Title: Collection of Tissue Samples in the Operating Theatre

Serial Number: TSOP 001  
Version Number: 2.0

Version Approver: Gareth Bicknell  
Version Approval Date: 19/12/2013

Version Author: Huma Zafar (BMS), David Barnes (Research Associate), Antonina Lach (Lab Scientist), Lucy Roche (Lab Scientist), Ellie Mawbey-Adamson (Tissue Procurer)

Area of Application: Operating Theatres  
Relevance: Operating Department staff and members of OMB Team involved in peri-operative collection of tissue samples.

<table>
<thead>
<tr>
<th>Date</th>
<th>Details of Review</th>
<th>Version number</th>
<th>No. of pages</th>
<th>Name of Reviewer</th>
<th>Next Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/07/10</td>
<td>New SOP (Author: Kim Wheway)</td>
<td>0.1</td>
<td>16</td>
<td>Karolina Kliskey</td>
<td>13/07/10</td>
</tr>
<tr>
<td>12/01/12</td>
<td>Version number inconsistent with stated approval status, itself inconsistent with OMB Master List. Reformatted. Updated to current context with related SOPs. Typos corrected. Regarded as first properly authorised version.</td>
<td>1.0</td>
<td>9</td>
<td>Gareth Bicknell</td>
<td>January 2013</td>
</tr>
<tr>
<td>11/03/13 – 19/12/13</td>
<td>Added tumour procedures/BRISQ; general clarification of instructions</td>
<td>2.0</td>
<td>11</td>
<td>Huma Zafar, David Barnes, Antonina Lach, Lucy Roche, Ellie Mawbey-Adamson, Kim Wheway, Bridget Watkins, Gareth Bicknell</td>
<td>December 2014</td>
</tr>
</tbody>
</table>

**YOU ARE INSTRUCTED TO READ THE FOLLOWING THOROUGHLY BEFORE PROCEEDING TO UNDERTAKE THE METHODS DESCRIBED.**

**UNDER NO CIRCUMSTANCES ARE THESE INSTRUCTIONS TO BE AMENDED OR ALTERED IN ANY WAY OTHER THAN BY THE AUTHOR / APPROVER.**
Table Of Contents

1 PURPOSE .............................................................................................................. 3
2 SAFETY INFORMATION .................................................................................... 3
3 DEFINITIONS .................................................................................................... 3
   3.1 HTA ............................................................................................................. 3
   3.2 COSHH ................................................................................................. 3
   3.3 BRISQ ..................................................................................................... 3
   3.4 OMB RESEARCH REGISTER .................................................................. 3
   3.5 SCRUB NURSE ...................................................................................... 4
   3.6 RUNNER ............................................................................................... 4
   3.7 STABILISATION ..................................................................................... 4
   3.8 EXPIRY DATE ....................................................................................... 4
4 REQUIREMENTS & RESPONSIBILITIES ......................................................... 4
   4.1 GENERALLY .......................................................................................... 4
   4.2 SPECIFICALLY ...................................................................................... 5
5 REFERENCES & RELATED DOCUMENTS ..................................................... 6
6 PROCEDURE .................................................................................................... 6
   6.1 PRE-RETRIEVAL CHECKS (OMB TEAM ONLY) ....................................... 6
   6.2 OTHER PRE-RETRIEVAL CHECKS (RUNNERS AND OMB TEAM) .......... 7
   6.3 TISSUE RETRIEVAL .............................................................................. 8
7 IMPLEMENTATION ......................................................................................... 10
8 TRAINING REQUIREMENTS ......................................................................... 10
9 STAFF RECORD OF ACKNOWLEDGEMENT ........................................... 11
1 Purpose

1.1 The purpose of this SOP is to ensure that tissue samples acquired during routine surgery are obtained and stored with the informed consent of the patient donor and in accordance with the legislative framework of the Human Tissue Act 2004.

1.2 The SOP also aims to ensure that tissue samples taken during surgery are of optimum quality for research purposes, and that certain criteria are reported (such as those required under Biospecimen Reporting for Improved Study Quality guidelines).

2 Safety Information

2.1 Human tissue samples are potentially hazardous to health and should therefore be handled with care and in accordance with the Operating Department’s departmental policy.

2.2 Please read the associated Control of Substances Hazardous to Health (COSHH) risk assessment before using this standard operating procedure.

2.3 Policy documents are held on the Oxford University Hospitals intranet.

3 Definitions

3.1 HTA

3.1.1 Human Tissue Authority

3.2 COSHH

3.2.1 Control of Substances Hazardous to Health

3.3 BRISQ

3.3.1 Biospecimen Reporting for Improved Study Quality

3.4 OMB Research Register
3.4.1 Register of surgeons who are authorised to obtain tissue for storage in the OMB.

3.5 **Scrub Nurse**

3.5.1 Member of the operating theatre team who is responsible for providing direct support to the surgical team during the procedure

3.6 **Runner**

3.6.1 Member of the operating theatre team who supports the Scrub Nurse.

3.7 **Stabilisation**

3.7.1 The act of rendering a sample unlikely to deteriorate in quality, e.g. by placing in RNALater. Stabilisation does not include placement in cell culture medium.

3.8 **Expiry Date**

3.8.1 This is usually stated by the manufacture on the packaging, and it is usually associated with a Lot Number. Where no expiry date is provided, OMB regards the expiry date as being 12 months after initial opening, unless otherwise agreed.

## 4 Requirements & Responsibilities

### 4.1 Generally

4.1.1 All Operating Department personnel involved in the operating procedure for removing tissue and handling tissue samples should have reached the level of competency required by departmental policy.

4.1.2 Research personnel who are acquiring tissue peri-operatively must have undertaken GCP training and have current certification. They must have been trained as OMB Team members, since procedural details preclude patient anonymity, and they must have a full or honorary Trust contract to be permitted to enter the Operating Department.

4.1.3 Surgeons authorising the tissue to be released for research should be on the OMB research Register held in the OMB Office.
NB – advice taken from the National Research Ethics Service states that GCP training and current certification is required only if the surgeon providing the surplus tissue is formally part of the research project or is the person consenting the patient for research.

4.2 Specifically

4.2.1 The OMB Team member is responsible for ensuring that the Surgeon has been consulted about attendance in the theatre session ahead of time.

4.2.2 The Scrub Nurse or member of the OMB Team is responsible for reminding the Surgeon at the start of the case that samples are required for research. S/He is also responsible for ensuring the samples are transferred into the specimen container(s), and confirming the tissue type, method of retrieval, and the anatomical site of origin. S/He is further responsible for ensuring that the Surgeon has signed the OMB Specimen Collection Form.

4.2.3 The Runner, or a member of the OMB Team, is responsible for preparing the appropriate number of specimen containers of required transport medium, ready for collection. This may involve liaison with the OMB Laboratory Technician.

4.2.4 The operating Surgeon is responsible for retrieving the tissue samples and instructing the Scrub Nurse or member of the OMB Team as to tissue type, method of retrieval and the anatomical site of origin. The operating Surgeon is also responsible for authorising release of tissue from Theatre.

4.2.5 For collection of tumour tissue sample(s) the Operating surgeon is responsible for identifying suitable tumour tissue(s) for OMB collection. This should be done with the support of the OMB team member, as soon as is practicable following extraction of the tumour.

4.2.6 The Runner, as part of the preoperative routine WHO checklist, will locate and check the ‘consent to procedure’ form to ascertain that it is signed and valid.

4.2.7 The Runner or member of the OMB Team is responsible for labelling the specimen containers and completing the appropriate OMB Specimen Collection Form. S/He is also responsible for checking the validity of the OMB Consent
Form, and for (re-)checking that the Surgeon has signed the OMB Specimen Collection Form.

4.2.8 The Runner is responsible for contacting the OMB Team by bleep (220), telephone (37645), or as detailed on the theatre whiteboard to arrange for sample pick-up.

4.2.9 The member of the OMB Team is responsible for transferring tissue samples from the Operating Department to the OMB Laboratory as soon as practicable, and for logging and processing the fluids in accordance with Laboratory SOPs.

5 References & Related Documents

5.1 OMB-MSOP 012 Printing a Theatre List

5.2 OMB-F 042 OMB Project Application

5.3 OMB-F 053 Statement of Understanding for Surgeons

5.4 OMB-F 002 OMB Consent Form

5.5 OMB-F 004 OMB Specimen Collection Form – Knee

5.6 OMB-F 005 OMB Specimen Collection Form – Shoulder

5.7 OMB-F 006 OMB Specimen Collection Form – Elbow

5.8 OMB-F 007 OMB Specimen Collection Form – Hip

5.9 OMB-F 068 OMB Specimen Collection Form – Tumour

5.10 OMB-F 069 OMB Specimen Collection Form – Spine

5.11 OMB-F 070 – OMB Specimen Collection Form – Non-Standard

6 Procedure

6.1 Pre-Retrieval Checks (OMB Team Only)

6.1.1 Unless you are part of the Surgeon’s own research group, use theatre lists (OMB-MSOP 012) to identify the Surgeon to be approached for permission to attend a theatre session.
6.1.2 Only approach Surgeons who have been included on an OMB Project Application (OMB-F 042), or who have signed a Statement of Understanding for Surgeons (OMB-F 053). This documents that all contributing Surgeons are aware of OMB, and of their duties regarding release of tissue to OMB under the terms of ethics and licence.

6.1.3 Unless you are a member of the Surgeon’s own research group, as a default, the preferred method of approach is to speak with the Surgeon on the day of surgery, at a time before s/he is operating on the desired patient (or other patients). For example, this may be during the morning theatre staff meeting, or when the Surgeon is scrubbing up.

6.1.4 The actual method of approach (in person, phone, email, etc.) and notice period (on morning of operation, 24 hours in advance, etc.) required must have been agreed well in advance of the first collection attempt. Unless you are a member of the Surgeon’s own research group, the details, and any subsequent changes, should be noted on OMB-F 042 or OMB-F 053. This documents the fostering of the collaborative relationship, and prevents one based on unannounced appearances in theatre, which may give theatre staff concern.

6.1.5 Remember to ensure that an appropriate number of specimen containers filled with a pre-agreed medium (such as cell culture medium, or RNALater) are available in the designated fridge in Theatres or in the OMB Laboratory.

NB – if handling by “scrubbed” staff is required, Trust standards of presentation and sterility must be met. Even if only handled by “unscrubbed” staff, cell culture media must have been decanted in a Class II microbiological safety cabinet to preserve medium sterility and minimise the risk of spore release.

6.1.6 Remember to wear “scrubs” in Theatre.

6.2 Other Pre-Retrieval Checks (Runners and OMB Team)

6.2.1 Ensure that the containers of pre-agreed medium have been clearly labelled with the medium’s basic name (e.g. DMEM, RNALater), the expiry date (see
Definitions), and the date of decanting and the initials of the person who performed decanting (if applicable).

6.2.2 Discard containers that have exceeded the expiry date, a date 4 weeks from the date of decanting cell culture media, or that have evident signs of contamination.

6.2.3 Remember that when the patient is transferred from the Anaesthetic Room to Theatre, it must be clear which/whether tissue samples will be:

- **Diagnostic**, i.e. a specimen for histopathology or microbiology
- **For research only**, i.e. a specimen for the OMB, or
- **For research via Pathology**.

6.2.4 Remember that:

- If a sample is **diagnostic**, Trust processes must be followed, and the sample cannot be released for research
- If a sample is **for research only**, the OMB Consent Form must have been signed by the patient. *In extremis*, the research section of the relevant NHS procedure consent will suffice
- If a sample is **for research via Pathology**, the routine Trust processes must be followed, but
  - the patient must also have signed an OMB Consent Form (*in extremis*, the research section of the relevant NHS procedure consent will suffice)
  - a purple Biobank sticker must be placed in the *tissue for research* section at the bottom right hand corner of the Histopathology Request Form (or you must use the equivalent electronic notification mechanism)

### 6.3 Tissue Retrieval

6.3.1 Locate the relevant OMB Specimen Collection Form for the procedure and affix a patient label.
6.3.2 Accept each sample from the Scrub Nurse and place it in a specimen container containing the required medium (e.g. DMEM or RNALater) as soon after extraction as practicable.

NB – this is very important to avoid deterioration of sample quality, but clinical care must always take precedence.

6.3.3 Ensure that all containers are labelled with patient stickers/details and that there is a specimen number to correlate with its equivalent on the OMB Specimen Collection Form.

6.3.4 Aim to identify each sample's anatomical site of origin, tissue type, method of retrieval, and time of removal (or cross-clamping, or other loss of oxygenated blood supply). If applicable, also aim to record the time of stabilisation (see Definitions). For tumours, also aim to include the position within the tumour, described in terms of proximity to a margin.

NB – this data is increasingly important for quality reasons (BRISQ), but clinical care must always take precedence.

6.3.5 Any other required information provided should also be documented, although it may also be obtainable from the medical notes at a later date (consent permitting).

6.3.6 If the volume of a sample exceeds pre-agreed parameters (e.g. 0.5 cm$^3$ of solid material in RNALater), it must be divided as soon as practicable by an OMB Team member.

NB – it may not be possible to do this in theatre.

6.3.7 Ensure that the appropriate OMB Specimen Collection Form is signed and dated by the Surgeon. This is the single most important function of the form, since it serves to prove that OMB has not accidentally acquired samples intended for Pathology, thus affecting clinical care.

NB – it may be that you have to wait until the end of the case to obtain a dated signature.
6.3.8 Place all specimen containers into a Biological Specimen Transportation Container (an opaque carrier vessel that protects against leaking specimens, and that also maintains confidentiality). Ensure the OMB Specimen Collection Form is included.

6.3.9 Samples may be kept at 2-8°C until released from the Operating Department.

6.3.10 If you are a member of the OMB Team trained in tissue acceptance and release, you must track and log tissue samples, as per OMB Laboratory SOPs, immediately on release from the Operating Department. This is a requirement of the licence.

6.3.11 If you are a Runner, or a member of the OMB Team without tissue acceptance and release training, bleep the OMB Team on 220 (or telephone 37645, or as indicated on the theatre whiteboard) and arrange for the pick-up of the specimen(s) from the Theatre Reception area.

7 Implementation

7.1 No practical changes to the QMS will be caused by the implementation of this SOP, but theatre relationships will be more robust.

7.2 OMB Team members involved in peri-operative collection of tissue should be advised of new version, but no re-training is necessary.

8 Training Requirements

8.1 GCP.

8.2 OUH Induction, especially Infection Prevention and Control and Information Governance.

8.3 OMB Training.
9 Staff Record Of Acknowledgement

9.1 I understand the contents of this document.

9.2 I have received the training appropriate to the procedures and feel competent to undertake them.

9.3 My supervisor agrees that I am able to perform the work covered by this SOP.

9.4 I understand that further ‘on the job’ or other training supervision may be required before working independently.

9.5 I understand that I may discuss my needs with my manager.

<table>
<thead>
<tr>
<th>Trainee</th>
<th>Trainer (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Position</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>