SOP Reference: BCNTB/SOP/005

Standard Operating Procedure for

Collection and processing of blood samples

Version number: 4

Date effective: date of final approval

Date of last review: March 2017

Date of next review: annual

Authorised by:

	Name	Designation	Signature	Date approved
BCNTB	Ms Uma Ekbote	Coordinator		May 2017
Breast Cancer Now	Dr Simon Vincent	Director of Research		May 2017
BCNTB Advisory Council	Professor Wayne Phillips	Chair		May 2017

Version Number	Revision History	Name of Reviewer/author	Effective date
1.0	1st Issue	Uma Ekbote	17 January 2012
2.0	Changes to tube processing steps	Dr. Balwir Matharoo Ball	25 February 2014
3.0	Changes to tube processing steps	Angie Berwick, Sameena Iqbal, Fabricio Barros	26 July 2016
4.0	Added Southampton processing details and reference to Sheffield's ccf DNA process SOP, HTA codes of practice and standards update	Pamela Reid, Cheryl Lenny, Kathy Potter, Uma Ekbote	10 March 2017, April 2017

PURPOSE AND SCOPE

1.1 Blood reflects the many processes that the body undertakes. In diseases blood can be used to monitor, screen and diagnose.

1.2 This SOP covers laboratory processing of blood and blood products.

1.3 This SOP applies to the Institutions defined in section 2.4

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 and the University of Southampton.

2.5 The University of Sheffield processed whole blood as per the description below until April 2016. From April 2016 onwards all bloods collected University of Sheffield are processed as per BCNTB/SOP/004.

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/009: Approach to Consent

3.4 BCNTB/SOP/004: Blood Processing for ccfDNA.

3.5 Control of Substances Hazardous to Health (COSHH) and Risk Assessments will be site specific according to national guidelines.

4.0 HAZARDS AND PRECAUTIONS

4.1 Staff should have Hepatitis B vaccination under the guidance of Occupational Health Service.

4.2 **Blood:** Infection risk, appropriate protective equipment should be worn.

4.3 **Needles:** Needles must be disposed of in appropriate sharps bin and never re-used or re-capped.

4.4 **Liquid Nitrogen:** This poses serious burns and asphyxiation risk. Protective equipment must be used.

5.0 PROCEDURE

5.1 Blood collection should be carried out by a suitably trained registered nurse, doctor, phlebotomist or other suitably trained staff.

5.2 The blood collection procedure should be followed as per site-specific practices but should take into account, if possible, the volume of collection and the order of the blood draw as outlined below. (**Note**: variation to the procedure below for University of Southampton)

5.3 Bloods drawn for diagnostic purposes should be prioritised.

5.4 Order of draw of blood:

Blood should be collected as clotted (red top) first followed by Lithium Heparin (green top) and then finally Potassium EDTA (ethylenediaminetetraacetic acid, lavender or purple top).

5.5 One blood should be collected in the following tubes from a registered manufacturer

5.5.1 4 - 8ml clotted tube with or without clot activator (red top)
5.5.2 4 - 8ml Lithium heparin tube, (green top)
5.5.3 4 - 8ml K_2EDTA (lavender or purple top)

5.6 Blood tubes should be labelled with patient name, hospital number, time sample taken or addressograph label or sample barcode

5.7 Once the samples are logged in the System, any patient personal identifiers or addressographs on the vacuettes should be removed in order to anonymise the samples. Only unique number or barcode should be used to identify the sample

5.8 Blood should be processed as soon as possible but within 4hrs and the time of drawn and processed to be noted

6.0 PROCESSING

6.1 **Clotted Tubes (red top)**
Sample must be mixed gently and left for minimum of 30 minutes to allow the blood to clot at room temperature.
Samples should be spun at RCF 850 to 1000 *g* for 10 minutes at room temperature. The serum should then be split equally in aliquots of 500 µl approximately, in 1.8ml screw top cryovials using a sterile Pasteur pipette or an automated pipette with sterile tips. Each vial should be labelled with a unique BCNTB barcode and can be placed on dry ice as an intermediate step before placing the tubes for storage in a -80°C freezer.

6.2 **Lithium Heparin (green top)**
Spin samples at RCF 850 to 1000 *g* for 10 minutes at room temperature. The plasma should then be split equally in aliquots of 500 µl approximately, in

1.8ml screw top cryovials using a sterile Pasteur pipette or an automated pipette with sterile tips. Each vial should be labelled with a unique BCNTB barcode and can be placed on dry ice as an intermediate step before placing the tubes for storage in a -80°C freezer.

6.3 **K_2EDTA (purple top)**

Spin samples at RCF 850 to 1000 *g* for 10 minutes at room temperature. The plasma should then be split equally in aliquots of 500 µl approximately, in 1.8ml screw top cryovials using a sterile Pasteur pipette or an automated pipette with sterile tips. Each vial should be labelled with a unique BCNTB barcode and can be placed on dry ice as an intermediate step before placing the tubes for storage in a -80°C freezer.

Once plasma has been harvested place a unique BCNTB barcode on the red cell tube (which will be retained for DNA extraction) or transfer the red cells and Buffy Coat to a smaller, barcoded vial and can be placed on dry ice as an intermediate step before placing the tubes for storage in a -80°C freezer. Black out any patient identifiable details.

6.4 **Booking & Logging of blood samples**

6.4.1 Blood samples are booked and logged in accordance with local guidelines: All sites use barcodes for blood samples

6.4.2 Once the samples are logged in the System, any patient personal identifiers or addressographs on the vacuettes should be removed in order to anonymise the samples. Only unique number or barcode should be used to identify the sample

N.B: site specific blood sample worksheet will be available on request.

6.5 **Temporary Storage & Transfer:**

6.5.1 For sites where transfer of samples is required for long-term storage, samples must be moved in batches, on dry ice, using an appropriate container.

6.5.2 The sample location must be updated in the sample database.

Variations from the accepted protocols

Southampton BeGIN study.

A variation relates to the isolation of plasma from unclotted blood. Plasma is isolated from whole blood collected into lithium heparin vacutainers. The whole blood is layered over Lymphoprep and spun. The plasma is then collected from the top layer.