Licence application assessment visit

Edge Hill University

HTA reference number 12632

Application for a licence 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**

23 April 2015

The HTA licence application assessment visit of Edge Hill University ("the establishment") identified three minor shortfalls against the HTA licensing standards. These shortfalls are to be addressed by a corrective and preventative action (CAPA) plan agreed between the HTA and the establishment.

The HTA also offered advice to establishment where a HTA standard is fully met, but where an area of practice could be further improved.

Site visit findings

The HTA found the proposed Designated Individual and the proposed Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment has a quality manual which includes policies and procedures relating to the licensable activity. The quality manual is in draft form and has not been formally ratified. This document needs to be reviewed to ensure that all procedures are up to date and contain sufficient detail.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The establishment intends to use an electronic system to assign sample identification numbers, record sample traceability, and store consent forms. The establishment has not implemented this system yet and so does not have a system to provide sample traceability.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment does not have documented risks assessments of the regulatory risks associated with the consent and storage of human tissues for use in research. *(See Advice item 6)*	**Minor**

Advice

The HTA advises the establishment to consider the following to further improve practices:

No.	Standard	Advice
1.	C1	The establishment has template consent forms and participant information leaflets, and requires that these documents are reviewed by the University research ethics committee for each study involving human tissue. The establishment is advised to consider reviewing these documents to provide clarity on the procedure for withdrawal of consent, to include details of the timeframe for participants to withdraw their consent.
2.	C2	The establishment may wish to consider reviewing its consent procedures to ensure that consent is sought in a suitably private environment. This may help to preserve participant confidentiality, and ensure that participants feel free to ask questions, and thereby help to ensure that consent is fully informed.

3.	C3	Staff seeking consent at the establishment will be required to complete consent training. The establishment is advised to consider creating a formal consent training package. This may include, for example, assessments of the competency of staff in seeking consent.
4.	GQ3	The establishment has well-defined training procedures for staff undertaking activities covered by the licence. The establishment is advised to extend this to include training specific to the HTA licence. This should include an overview of the Human Tissue Act 2004 (HT Act) and the HTA's codes of practice. The DI may wish to consider including existing training packages; for example, the MRC 'Research and Human Tissue Legislation e-learning Module', part of the MRC Data and Tissues Toolkit (both of which were developed with input from the HTA), as part of the staff training programme: www.rsclearn.mrc.ac.uk/.
5.	GQ5 / PFE4	The establishment informed the HTA that they do not intend to distribute samples of relevant material to other organisations. The establishment is advised that should they start to distribute samples, they should ensure that robust procedures are in place including documented risk assessments and agreements with receiving organisations. These agreements should include details of the responsibilities of each party and the scope of consent obtained for the use of the samples.
6.	GQ8	The establishment should document risk assessments for the regulatory risks associated with the consent and storage of human samples for use in research. The establishment is advised that the regulatory risks may include, but are not necessarily limited to: • storage and use of relevant material without valid consent; • loss of traceability of relevant material; • failure of storage facilities or improper storage of relevant material, and; • accidental or inappropriate disposal of relevant material. The risk assessments should be reviewed regularly and all staff undertaking licensed activities should be aware of these risk assessments.
7.	PFE3	The establishment intends to store copies of consent forms on an electronic system. The establishment is advised to review access to consent forms stored on this system to ensure that participant confidentiality is maintained.
8.	PFE3	The establishment is advised to consider labelling storage units to indicate that they contain human samples stored under the HTA licence. These labels could also include the details of the person responsible for the storage unit, the acceptable temperature range and actions to be taken in the event of deviation from this temperature range.
9.	PFE4	The establishment has a procedure for the transport of samples ('HT5 Policy and Procedure for Local Transport of Human Tissue'). The establishment is advised to review this procedure to ensure that it contains sufficient detail of the acceptable modes of transport, transport conditions, traceability records and that a documented risk assessment must be undertaken.

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: 24 September 2015

Appendix 1: HTA standards

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