**Site visit inspection report on compliance with HTA licensing standards**

**Liverpool School of Tropical Medicine**

**HTA licensing number 12548**

**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**

**11 & 12 December**

**Summary of inspection findings**

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

Although the HTA found that the Liverpool School of Tropical Medicine had met the majority of the HTA's standards, three minor shortfalls were found against Governance and quality system and Traceability standards. These were in relation to risk assessments and disposal records.

**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

This report refers to the licensed activities carried out at the Liverpool School of Tropical Medicine (the establishment), which is licensed under the Human Tissue Act 2004 (HT Act) for storage of relevant material for use for a scheduled purpose. Since the previous inspection, the establishment added a satellite premises to the licence in August 2017. The satellite is under the same governance systems as the hub site. The licence covers the hub site at the Liverpool School of Tropical Medicine (LSTM) and the satellite site at the Liverpool Life Sciences Accelerator. The Licence Holder (LH) is the LSTM, with the Director as the named contact. The Designated Individual (DI) is the Dean of Biological Sciences. There are Persons Designated (PDs) in each research group to support the DI.

Human samples are stored for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'. The establishment has been licensed since 2009 and this was the second routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The establishment carries out a wide range of studies in relation to tropical diseases. There are approximately six different research groups. The majority of research projects involve samples imported from outside of England, Wales and Northern Ireland. Although the consent requirements of the HT Act do not apply to these samples, the establishment confirmed, and provided documentation to evidence, that suitable consent is in place as part of good research practice and they have Material Transfer Agreements (MTAs) in place with all external establishments.

There are a small number of samples that are obtained from the UK. Consent for these samples is sought only by clinicians trained in seeking consent.

The establishment has a Research Tissue Bank (RTB) which has generic ethical approval from a recognised Research Ethics Committee (REC). Research groups must go through a formalised process, that includes completing an application, when requesting samples. The application is reviewed by the Human Tissue Compliance group before a decision is made to allow the research group to store and use the samples.

The establishment also stores human samples for research projects that have project specific ethical approvals from recognised RECs. Although these are exempted from the licensing requirements of the HT Act, advice was given in relation to the records for the projects (see *Advice*, item 5).

Relevant material is stored in a number of different areas at the hub and satellite site. This includes storage at room temperature, 4$^{o}$C, -80$^{o}$C, and in liquid nitrogen.

Both sites are secured 24 hours a day and only authorised personnel have swipe card access. Visitors must be accompanied and are required to sign in and out at the main entrance. The majority of working collections are stored in freezers located within controlled-access laboratories. All of the freezers are kept locked. All freezers are fitted with automated alarms that are triggered by deviations from the set acceptable temperature ranges. The alarm systems are routinely tested; however, trends are not reviewed (see *Advice*, item 3). Freezers are maintained and servicing records were reviewed during the inspection. The establishment has contingency arrangements for all temperature controlled storage.

The liquid nitrogen store is located at the hub site, which has controlled access, and the tanks that contain relevant material are secured by locks. There is also a small collection of relevant material stored in locked cabinets within a controlled-access laboratory.

There are overarching governance documents; however, staff working under the licence were not aware of risk assessments relating to licensable activities (see minor shortfall against standard GQ6(c)).

Each specific project uses the same database and methods to facilitate the traceability of material. It is the responsibility of the Principal Investigator to update the DI annually of activities. Projects and associated collections are audited on a regular basis (see, *Advice* item 1).

**Description of inspection activities undertaken**

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the establishment, previous communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and interviews with staff involved in consent seeking, quality management and sample management. The inspection also included a visual inspection of the areas where samples are stored under the licence and audits of sample traceability. Audits of the following, randomly-selected samples were conducted and no discrepancies were found:

- Two samples, from computer records to frozen storage and consent documentation
- One sample, from computer records to frozen storage
- Two samples, from computer records to room temperature storage
- One sample, from computer records to fridge storage
- Two samples, from computer records to liquid nitrogen storage
- One sample, from computer records to cold room storage

## Inspection findings

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

## Compliance with HTA standards

Three minor shortfalls were found in relation to risk assessments and documentation for disposal.

### Governance and Quality

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| 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. | Documented risk assessments are in place for some of the practices relating to licensed activities; however, there are no risk assessments covering the following:<br>• Storage of samples after withdrawal of consent<br>• Security arrangements<br>• Storage failure<br>• Transport of samples | **Minor** |
| c) Staff can access risk assessments and are made aware of risks during training. | Staff within the research groups were not aware of risk assessments relating to the samples themselves or licensed activities.<br><br>In addition, there is no formalised process for distribution of risk assessments to staff or sign off that staff have read and understood them. | **Minor** |

### Traceability

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| T2 Bodies and human tissue are disposed of in an appropriate manner | | |

| | | |
|---|---|---|
| b) The date, reason for disposal and the method used are documented. | The inspection team were informed that there was a folder for disposal records; however, the date, method and reason for disposal were not routinely documented. | **Minor** |

**Advice**

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ2(a) | A thorough process for traceability audits is undertaken at the establishment. The DI is advised to also include vertical audits of records and specimens so that he can assure himself that specimens are fully traceable from consent to disposal.<br>Audits should also include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement (e.g. audits of staff entering information on the sample database). |
| 2. | GQ6(c) | The process for reviewing risk assessments should be formalised and include a sign off that staff have read and understood them. |
| 3. | PFE2(c) | Temperature records should be reviewed regularly to identify trends so that staff may be able to spot when storage conditions may be deteriorating and they are alerted to developing equipment failure. |
| 4. | T1(c) | Refrigerators, freezers and other vessels which contain human tissue should be appropriately labelled so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with other tissues. |
| 5. | N/A | The DI should ensure there is a robust process in place to monitor when REC approval is coming to an end so he can identify when samples should be transferred under the HTA licence, disposed of in line with consent given or apply for extended REC approval within a required timeframe. |

**Concluding comments**

While the majority of HTA's licensing standards were found to be met, a number of areas of practice were identified for improvement, including three minor shortfalls in relation to risk assessments and disposal records. Advice was also given to the establishment on a range of matters.

The HTA requires the 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 shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 9 January 2019**

**Report returned from DI: 10 January 2019**

**Final report issued: 15 January 2019**

**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: 31 May 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 |
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| **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.<br>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.<br>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.<br>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.<br>e) Language translations are available when appropriate.<br>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.<br>b) Records demonstrate up-to-date staff training.<br>c) Competency is assessed and maintained. |

| Governance and quality system standards |
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| **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.<br>b) There is a document control system.<br>c) There are change control mechanisms for the implementation of new operational procedures.<br>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.<br>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.<br>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** |
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| 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 |
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| 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 |
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| **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.