Site visit inspection report on compliance with HTA licensing standards
Inspection date: **22 and 23 January 2020**

University Hospital of Wales
HTA licensing number 12107

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 Hospital of Wales	Licensed	Not licensed
Velindre Hospital	Licensed	Not licensed
Llandough Hospital	Licensed*	Not licensed
Royal Gwent Hospital	Licensed*	Not licensed

* = Establishment is licensed to carry out this activity but is not currently carrying it out.

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 University Hospital of Wales (UHW; 'the establishment') had met the majority of the HTA's standards, two major shortfalls were found against standards for Consent and Governance and Quality systems.

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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
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.	There are inadequate agreements with Clinical Trials teams that have stored samples at the establishment. This situation had led to the discovery of some samples that have been stored and/or used for research but for which consent cannot be evidenced, or for which consent has been declined. Relevant samples are now quarantined pending the outcome of internal investigations and actions.	**Major**

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.	At the time of inspection, the establishment did not have approved policies or procedures in place for the release of samples that were being stored after Clinical Trials had ended, although these documents were being drafted. The establishment confirmed that, to date, all clinical samples released had been at the request of the Clinical Trial sponsor, rather than after review by the tissue bank's scientific committee; as would occur for other samples housed in the tissue bank. See *Advice*, item 1.	**Major**

The HTA requires the DI 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.

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to review the wording in the Wales Cancer Bank (WCB) SOPs for 'receiving and storing non-WCB consented samples' and 'receiving Clinical Trial samples' to clarify that: • all samples from external parties without current recognised Research Ethics Committee (rREC) approval will be held in the WCB under the governance of the HTA licence; • non-WCB staff will only have access to the samples and storage area under the direct supervision of WCB staff; • it is the responsibility of the DI to have an assurance that appropriate consent is in place for the samples to be stored for use for the scheduled purpose of research; and • that all samples held in the WCB will be released following the SOP for release of samples from the WCB.
2.	GQ3(a)	Establishment staff undergo Human Tissue Act training during the induction process, and when the training material is periodically updated. The DI is advised to consider a process where staff undergo HT Act refresher training at regular intervals.
3.	T1(c)	During a review of samples stored in the -80°C freezer it was noted that the hand written label on a sample rack had worn off. Traceability was maintained, but the DI is advised to implement a more robust method for labelling sample racks.
4.	PFE2(c)	The establishment has purchased a commercially available continuous monitoring and alarm system for their fridge and freezer units. The DI is advised to consider implementing a process to trend the routine temperatures

		of the units. Deviations in these temperatures may provide an early warning of a potential unit failure before it occurs.

Background

UHW has been licensed by the HTA since June 2007. This was the second site visit inspection of the establishment; the last inspection took place in February 2009. This licence exclusively covers the WCB, with other licensable research activities occurring under an alternative HTA licence. The WCB obtains tumour samples and normal tissue from living donors undergoing treatment at a number of hospitals throughout Wales. Samples may also be collected from healthy relatives and partners of volunteers. Since the previous inspection, the establishment has removed a number of satellite sites from the licence. Velindre Hospital is the only one of the three satellite sites currently undertaking licensable activities.

In addition to the recruitment of volunteers to provide samples for the WCB, the establishment also hosts samples for ongoing cancer Clinical Trials under rREC approval. As Clinical Trials have come to an end, the establishment has begun to transfer remaining trial samples into the WCB tissue bank, for storage for use in future research. Due to recently identified issues, these samples are currently in quarantine and have not been made available for use through the WCB (see shortfalls and advice items above).

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

Standards GQ3(c) and PFE2(b) were not applicable to the activities undertaken by the establishment. All remaining 45 licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to licensed activities, volunteer consent documentation, equipment records, risk

assessments, temperature monitoring for the storage units and staff training records. In addition, the databases used to record and track relevant material were reviewed.

Visual inspection

The inspection team undertook a visual inspection of areas where licensable activity is undertaken at both UHW and Velindre Hospital. This included a visual inspection of the areas where relevant material may be received, checked, and logged into the relevant database. It also included areas where relevant material, and records, may be stored. As no licensable activities were being undertaken at the Royal Gwent Hospital or Llandough Hospital the two satellites were not visually inspected on this occasion. The inspection team did, however, review donor consent records and sample tracking records from both sites.

Audit of records

Audits of 27 randomly selected samples were conducted:

- six samples from the WCB at UHW, comprising whole blood and tissue at -80°C, were audited from sample to record. All samples were fully traceable and appropriate consent records were in place;
- ten samples from the WCB at UHW - currently in quarantine and from ended Cancer Clinical trials - were audited, from record to sample. This comprised samples collected from five Clinical Trials - and included blood products, saliva and urine stored at -80°C - and paraffin-embedded blocks and slides, stored at ambient temperature. A minor discrepancy was found where a handwritten label had been rubbed off one rack (see *Advice*, item 3), but all samples were fully traceable. Database and paper records indicated that Clincal Trial staff had confirmed consent was in place and, in all cases, there was a sample collection date and date when consent had been provided; and
- eleven samples stored at Velindre Hospital - comprising blood products and saliva stored at -80°C, and paraffin-embedded blocks and slides stored at ambient temperature - were audited from record to sample, and from sample to record. Samples audited included those collected at Velindre Hospital and recently transferred from the Royal Gwent Hospital when they ceased licensable activities. All samples were fully traceable and appropriate consent records were in place.

Meetings with establishment staff
The visit included discussions with the DI, Corporate Licence Holder contact, Research Co-ordinator and the Human Tissue Manager. In addition, roundtable discussions were held with establishment staff involved in: recruiting and obtaining consent from volunteers; receiving, logging and storing relevant material; facilitating access to samples in the WCB, and; governance and quality systems.

Report sent to DI for factual accuracy: 12 February 2020

Report returned from DI: 19 February 2020

Final report issued: 05 March 2020

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: 19 August 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.