Site visit inspection report on compliance with HTA licensing standards
Inspection date: **30 October 2019**

College of Medical and Dental Sciences

HTA licensing number 12358

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
Hub site College of Medical and Dental Sciences	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.

Although the HTA found that the College of Medical and Dental Sciences (the 'establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and Quality.

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.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The audit schedule does not stipulate when audits will occur; what licensable activities will be reviewed; or who will be responsible for completing corrective actions.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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.

Advice

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

Number	Standard	Advice
1.	GQ1(d)	The DI attends a number of meetings with senior staff members to discuss matters relating to HTA-licensed activities. The DI does not, however, attend any meetings with staff carrying out licensable activities. The DI may wish to consider attending/chairing a meeting for staff carrying out HTA licensable activities. This may facilitate the DI in their statutory duties.
2.	GQ4(a)	There are currently three documents addressing document control. There are plans to control documents via the quality management system currently employed as a document repository. The DI is advised to ensure only a single document is in circulation, to add clarity to the process of document control until the new system is operational.
3.	T1(e)	The DI is advised to request acknowledgement of receipt of relevant material, transferred by courier, from those receiving samples from the Research Tissue Bank. This should provide stronger assurance that the material has been received and traceability has been maintained.
4.	PFE3(c)	The inspection team witnessed staff accessing storage areas and handling vessels containing human tissue without wearing gloves. The DI is advised to review relevant risk assessments and consider how to ensure that staff wear the appropriate personal and protective equipment provided.

Background

The College of Medical and Dental Sciences has been licensed by the HTA since October 2007. This was the third site visit inspection of the establishment; the most recent previous inspection took place in September 2015.
One research tissue bank operates under the licence:
Human Biomaterials Research Centre (HBRC) (15/NW/0079)

Since the previous inspection, there has been a change in the DI. There have been no other 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 inspection team covered the following areas during the inspection:

Standards assessed against during inspection
The standard PFE2(b) was not assessed during this inspection as it was not applicable. The remaining 46 out of the total 47 were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The inspection included a review of policies and procedural documents relating to licensed activities, staff training records, audit schedule, risk assessments, incident reports, meeting minutes, transport agreements, cleaning records and temperature monitoring records for the storage units.

Visual inspection
The inspection included a visual inspection of the -80^{o}C and -20^{o}C freezer room, the cryostore room and the room temperature block store where relevant material was being stored within the establishment.

Audit of records

Audits of the following randomly-selected samples were conducted:

- Six samples from the HBRC RTB -80ºC and -20ºC freezer room were audited from sample to records. All samples were fully traceable and appropriate consent records were in place.
- Three samples from the HBRC RTB cryostore room were audited from sample to records. All samples were fully traceable and appropriate consent records were in place.
- Three samples from the room temperature block store were audited from sample to records. All samples were fully traceable and appropriate consent records were in place.
- Two samples from the HBRC RTB were audited from database to sample. All samples were fully traceable and appropriate consent records were in place.
- Disposal records on the database were reviewed. Two samples were audited from database record to storage location. Samples were not in the previous storage locations and were presumed disposed of, as per database records. Date and method of disposal was recorded.

  A number of samples disposed of between 01/06/2019 and 29/10/2019 had reason for disposal as 'no consent records'. Following the inspection, further information and assurances were sought by the HTA. Although a considerable number of samples had been retained outside of the requirements of the establishment's internal procedures, the HTA has been assured that the samples that were disposed of had not been accessed and used at any point for a scheduled purpose. The HTA were also assured that no samples are currently being stored without valid and appropriate consent. The HTA is satisfied that the establishment has taken appropriate remedial action and put appropriate measures in place to prevent the unauthorised retention of samples in the future; the HTA will ensure that the actions taken to address the one minor shortfall will strengthen current arrangements in this regard.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including research technicians, Operations Manager, research and governance compliance staff, consent seeking co-ordinators, Persons Designated and the DI.

Report sent to DI for factual accuracy: 22 November 2019

Report returned from DI: 5 December 2019

Final report issued: 5 December 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: 20 January 2020

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 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.

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

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