Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-3 **Version: 3.2**

Title: **Working With Human Tissues and Cells**

Purpose: To provide guidance to individuals intending to work with human material at ISTM to ensure that all staff comply with the Human Tissue Act 2004 and Human Tissue (Quality and Safety for Human Application) Regulations 2007.

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	1.0
1.0	2.3, 2.4, and 2.9 22nd July 2009	2.0
2.0	Change of HTA officer	2.0
2.0	2.1, 2.4	3.0
3.0	Inclusion of 2.6-2.9	3.1 (post-inspection update)
3.1	Update of 2.6	3.2 (Post-report update)

1. Introduction:

Work with human material in England, Wales and Northern Ireland is regulated by the Human Tissue Authority (HTA) further to the Human Tissue Act 2004. To carry out any work with material of human origin it is necessary to be licensed by the HTA and to adhere to their Codes of Practice. If there is any intention that the material may be destined for human application practices are further regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Furthermore, the use of materials of human origin may pose a risk to the researcher and the wider public in terms of disease transmission if appropriate working practices are not adopted.

Before considering working with material regulated by the HTA please consult SOP HTA-2 for guidance on procuring relevant materials.

Human material should only be handled by those individuals with the appropriate training and an awareness of the relevant regulations, any individual who is unsure whether they are suitably trained should contact a senior member of staff. Additionally persons handling material of human origin should be immunised against Hepatitis B and their response to the immunisation checked.

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.

2. Procedure:

2.1 Full risk assessments should be performed on all procedures to be used prior to any work being done with human material consisting of a Biological Risk Assessment and a COSHH assessment.

2.2 When relevant materials arrives it must be logged electronically using the HTA-8 spreadsheets. A copy of these should be sent immediately to the local HTA officer (either Alan Harper (GHRC) or Dr Dan Tonge (Huxley). The record must be updated immediately if the material is processed, changed in storage location or disposed of. Any cells derived from the tissue must be logged of using the HTA-9 spreadsheet and a copy sent to the local HTA officer.

2.3 If a leaking or broken specimen arrives do not touch it or any others with which it has been in contact. Contact a senior staff member to deal with the specimen.
See SOP **HTA-4 Handling Leaking or Broken Specimens**.

2.4 Human material must only be handled in appropriate areas and under conditions described in the Biological Risk Assessment. An appropriate area will have an appropriate work surface which is impervious to water, resistant to acids and alkalis, solvents and disinfectants and is easy to clean. Any material found outside designated areas, including common areas and office areas will be removed and incinerated by a senior member of staff.

2.5 Samples consisting of human material must be stored in designated rooms and storage locations (contact local HTA officer for details). The exact environment and storage location must be described in the HTA-8 or HTA-9 spreadsheets. Samples intended for human application should be stored separately.

2.6 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) Species and cell/Tissue Type – 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

2.7 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.

2.8 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.

2.9 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.

2.10 Where possible work should be done within a Class II laminar flow hood to maintain the sterility of the sample and to protect the user from aerosols. Work done on material intended for human application **must** be carried out in accredited clean room facilities only.

2.11 When working with relevant material, short trousers or open toed shoes are not permitted. Long hair should be tied back and jewellery should be removed and stored safely until the procedure(s) are completed.

2.12 Never mouth pipette in any laboratory area.

2.13 Never lick labels in any laboratory area.

2.14 To minimise the risk of the transmission of possible sources of infection from the sample to the researcher the following personal protection practices should be adopted:

I) To reduce the time spent handling the material process samples in batches.

II) Minimise the use of sharps including scalpels, glass pipettes, needles, scissors etc.

III) Long sleeved, Howie-type lab coats must be worn. Non-protective garment sleeves should not protrude beyond the cuffs of the lab coat.

IV) If samples are to be homogenised this must be done within a laminar flow hood, plastic aprons should be worn over lab coats and discarded immediately into a yellow clinical waste bag/bin upon moving away from the laminar flow hood.

V) Facial barrier protection in the form of chin-length face shields, masks or hood sashes must be used whenever there is a risk that splashes, sprays, droplets or aerosols may be created. Opening some containers may create aerosols.

VI) Always wear disposable gloves when handling human material, if possible, and as long as dexterity/sensitivity is not compromised, wear two pairs of gloves when handling material.

VII) Replace gloves as soon as they become visibly soiled, punctured or torn.

VIII) Gloves used for handling human material must not be used outside the designated area and must be disposed of in the yellow clinical waste bags/bins.

IX) Wash hands frequently, and immediately if contaminated by a sample.

X) If skin is punctured encourage bleeding and wash thoroughly with soap and

water.

Any contamination of mucous membranes or broken skin by a sample must immediately be reported to the Head of Department, Senior Laboratory Staff and be recorded by the person responsible for the work, or delegated appropriately.

2.16 To minimise the risk of contamination of the working environment the following working practices should be adopted:

I) During the work full attention must be given to the control of splashing and contamination of the bench area, care should be taken to avoid the transfer of human material to the equipment and surfaces.

II) Following completion of the procedure surfaces and equipment should be disinfected using freshly prepared disinfectant and disposable paper towels. If contamination is suspected at any point surfaces and equipment should be disinfected immediately. Used paper towels should be disposed of in clinical waste bags/bins.

III) Samples/materials associated with human material should be decontaminated with 1% Virkon solution overnight. Decontaminated samples can then be treated as standard clinical waste and disposed of appropriately.

3. References:

http://www.hta.gov.uk/guidance/codes_of_practice.cfm

http://www.hta.gov.uk/guidance/licensing_guidance/expected_standards_directions.cfm