SOP- breast cancer tissue collection

Organisation: University of Manchester

Document version number: v.1

Date written: 18.1.22

Funded by UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

the document or any part thereof, except to the extent that such liability cannot be excluded by law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents. The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by
UK Research and Innovation

Coordinated by
CATAPULT Cell and Gene Therapy

Division of Cancer Sciences

Standard Operating Procedure

(Version 1.0)

iMATCH: breast cancer tissue collection
(Adapted from iMatch WP2.2)

Revision History		
Number	**Date**	**Reason for Change**
1.0	**18/1/22**	

Prepared By:	**Checked By:**	**Authorised by:**
Signed: Dominique Jones	**Signed:**	**Signed: Edmondson**
Print: **Marcus Price**	**Print:**	**Print:**
Date: **18/1/22**	**Date:**	**Date: 21/2/22**
Date of next review:		

Standard Operating Procedure for patient recruitment for Breast Cancer tumour samples for adoptive T-Cell therapy.

Contents

1. Introduction.

Advanced immunotherapies such as adoptive T-Cell therapy use a sample of patient tissue to create a personalised immunotherapy treatment. For oncology patients this could include taking immune cells from the blood and modifying them to attack the tumour (CAR-T Cell therapy) or taking a sample of the tumour itself, extracting the T-cells already in situ and expanding those into a treatment (adoptive T-Cell therapy, (ACT)). For ACT, the sample of tumour is collected from the donor during either routine surgery or a research specific biopsy. T-cells are then extracted and stored until the patient requires treatment. At this

point the T-cells are expanded (grown), forming a bespoke immunotherapy treatment to be returned to the donor.

This SOP will describe the process for screening, identifying, and approaching patients with breast cancer for the purpose of recruiting them for prospective tumour sample collection for adoptive T-cell therapy clinical trial. Consent to tissue procurement may be conducted separately to consent to clinical trial or concurrently, depending on the procurement procedure (prospective collection or trial specific collection).

Breast cancer clinics and surgery are conducted at two main sites in Greater Manchester: The Nightingale Centre at Wythenshawe hospital and North Manchester General Hospital, both part of Manchester University Hospital NHS Foundation Trust (MFT). As such the patient pathways have minor variations which will be reflected in the SOP as required.

1.2. Purpose.

The purpose of this SOP is to standardise the recruitment process for prospective tumour sample collection.

This SOP does not cover the following:

- any clinical trial which may utilise the patient's stored sample,
- the tissue sample collection process.

1.3. Relevant Information.

- Manchester University Hospitals NHS FT Bio-bank Patient Information Sheet (*BRC Biobank Patient Information Sheet 'Giving Blood, Tissue and other Body Samples for Biomedical Research*)

- MFT Biobank Informed Consent form (*MFT Biobank Consent form*). Consent forms can be obtained from the biobank, which is located in the Oxford Road Campus, clinical sciences building.
- For further information and contact details for the MFT bio-bank please follow this link- https://research.cmft.nhs.uk/facilities-services/biobank-and-pathology
- Breast cancer Tissue collection Standard Operating Procedures.
- Core Needle Biopsy Protocol.
- Relevant clinical trial documentation.

2. Patient pathways.

2.1. Wythenshaw.

Triple negative patients have already undergone an extensive round of clinic and treatment appointments by the time they are they are eligible for surgery. Diagnostic appointments are conducted at a one stop shop at the Nightingale Centre at the Wythenshaw site with results returned to clinicians within five days. Decisions on how to treat are then made at the Breast Oncology Multidisciplinary Team Meeting (MDT). Patients undergoing neo-adjuvant chemotherapy will have a mid-treatment scan which is assessed at MDT. At this MDT a decision is made as to whether the treatment is complete or if the patient requires surgery. Patients recommended for surgery will be offered an appointment to discuss the operation and consent if they wish to proceed. They will have a pre-operative assessment at which they may be approached to discuss sample collection.

2.2. North Manchester Genera Hospital.

As with Wythenshaw, it is a lengthy process before the patient may be eligible for surgery. Diagnosis and results are given in a one stop shop at NMGH. Treatment decisions are made at the MDT. Patients requiring chemotherapy are referred to either The Christie or Royal

Oldham hospital. Patients have a mid-treatment scan and if surgery is recommended at the Pennine MDT this will take place at NMGH. Patients will be invited to an out-patients clinic at NMG to discuss this. If they consent to surgery, they will undergo a pre-operative assessment.

3. Patient screening.

3.1 Eligibility criteria.

Patients with a diagnosis of triple negative breast cancer who have undergone neo-adjuvant chemotherapy and the Multi-disciplinary Team meeting (MDT) have agreed the patient can proceed to surgery.

3.2 Patient identification.

Patients may be screened at the Breast Oncology MDT or from the daily pre-operative list. There is a dedicated breast oncology research team who may be able to perform this task. The breast oncology MDT takes place every Monday at 12.30 p.m. at the Nightingale Centre lecture theatre.

3.3 Virology.

Advanced therapies require patients to be negative for virology on consent. Donors will have blood samples collected in theatre which will undergo virology screening by the industry partner. Patients must provide informed consent prior to testing. The virology screen will test for the following- HIV 1 and 2, Hepatitis B and C, Cytomegalovirus (CMV), Epstein-Barr virus (EBV), human T-lymphotropic virus (HTLV) and syphilis.

4.0 Consenting.

As Wythenshaw and NMGH are part of the Manchester University NHS Foundation Trust it may be possible for the patient to be consented under the MFT biobank. See Relevant Information (section one) for details on how to contact the MFT biobank. Patients may be approached to discuss consent either at the pre-operative assessment or on the day of surgery (biobanking only). Please liaise with nursing team as to the most appropriate time to approach the patient.