Site visit inspection report on compliance with HTA minimum standards

Liverpool John Moores University

HTA licensing number 12528

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**

24 June 2014

Summary of inspection findings

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

Although the HTA found that Liverpool John Moores University (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to participant information sheets and consent forms.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set out in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Liverpool John Moores University ('the establishment') is licensed under the Human Tissue Act 2004 ('the HT Act') for the storage of relevant material for use for a scheduled purpose. Relevant material is stored under the authority of this HTA licence within the School of Exercise and Sports Science for a range of uses, principally:

- research into the disorders, or the functioning, of the human body. Donors are usually healthy volunteers recruited from university staff or students or, occasionally, participants in sporting activities. Sample types collected include blood, urine, faeces and muscle biopsies. Samples are stored in cryovials in –80 ^{o}C freezers, except for tissue from frozen sections that is mounted on microscope slides, which is stored at –20 ^{o}C. Participant recruitment is ongoing. Some projects have favourable ethical opinion from NHS Research Ethics Committees (RECs) and are therefore exempted under the Human Tissue Act 2004 (Ethical Approval, Licensing and Supply of Information about Transplants) Regulations 2006 from the licensing requirements of the HT Act. Research projects may, instead, be considered either by School or University research ethics committees. Relevant material being stored by the establishment for research projects which have approval solely from the School or University ethics committee is stored under the authority of this HTA licence (refer to advice item 8);
- skeletal material which is believed to be less than one hundred years old is stored for use in anthropological research. These specimens are stored at ambient temperature in locked cabinets which are temperature and humidity monitored via dataloggers;

The establishment has been licensed by the HTA since September 2008. This report describes the first, routine, site visit inspection of this establishment in June 2014. The inspectors interviewed staff involved with licensable activities, reviewed documentation and carried out a visual inspection of four locations where relevant material is stored under the authority of the HTA licence. Consent forms and participant information sheets for three projects that had been reviewed by the School or the University research ethics committee were examined (refer to minor shortfall against consent standards C1, C2). Traceability records for five specimens in two of the four storage locations were audited. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
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 establishment has a documented policy stating the information which the 'participant information sheet' for a research study should include. However, 'participant information sheets' for some projects reviewed at the inspection did not contain all information required by that policy, although many of the general principles were covered. Also, some partially completed participant consent forms were seen in those project files. Taken together, there is a risk that fully informed consent for donation of tissue might not be obtained or at least, could not be evidenced. Consideration should also be given to ensuring consistent application of the policy.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.		

Advice

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

No.	Standard	Advice
1.	C3	The establishment intends to perform research using sub-cellular materials such as DNA. The DI is advised to include the HT Act's consent requirements in relation to analysis of DNA samples in the University's 'Guidance on Research and the HT Act 2004' and the training presentation on consent for researchers. More details can be found in the HTA's Code of Practice on Consent: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm
2.	GQ1	The DI is advised to ensure that all policies and procedural documents in SharePoint are amended to state the date of the most recent review.
3.	GQ1	In addition to the documented policies and procedures reviewed at the inspection, flowcharts for such activities as seeking participant consent and adverse incident reporting were also seen. Recognising that these were developed to assist staff, the DI is advised to consider whether the flowcharts could, for example, be appended to existing policies and procedural documents, or be expanded to become standard operating procedures (SOPs) in their own right.

4.	GQ1	The DI is advised to clarify in the 'Guidance on Research and the HT Act' policy under what circumstances NHS REC approval will be required for a research project, and the circumstances under which either School or University research ethics committee review will be sufficient.
5.	GQ4	The DI is advised to review the scope and format of audits of tissue collections and traceability records, and to develop a standard form to capture audit findings, including non-conformances. The DI is also advised to update the audit SOP to reflect the auditing procedures currently being undertaken and, in future, any changes that are proposed. A wide range of tissue collections are held under the licence, such as a closed collection of skeletal material, and projects with temperature-sensitive tissue samples mounted on microscope slides. Audits of such diverse collections do not necessarily need to have the same periodicity, or sample size. However, the DI is advised to confirm that audits are conducted using a consistent method and assess whether tissue is fully traceable from consenting through to storage and to its eventual disposal.
6.	GQ4, GQ7	The 'adverse events' policy states that mislabelling of samples, or an incorrect storage location of a sample in a freezer, is to be logged as an adverse event. However, it does not appear that when such errors were noted in a recent audit that an adverse event was logged. The DI is advised to consider whether the mislabelling of samples, or an incorrect storage location of a sample in a freezer, should continue to be categorised as an adverse event and, if he does consider these to be so, he should ensure these are reported when found.
7.	GQ8	The establishment has 'generic' and 'project' risk assessments of processes and premises, which generally identify the main risks and outline their mitigating measures. The DI is advised to review all documented risk assessments to ensure these adequately cover risks to participant consent, sample traceability and storage, and also describe all existing risk mitigation measures. The DI is also advised to review how the 'what further action is needed' column of the generic risk assessment template is used. For example, specimen storage cabinets in one laboratory are temperature- and humidity-monitored. Further action which could assure the DI that specimens continue to be stored under suitable conditions is to periodically review monitoring data, supported by development of a contingency plan for storage of specimens in the event of significant temperature or humidity excursions.
8.	D2	The DI is advised that the policy 'Disposal of human research tissue samples' should state the reasons samples of relevant material have been disposed of should be recorded, in line with the HTA's Code of practice on Disposal of human tissue: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm

Concluding comments

Despite the minor shortfall, aspects of strength were noted. There is a clear and comprehensive consent training presentation which is delivered to all researchers. The tissue traceability database is well-structured. Storage areas for relevant material are secure, and their environment is appropriately monitored.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to further strengthening governance and quality systems. Following recent staff changes the establishment has been reviewing its systems and processes; moreover, the DI has only recently taken on this position. The HTA is reassured by the DI's endeavours to review quality management systems with input from senior colleagues.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the minor shortfall identified during the inspection.

Report sent to DI for factual accuracy: 10 July 2014

Report returned from DI: 23 July 2014

Final report issued: 24 July 2014

Inspection CAPA Plan Closure Statement:

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: 6 February 2015

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.