Site visit inspection report on compliance with HTA minimum standards

Queen's University Belfast

HTA licensing number 12059

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**

26 November 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.

Queen's University Belfast (the establishment) was found to have met all HTA standards. Advice has been given on some consent and governance and quality system standards.

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

Queen's University Belfast ('the establishment') is licensed under the Human Tissue Act 2004 ('the HT Act') for the storage of relevant material which has come from a human body for use for a scheduled purpose. This establishment stores relevant material for the scheduled purpose of 'research in connection with the disorders, or the functioning, of the human body.' This tissue includes: whole blood; saliva; urine; buffy coats, and; ocular tissue. Tissue collections under this HTA licence are stored in the Centre for Public Health and the Centre for Experimental Medicine at the Royal Hospitals Trust site in Belfast.

All samples collected by the establishment since commencement of the HT Act have been from living donors. There is no removal of relevant material from deceased persons under this HTA licence.The establishment also stores some post mortem tissues (paraffin wax embedded tissue blocks and microscope slides). The majority of these samples originate from an overseas institution. The establishment also stores some PM tissue collected within the United Kingdom, which pre-dates the HT Act ('existing holdings') .

The majority of research projects involving storage and use of relevant material have received favourable opinions from NHS Research Ethics Committees (RECs) and are thus exempt from the HT Act's licensing requirements under the Human Tissue 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. Relevant material that is rendered acellular within a few days of receipt at the establishment is also exempted from the HT Act's licensing requirements. However, the establishment does store relevant material for research projects that have not been reviewed by an NHS REC, or where NHS REC ethical approval has lapsed, which fall under the HT Act's licensing requirements.

Projects have strict donor eligibility and exclusion criteria. Potential donors may include Trust patients and volunteers from the community. Staff seeking consent undertake Good Clinical Practice (GCP) training and attend a detailed presentation covering the HT Act and the principle of informed consent; it is a requirement for persons working with human tissue to attend refresher training every three years. They will explain the nature of the research to potential donors, with reference to detailed participant information sheets. Where samples are received from other UK or overseas institutions, the establishment assures itself that appropriate consent is in place through material transfer agreements (MTAs) with those institutions.

Samples are donated at Trust premises or, occasionally, in community settings before being transported to the establishment. Each donor is assigned a unique identification (ID) number; linkage of the donor and their ID number is contained within the project Master File. Sample traceability through the donor's ID number is maintained using the university-wide electronic Tissue Register and also, for some collections, local databases or spreadsheets. All collections, whether stored under the HTA licence or with REC approval, are tracked in the Tissue Register.

The establishment also distributes samples to other research institutions under MTAs.

Depending on the nature of the samples, storage is at ambient temperature (blocks and slides), 4 ^{o}C or –80 ^{o}C. Fridge and freezer temperatures are logged electronically and records are reviewed regularly for trending purposes. Escalation protocols exist should a temperature excursion occur, and freezer alarms are challenged periodically by narrowing the acceptable temperature ranges.

Samples are typically consumed through their use in research experiments. For any samples that are considered unsuitable for research, disposal is by incineration following defined clinical waste procedures. The date, method and reason for sample disposal are recorded in the Tissue Register.

The university Research Governance Department's policies and procedures, applicable university-wide, are complemented by specific documents for human tissue-related activities, controlled by the Human Tissue Steering Group. This Group comprises the DIs of the university's three HTA licences and Research Governance staff, and oversees all activities involving relevant material at the university. The Research Governance Department also scrutinises adherence to policies and procedures through a rolling programme of audits.

The establishment has been licensed by the HTA since June 2007. This report describes the first, routine, site visit inspection of this establishment in November 2014. The inspectors reviewed tissue storage locations, documentation and interviewed a selection of staff involved in research governance and the collection, storage and use of relevant material. The traceability of six sets of samples from four projects was audited. For every sample, full traceability through the Tissue Register or supporting database or spreadsheet, to the donor consent form as applicable, was maintained. For one collection, locating the samples in the relevant freezer was not straightforward, although these were eventually found there (refer to advice item 2).

The establishment holds other HTA licences under the HT Act (licensing numbers 12044 and 12113). Activities taking place under those licences were inspected in August 2013 and were not reviewed again at this inspection.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1, D1	When giving consent for sample donation, potential donors are informed they can withdraw their consent at any time. In some projects, donors may provide several samples during the course of the study. The DI is advised to ensure that if a donor wishes to withdraw from a study, the person receiving that instruction understands whether the donor wishes for any samples already donated to remain available for use for research, or whether the donor wishes all samples to be disposed of. In either case, the DI is also advised the donor's instructions should be recorded clearly in the Tissue Register, to minimise the risk of samples being retained for use for research without valid consent.
2.	GQ6	For one collection of samples stored under the licence, it became apparent in the traceability audit that a detailed understanding of processes for receipting and recording samples into storage was limited to a small number of individuals. This collection already comprises several hundred samples, with sample collection ongoing. The DI is advised to consider whether processes for receipting and recording of samples into this collection could be simplified to further mitigate any risk of loss of tissue traceability.
3.	GQ8	The establishment has well established and thorough procedures for seeking donor consent. However, documented regulatory risk assessments do not consider the potential risk that samples may be stored without informed consent. The DI is advised to assess formally, within documented risk assessments for each project, the potential risk of storage of samples for use for research without informed consent.

Concluding comments

The establishment has met all licensing standards. Examples of strength were noted. The establishment's consent training presentation provides a good overview of the legislation and the principles of informed consent. Staff demonstrated a strong commitment to good governance of human tissue collections. A robust governance framework underpins the university's HTA licences, through the Research Governance Department and the Human Tissue Steering Group. University policy documents provide clear instruction on development of project-specific protocols and risk assessments. Auditing of a proportion of projects by the Research Governance Department takes place annually. Storage environments are appropriately monitored and maintained.

The HTA has given advice to the DI with respect to consent, traceability and risk assessment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 08 December 2014

Report returned from DI: 10 December 2014

Final report issued: 10 December 2014

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.