Human Tissue Act Compliance
Final Internal Audit Report

August 2021

Hywel Dda University Health Board

NWSSP Audit and Assurance

Partneriaeth Cydwasanaethau
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Executive Summary

Purpose

The purpose of the review is to establish whether clear and appropriate arrangements are in place to manage and monitor compliance with the Human Tissue Act.

Overview

Key matters arising concerned the lack of an annual audit programme within the Biobank in line with Human Tissue Authority Code of Practice and Standards, and the Biobank standard operating procedures.

Other matters arising concerned areas for refinement and further development.

Report Classification

		Trend
Reasonable 	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.	n/a

Assurance summary[1]

Assurance objectives		Assurance
1	Licencing Arrangements	Substantial
2	Monitoring and Recording Compliance	Reasonable
3	Policies and Procedures	Reasonable
4	Incidents and Complaints	Substantial
5	Reporting Arrangements	Reasonable

Matters Arising

		Control Design or Operation	Recommendation Priority
1	Research (Biobank) Internal Audits	Design	High
2	Good Clinical Practice Training Review	Operation	Medium
3	Biobank Risk Register	Operation	Low
4	Reporting HTA Compliance to the Board	Design	Medium

[1] The objectives and associated assurance ratings are not necessarily given equal weighting when formulation the overall audit opinion

1. Introduction

1.1 The review of the management and monitoring of compliance with the Human Tissue Act (HTA) 2004 was completed in line with the Hywel Dda University Health Board Internal Audit Plan for 2021/22. The relevant lead Executive Director for this review was the Medical Director.

1.2 The HTA was established to regulate activities concerning the removal, storage, use and disposal of human tissue. This is defined as material that has come from a human body and consists of or includes, human cells. The activities of storing and importing human tissues and cells can only be carried out by an establishment holding an appropriate HTA license.

1.3 The following potential risks were considered during this review:

- The Health Board is not aware of the risks associated with HTA compliance; and
- Reputational damage, penalties and loss of licenses to operate.

1.4 Testing was undertaken within the two licensable functions operating in the Health Board – Mortuary Services (Post-Mortems) and Research.

2. Detailed Audit Findings

Objective 1: Appropriate arrangements are in place to meet HTA licensing requirements

2.1 The Human Tissue Authority is the national regulatory body that ensures human tissue is used safely and ethically, and with proper consent. All organisations dealing with human tissue are required to comply with the standards and guidance in order to obtain a licence to operate. The two licensed activities that the Health Board undertakes in relation to HTA compliance are Mortuary Services/ Post-Mortems and Research.

2.2 Hywel Dda University Health Board has held a Human Tissue Act licence for Mortuary Services since 2011 and for Research since 2016, which enables tissue and data to be stored in a Biobank outside of the Health Research Authority (HRA)/ Health and Care Research Wales (HCRW) ethical approval process.

2.3 We can confirm that both licences were current and valid, and reflected the functions relating to HTA that the Health Board undertakes. In addition, the licencing arrangements regarding satellite establishments were reviewed and found to be satisfactory.

2.4 The HTA requires the identification of 'Designated Individual(s)' within licenced areas. We can confirm that the Designated Individuals within Mortuary Services and Research were the Consultant Histopathologist and Research & Development Director respectively.

Conclusion:

2.5 Noting the above, we have assessed Substantial assurance for this objective.

Objective 2: Mechanisms for monitoring and recording compliance are robust

Mortuary/Post-Mortem

2.6 The Pathology Department has an established quality audit schedule in place for 2021 for all elements within their locality, including Mortuary Service. A sample of five audits was selected pertaining to the Mortuary Services with backing evidence obtained to verify completion. Four were evidenced as completed and one was ongoing at the time of fieldwork. The detailed audit schedule is recorded and retained in the mortuary quality management software system *Q-Pulse*.

2.7 A 'HTA Standards and Compliance Audit' was also undertaken by the Pathology Quality Manager in September 2020 focusing on compliance with the relevant HTA standards. Audit selected a sample of five actions from the action plan with evidence obtained to corroborate that the recommendations had been implemented.

2.8 Issues arising from the quality audits and gap analysis reviews were discussed at the Mortuary Governance meetings during 2021.

Research

2.9 The mechanisms for the monitoring and recording compliance within the Research Department is undertaken on an exception basis only, with ad hoc audits being triggered in response to any discrepancies or issues that come to light.

2.10 Concluding discussions with the Advanced Biomedical Scientist (Research), the Research Department does not have an audit programme in place due to insufficient resource to schedule and coordinate a programme of annual audits. However, the Human Tissue Authority's Code of Practice and Standards, in addition to the *Biobank Policy (SOP 6)* states that an annual audit programme should be in place. **[See Matters Arising 1]**

2.11 Triggered audits undertaken in response to any discrepancies or issues that come to light are submitted to the Research Quality Management Group (RQMG). A review of the RQMG minutes for 2021 noted the submission and discussion of triggered audits at these meetings.

Conclusion:

2.12 Noting the above we have concluded Reasonable assurance for this objective.

Objective 3: Policies and procedures have been developed and appropriate training provided to staff to support compliance with the Human Tissue Act

Mortuary/Post-Mortem

2.13 All Mortuary Services policies, standard operating procedures (SOPs) and regulatory standards were held within the *Q-Pulse* system complete with document management information including version number, activation and review dates. In addition, corporate policies such as the *Consent to Hospital Post-Mortem Examination Policy* that are available to all staff on the Health Board's intranet site.

2.14 All Mortuary Service staff are required to read and understand all uploaded policies, SOPs and regulatory standards placed on the system. To facilitate this process, employees are provided with accounts and access to *Q-Pulse* system that sends alerts when new policies or SOPs are uploaded. We can confirm training logs are retained for staff working within Mortuary Services.

Research

2.15 The corporate policy in place for Research is the *Biobank Policy* that was updated and approved in April 2020 in response to the impact of the Covid-19 pandemic, and is available to staff on the Health Board intranet site. The policy contains a suite of SOPs that cover all licensable activities such as storage, transport and disposal of biobank material, and the reporting of adverse events.

2.16 All staff are required to read and understand the policies and SOPs in place. A review of the training logs confirm staff had received the required biobank training.

2.17 During the Covid-19 pandemic, Research were involved in collecting samples from coronavirus patients to help them in their work. To aid them in this process, doctors were

asked to collect the samples on behalf of the Biobank. We understand that individuals collecting human tissue samples for research purposes are required to undertake the Good Clinical Practice (GCP)[2] training. However, due to the increased workload on doctors on high priority 'red zone' wards during the pandemic and the lack of availability to undertake formal training, the Research team provided internal, bespoke training aligned to the GCP programme to ensure training standards were maintained. A log of training provided was maintained.

2.18 We recognise the proactive response taken by the Research Team to provide bespoke training during the Covid-19 pandemic period, and the Advanced Biomedical Scientist (Research) confirmed that a review would be undertaken to establish whether the doctors currently collecting samples would require the formal GCP training later this year. However, this review should be expedited in order to reduce the risk of potential financial/licencing/custodial penalties if breaches in the collection of tissue samples were to be identified. **[See Matters Arising 2]**

Conclusion:

2.19 Doctors involved in collecting tissue samples have not received formal GCP training (only bespoke in-house training during the pandemic). Consequently, we have assessed Reasonable assurance for this objective.

Objective 4: Action is taken to address issues identified through incidents and complaints, including actions and recommendations raised by the regulatory body

Mortuary/Post-Mortem

2.20 Under the terms of the HTA license, there has been a requirement that the HTA must be notified of all reportable incidents (HTARI's) that have occurred at licensed establishments in the Post-Mortem sector since 1st May 2010.

2.21 To capture this, all adverse events, including near misses, are reported via the Datix (and reflected on the *Q-Pulse* system) to ensure that the appropriate level and quality of investigation takes place and a log of all adverse events is kept to enable the tracking and trending of all events reported. We can confirm that a *Reporting HTA Reportable Incidents (HTARIs) in the Post-Mortem Sector* SOP was in place and available to staff on the *Q-Pulse* system.

2.22 There had been two incidents relating to HTA reported in Datix and *Q-Pulse* during 2021. Audit confirmed that the root cause had been established for each incident and appropriate corrective action taken. Both incidents were correctly not recorded as HTARIs.

[2] Good Clinical Practice (GCP) training was unavailable during the Covid-19 pandemic in 2020

Research

2.23 The Research Department are also required to report all adverse events, including near misses, via the Datix. We can confirm that a *Reporting of Adverse Events* SOP was in place and available to staff in the published *Biobank Policy.*

2.24 There had been one incident relating to HTA reported in Datix during 2021. Audit confirmed that the root cause had been established for the incident and appropriate corrective action taken. This incident was correctly not recorded as HTARIs.

Risk Registers

2.25 The risk registers for Mortuary Services and Research were obtained and reviewed to establish whether risks identified following incidents had been recorded. Pathology's risk register contains a relatively new risk relating to critical staffing levels at the Mortuary (Risk Reference 1152) and has been escalated to Executive level.

2.26 The Biobank is on the service level Research and Development risk register. We noted that no update has been provided since January 2021 for one risk relating to data management of a manual paper log system (Risk Reference 757). However, following feedback of this issue, the risk register was subsequently updated to reflect the current position. **[See Matters Arising 3]**

Conclusion:

2.27 Noting the above, we have assessed Substantial assurance for this objective.

Objective 5: There is regular reporting of Human Tissue Act compliance to the Health Board

Mortuary/Post-Mortem

2.28 Governance (Quality) meetings are held on a monthly basis. A review of the minutes for the period March – June 2021 confirmed that HTA matters were being discussed with action logs produced documenting the progress against the matters arising.

2.29 Concluding a review of group minutes and papers, and discussion with Mortuary Service staff, there is no direct reporting of HTA compliance issues or information to a statutory sub-committee of the Board with the exception of the Legislation Assurance Framework document that is completed annually.

Research

2.30 An established Research Quality Management Group is held on a bi-monthly basis and is attended by key personnel from the department. We can confirm that reports from these meetings are submitted to the Research and Innovation Sub-Committee[3] (RISC) that meets on a bi-monthly basis. A review of minutes and papers for the period February – May 2021 confirmed update reports are provided on a regular basis. In addition, was can also confirm

[3] Previously known as the Research and Development Sub-Committee

the reporting of ad hoc papers to the RISC such as the 'Biobank Briefing Report' that was due at the July 2021 meeting.

2.31 Concluding a review of minutes for the period February – April 2021, we can confirm that RISC progress updates were submitted to the Quality, Safety & Experience Assurance Committee for discussion, whilst other supplementary updates such as the 'The Impact on Research Activity of Redirection of Staff Resource to the Operational Pandemic Response' was provided by the Medical Director at the February 2021 meeting.

Reporting to the Health Board

2.32 We were unable to identify evidence of assurance reporting to the Board or appropriate sub-committee in relation to HTA compliance, regulatory assessment outcomes or licence status. **[See Matters Arising 4]**

External Reporting Arrangements

2.33 The Health Board is required to complete a HTA compliance report for premises that hold a licence with them every two years. Completion of the assessment is compulsory under the standard licensing conditions. We reviewed the reports undertaken in 2019 and confirmed continuation of licencing arrangements communicated to the Designated Individuals. The completion of the compliance reports for the HTA for Mortuary Services was ongoing at the time of our review, whilst the report for Research is due later this year.

Conclusion:

2.34 In the absence of assurance reporting to the Board, we have assessed Reasonable assurance for this objective.

Appendix A: Management Action Plan

Matter Arising 1: Research (Biobank) Internal Audits (Design)		**Impact**
The Research Department does not have an annual audit programme in place and therefore the monitoring and recording of compliance is undertaken on an exception basis only, with ad hoc audits being triggered in response to any discrepancies or issues that come to light. The Human Tissue Authority's Code of Practice and Standards, in addition to the *Biobank Policy (SOP 6)* requires than an annual audit programme be developed and implemented.		Potential risk of: • The Health Board is not aware of the risks associated with Human Tissue Act compliance.
Recommendation		**Priority**
The Biobank Lead should ensure an annual internal audit programme is implemented and conducted in accordance with the agreed standard operating procedures.		**High**
Agreed Management Action	**Target Date**	**Responsible Officer**
Following this report, an audit of the Biobank was commenced on 26th of July 2021 and a request has been made to the R&D Quality Assurance team to include an annual Biobank audit as part of their schedule of audits.	6th August 2021	Priya Sai-Giridhar (Advanced Biomedical Scientist – Research)

Matter Arising 2: Good Clinical Practice Training Review (Operation)		**Impact**
We recognise the proactive response taken by the Research Team to provide bespoke training during the Covid-19 pandemic period, and the Advanced Biomedical Scientist (Research) confirmed that a review would be undertaken to establish whether the doctors currently collecting samples would require the formal GCP training later this year. However, this review should be expedited in order to reduce the risk of potential financial/licencing/custodial penalties if breaches in the collection of tissue samples were to be identified.		Potential risk of: • Reputational damage, penalties and loss of licenses to operate.
Recommendation		**Priority**
Research Department management undertake a prompt review of doctors currently collecting tissue samples and ensure formal GCP training is provided for those who will continue this task if necessary.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
There are only five doctors who we don't have evidence of a full GCP certificate. These five have moved to different specialities or different health boards and will no longer collect for the Biobank's COVID collection. Full GCP training is available as e-learning. The Research department maintains a file of all those that went on to do full GCP training. Training with our R&D Quality Assurance Officer will commence now that restrictions have lifted.	29th July 2021	Priya Sai-Giridhar (Advanced Biomedical Scientist – Research)

Matter Arising 3: Biobank Risk Register (Operation)		**Impact**
We noted that one risk in regard of auditing and data management of the Biobank (Risk Reference 757) had been identified on 28th June 2019. Whilst the risk register was subsequently updated to reflect the current position following feedback from Internal Audit during fieldwork, regular updates and reviews should be undertaken and recorded on the risk register in line with the extant *Risk Management Policy and Strategy*.		Potential risk of: • Reputational damage, penalties and loss of licenses to operate.
Recommendation		**Priority**
Research Department management should ensure risks recorded on their risk register are regularly reviewed and updated to document action taken/ongoing to mitigate risks.		**Low**
Agreed Management Action	**Target Date**	**Responsible Officer**
The risk register will be regularly reviewed and updated with the Health Board's Assurance and Risk Officer.	29th July 2021	Priya Sai-Giridhar (Advanced Biomedical Scientist – Research)

Matter Arising 4: Reporting of HTA Compliance to the Board (Design)		**Impact**
There was no evidence of assurance reporting to the Health Board or appropriate sub-committee on HTA compliance, assessment outcomes or licence status.		Potential risk of: • The Health Board is not aware of the risks associated with Human Tissue Act compliance.
Recommendation		**Priority**
Management should ensure the periodic assurance reporting of HTA compliance, licence status and any relevant issues to the Health Board or appropriate sub-committee.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
The Pathology Strategy Group monitor HTA Compliance. The respective assurance reporting will be reviewed and considered at the Effective Clinical Practice Panel to determine a reporting route through to main board committees. This revision in reporting structures will be agreed with the Board Secretary and the Assurance & Risk Directorate.	31st December 2021	Phil Kloer (Medical Director)

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

 **Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
 **Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
 **Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
 **No assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
 **Assurance not applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

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