Collection of tissues for isolation of tumour infiltrating lymphocytes – a process overview

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– a process overview

Introduction and rationale

Lymphocytes present in the tumour microenvironment are known as tumour infiltrating lymphocytes (TIL) and are hallmarked by their specific adaptation to target the cancer cell. They thus, potentially, represent a novel therapeutic which, following extraction from the tumour and ex vivo expansion can be administered to a patient as an autologous treatment.

Crucial to this process is the ability to extract TIL from the host tissue which clearly requires tumour tissue to be sampled whilst maintaining both a sterile chain and a traceability pathway.

The following notes provide points to consider when setting up a new pathway and provide signposts to the correct SOPs, which will need modification for each individual pathway.

Research vs therapeutic

Consideration will need to be given as to whether the samples to be collected are to be used for research purposes or to develop a therapeutic product. A therapeutic product must maintain both a sterile chain and a traceability pathway from sample harvesting right through to patient administration of the final product. As such, samples will generally need to be collected in the clinical area such as an operating theatre or interventional radiology suite (as opposed to being collected in a pathology area). The following SOPs have been developed with this in mind.

If samples are only to be used for research purposes a sterile chain is not required (although a clean chain is still recommended). These protocols can therefore be amended accordingly

Tissue type and quantity

Broadly speaking tissue samples can be classed as either samples which are surplus to diagnostic purposes, or samples where tissue architecture must be preserved

Samples which are surplus to diagnostic purposes include cases where tissue samples can be taken at the time of surgery which are not required by the pathology team. Generally this will be cases where there is extensive disease at the time of surgery or at the time of recurrence when assessment of surgical margins is not important.

In contrast, for small tumours or for all cancers where the assessment of surgical margins is important the tissue architecture must be preserved at the time of surgery to allow the pathology team to undertake the necessary assessment of the tumour. We have demonstrated that tissue collection and TIL extraction and expansion is possible in this situation but

SOPs have been generated for both scenarios and it is the role of the tumour collecting team to liaise with the clinical team to assess which situation applies to the tissue type in question.

Locations of clinical teams

Whilst all non surgical oncology is delivered from the Christie hospital surgery may take place in one more different trusts. Details of these and where surgery takes place by cancer site is listed at doc2. Individual SOPs may need to be generated for each trust.

Generating a project specific SOP

The following SOPS have been generated as templates which can be modified for any planned project.

Any given tissue collection project is likely to need three SOPs to be adapted for use; a clinical SOP to cover patient identification, recruitment and consent, a tissue collection SOP to cover tissue accrual and initial tissue handling, and a tissue processing SOP to cover the laboratory processing of the tissue once collected.

Finally a data handling SOP may also be required depending on the needs of the specific project.

SOP templates and index to other files

File name	description	Location
Clinical SOPs		
Provision of services	Description of location of services in GM by cancer type and notes on regulatory processes already in place	Doc 2
Clinical SOP development	How to map the patient pathway	Doc 3
Biobanking consent	SOP template for gaining consent for patients to contribute to biobank	Doc 4
Ovarian cancer	SOP suitable for use with ovarian cancer patients	Doc 5
Breast cancer	SOP suitable for use with breast cancer patients	Doc 6
Hepatobiliary cancers	SOP suitable for use with hepato biliary cancers including those with oligometastatic colorectal cancers	Doc 7
Neuro cancers	SOP suitable for use with neuro cancer patients	Doc 8
Tissue collection SOPs		
Surplus to requirements	Generalized Tissue Collection	Doc 9

	Where tissue, surplus to requirement, is available and can be collected without effecting standard of care	
Preservation of tissue architecture	Generalized Tissue Collection where tissue microarchitecture must be preserved to protect the standard of care	Doc 10
Tissue Processing SOPs		
TIL from ovarian tumours		Doc 11
Data Handling SOP		
Data management		Doc 12