Licence application assessment visit on compliance with HTA minimum standards

Royal Holloway, University of London

HTA licensing number 12657

To be 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**

5 January 2017

Background

A site visit of Royal Holloway, University of London ('the establishment') was carried out as part of the licence application assessment.

This report summarises the visit and provides advice to the establishment to support post-licensing compliance.

Initially, the establishment will be storing blood samples pertaining to a study named British Repository of DNA in stroke (BRAINS), which will be transferred from Imperial College London (Hammersmith Campus); however, other storage may take place in the future. The study aims to establish a DNA repository of haemorrhagic and ischaemic stroke patients of adult age > 18 years old, which occurred at any time. At the time of the inspection, there was no storage of tissue at the establishment.

A visual inspection of the establishment was undertaken and included areas where human tissue will be stored for the purpose of research within the scope of the Human Tissue Act 2004. The relevant material are blood samples taken from patients at various NHS Trusts. Consent for these samples will be taken by trained research nurses who have had good clinical practice (GCP) training.

Tissue will be stored in a dedicated -80 degrees Celsius freezer and may be sent to other establishments, for research analysis, including to those in other countries such as Canada and Qatar. No DNA isolation or analysis will take place on site and tissue will not be returned to the site once it leaves, as it is used up entirely during analysis.

There is CCTV monitoring of the building and an electronic swipe-card entry system to the building out of hours. Entry to the laboratory is restricted and it is locked when not in use. The freezer that will hold the relevant material in the laboratory will also be locked with few members of staff having access to the key. Temperatures will be manually monitored at first with a view to potentially getting a wireless monitoring system in the future. There is a contingency procedure in place for equipment breakdown.

There was a round-table discussion with the proposed Designated Individual (DI), and the Health & Safety coordinator for Biosafety. The discussion included; consent; premises; facilities and equipment; governance and quality management systems and traceability systems. Staff do not seek consent.

Advice

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

No.	Standard	Advice
1.	N/A	Although the proposed DI is suitable, he has a limited day-to-day oversight of regulated activities and is therefore advised to appoint a Person Designated (PD).
2.	C1	Consent arrangements for this study are standardised across participating sites but no documented assurances were seen to confirm that consent is being obtained in accordance with the requirements of the Human Tissue Act 2004 and HTA's codes of practice. The proposed DI is advised to assure himself that appropriate consent is being taken by adequately trained people in the various NHS Trusts. The proposed DI needs to be aware of procedures relating to storage while awaiting consent, if consent can be withdrawn and how this is captured.
3.	GQ1	Currently there are several documented procedures pertaining to the tissue. At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities: • consent; • collection; • receipt; • labelling; • specimen preparation / preservation; • storage; • relevant transport arrangements; • cleaning and decontamination; • disposal. A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in

		the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained. People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs.
4.	GQ2	The proposed DI is implementing an internal audit schedule relating to the tissue. Audits should demonstrate compliance with HTA standards and demonstrate whether the establishment are meeting the requirements of their own systems. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work. Some establishments may be able to make use of existing in-house expertise or services.
5.	GQ3	The proposed DI is advised that all new staff working with the tissue will need training and/or a brief induction to be aware of the regulatory requirements that apply when working with human tissue.
6.	GQ6	Samples are currently recorded using a paper-based system. The proposed DI is advised to consider whether records could be managed electronically, which may help with traceability and future management of larger sample groups. A centralised system for the storage of records can help to ensure that records are regularly backed-up.
7.	GQ7	Although adverse events will be managed, the proposed DI is advised to document the agreed system, not least to ensure that events and consequent actions are logged and shared for future learning.
8.	PFE3	The establishment is advised to label the outside of the proposed freezer where relevant material will be stored to make staff aware that human tissue is being stored there. This may help to reduce the risk of sample mix-ups and ensure staff are aware of the need to manage these samples in line with the regulatory requirements.
9.	PFE3	The proposed DI is implementing freezer temperature monitoring. Documented temperature monitoring will allow the establishment to easily visualise and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regularly tested and manually challenged periodically to ensure that they are operating as expected.

10.	D1	The establishment is not planning to routinely dispose of tissue. In terms of general disposal advice, establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, reason and method. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.

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.