Licence application assessment visit on compliance with HTA minimum standards

University of Huddersfield

HTA reference number 12641

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

19 November 2015

Background

A site visit was carried out at the University of Huddersfield, School of Applied Sciences ('the establishment') as part of the licence application assessment. A visual inspection of the establishment included the storage room where human tissue will be stored. Tissue will be stored at either -80°C, -20°C, 4°C or at room temperature. There is no liquid nitrogen storage. Discussions took place with the proposed Designated Individual (DI) and Persons Designated (PD) involved in research, in regard to consent; premises, facilities and equipment; governance and quality management systems and traceability systems. At the time of the licence application assessment visit, research groups were storing human tissue under the governance of ethical approvals from NHS Research Ethics Committees.

The School of Applied Sciences has seven distinct research groups, some of which will store tissue under the licence. The research groups are: 1) Industrial Biotechnology and Chemical Engineering; 2) Synthesis, Catalysis, and Medicinal Chemistry; 3) Molecular and Cellular Biology; 4) Pharmacy and Pharmacology; 5) Evolutionary and Environmental Genomics; 6) Functional Materials Chemistry; and 7) Supramolecular, Co-ordination and Structural Chemistry. Each research group storing tissue under the licence will have a PD to help oversee licensable activities.

This report summarises the shortfalls that have been identified and provides advice to the establishment to ensure post-licensing compliance.

Compliance with HTA standards

Consent shortfalls

Standard	Findings and shortfall	Action
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice.	The types of research and the methods of obtaining tissue that will take place after the establishment has been licensed have not yet been finalised. Before the establishment begins tissue collection and storage under the licence, it is required to develop and document its approaches for seeking and obtaining consent. At a minimum, this should include the following: • how staff will be trained in seeking consent • how consent will be sought including studies that involve staff as participants • how consent forms and participant information sheets will be approved	The proposed DI to address via the CAPA plan agreed with HTA.

Governance and Quality system shortfalls

Standard	Findings and shortfall	Action
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Before the establishment begins tissue collection and storage under the licence, they are required to develop a traceability system. This will assist in the traceability of samples, irrespective of whether they are stored under the licence or under project-specific REC approval. Each sample should be uniquely identifiable. The procedure for collection and labelling of tissue should be documented in an SOP. .	The proposed DI to address via the CAPA plan agreed with HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments in relation to health and safety matters are in place; however risk assessments relating to licensable activities are required. Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • storage failure or other damage affecting human tissue quality for useful research; • loss of human tissue; • sample mix-up or loss of traceability; • transport of specimens to and from the establishment ; • security arrangements; • incorrect disposal.	The proposed DI to address via the CAPA plan agreed with HTA.

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 23 March 2016

Advice

No.	Standard	Advice
1.	C1	The sample consent form seen during the assessment visit did not include the participants understanding of how tissue will be taken, stored and used for research. The proposed DI is advised to include these to ensure that participants understand for what purposes they have given their consent. (see also shortfall against C1)
2.	C3	Staff must be trained and assessed as competent before they seek consent. (see also shortfall against C1)
3.	GQ1	The following documents should be amended: **1. Quality Manual for Human Tissue** Section 13.5 Audit: Please remove the reference to the HTA conducting external audits on an annual basis. (The HTA schedules site visit inspections of licensed establishments using a risk based approach) **2. Adverse Incident Reporting Policy** Please remove the reference to reporting SAEs as this only applies to the Human Application sector not the Research sector.
4.	GQ1	All SOPs should be subject to document control and include: • Revision history and version number • 'Effective from' date • Review date (at least every three years) • Pagination • Author and reviewer names This will ensure that staff read the most up to date SOPs and alert staff when an SOP is up for review.
5.	GQ2	The Quality Manual states that internal audits will take place yearly. The proposed DI is advised to develop an audit schedule and formalise it to include which areas of licensable activity will be covered. The audits should include how audit findings and corrective and preventative actions will be managed.
6.	GQ6	The proposed DI should be aware of the expiry dates of ethical approval and, additionally, that when ethical approval ends tissue is subject to the licensing provisions of the HT Act and therefore needs to be stored under the governance of the HTA licence.
7.	PFE2	The proposed DI is advised to develop an SOP which covers the cleaning and decontamination of freezers, fridges and other equipment.

8.	PFE3	Documented contingency procedures should be in place in case of fridge or freezer breakdown. Staff should be made aware of these procedures.
9.	PFE3	The proposed DI is advised to put a label on the outside of the fridges and freezers for 'Human Tissue Only' to mitigate the risk of someone else using the fridge or freezer for storage. There is an audible alarm that will be triggered if the temperature reaches an unexpected level. The proposed DI should consider connecting the alarm to a call out security system or arrange for regular checks of the freezers and fridges. This is especially important when the department is not staffed for extended periods of time such as bank holidays.
10.	PFE5	The proposed DI is advised to develop and formalise procedures for maintenance and servicing of the fridges and freezers and testing of fridge and freezer alarms. This can also include temperature monitoring of the fridges. Temperatures should be reviewed for trend analysis. This will give staff an indication if the current temperature is approaching a level at which action may need to be taken.
11.	D1	Regarding the dedicated drawer in the freezer for tissue awaiting disposal: the proposed DI is advised to clearly label the drawer as 'Disposal Only' to mitigate the risk of wrongful disposal of tissue. This should be referenced in the disposal SOP.

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.