Licence application assessment visit report on compliance with HTA licensing standards

University of Lincoln

Proposed HTA licensing number 12678

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**

25 July 2018

Summary of visit findings

Although the HTA found that the University of Lincoln had met the majority of the HTA's licensing standards, one minor shortfall was found against Premises, facilities and equipment with regard to the monitoring of storage units.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

The University of Lincoln ('the establishment') is an academic institution undertaking research into a variety of health-related conditions. Following the grant of a licence, all tissue will be stored at the Joseph Banks Laboratories within secure areas with swipe card or key access.

At the establishment, all new research projects must be approved by the University of Lincoln Human Research Ethics Committee or have approval from an HRA-recognised research ethics committee (REC).

Researchers who wish to work with human tissue will be registered to use human material and will be required to demonstrate competency by evidencing familiarity with relevant documentation, undergoing a documented training programme and maintaining a training portfolio. Registration will be required to be renewed every three years. Consent training for use for human tissue in research will provided in-house by the proposed DI and via an external e-learning training module. All training will be evidenced in the researcher's training portfolio. Guardianship of this is through the Human Tissue Oversight Group.

The establishment has a well-developed quality system in place to maintain the traceability of human tissue samples that will be stored under the governance of the HTA licence. All samples to be stored at the establishment will be treated as relevant material and are covered by a single set of policies and procedures.

Samples will be stored in a liquid nitrogen storage unit in a specified rack. Temperature and liquid nitrogen levels are monitored weekly on paper record. There is an audible alarm to alert staff to decreased levels of liquid nitrogen but there is no notification system to alert staff to excursions outside of working hours (see shortfall against PFE2(c)). Samples will be also stored in a freezer at -80°C and temperatures are monitored weekly on paper record. There is an audible alarm and a call-out system to alert staff to temperature excursions outside of set ranges during non-working hours via the University security department. There is a secure, dedicated contingency back-up freezer in a separate location in the event of storage temperature failure. The freezers are maintained under contract. Samples will be also be stored at 4°C in a separate laboratory and at ambient temperature. No temperature monitoring is currently undertaken for storage at 4°C and there is no alarm system in place to alert staff to temperature excursions outside acceptable limits (see shortfall against PFE2(c)).

Description of visit activities undertaken

This report describes the licence application assessment visit of the establishment on the 25 July 2018. The visit included a visual inspection of the storage areas, including the contingency storage area, a review of documentation and meetings with the proposed DI and quality manager.

Visit findings

Compliance with HTA standards

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	There is no alarm system for storage at 4°C to alert researchers of temperature excursions outside of acceptable limits. There is no external call-out system for the liquid nitrogen or 4°C storage units if levels or temperatures fall outside of acceptable limits outside of working hours. Temperatures of the -80°C and 4°C storage units, and liquid nitrogen fill levels in the liquid nitrogen dewar, are currently only monitored weekly. See *Advice*, item 1	**Minor**

Advice

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

No.	Standard	Advice
1.	PFE2(c)	The proposed DI is advised to: • Monitor the fill levels and temperatures of the liquid nitrogen dewar, the -80°C and 4°C storage units daily during weekdays. • Periodically review temperature monitoring data for trends in order to be aware of any drifts in temperature. This is to ensure preventative actions can be put in place to avert any potential failure in storage. • Challenge the alarm call-out system for the storage units (when in place) to ensure that, when temperature or fill level deviations are detected, the system operates successfully. • Label the -80°C and 4°C storage units with the lower and upper alarm set points to ensure researchers are aware of the acceptable temperature limits.

Concluding comments

This report describes the licence application assessment visit of the University of Lincoln (proposed HTA licensing number 12678), which applied to be licensed under the HT Act for storage of relevant material which has come from a human body for use for scheduled purposes.

The HTA found the proposed DI and proposed Licence Holder to be suitable.

A number of strengths were also found during the site inspection visit:

- There is a harmonised approach to the governance of relevant material which will be stored under the HTA licence and with approval from recognised RECs, even though the latter are not subject to HTA licensing requirements. This streamlined approach will reduce the risks associated with varying practices.

- There is a well thought-out quality management system in place, supported by training materials and documentation, with a dedicated quality manager in place.

- All work with human tissue is overseen by the Human Tissue Oversight Group which will govern and have oversight of the custodianship of human tissue.

There is one area of practice that requires improvement, with a minor shortfall against standard PFE2 (c) regarding the monitoring of storage facilities and the call-out procedures in the event of excursions outside acceptable ranges.

The HTA requires the proposed Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 14 September 2018

Report returned from DI: 18 September 2018

Final report issued: 25 September 2018

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: 05 March 2019

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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.
b) Records demonstrate up-to-date staff training.
c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.
b) There is a document control system.
c) There are change control mechanisms for the implementation of new operational procedures.
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities.
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

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.