**Standard Operating Procedure**

**(Version 1.2)**

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| **iMATCH Tissue Collection – OVARIAN CANCER** |

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| **Revision History** |
| **Number** | **Date** | **Reason for Change** |
| **1.0****1.1****1.2** | **25/11/19****11/02/21** | General revisions due to development of protocol.2 year review |

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| **Print:** | **Print:** | **Print:** |
| **Date:****29/11/2018** | **Date:** | **Date:****30/11/18** |
| **Date of next review:****25/11/2022** |  |  |

1. **Introduction**

As part of iMATCH Work Package 2.1, this standard operating procedure provides a basis for the standardised collection of solid tumour and fluid samples from ovarian cancer patients undergoing surgical treatment at Saint Mary’s Hospital, Manchester. The ongoing collaboration with surgical teams at Saint Mary’s and further development of this protocol will allow for tissue collection for both ovarian cancer research and also for therapeutic processing for TIL harvest (Work Package 2.2) to become a routine procedure during primary or interval debulking surgeries in this centre. This protocol should be adaptable, both to new tumour sites, and other cancer centres in Greater Manchester.

1. **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 research purposes undertaken within the institute/trust as part of iMATCH Work Package 2.1.

Departmental standard operating procedures will already exist within the institute/trust. These must be read and followed in conjunction with this document.

1. **Location**

This document pertains to collection of tissue and fluids in theatre and its transport and subsequent processing in university laboratories. Tissue may also subsequently be transported to other sites by a collaborator, assuming the relevant documentation is in place. Details of these collections will be agreed in advance by personnel responsible for tissue collection.

1. **Objective**

The ultimate aims of this document are to ensure that tissue and fluid specimens are collected under appropriate consent, given appropriately labelled identifiers, and that the samples are temporarily stored before processing and storage.

1. **Scope**

This document refers to the collection of tissue for the MFT Biobank for use in the research carried out into ovarian cancer within the Division of Cancer Sciences, 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.

1. **Responsibilities**

6.1. The collection of tissues and fluids containing malignant cells from patients suffering from ovarian 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 standard operating procedures for the Saint Mary’s theatres.

6.3. Following sampling of the tissues, the clinical team is responsible for contacting members of the UoM iMATCH team (detailed on page 5) to ensure that samples are delivered and processed within 30 minutes of their sampling in theatre.

6.4. Clinical fellows and researchers are under the direct supervision of the institution / trust line management.

6.5 Clinical fellows and researchers, in collaboration with the clinical care team for the following:

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

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

 6.5.3. Accurately completing any accompanying documentation

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

 6.5.5 Liaising with other trust and DOCS staff.

1. **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](http://www.blood.co.uk))

7.7. MCRC Biobank list of SOPs and Guidance documents

**STANDARD OPERATING PROCEDURE**

**iMATCH Tissue Collection**

**B. Contact list**

iMATCH Research Technician [Contact details removed]

**A. Tissue collection kit**

* Checklist (page 7)
* Plastic biohazard bags
* 2x blood kits (1x EDTA Vacutainer and research label in a biohazard bag)
* Permanent marker and pen
* Sterile pots (no formalin)

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

**1. Briefing**

* 1. Attend theatre briefing on day of surgery.
	2. Request:
* Tissue from **all** tumour sites where applicable, to be collected ‘dry’ (not in formalin).
* Where available, 20 - 100mL ascitic fluid.
* 1x 9mL K2EDTA blood samples from anaesthetist if not already collected on the ward. Blood samples **must** be labelled by clinician taking sample before storage.
	1. Write name and contact details on surgical board if not staying for duration of surgery. Request to be contacted by a member of the theatre team when specimens are removed.

**2. Tissue collection**

2.1) Use an incopad and sterile instruments requested from scrub nurse to collect samples from whole tumours. Do not bring additional instruments into theatre. Place samples in labelled sterile pots detailing tissue type, pseudonymised collection identifier, collection date and time.

2.2) Specimens to be collected:

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| **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. | 1cm3, can comprise several smaller biopsies |
| Tissue from laparotomy | Omental biopsy is preferred but other sites are acceptable, try to avoid obviously necrotic ovarian tumours. | 1-5cm3, can comprise several smaller biopsies |
| Blood | In EDTA tubes. | x1 9mL samples |

2.3) Return whole tissue specimens to pots and inform nurses that all samples have been collected for research.

2.4) Ensure that all instruments are returned to a member of the theatre team or that the theatre team are aware of the whereabouts of instruments.

2.5) Place all samples (solid tumours, ascites and blood) in plastic biohazard bags and place in a blue tissue collection zip bag labelled with UN3373 Biological Substance Category B stickers and containing emergency contact details of members of the iMATCH tissue collection team.

2.6) Collect white research consent form and ensure that pseudonymised patient identifier, NHS number (10 digits), hospital/district number and collection date/personnel are recorded on the top of the form. Record collection in theatre specimen book.

**3. Tissue transport/collection**

3.1) Transport specimens directly to the laboratory to be processed. Specimens must be handed off directly to the person in charge of processing, or stored appropriately (at 4°C, in appropriate storage buffer) for later processing.

3.2) A record of the specimen collection, details of specimen storage locations and a copy of the research consent form must be saved to the specimen collection Access database as soon as possible after collection.

3.3) Hard copies of research consent forms must be stored securely.

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