Inspection report on compliance with HTA licensing standards
Inspection date: **8 March 2022**

University of Reading
HTA licensing number 12508

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
University of Reading	Licensed	Not licensed

Summary of inspection findings

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

University of Reading ('the establishment') was found to have met all of the HTA's standards.

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

Compliance with HTA standards

All applicable standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	GQ1(c)	The establishment will be implementing a new traceability system in the next few months. The DI is advised to incorporate testing of the new system as part of change control, before replacing the old system of recording sample traceability.
2.	GQ2(b)	To improve the audit trail, the DI may wish to consider documenting the corrective actions on the audit proforma or attaching these to the paperwork itself.
3.	GQ2(a)	To assist in demonstrating compliance with our standards and whether the establishment is meeting the requirements of their own systems, the DI is advised to consider extending the scope of audits. Possible examples include those related to process observations and a full audit against the HTA's licensing standards.
4.	GQ4(a)	Consent forms are retained for up to five years by the establishment as set out within the 'Management and Retention of Records for working with Human Tissue'. In the absence of other supporting evidence, the DI should consider, and – if necessary – formally assess, the risk/s of disposing of consent records while tissue is still being stored for a scheduled purpose.

		Although this has not been an issue in the past, an issue could arise in the future because the current spreadsheet does not record the consent given for a sample and, if the consent record is disposed of, there is a risk of not being able to fully trace a sample back to the corresponding consent.
5.	GQ5(b)	The establishment has in place incident forms to document adverse events that involve human tissue. The DI should consider documenting the reason for closure of a corrective action following an incident on this form or attaching this information with the form to improve the audit trail.
6.	GQ6(a)	To strengthen existing risk assessments, the DI is advised to consider the following: • that all mitigations are appropriate and relevant for a given risk; • relevant standard operating procedures and/or policies, where appropriate as evidence of mitigation, are cited; and • a risk matrix approach is used to enable the scoring/rating of risks.
7.	T1(c)	The Research Nurse carries out an informal 'spot-check' of consent forms to check that they have been completed fully. The DI should consider recording this check so that there is evidence that these are being carried out.
8.	T1(c)	The consent forms are linked to each stored sample; however, the DI may wish to consider recording that consent has been obtained for all tissue in the new traceability system. This may be particularly relevant if a decision is made to dispose of consent forms while tissue is still being stored.
9.	T2(b)	The DI is advised to consider adding a separate tab for reason for disposal, as the current system relies upon the individual updating the traceability spreadsheet to add this information and this may help to mitigate the risk it could be missed.
10.	PFE2(c)	The DI is advised to undertake periodic testing, including manual challenging, of temperature alarms - and the call-out system - to ensure that they are operating as expected. Furthermore the DI may wish to consider adding notices to the freezers containing the alarm trigger points.

11.	PFE2(d)	In addition to the on-site contingency plan, the DI is advised to consider whether there is any realistic prospect or scenario that off-site contingency arrangements may be needed and take the appropriate actions.

Background

The Department of Food and Nutritional Sciences at University of Reading undertakes nutrition and gut-based research, and stores between 5000 to 6000 blood, urine and faecal samples.

The establishment has been licensed since 2010. This was the second inspection of the establishment; the most recent previous inspection took place in 2011.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

Of the 47 HTA standards, 46 standards were assessed (standards published 3 April 2017). HTA standard PFE2(b) was not applicable.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to, standard operating procedures for licensable activities, key policies, study audits including an audit against HTA standards, meeting minutes, staff training records, traceability records, temperature monitoring data and incidents.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards.

Audit of records

No traceability audit was carried out; however, a review of the establishment's audits was undertaken as part of the assessment, reviewing key areas such as sample receipt, storage and disposal. There were no issues identified.

Meetings with establishment staff

A round table discussion was carried out with establishment staff and included the DI and key staff members involved with licensable activities, including a research nurse involved in consent training staff and consent-seeking.

Report sent to DI for factual accuracy: 29 March 2022

Report returned from DI: 11 April 2022 (with comments)

Final report issued: 12 April 2022

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next inspection.

   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 the final inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.