Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-2 **Version: 3.2**

Title: **Acquiring Human Tissues and Cells**

Purpose: To ensure that all applicable human material is sourced in compliance with The Human Tissue Act (2004), The Human Tissue (Quality and Safety for Human Application) Regulations 2007 and local rules.

Written By:	Tina Dale	Date: 23.02.09
Approved By:	Nicholas Forsyth	Date: 24.02.09
Effective Date:	13.12.16	Review Date:13.12.16

SOP History:

VERSION	AMENDMENT	CURRENT VERSION
3.1 (post inspection review)	None	1.0
1.0	Section 2.10 22nd July 2009	2.0
2.0	Change of HTA officer	2.0
3.0	Update header Update of Contact details Update of Sections 2.1, 2.2, 2.6, 2.7, 2.8 and 3	3.1
3.1	Substituted 2.13. Introduced 2.14-2.16. Included details of cell number in labelling.	3.2 (post inspection review)

1. Introduction:

The 2004 Human Tissue Act requires that all establishments acquiring, storing, using or disposing of human tissues are licensed and regulated for these activities by the Human Tissue Authority (HTA). The remit of the HTA was further extended in 2007 to ensure compliance with the EU Tissues and Cells Directive. In the UK this is via The Human Tissue (Quality and Safety for Human Application) Regulations 2007. These regulations are relevant to material that has come from a human body which consists of or includes human cells **and** is intended for human application. Institutions licensed by the HTA should comply with the HTA Codes of Practice and, where the material is intended for human application, the Directions issued regarding the 2007 Regulations.

*ISTM is currently licensed to undertake acquisition storage, use and disposal of human materials for research purposes. if the desired use is not related to research studies, please contact Dr Alan Harper (a.g.s.harper@keele.ac.uk) for further information.

Please note: There are no facilities within the Keele Laboratories for handling samples with a high probability of infection risk including, but not limited to IV drug users, homosexuals, some tattooed individuals, known HIV positive individuals and known hepatitis patients. Do not attempt to procure this type of material. If such samples are received contact a senior member of staff who will dispose of the material safely.
If CJD samples are to be received please contact the relevant head of department or Consultant Microbiologist (Dr Orendi) for advice before handling.

2. Procedure:

2.1 All self- or internally-funded human tissue research projects involving relevant materials obtained from non-commercial sources should be subject to Independent Peer Review (IPR) prior to application for ethical approvals. If a human tissue project has been funded externally in a process in which peer review has not been obtained as part of the application process, these should also apply for IPR. This can be done by completing the IPR form from the Keele Research Governance Website (Link below). Further guidance can be sought from Nicola Leighton (contact details below)

2.2 Following successful independent peer review, any study utilising relevant human materials **MUST** receive ethical approval from the Keele Research Ethics Committee (REC) for healthy human tissue, or the NHS REC for NHS-based studies. Section 3 for links to the application forms. For guidance with these applications, please contact the individuals below as appropriate.

Keele University contacts:	**University Hospital North Midlands Trust (UHNM) contact:**
For NHS-based studies **Emma Skinner** Sponsor QA Manager Directorate of Engagement and Partnerships iC2 Building Keele University ST5 5NH Telephone: 01782 733374 E-mail: e.skinner@keele.ac.uk ***For all other research*** **Nicola Leighton** Research Governance Officer Directorate of Engagement and Partnerships iC2 Building Keele University ST5 5NH Telephone: 01782 733306 E-mail: n.leighton@keele.ac.uk	***For NHS-based Studies*** **Dr Darren Clement** Research and Development Manager Honorary Senior Research Fellow – Keele University Research and Development Department Academic Research Unit Courtyard Annexe – C Block Royal Stoke University Hospital University Hospitals of North Midlands NHS Trust Newcastle Road, Staffordshire, ST4 6QG Telephone: 01782 675379 Email (PA): louise.barlow@uhns.nhs.uk

2.3 If material is being obtained from commercial sources, then no ethical approvals or IPR are required. However a clear ethical statement should be obtained confirming that the materials were sourced using methods that meet the regulatory requirements of the HTA.

2.4 Any work to be carried out using human embryonic stem cells (hESC) must be approved by the UK Stem Cell Bank (UKSCB). All hESC should be sourced from the UKSCB. If cells are not soured from the UKSCB then Approval to Import should be sought from the UKSCB.

2.5 Acquisition of human tissue samples from non-commercial sources external to Keele University of UHNM must be conducted under a material transfer agreement. These must be developed in association with the Directorate of Engagement & Partnerships at Keele University.(https://www.keele.ac.uk/admin/directorateofengagementpartnerships/). Staff should contact Clare Stevenson to discuss the requirements of their research project (Clare Stevenson, Academic Legal Services Advisor, 01782-734491; c.stevenson@keele.ac.uk)

2.6 Where it is necessary to have Material Use Licenses (MUL) or Memoranda of Understanding (MOU) or other agreements, these must also be developed in association with the Directorate of Engagement & Partnerships at Keele University as outlined in **2.6** above.

2.7 A copy of any agreements with suppliers should be held by the local research team, and a copy should be provided to the human tissue officer for their records.

2.8 Prior to acquisition of human tissue samples, the principal investigator should complete and submit the following documents to the human tissue officer (a.g.s.harper@keele.ac.uk):

- HTA-31: Human Tissue Risk Assessment
- HTA-41: Standard Operating Procedure for human tissue projects
- HTA-42: Human Tissue Users register (*for all members of research team*)
- HTA-43: Human Tissue Handling logbook (*for all members of research team*)

2.9 All human tissue samples used for research must have been acquired with the informed written consent of the donor (or their nominated representative) using the procedures detailed in the HTA-37 SOP. Where consent is being sought directly by the investigators or on behalf of the investigators signed consent forms must be obtained for all samples, these must be stored securely by the Chief Investigator of the study in a locked, metal filing cabinet, or on a password protected device. Completed consent forms must be made available for inspection upon request by any Secretariat-approved internal or external auditing body.

2.10 Tissue samples obtained from non-hospital sources such as licensed tissue banks will have established consent procedures. If using tissues obtained from a tissue bank, LREC consent documentation need not be held by the Chief Investigator, although confirmation of its appropriate acquisition by the supplier should be established via the MTA.

2.11 All relevant tissue arriving on the premises must immediately be logged using the HTA-8 spreadsheets. Templates and Standard Operating Procedures for these are available on the HTA website on the ISTM and Keele Research Govenernance pages or by email to a.g.s.harper@keele.ac.uk. A line on the HTA-8 spreadsheet should indicate a single sample. If a sample is split into multiple batches, then each aliquot should be designated an individual row of the spreadsheet. All spreadsheets must be updated immediately to reflect changes in storage location or use/disposal of any individual sample. See Standard operating procedure for HTA-8 for more details.

2.12 If primary cells are further recovered from the human tissue, then these should be recorded on the HTA-9 spreadsheets (from same sources as HTA-8 spreadsheet; see 2.7 above). If all remaining tissue material was discarded mark as disposed of in the associated HTA-8 spreadsheet. A line on the HTA-9 spreadsheet should indicate a single sample. If a sample is split into multiple batches, then each aliquot should be designated an individual row of the spreadsheet. All spreadsheets must be updated immediately to reflect changes in storage location or use/disposal of any individual sample. See Standard operating procedure for HTA-9 for more details.

2.13 All human tissue samples must be labelled clearly and legibly with the following information:

i) A unique Sample ID – every sample aliquot must have a unique identifier which can be used to track it through the stages of it acquisition, use and disposal from the licensed sites. The Unique ID should begin with the Principal Investigators Initials to facilitate sample identification, and then a unique alphanumeric string should be used to uniquely

identify each individual aliquot.

ii) <u>Species and cell/Tissue Type</u> – tissues must be identified as being of human origin, and must also contain detail of the cell/tissue stored. Details of cell number or concentration should also be recorded.

iii) <u>Date sample received/derived</u> - The date which the samples were acquired or derived from the original tissue sample should be recorded.

This information must match with what is recorded in the HTA-8/9 logbooks for these tissue samples

2.14 Sample aliquots should be held in boxes, racks or other secure containers. These containers should be made of a material durable enough to provide physical protection to the samples at the temperature at which they are stored. Samples should be arranged in an organised manner within these containers (e.g. in ascending Sample ID number or date of collection) to facilitate ease of auditing as well as providing an additional back-up for identification if a label is damaged.

2.15 The outside of the container should be legibly and securely labelled with the following information:

i) Study name/identifier

ii) Species and cell/Tissue Type

iii) Start and end dates for the research study

iv) Name of Principal investigator (and user)

iv) Details of Biological and Chemical Hazards that may be contained within

If multiple boxes for a study, then there should be an indication of the samples contained within each box by unique sample ID number.

2.16 Researchers should regularly check the labelling of the samples and containers to ensure that labels have not been smudged or degraded. If they have been this must be corrected immediately. If a sample has become unidentifiable this must be reported as an adverse event using the HTA-32 adverse event reporting system.

2.17 Transportation of human tissue samples to Keele's HTA-licensed buildings must be

conducted in accordance with the SOP for transportation (HTA-36 document).

2.18 All Relevant Materials MUST be stored in ***approved locations*** within HTA-licensed premises (the Guy Hilton Research Centre or Huxley building). ***Approved locations*** will bear an HTA identification label with a unique identifier for that storage location. These fridges, freezers, liquid nitrogen dewars, incubators and cold rooms are subjected to weekly monitoring to ensure that the storage conditions are suitable for purpose. However research teams should also consider strategies to maintain their storage conditions in optimal conditions (e.g. cleaning rotas, defrosting) and contingency plans in case of failure.

2.19 If the desired storage location does not bear an HTA identification sticker, then you must let the local technical staff (GHRC – Katy Cressy or John Misra; Huxley – Jayne Bromley) and/or the human tissue officer know as soon as possible to ensure that these locations can be designated and included in the weekly storage audits

2.20 Materials intended for human application must be stored separately.

3. References:

HTA codes of practices

https://www.hta.gov.uk/guidance-professionals/codes-practice

https://www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf

Peer Review and Ethical Approval documentation

https://www.keele.ac.uk/researchsupport/researchgovernance/peerreview/

https://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/