SOP Title  Traceability

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<tr>
<td>Author</td>
<td>Marie Hamard</td>
<td></td>
<td>17/10/2017</td>
</tr>
<tr>
<td>Reviewer</td>
<td>Sandrine Rendel</td>
<td></td>
<td>20/10/2017</td>
</tr>
<tr>
<td>Authoriser</td>
<td>Christopher Kennard, HTA Licence 12217</td>
<td></td>
<td>20/10/2017</td>
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2. PURPOSE AND SCOPE

2.1 Multiple research studies and tissue banks store human tissue samples at the University of Oxford under HTA licence 12217, for research into a wide range of biological processes and diseases.

2.2 The licence's Designated Individual (DI) is committed to ensuring full compliance to the Human Tissue Act[21] and the HTA Codes of practice[22], which include the ability to demonstrate a complete audit trail for all human tissue samples stored for scheduled purposes.

2.3 The purpose of this Standard Operating Procedure (SOP) is to describe the procedure required to document and maintain human material traceability from the point of collection or receipt to disposal or distribution of material stored under Human Tissue Authority (HTA) Research licence 12217, as required by the HTA's standards for the Research sector.

2.4 This Standard Operating Procedure (SOP) applies to all personnel working under HTA licence 12217 who collect, use or store human tissue for scheduled purposes.

2.5 Exclusions:

a) This does not apply to sample collections that are already under the governance of other University licences (12168 Clinical Trials Service Unit, 12326 Oxford Centre for Diabetes Endocrinology & Metabolism, 12433 Weatherall Institute of Molecular Medicine, 22496 Oxford DRWF Human Islet Isolation Facility, or 12178 Medical Sciences Teaching Centre).

b) This does not apply to sample collections held under a current and valid approval from a recognised research ethics committee (REC). Note: University ethics committees are not considered to be recognised RECs.
3. PROCEDURES FOR COMPLYING WITH TRACEABILITY STANDARDS

3.1 Sample records and tracking

3.1.1 If applicable, all personnel carrying out sample collection must ensure that the appropriate consent form has been completed prior to proceeding with sample collection (refer to core SOP HTA001: Consent\(^6\)).

3.1.2 Copies of the consent form(s) must be filed with the study or Research Tissue Bank records, and if possible available electronically for easy access by personnel using or releasing tissue samples. Refer to HTA001: Consent for details of acceptable records of consent.

3.1.3 For samples received from a third party where consent forms are not transferred with the samples, appropriate agreements (e.g. Material Transfer Agreement, Service Level Agreement) must be in place documenting consent provisions.

3.1.4 All collections of relevant material registered under HTA licence 12217 must be fully catalogued and a complete inventory held of all samples. Collections for which a complete inventory is not available may be registered under the licence under quarantine conditions until the cataloguing is complete (see HTA006: Quarantine, Registration and Audit\(^6\)).

3.1.5 An identification system must be in place which assigns a unique code to each donation and to each of the products associated with it. Where applicable, consent forms should be traceable to this code by authorised personnel.

3.1.6 A register of stored material must be kept which includes details of:

a) When and where the tissues and/or samples were acquired and received, and from whom if applicable;

b) The consent obtained. Consent restrictions should be recorded in database records to ensure they are followed upon distribution (e.g. consent to export samples, consent to extract DNA, etc.);

c) All sample storage locations;

d) Whether the samples were disposed of and if so, the reason for disposal, the method and date of disposal must be recorded in a disposal log. Refer to HTA005: Disposal\(^5\);

e) The uses to which any material was put;

f) When and where the material was transferred, and to whom if applicable.

3.1.7 The format of this register should be electronic where possible with robust back-up provisions; where this is not possible, paper registers may be kept with provisions in place to limit the risk of accidental loss or destruction of records.

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3.1.8 If applicable, coding / anonymisation must be carried out in line with local SOPs. Samples released to researchers should not be labelled with donor identifiers unless this is specifically authorised by the study’s ethical approval.

3.1.9 The precise physical locations and positions of stored samples (e.g. building, room, freezer, shelf, rack, box, position in the box) must be logged within the collection register of stored material (e.g. database or spreadsheet).

3.1.10 Samples which are used or processed, resulting in change of storage location or a change in sample status (e.g. rendered acellular, passaged cell line) or samples which are used to exhaustion must be recorded within the collection register of stored material (e.g. database or spreadsheet).

3.1.11 Personnel carrying out sample disposal for any reason must follow the Disposal SOP for HTA licence 12217G. This include the requirement for completion of the Disposal logM or appropriate local equivalent.

3.2 Sample coding and labelling

3.2.1 All new collected human samples and all new samples obtained after processing must be anonymised / link-anonymised by assigning each sample with a unique identifier at the point of donation or at the point of creation if the sample is a derivative.

3.2.2 The method chosen to code samples may vary depending, for example, on collection type, available space on sample container, the database type used and historic practice. However, in general:

a) Each sample, even if originating from the same donor/participant should be given a unique identifier.

b) Multiple aliquots of a single sample must also be uniquely labelled to ensure the entire sample collected is traceable from collection to exhaustion/destruction and in case of consent withdrawal. If this is impossible, the sample register must contain an up-to-date and accurate record of how many aliquots exist.

c) Where possible, the sample code should refer to the sample collection or study it is stored in.

3.2.3 Consideration should be given to potential risks to the integrity of labels related to storage conditions (e.g. sticky labels may fall off frozen containers, pen or pencil labelling may become smudged, labels may become compromised if immersed in chemical agents such as solvents). Whenever possible, carry out labelling or over-labelling with printed labels to avoid smudging, if the storage conditions allow it.

3.2.4 For significant, historic collections that are considered to be valuable for future research, where the labelling does not comply with the above coding principles:
a) Where there is the capacity and resource, the process of retrospective re-labelling of the samples with unique identifiers should be undertaken.

b) Where there is not currently the capacity or resource for re-labelling, the samples may be stored as they are, on the basis that they must be over-labelled or re-potted before being released for use in research.

c) Only when overlabelling or re-potting is not possible, the samples may be stored on the basis that they are only released for use in research under a Confidentiality Agreement.

3.3 Transfer of samples to or from the University of Oxford

NOTE 1: Material Transfer Agreements (MTA) provide a suitable formal agreement to satisfy the human material movement/transport requirements of the HTA. These contracts govern the transfer of relevant human material for scheduled purposes between two organisations and ensure that material transferred is used in accordance with the consent obtained. In addition to providing a formal record of human material movement an MTA can define the rights of the provider and recipient in terms of Intellectual Property (IP) and or commercial application of the material or its derivatives. MTAs are generally supplied by the human material provider. More information on research contracts such as MTAs may be found on the University’s Research Services website.

3.3.1 Transport of relevant material between two establishments within England, Wales and Northern Ireland for the purpose of research is permissible where both establishments hold a HTA licence or where one of the following exemptions applies:

a) Transfer of the material is covered by project specific NHS Research Ethics Committee (REC) approval.

b) The tissue is being held for no longer than 7 days incidental to transportation to an establishment which holds a HTA licence or where one of the exemptions applies.

c) The receiving establishment renders the tissue acellular within 7 days of receipt and the distributing establishment holds a HTA licence or one of the exemptions applies.

d) The tissue is distributed from a Research Tissue Bank (RTB) located on HTA licenced premises and which holds generic NHS REC approval.

e) The tissue is not HTA relevant (acellular).

f) The tissue is from the deceased and more than 100 years have elapsed since the donor’s death.

3.3.2 An appropriate Material Transfer Agreement (MTA) or Tissue Transfer Agreement (TTA) or Service Level Agreement (SLA) must be in place prior to transferring relevant human material samples outside of the organisation i.e. NHS to University of Oxford, University of Oxford to anywhere outside of University of Oxford.
3.3.3 Samples which are transferred before or following processing must follow procedures detailed in the section on Sample coding and labelling above, and any relevant local SOP on packaging and transport of samples.

3.3.4 Any sample transfer must be recorded in a transfer log (such as the template HTA_TEMP010(6)) and the sample tracking database or spreadsheet updated.

3.4 Import/export of samples

**NOTE 2:** The import and export of relevant material is not a licensable activity under the HT Act. However, the storage of the material once it is imported may be licensable if this is for a Scheduled Purpose. The geographical scope of "import" and "export" according to the HT Act is as follows:

"Import" means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

"Export" means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

It is the responsibility of the individual importing human material (into England, Wales or Northern Ireland) or exporting human material (out of England, Wales or Northern Ireland) to ensure that guidance defined by the HTA codes of practice and the requirements of counties receiving the material are followed.

3.4.1 The Principal Investigator (PI) wishing to transfer material into the University of Oxford must complete appropriate Material Transfer Agreement paperwork available via the University of Oxford Research Support website including the 'MTA Information Form - Incoming Materials'. The source or supplying institute may wish to instigate this process and provide their own documentation for review by Research Services.

3.4.2 In addition, if the imported material is being transferred into a collection registered under licence 12217, a Material Import Registration form must be completed. This includes details of:

a) The aims and objectives of the project for which the sourced material will be used;

b) A brief statement explaining the reasons to import material and if applicable, why it cannot be sourced within England, Wales or Northern Ireland;

c) Details of the consent process for material (samples and data). If a third party is importing the material, a SLA should be in place demonstrating that there is a record of consent in a suitable format.

d) Details of the ethical approval that the material will be used under.

e) The Material Import Registration form should be submitted to the collection’s custodian, the Human Tissue Governance Team (HTGT), the DI and to the relevant
Departmental Person Designated. The HTGT and the DI will review the information provided.

3.4.3 When the Research contracts team and the DI (if applicable) are satisfied with the information provided, a Material Transfer Agreement will be put in place in order to formalise the terms of agreement for the transfer of research material. Research Services will sign research-related agreements on behalf of the University. PIs are not authorised to sign these agreements.

3.4.4 The PI must ensure that a copy of the finalised signed MTA is logged with the HTGT.

3.4.5 If samples of relevant material are imported into a collection registered under licence 12217, the collection’s custodian must ensure that the samples comply with local and core licence policies and procedures, including:

   a) A quality management system including appropriate SOPs for activities relating to the imported samples;

   b) The tracking, coding and labelling considerations described above, ensuring that a robust audit trail is maintained.

3.4.6 If the imported samples are being registered under licence 12217 as a new collection, the sample custodian must apply to register the samples according to the procedures detailed in HTA006 – Quarantine, Registration and Audit⁵.

3.4.7 The storage of tissue for use in research is licensable unless the research is ethically approved by a recognised Research Ethics Committee (REC). This means that ethical approval from an overseas authority would not be recognised by the HTA. In this case, the PI wishing to import relevant material has the following options:

   a) The material may be accepted into a Research Tissue Bank registered under the licence, then released to the PI under the tissue bank’s ethical approval;

   b) The PI may seek ethical approval from a REC recognised by the HTA for the use of the imported samples;

   c) The PI may seek to conduct the research on the imported samples under an existing local recognised REC approval. This would require documented approval by the Chief Investigator named on the ethics approval, and may require the submission of an amendment to the ethical approval to the REC, to accommodate an additional source of material.

3.4.8 Unless an existing MTA is in place (e.g. Research Tissue Banks), the Principal Investigator wishing to export material from the University of Oxford must complete appropriate Material Transfer Agreement paperwork available via the University of Oxford Research Support website⁶; a ‘Material Release Form for outgoing human tissue materials’ should be completed.

3.4.9 Researchers exporting human samples must ensure that this is in accordance with the consent which has been obtained, and that any ethics approval in place allows it.

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3.4.10 When human bodies, body parts and tissue are carried by post or courier, the packaging should conform to the international standards for the transport of hazardous clinical material; a local SOP must be in place detailing the procedure to follow.

3.4.11 Imports and exports of human tissue must normally be declared to HM Revenue and Customs. Import and export entries, declarations and related documentation must be retained for a minimum of three years and up to six years.

3.5 Traceability during transportation of samples

3.5.1 A local SOP on sample transport should detail arrangements for the creation of shipping manifests (lists of content, for example a tissue transfer log), as well as arrangements for the receiver of the specimens to acknowledge receipt of a shipment. The acknowledgement should contain information on exactly what was received, with cross reference to the manifest, detailing any discrepancies.

3.5.2 Sample inventories must be kept up to date so that they reflect accurately what is being stored.

3.5.3 If not directly recorded in the inventory, there must be a cross reference to records documenting which samples have been transferred, when and where the material was transferred, to whom and for what purpose.

3.5.4 A full audit trail must be kept to document the material transfer, including:

   a) A Tissue Transfer Log (e.g. HTA_TEMP010<sup>19</sup>) documenting details of all transported sample types, unique identifiers and despatching and receiving personnel. The Tissue Transfer Log should be signed by the receiving party and a copy kept in file;

   b) Records of any agreements with courier or transport companies;

   c) Records of any agreements with recipients of relevant material (such as a Material Transfer Agreement, Tissue Transfer Agreement of Service Level Agreement).

3.5.5 Staff should refer to any local documents such as SOPs, Risk Assessments and Control of Substances Hazardous to Health (COSHH) forms for information on local procedures for preparing samples for transportation, appropriate packaging and labelling and shipping samples.

3.6 Sample disposal

3.6.1 Sample disposal must be conducted according to the Disposal SOP for HTA licence 12217<sup>18</sup> and an appropriate Disposal Log (e.g. HTA_TEMP018<sup>18</sup>) documenting the date, reason for disposal and the method used must be filled in and kept in file.

3.6.2 Staff should refer to local SOPs, Risk Assessments and COSHH forms relating to specific local procedures and precautions to conduct sample disposal.
3.7 Loss of traceability

3.7.1 Loss of sample traceability is a shortfall against the HTA Traceability Standard and must be reported to the DI for the licence using the Adverse Event and Impact Assessment Form (HTA_FRM003)\textsuperscript{b} and Adverse Event and Impact Assessment core SOP (HTA003)\textsuperscript{b}.
4. FORMS/TEMPLATES TO BE USED
Material Import Registration Form (HTA_FRM007)
Template Disposal Log (HTA_TEMP002)
Template Tissue Transfer Log (HTA_TEMP010)

5. INTERNAL AND EXTERNAL REFERENCES

5.1 Internal References

11 Consent core SOP (HTA001)
12 Quarantine, Registration and Audit core SOP (HTA006)
13 Disposal core SOP (HTA005)
14 Template Disposal log (HTA_TEMP002)
15 Information on research contracts from University of Oxford Research Services website: https://researchsupport.web.ox.ac.uk/contracts
16 Template Tissue Transfer Log (HTA_TEMP010)
17 Material Import Registration form (HTA_FRM007)
18 Adverse Event and Impact Assessment Form (HTA_FRM003)
19 Adverse Event and Impact Assessment core SOP (HTA003)

5.2 External References

