SOP- Biobanking consent

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Division of Cancer Sciences

Standard Operating Procedure

(Version 1.0)

iMATCH: Biobanking consent
(Adapted from iMatch WP2.2)

Revision History		
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iMATCH Bio-banking Consent Standard Operating Procedure.

Contents

Introduction.

Bio-bank consent is a generic agreement from the patient that any approved researcher may use their tissue for approved medical research purposes. Bio-banking a sample enables the tissue to be used in various approved projects without the requirement of separate study specific consent.

As part of the iMATCH project basic research is being conducted to assess how amenable different tumour types are to extraction of Tumour Infiltrating Lymphocytes (TIL). For this eligible patients need to give consent for their tissue to be used in research. This research will be conducted by University of Manchester researchers working at St Mary's under the Manchester University Hospitals (MFT) Human Tissue Authority licence, held by the MFT bio-bank.

This SOP will describe the process for consenting patients under the biobank for the use in iMATCH research.

This SOP does not:

- cover consent to any tissue collection intended as a started material for an advanced therapy.
- Cover consent to any clinical trial involving patient tissue.

This SOP may be used in conjunction with recruitment to other sample collection protocols, if the patient is deemed eligible for more than one study.

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 bio-bank, which is located in the Oxford Road Campus, clinical sciences building.

- For further information on the MFT bio-bank please follow this link- https://research.cmft.nhs.uk/facilities-services/biobank-and-pathology
- Version control documentation can be found on the MFT shared drive 'iMATCH- e site file – Participant Information.

Responsibilities.

- It is the responsibility of the research practitioner/nurse to screen patients for eligibility at the MDT.
- It is the responsibility of the Research Practitioner/nurse to discuss and consent patients to the biobank.
- It is the responsibility of the research practitioner/nurse to update the screening/recruitment logs.
- It is the responsibility of the Research Practitioner/nurse to liaise with the Research Technician regarding patient consent and theatre listing.
- It is the responsibility of the Research Technician to attend the theatre team brief on the day of surgery to advise them of the need for tissue samples.
- It is the responsibility of the Research Technician to arrange collection of tissue samples from theatre.
- It is the responsibility of the Research Technician to inform the MFT biobank of the patients' consent and sample collection.

1. Consenting.

There is no formal training for bio-bank consenting. You may wish to arrange to shadow someone experienced in consenting to bio-bank before approaching patients. For more information please contact the MFT bio-bank manager.

1.1 Approaching in clinic.

On the day of the patient's clinic appointment, attend Women's Outpatients (ground floor, St Mary's atrium) to discuss with the patient's clinician and Macmillan nurse who you would like to see. As well as their clinic appointment, patients undergoing surgery will usually have a pre-op assessment that day, along with additional tests as requested by their clinician and a discussion with their Macmillan nurse. There is no set format for these; who a patient sees and when will vary according to need and availability of staff. The patient's Macmillan nurse will be able to advise the best time to speak to the patient**. Patient's must only be approached when the have consented to surgery.**

Please provide patients with a copy of the Bio-bank Patient Information sheet to read and discuss the information with them.

If they agree to consent, they need to sign the bio-bank consent form. This is a generic consent form used for all samples collected under the MFT bio-bank HTA licence. It does not specify the type of research that will be conducted on the patient's sample. The bio-bank consent **cannot** be used for research which requires specific informed consent.

Once consented please give the patient the green copy of the bio-bank consent form. The other three copies need to go in the Clinical Research tab in the patient's medical notes and document the conversation on the continuation sheet. The notes are placed in the staff hub in WOP by the clinician straight after the patient's appointment.

1.2 Surgery listing.

Once the patient has consented please identify when the patient has been listed for surgery. The theatre list is sent out the Friday before surgery for the following week. If you have access to ORMIS the listing can be found on there also. Information on accessing ORMIS can be found on the MFT Gynae research shared drive > iMATCH file > Recruitment.

Please email/discuss with the research technician details of the surgery date**. If emailing, ensure to use the MFT encryption policy.** Please include patient initials, NHS number, date of surgery,

surgeon and which theatre to attend and type and stage of tumour if this has been established. Further information as to the types of samples which may be available for the technician will be helpful. They require omental samples, ascetic fluid, solid tumour (ovarian or peritoneal) or peritoneal fluid.

Approaching the patient on the day of surgery.

1.3 Consenting in Admissions.

For gynaecological surgery the patient will be admitted to Ward 62 at 07.00 for morning surgery and 11.00 if there is a dedicated list for afternoon surgery. Patients will be seen by the admissions nurse, surgeon and anaesthetist in the order of the theatre list. Medical and anaesthetic staffs start their reviews at around 07.45 so it may be preferable to see the patient prior to this.

Patients are allocated a room on Ward 62 where they will be seen by the theatre team. If their medical notes are outside the allocated room then the patient is available.

Once recruited please give the patient the green copy of the consent form and a copy of the PIS. All other copies of the consent and copy of the PIS need to go in the medical notes in the Clinical Research tab. Document the conversation on the continuation sheet.

1.4 Consenting on the Ward.

Patients may be admitted prior to the day of surgery. This will be flagged on Chameleon, along with which ward the patient is currently on. Recruitment is permitted on the wards. It may be preferable to see the patient on the ward prior to the day of surgery, if possible.

Once consented please give the patient the green copy of the bio-bank consent form and a copy of the PIS. The other three copies need to go in the Clinical Research tab in the patient's medical notes along with a copy of the PIS.

n.b. Regardless of where the patient is seen consent must be obtained prior to the surgical team meeting at 08.15. Once consent is obtained please inform the Research Technician (please discuss how to do this prior to seeing the patient). They will attend the theatre team meeting to arrange sample collection.

If no one is available to consent in clinic and there is a risk the patient could be missed at admissions – please contact the medical secretaries. They have access to the surgeons' diaries and will be able to check when a patient will be listed for surgery. The secretaries contact details can be found on the anaesthetic meeting minutes (see section 2.2). This will enable cover to be identified prior to clinic.

1.5 Eligibility Criteria.

- Has been diagnosed with or has a suspected ovarian cancer.
- The (suspected) ovarian cancer is or is likely to be high stage- stage 3 or 4 and high grade (also referred to as G3 and poorly differentiated).
- The patient is capable of giving informed consent.
- Tumour size- needs to be sufficient for pathology as well as research. n.b. if the patient is having neo-adjunctive chemotherapy it is possible there will be insufficient tissue at surgery.

2. Communications.

2.1 Notification of bio-bank consent- Research Technician.

Once a patient has signed the bio-bank consent form, please advise the iMATCH Research Technician of the patient's name, date of surgery and the name of the surgeon and additional useful information about the condition.

2.2 Notification of bio-bank consent -theatre team.

Generally the Research Technician will attend the theatre team briefing to notify the theatre staff of the need for samples. However there are occasions when patients are admitted early and so do not appear on the week's theatre list (drawn up the Wednesday before). The patient may therefore be missed. A note can be added to ORMIS by theatre admissions that consent has been obtained for bio-banking.

To request the theatre list please email admissions or the Advanced Nurse Practitioner.

2.3 Pathology and radiology reports.

The Research Technician will inform you when the sample has been collected and will give you a sample ID code. Please forward the final pathology report (pseudo anonymised) via encrypted email to the Research Technician. Diagnostic reports are available on CWP and Chameleon. Save to the iMATCH file – Recruitment- Reports.