: ____________

Tissue Bank: ____________________________ Date: ____________

One copy for Patient. One copy for Tissue Bank

Version: 4 (8 March 2010)

TTB SOP CC001.R00
## 5.0 Appendix B: LRTB SOP D01

| Title | LTHT / UoL Human Tissue Act Standard Operating Procedures
| Consent Procedure for LTHT patients |
| Scope | Details of the procedure for consenting LTHT patients for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence |
| Version | 2.0 |
| Date | January 2011 |
| SOP ID | LRTB_SOP_D01 |

### Details:

| Author | Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence |
| SOP Pages | 10 |
| Version No. of replaced SOP | 1.0 |
| Effective date of replaced SOP | Date of approval of this SOP |
| Review date for updated SOP | Annually from date of approval or review |

#### Approval:

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### Distribution & Storage:

**Distribution to**

Persons Designated, LTHT/UoL HTA Research Licence

**Location of Document**

Paper: HTA Manager, Risk Management, The Trust Headquarters, St James's University Hospital

Electronic: Research Support Unit, Website, UoL
**Title**

LTHT / UoL Human Tissue Act Standard Operating Procedures

**Scope**

Consenting Procedure for LTHT patients

Details of the procedure for consenting LTHT patients for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence

**Version**

2.0

**Date**

January 2011

**SOP ID**

LRTB_SOP_D01

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Section A

Introduction

1.1 Different sample types (blood or other bodily fluids, surgical resections etc) and data are collected from patients and other donors in Leeds for future unspecified research into a wide range of conditions including the investigation of normal cellular functions and their disruption in disease states, whether cancer or non-cancer. The tissue collections resulting from these different research activities are grouped under one research licence granted by the Human Tissue Authority to cover both Leeds Teaching Hospitals NHS Trust and the University of Leeds and referred to as the Leeds Research Tissue Banks. The single individual responsible for ensuring that robust processes and procedures have been developed for compliance with the Act is the Designated Individual (DI) for Research.

1.2 This SOP has been written to formally establish a consistent procedure for the process of consent for LTHT patients.

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of consent for LTHT patients.

Section B

Applicability

1.1 This SOP is relevant to all staff collecting and storing human tissues relevant to the Act. The list of relevant tissues can be found on the Human Tissue Authority website by following the link: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

1.2 This SOP can also be used as a training tool for new members of staff who have never worked with human tissues before, or who need to follow a new process.
Section C LTHT / UoL Standard Operating Procedures

Consenting Process for LTHT patients

1.0 Staff

1.1 The process of consent and all handling of patient identifiable material will be undertaken by Trust staff or staff with an honorary Trust contract.

1.2 Staff are bound by the LTHT policies on patient confidentiality and data protection, and must be familiar with the policies as they apply to tissue collection as per SOP LR TB M01 (Data protection and confidentiality).

1.3 If the member of staff obtaining consent is not a member of the patient’s clinical management team, such as a research nurse, the clinical team should ask the patient for permission to involve the research nurse in the consenting process. This dialogue must be recorded in the patient’s case notes by the member of staff concerned or by use of a signed permission to approach form which must be stored in the patients case notes (see 6.0).

1.4 All staff undertaking consent must be suitably trained and such training must be documented as per SOP LR TB M04 (Training).

2.0 Consent Pathways

2.1 Given the necessarily wide range of clinical care pathways, there will be local variation in the consent pathway depending on the types of clinical procedures and the organization and timings of local clinics and/or admissions procedures.

2.2 The general information required to document the consent pathway is shown in section 2.5.

2.3 The specific consent pathway and names, designation and contacts details of those involved in the different stages of the process must be documented and kept in a site file by the local Person Designated (PD), with an electronic copy to the DI, as per example in section 7.0.

2.4 Any changes to the consent pathway must be reflected in the flow charts and communicated to the DI.
2.5 General Consent Pathway

CONSENT PATHWAY

Patient approached by member of clinical team and given patient information sheet and asked for permission to give their details to a research colleague either verbally or by use of a permission to approach form (unless member of clinical / specialist team is taking consent)

The member of the clinical team documents the patient’s verbal consent for contact by the research team in the patient’s notes or files the permission to approach form and consent / research nurse is contacted.

Consent/research nurse or member of clinical team speaks to patient and obtains their consent.

Consent is registered on the LTHT Patient Registration System (PRS), hosted by LTHT with the date of consent, the reference and version number of the consent form/information sheet and details of the specific project as per SOP LRTB IT01 (LTHT Patient Consent Registration).

The LTHT Patient Registration System (PRS) issues a unique ID for each consent form in use and to each patient who has consented, to maintain the link between patient identifiable data and samples but render samples anonymous to researchers.

Samples are taken as per local protocol. Tubes labeled with the unique patient / consent ID.

Samples are logged into the LTHT / UoL Laboratory Management and Tissue Tracking System (Medical Achiever) using the unique patient / Consent ID and sample specific labels are produced and affixed to the tubes.
3.0 Specimens

3.1 Different research applications require different specimen types, and the details of their collection must be documented as a flow chart of the specific pathway within the site file of each research group.

3.2 Specimens may be split into different samples following processing, each of which will be given a unique sample code to ensure traceability of all daughter samples back to the original specimen and therefore patient using the LTHT / UoL Laboratory Management and Tissue Tracking System (Medical Achiever).

4.0 Responsibilities of person taking consent

4.1 A checklist for consent is detailed on the next page to ensure uniform patient interviews.

4.2 The individual obtaining consent should ensure that:

4.2.1 A member of the clinical team has determined whether the patient can be approached for consent, has had a preliminary discussion with the patient and documented their consent to be approached or obtained a signed "permission to approach" form (applies only if the individual taking consent is not a member of the relevant clinical team). No action should be taken before this has been done.

4.2.2 The patient fully understands the information sheets before consenting and has had the opportunity to ask any additional questions.

4.2.3 Patient consent is recorded on the LTHT Patient Registration System (PRS), as per SOP LRTB IT01 (LTHT Patient Consent Registration).

4.2.4 Documentation is completed and stored as per SOP LRTB D03 (Patient or Donor Documentation).

4.2.5 Theatre, pathology or other relevant staff are notified and tissue collection is organised.

4.2.6 All samples are labeled with the LTHT unique patient / consent ID.

4.2.7 Samples are processed according to local protocol. Any deviation to sample procurement protocols is recorded by the person responsible for the change against the relevant sample(s).

4.2.8 The consenting pathways are kept current by reporting any necessary change in procedure to the DI for research (HTA Research DI.PoPath.LGI@leedssth.nhs.uk).
**4.2.9** All samples generated from the original specimen are coded and stored using the LTHT / UoL Laboratory Management and Tissue Tracking System (Medical Achiever).

**5.0 Informed Consent Checklist**

Name of donor ........................................ Hospital No.................

Name and designation of person taking consent ............................................

Date ........................................

The following items have been explained and discussed with the donor during the interview.

- Personal introduction, job description and how may be contacted.
- Tissue for donation when taken as part of a diagnostic or therapeutic procedure is surplus to diagnostic or other clinical requirements.
- Consent for additional samples (note number and type).
- No aspect of their treatment is affected by donation (or non-donation).
- Donation is not obligatory.
- Donation is confidential (as is non-donation).
- Tissue donated becomes anonymised. There will be no direct contact from the research group.
- Relevant medical information will be stored in a secure database and only passed on to the recipients of tissue in an anonymised form.
- There is no financial inducement to patient or clinician.
- Tissue is not sold but costs may be recovered.
- Researchers or their organizations may apply for patents for any treatment or diagnostic test successfully developed from the research and could potentially make a profit.
- Benefits to patients are humanitarian rather than personal.
- Patient has been given an information leaflet.
- The process for withdrawal of consent has been explained.
6.0 Permission to approach form

Dr/Mr/s ........................................... a member of my clinical team, has explained that I could be invited to contribute to medical research. I am happy for a research nurse to approach me to explain this in detail, so that I can decide whether or not I want to participate.

Patient name: ........................................

Signature: ...........................................

Date: ..............................................
7.0 Tumour and site specific pathways

Examples of a possible pathway

Patient identified at MDT or
Patient identified by Consultant etc

Patient approached by specialist nurse (breast, urology other) and given patient information sheet, and asked to sign permission to approach form or verbal consent to approach is obtained and documented in the case notes

Following receipt of consent to be approached from the patient, specialist nurse tells Surgeon’s secretary that patient has been approached.

Surgeon’s secretary notifies research group representative when patient is likely to be admitted to ward for operation.

Patient arrives on ward for surgical operation, approached by research related individual for consent for blood and tissue

Generic consent pathway then followed with details of types of samples and collection procedure
### Section D Definitions

**The Act**  
The Human Tissue Act, 2004

**DI**  
Designated Individual as defined by the Human Tissue Authority

**HTA**  
The Human Tissue Authority

**LTHT**  
Leeds Teaching Hospitals NHS Trust

**PD**  
Person Designated as defined by the Human Tissue Authority

**R&D**  
Research & Development Department, Leeds Teaching Hospitals NHS Trust

**SOP**  
Standard Operating procedure

**UoL**  
University of Leeds

### Section E References

Human Tissue Act, 2004

Human tissue Authority, Codes of Practice

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### 6.0 Appendix C: BCITB/SOP01

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<td>Prof. L. J. Jones</td>
</tr>
<tr>
<td><strong>AUTHOR</strong></td>
<td>Darling Moro</td>
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**DOCUMENT REVIEW HISTORY**

Minor changes such as spelling mistake corrections etc are allowed without review, but should be brought to the attention of the author of this SOP and/or the individuals responsible for its implementation.

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1. Introduction:

Human breast tissue, blood and associated clinical data are collected from patients and other donors in London for future research into a wide range of conditions including the investigation of normal cellular function and its disruption in diseases states, whether cancer or non-cancer. All the breast tissue collected for research purposes falls under one research licence, granted by the Human Tissue Authority to the HTRC centre (part of Barts and the London Hospital Trust) and having the Barts Cancer Institute Tissue Bank (part of Charterhouse Square Tissue Banks) as a satellite licence holder centre. The single individual responsible for ensuring that robust processes and procedures have been developed for compliance with The Act is the Designated Individual (DI).

Gaining written Informed Patient Consent from research participants is a vital part of the research process and it is implemented to ensure that the patients can reach a genuine informed decision about whether or not to participate in a research study. It provides written information to potential donors, and represents an ongoing agreement made by the patient to donate their tissue for storage and use in research studies after risks and benefits have been thoroughly explained.

This SOP has been written to formally establish a consistent procedure for the process of consenting affiliated BCIBTB patients.

2. Applicability:

This SOP is relevant to all staff collecting and storing human tissues relevant to the Act. The list of relevant tissues can be found on the Human Tissue Authority website by following the link:

http://www.hta.gov.uk/legislationpoliciesandcodesofpracice/definitionofrelevantmaterial.cfm

This SOP can also be used as a training tool for new members of staffs who have never worked with human tissue before or who need to follow a new process.

3. Responsibility/Principal Investigator:

P.I for seeking consent is Prof. Louise J. Jones.
C/O Barts Cancer Institute, SMD Queen Mary University of London, Centre of Tumour Biology, John Vane Science Centre, Charterhouse Square
EC1M 6BQ Tel 0207 882 3557

3.1 The process of consent and all handling of patient identifiable material will be undertaken by Prof Jones’s research group, Trust staff, or staff with an honorary Trust contract.

3.2 Staff are bound by QM policies on patient confidentiality and data protection.
4. Responsibility of person taking consent:

A form for consent is detailed on the page 4 to ensure uniform patients interviews.

4.1 The individual obtaining consent should ensure that:

4.1.1 The patient fully understands the information sheets before consenting and has had the opportunity to ask any additional questions.

4.1.2 Patient consent is recorded on the Tissue Tracker System.

4.1.3 Documentation is completed and stored.

4.1.4 Theatre, pathology or other relevant staff are notified and tissue collection is organised.

4.1.5 All samples are labelled with the TB unique patient code.

4.1.6 Samples are processed according to local protocol. Any deviation to sample procurement protocols is recorded by the person responsible for the change against the relevant sample(s).

4.1.7 The consenting pathways are kept current by reporting any necessary change in procedure to the DI for research (Prof. Louise J. Jones).

4.1.8 All samples generated from the original specimen are coded and stored using the Tissue Tracking System.

5. Consent Pathway:

Patients undergoing breast surgery are identified by MDM/surgical theatre lists/consultant.

Consent nurse/member of the research team speaks to the patient about the significance of collecting tissue for research. They are then given the Patient Information Sheet (PIS) and are guided through the paper in detail, allowing the patient to formulate eventual questions. Once all questions are answered comprehensively, their consent is obtained. If an interpreter is required the consent form must also be signed by them.

The Consent Form (PCF) is registered on the Patient Consent Database with the date of consent. This allows for the PCF to have a unique ID that it is specific to each patient that has consented, and to maintain the link between patient identifiable data and samples but render samples anonymous to researchers.

PCF are in triplicate. The white copy will be added to the patients’ hospital notes; the pink copy is kept for the BCI/BCC Tissue Banks record and assigned a unique TB number via the Item Tracking System. The yellow copy remains with the patient.

Samples are collected as by local protocol (SOP03 and SOP04).
Samples are then logged into the Tissue Tracking System using the unique patient ID and sample specific labels are produced and affixed to the tubes.

6. Informed Consent Form:

File Name: Patient Consent Form

Hospital No. ………………………………………

I (name of patient) ………………………………………………………………………………………………………

agree to donate any tissue/fluid which may be removed during my forthcoming operation / procedure (name of operation/procedure)……………………………………………………………………………………………………

I agree to recognised research institutions or pharmaceutical companies or individual researchers for research, teaching, audit or quality control purposes. The research could include the discovery, testing or production of medicines and methods for the diagnosis of disease.

I understand that:

• The donation of this tissue is voluntary and that I may withdraw my consent at any time.

• My donated tissue and medical details will be anonymised. Relevant information from my medical records will be recorded and held on a computer database and supplied anonymously to the relevant researcher and/or company.

• I agree / do not agree that I may be approached at future visits to the Breast Clinic for additional blood samples

Agree [ ] Do not agree [ ]

However,

• Access to personal identifiable data will be restricted to approved personnel only
• Tissue is not sold, but costs are recovered on a non-profit-making basis

• Any tissue which remains unused after 30 years will be disposed of in a lawful manner

• Neither I nor the Tissue Banks will benefit financially if this research leads to a new treatment or medical test

• The tissue will not be used for research that involves reproductive cloning, however it may undergo genetic testing to determine whether genetic makeup has any connection with disease

• I have received an information leaflet with more detail about Tissue Donation and had the opportunity to discuss it with a Liaison Nurse and/or doctor.

• I understand that part of the sample may be donated to the Breast Cancer Now Tissue Bank.

• I understand that the tissue used in this research would otherwise be discarded

Patient/Donor:
Name...........................................................Signature:..................................................Date……

The following should be signed by the Clinician/Investigator responsible for obtaining consent

As the Clinician/Investigator responsible for this research or a designated deputy, I confirm that I have explained to the patient/volunteer named above the nature and purpose of the research to be undertaken.

Practitioner seeking consent:
Name...........................................................Signature:..................................................D ate……

TO WITHDRAW YOUR CONSENT TO DONATE TISSUE FOR RESEARCH PLEASE CALL PROF L.J. JONES ON 0207 882 3573 OR EMAIL L.J.JONES@QMUL.AC.UK.
7. Definitions:

The Act: The Human Tissue Act, 2004

D.I: Designated Individual as defined by the Human Tissue Authority

HTA: The Human Tissue Authority

BCI Tissue Bank: Barts Cancer Institute Tissue Bank

BCC Tissue Bank: Breast Cancer Now Tissue Bank

PD: Person Designated as defined by the Human Tissue Authority

R&D: Research & Development Department, Queen Mary’s University of London.

SOP: Standard Operating Procedure

TB: Tissue Bank

MDM: Multi Disciplinary Meeting

PIS: Patient Information Sheet

PCF: Patient Consent Form
7.0 Appendix D: Nottingham

Detailed SOP will be made available pending local management approval