SOP- Generalized Tissue Collection **w**here tissue, surplus to requirement, is available and be collected without effecting standard of care

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

relevant to particular circumstances. Although we make all reasonable efforts to ensure the information is up to date, we make no representations, warranties or guarantees in that regard. In no event shall the creator(s) be liable for any direct, indirect, special, consequential or other claims, losses or damages that are related to the use or reliance whatsoever in the content of 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

Standard Operating Procedure

(Version 1.0)

iMATCH: Generalized Tissue Collection
Where tissue, surplus to requirement, is available and be collected without effecting standard of care
(Adapted from iMatch WP2.2)

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

Prepared By:	**Checked By:**	**Authorised by:**
Signed:	**Signed:**	**Signed:**
Print: **Marcus Price**	**Print:**	**Print:**
Date: **18/1/22**	**Date:**	**Date:**
Date of next review:		

1. **Introduction**
   As part of iMATCH Work Packages 2.1 and 2.2, this standard operating procedure provides a basis for the standardised collection of solid tumour and fluid samples from cancer patients undergoing surgical treatment, where there is excessive tumour tissue available which can be collected without effecting the normal standard of care. The purpose of tissue collection in these cases is for the extraction, expansion and storage of tumour-infilitrating lymphocytes (TILs) from the patient's tumour to be used as a personalised advanced cell therapy (ACT) under the aims of iMATCH and the SAMPLE trial (TRIAL CODE). This protocol should be adaptable, both to new tumour sites, and other cancer centres. *[Relevant considerations to adapting this protocol are highlighted in this manner]*
2. **Purpose**
   The purpose of this document is to provide clear guidance on the procedures to be followed during the acquisition of tissue and fluid samples for therapeutic purposes undertaken within the institute/trust as part of iMATCH Work Package 2.2 and the SAMPLE trial.
   Departmental standard operating procedures will already exist within the institute/trust. These must be read and followed in conjunction with a specific protocol adapted from this document.
3. **Location**
   This document has been developed from collection of tissue and fluids in theatre (2nd Floor, St Mary's), its transport and subsequent processing in the 5th floor laboratories of St. Marys Hospital. Any adapted protocols should consider local rules and conditions
4. **Objective**
   The aim of this document is to provide a basis for the development of a site specific protocol for the collection of tissue and fluid specimens in a sterile manner under appropriate consent, given appropriately labelled identifiers, and that the samples are in the custody of the personnel responsible for tissue collection or securely and temporarily stored before transport, processing and storage. In scenarios where there is a sufficient volume of specimen that removing some of this material will in no way effect the current standard of care for the patient.
5. **Scope**
   This document refers to the collection of tissue for iMATCH WP2.2 and the SAMPLE trial (undertaken jointly by the University of Manchester and Immetacyte Ltd.) for use in the production of ACTs for ovarian cancer patients treated at St. Mary's Hospital, Manchester, within the scope of the aims of the iMATCH consortium. The ultimate aims of this document are to ensure that tissue and fluid specimens are collected as quickly as possible under appropriate consent, sampled in such a manner as to ensure that there is no interference with or loss of information, placed into appropriately labelled containers, and that the samples are temporarily stored

before processing and storage, so as to be usable in the production of a medical product, manufactured to good manufacturing practice standards.

6. Responsibilities

6.1. The collection of tissues and fluids containing material of interest from patients suffering from cancer is the responsibility of the clinicians operating on or caring for the patient.

6.2 All staff handling tissue are to undergo appropriate training by members of the iMATCH team in addition to conducting work under standard operating procedures developed from this document.

6.3. Following sampling of the tissues, the clinical team is responsible for contacting members iMATCH team (detailed on page 5) to ensure that samples are delivered and processed within 30 minutes of their sampling in theatre. *[In developing a protocol from this document for another site, this processing time may need to be altered]*

6.4. Clinical fellows, researchers and other tissue collectors remain under the direct supervision of the institution / trust line management.

6.5 Clinical fellows, researchers and other tissue collectors, in collaboration with the clinical care team are responsible for the following:

6.5.1. Patient identification and consent, specimen labelling, early storage, and transportation of the samples

6.5.2. Maintaining an appropriate chain of custody from sample collection, until transfer to laboratory staff or other appropriate team member.

6.5.3. Maintaining a sterile sampling field, and storage conditions until sample transfer, to ensure a medical product can be produced to GMP regulations

6.5.4. Ensuring that sampling and storage occurs within a timely manner once tissue is *ex vivo*.

6.5.5. Accurately completing any accompanying documentation

6.5.6. Investigation or being aware of back up procedures in the eventuality that a problem arises during sampling or transportation (e.g. blood spillage)

6.5.7. Liaising with other trust and DOCS staff.

7. Related Documents

7.1. Guidelines for Good Clinical Practice (GCP)

7.2. Human Tissues Act 2004

7.3. COSHH regulations 1988

7.4. Local risk assessments / safe operating procedures

7.5. Local Standard operating procedures

7.6. National Blood service (www.blood.co.uk)

7.7. MCRC Biobank list of SOPs and Guidance documents

STANDARD OPERATING PROCEDURE

iMATCH Tissue Collection WP2.2

A. Example tissue collection kit

- Sample collection checklist *[Example on page 8]*
- Sample pot (sterile, for primary containment)
- Plastic biohazard bags (for secondary containment)
- Insulated bag or other appropriate container, which will contain any potential sample spillages, and appropriately labelled with custodian contact information and UN3373 labels (for tertiary containment)
- Permanent marker

No instruments (scissors, blades, forceps) to be taken into theatre.

B. Contact list

Courier / Transport team: Tel XXXXX XXX XXX, email: XXXXXX@XXXX

Laboratory contact: Tel XXXXX XXX XXX, email: XXXXXX@XXXX

If possible, ensure multiple contacts are listed, to best allow the clinical/collection team to seek advice if needed.

1. Briefing

1.1) Attend theatre briefing, if possible, on day of surgery. To set up any required equipment, and minimize disruption to normal theatre operation during the procedure

1.2) Request samples *being specific as possible with regards to the tissue being requested, and if possible, the manner in which it is sampled, and the responsible clinician*:

i.e

- A – X volume of solid tumour tissue
- B – x volume of drained fluid
- C – X volume of blood in X number of vials containing X preservative

1.3) Write name and contact details on surgical board if not staying for duration of surgery. Ask to be called when tissues removed.

2. Tissue collection

2.1) Use an incopad and sterile instruments requested from scrub nurse to collect samples from whole tumours. Place in labelled sterile pots detailing tissue type, relevant patient identifiers, and sample purpose (i.e. TIL extraction). *[This will need detailed collaboration with local theatre teams. Special consideration is to be taken to ensure sterility, and chain of custody, to ensure sample can be used in manufacturing and processes to GMP standards]*

2.2) Example tissue to be collected:

Sample type	Details	Amount required
Ascites	Aim for early catch to avoid blood contamination of late catch sample.	100mL (smaller volumes are acceptable)
Tissue from laparoscopy	Omental biopsy is preferred but peritoneal biopsies are acceptable, generally try to avoid ovarian biopsies.	1cm^3, can comprise several smaller biopsies
Tissue from laparotomy	Omental biopsy is preferred but other sites are acceptable, try to avoid obviously necrotic ovarian tumours.	1-5cm^3, can comprise several smaller biopsies
Blood	In EDTA tubes.	x2 7mL samples

2.3) Return whole tissue samples to pots and inform nurses that all tissue has been collected.

2.4) Ensure that all instruments are returned to a non-sterile nurse or that nurses are aware of the whereabouts of instruments.

2.5) Place all samples (solid tumours, ascites and blood) in plastic biohazard bags and tertiary containment bag/box.

2.6) Collect patient consent form and ensure NHS number (10 digits) is recorded. *[or other agreed patient identifier]*

3. Tissue transport/collection

3.1) Tissue to be taken directly to CT.L5.330 to be processed. Must be handed off directly to person in charge of processing, or securely stored appropriately (at 4°C) for later processing. *[If it has been determined prior, that a given sample type will be viable after a period of storage]*

[In our example, surgery and subsequent processing takes place within the same building. In adapting this protocol for use in environments where the processing facility is further removed this section will need to be expanded upon, with some consideration to the following details;

- *How will sample integrity be maintained in the event of mishandling?*
- *How will the sample be identified in the event of accident or loss?*
- *How will the patients' details be protected?*
- *Will a third party need to be involved, i.e., a commercial courier. If so, how will this affect the chain of custody*
- *How will the members of each site communicate, in order to ensure successful hand off and receipt of samples*
- *Will there be any cut off times in place (for example, due to lab closure or courier limitations). If so, what contingency steps may be inserted in order to preserve the viability of the samples.*

4. Sample collection checklist

Processing Contact
XXXX XXXXX Tel XXXX XXXX XXX

Sample ID **Date**

ITEM	Initial
Patient given appropriate consent for research	.....
Attended surgical briefing. Following samples requested:	.....
Contact details confirmed with surgical team	.....
Samples Collected in sterile manner, and in tertiary containment	.....
Samples Collected	.....
Collected copies of signed research consent forms, and other accompanying documentation	.....
Tissue handed off to: processing / courier / Storage (delete as appropriate)	.....
Collection details logged and consent form securely stored	.....