

Draft Minutes of the Human Tissue Authority Board

Date: 26 June 2025

Time: 10.00 – 12.30

Venue: Wandle 40/41, 2 Redman Place, London E20 1JQ

Meeting Number: 112

Attendees:

HTA Board Members

Lynne Berry, HTA Chair

Mhairi Anderson

Gary Crowe

Ellen Donovan

Helen Froud

Andy Greenfield

Dave Lewis

Gina Radford

Steve Stanbury

David Stanton

Jessica Watts

*David Lock

Observers

*Rowan Carbury, Quality & Nursing Directorate, Welsh Government

*Attending remotely

The meeting was open to members of the public to observe remotely on request, and also observed remotely by a number of HTA staff

HTA Senior Management Team

Colin Sullivan, Chief Executive

Louise Dineley, Director of Data, Technology and Development

Nicolette Harrison, Director of Regulation

John McDermott, Deputy Director of

Performance and Corporate Governance

Katrina Leighton-Hearn, Director of Finance and Resources

HTA Staff

Richard Mabbitt, Private Office Lead *minutes*

Debra Morgan, EA, Private Office

Jon Spencer, Head of Communications

Michelle Spencer-Williams, Policy Manager

Morounke Akingbola, Head of Finance and Corporate Governance

Department of Health and Social Care

Helena Youmans, Policy Adviser, Human Tissue Policy and Ethics of Consent

1. Opening Administration

Item 1.1 – Chair's introduction

1. Lynne Berry welcomed attendees. She noted that the nature of HTA's remit meant maintaining public trust and confidence was a priority. As a public body, transparency about how the HTA worked and made decisions was vital.

The annual Board meeting held in public to provide the opportunity for members of the public and licensed establishments to observe the meeting and ask questions.

2. This was the first meeting of the Board attended by new members Helen Froud, Steve Stanbury, David Stanton and Gina Radford. The Board welcomed Helena Youmans (representing the DHSC sponsor team), Rowan Carbury was observing the meeting on behalf of the Welsh Government.
3. Members' pre-meeting observations on papers had been shared with the Senior Management Team who had responded to individuals and would address the main points raised under appropriate agenda items.

Item 1.2 – Apologies for absence

4. All Board members were in attendance, David Lock attending remotely.

Item 1.3 - Declarations of interest

5. The Board noted that the Register of Members' Interests had been republished to include entries for new members. Lynne Berry reminded members that, irrespective of annual updates, Members needed to proactively alert HTA of changes or new declarations as soon as possible, with Declarations of Interests a standing item at Board and Committee meetings.
6. The Board noted
 - a) David Lock's new declaration: "June 2025 and continuing – short-term remunerated policy advice for DHSC which is not directly or specifically related to the HTA".
 - b) David Stanton's existing declarations as Member of the Civil Service Senior Salary Review Body; and Member of the Ministry of Defence Research Ethics Committee.
7. The Board did not consider that these or members' other declared interests posed substantive conflicts at this time.

Item 1.4 - Minutes of meeting of 6 March 2025

8. The Board AGREED the minutes of the previous Board meeting (HTA 11-25).

Item 1.5 - Actions Log

9. The Board was content with progress against actions logged in paper HTA

12-25. On Action 3.1 (meeting of 19 September 2024) it noted that the timing of HTA's responses to Phase 2 of Sir Jonathan Michael's Inquiry remained dependent on the timing of the Inquiry Phase 2 report anticipated later in 2025

2. Assurance / Reporting items

Item 2.1 - Chair's Report

10. Lynne Berry reported that new Board members' induction and onboarding was proceeding well, and thanked staff for their support. She would be discussing with new members and Committee chairs potential deployment to RemCo and ARAC. She noted that David Stanton had been appointed by DHSC to take on the ARAC chair role. The arrival of new Board Members also strengthened the Board's capacity to fulfil ongoing statutory duties on Living Organ Donation Panel casework.
11. She reported that the appointment process for a Northern Ireland member had now progressed to shortlisting stage, with the final decision to be made by the Health Minister in Northern Ireland in due course.
12. She had held appraisal meetings with members, with objectives to be finalised once her own Chair's appraisals had been completed and objectives set by the Sponsor Department.

Item 2.2 - Audit and Risk Committee (ARAC) Chair's Annual Report

13. Gary Crowe, Chair of ARAC, spoke to paper HTA 13-25. He summarised ARAC's role providing Board and CEO with an independent view of the organisation's internal controls, operational effectiveness, governance, and risk management, and provided a narrative summary of ARAC proceedings over the 2024-25 and up to its most recent meeting on 10 June.
14. The Board noted:
 - a) That ARAC had approved the draft 2024-25 Annual Report and Accounts (ARA), which were now being finalised prior to sign-off by Colin Sullivan as Accounting Officer, and submission to the Comptroller and Auditor General with a view to laying before Parliament before recess, if possible. Members would be briefed further on the near-final ARA in the development session immediately after the meeting, and the full document would be shared with members for information (**Action: Katrina Leighton-Hearn**).
 - b) The year's internal audit programme and the overall 'Moderate' assurance rating. The Board was content that this was appropriate for a small ALB. It

noted that the one 'Limited' audit conclusion (on contractual arrangements for HR services) was being actively addressed. The Board noted that Katrina Leighton-Hearn was working with GIAA's new Audit lead for HTA to clarify service standards and expectations. ARAC had encouraged officers responding to audit recommendations to ensure due prioritisation of the most impactful actions and to be mindful of optimism bias in agreeing reporting timescales with GIAA.

- c) ARAC had reviewed the Strategic Risk Register as a standing item, with the most recent iteration modified to better reflect HMT Orange Book risk headings, including the addition of a risk on Strategy. The People risk remained at a "red" rating.
 - d) ARAC's standing review of cyber security, including monitoring a successful transition to the Cyber Assessment Framework.
15. The Board noted that this had been Gary Crowe's last meeting as ARAC Chair. He was in discussion with David Stanton, who would take over the role in September, to support an effective handover of responsibilities. He would also help with the induction of any new ARAC members.

Item 2.3 Remuneration Committee (RemCo) Chair's report

16. Ellen Donovan, Chair of RemCo, spoke to paper HTA 14-25 summarising RemCo's work over the last financial year, up to its meeting of 6 June 2025. She reported that the Committee:
- a) Had fulfilled both its formal role around decision making on staff and senior executive pay, and its advisory role on people matters (including in the latter part of the year advice on the development and implementation of the People Strategy).
 - b) Was pleased that the People Strategy had been launched to schedule, with the appointment of an experienced Interim Head of People Strategy Delivery to co-ordinate its implementation.
 - c) Had taken stock of the early actions completed and underway and were pleased with progress overall. It felt that the organisation leadership now had better insight on patterns and trends in staff satisfaction and the organisational characteristics that impacted staff recruitment and retention.
 - d) Welcomed the Executive's commitment to the people agenda and felt that RemCo was well-sighted on progress. It recognised that the strategy was ambitious and felt that further prioritisation and dialling up or down of activity might be necessary in the light of experience.
17. The Board noted that RemCo had held a special meeting before the present meeting to discuss 2025-26 pay arrangements for the organisation in line with departmental limits and guidance. The Committee had considered and agreed

detailed proposals on staff pay, which would now be submitted to DHSC for approval. A further RemCo meeting to agree 2025-26 pay arrangements for Executive and Senior Management would be arranged in line with departmental advice in due course.

18. Dave Lewis, as the 'link' member between ARAC and RemCo noted that People Strategy implementation was an area where the work of the two Committees was particularly complementary. ARAC had welcomed the additional assurance provided by RemCo's understanding of and input to the detail of the People Strategy and its implementation plan.

Item 2.4 – Department of Health and Social Care (DHSC) Sponsor Team report

19. Helena Youmans reported that
 - a) Samantha Jones had been appointed as Permanent Secretary at the DHSC and she looked forward to working with DHSC's ALBs.
 - b) DHSC engagement with health system partners continued, particularly around the amalgamation of NHS England functions into the Department.
 - c) DHSC was working through the detailed implications of the Spending Review announcement on 12 June, which had highlighted the government's prioritisation of reducing waiting times; improving NHS estate maintenance and delivering NHS productivity increases.
 - d) The cross-government review of ALBs would begin this year. She thanked HTA for responding to the recent commission on the Department for Business and Trade's review of regulatory and administrative burdens on business.
20. Lynne Berry thanked Helena Youmans and DHSC colleagues, noting the good contacts maintained with DHSC. The Quarterly Accountability Meeting between senior DHSC officials and HTA staff was scheduled for 10 July.

Item 2.5 - CEO Report

21. Colin Sullivan introduced paper HTA 15-25 reporting on a busy year for the HTA. He reported that, overall, the organisation had maintained a high level of service against its operational targets, while taking forward additional key activities and responding effectively to matters arising.
22. The Board discussed action being progressed in the broad area of improving the dignity of the deceased. The Board was pleased that insight into the type and level of shortfalls in the Post Mortem and other sectors would feed into HTA's assessment of how best to review and update its Codes of Practice, and that arrangements were in hand to communicate more widely the nature

of shortfalls among the sector. The Board noted that the impending Phase 2 report from the Inquiry by Sir Jonathan Michael into the issues raised by the David Fuller case would feed into the review of the Codes. He highlighted that the HTA stood ready to assist the Government in its implementation of the Phase 2 recommendations that are accepted by Ministers. The Board asked to be kept fully aware of developments here **Action: Nicolette Harrison.**

23. The Board noted the overarching importance over the reporting year and going forward of effective oversight and management of people issues. It welcomed the roll-out of the People Strategy, noting the re-launch of a Staff Forum, and proposals for pulse surveys to monitor the initial phases of strategy implementation. The Board asked for continued RemCo sight of strategy implementation and impacts, with a further report to the Board in due course. **Action: Katrina Leighton-Hearn and Ellen Donovan.**
24. The Board recognised the longer-term planning challenges for the HTA and peer bodies given the Government's reviews of the health service delivery landscape, and the role of ALBs. The uncertainty this generated risked impacting on staff wellbeing and job satisfaction, and the Board was pleased that staff were being kept informed of developments as they unfold.

Item 2.4 - HTA Performance Report

25. The Board reviewed paper HTA 16-25 which set out HTA's performance in Q4 of 24/25 against objectives and operational delivery targets, along with an indicative report of early performance in Q1 of the current year. The Board acknowledged the successful delivery of the 2024-25 Business Plan through active Portfolio Management.
26. The Board noted overall RAG performance over the 2024-25 year against HTA's 13 Key Performance indicators (KPI). The Board:
 - a) Welcomed solid performances against the nine KPI marked green, noting good progress on the ICT and cyber security-related KPIs, and the important strategic role of the Head of IT here.
 - b) Noted that the amber status of KPI's related to FOI and Enquiries were related to a website issue (reported to the March Board meeting) impacting receipt of enquiries in December and January. The Board was content that remedial action had been taken with performance now back on track.
 - c) Noted that while there had been some improvement in staff attrition in recent months, the KPI* here remained at "red" The Board recognised that this remained a challenging KPI, given HTA's size and organisational characteristics. It was pleased that work was under way

to understand variations in and underlying causes of staff turnover. It was also heartened that the sickness absence KPI was at green.

- d) Noted that the KPI related to processing new licence applications within 90 days was also marked as red for the year-end position, although was green for Quarter 4. It acknowledged that this was a demand led area of operations, with a highly variable level of new applications and was an iterative process. The KPI in the Business Plan for 2025-26 would therefore be calculated over a rolling twelve-month period to give a more realistic picture of what success looked like over the longer term.

*[*Secretary's note: para. 31 of the final published version of paper HTA 16-25 was corrected after the meeting to remove ambiguity in the calculation]*

- 27. Board members also noted the successful completion of all “must do” projects, that were committed to for the 2024-25 year, acknowledging the flexibility shown in bringing online mid-year an additional project to support DHSC’s preparation for the regulation on standards of quality and safety for Substances of Human Origin intended for human application coming into force in Northern Ireland in 2027. In addition to the formal projects on the Business Plan, the Board noted progress on additional work including:
 - a) the signing of revised Memoranda of Understanding with CQC and UKAS to facilitate data and intelligence sharing and support joint working.
 - b) Improvements to the security of HTA’s website, which (with around 400,000 visits) remained HTA’s primary digital presence.
- 28. The Board was content with the summary Finance and Audit and Risk reports included in the paper. Louise Dineley provided further explanation of the Strategy Risk.
- 29. The Board felt that, over 2024-25 and into Q1 of 2025-26, HTA leadership and staff had been agile in prioritising staff resource to deal with “must do” regulatory activity, in the context of both external and internally driven change. The Board fully expected to see further changes to the policy and delivery landscape as a result of the Government’s ongoing regulatory reforms and asked that it was kept updated in standing reports and additional communications as required. The Board highlighted the importance of strong staff capacity, capability and culture to meet these challenges, and the key role of the People strategy. The Board therefore asked HTA staff to consider whether the current MoSCoW prioritisation for the People Strategy project needed to be raised to “must do” in the 2025-26 Business plan, or whether the current designation of “should do” was sufficient in the context of other work and statutory commitments. **Action: John McDermott** to arrange for a

Change Control request to be discussed further at the next Portfolio SMT meeting, with an update to Board at its September meeting.

30. Finally, the Board welcomed the Executive's regular reporting on Health and Safety matters, also noting the new formal KPI that would be tracked across the year to allow greater scrutiny of this topic.

3. Information Items

Item 3.1 – 12 Month Evaluation of the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024.

31. Louise Dineley and Jon Spencer introduced paper HTA 17-25, briefing the Board on findings from the 12-month review of the implementation of these Regulations, also referred to as 'Duty to Report' (DtR). Board members noted the background set out in the paper and the key findings, including strengths and areas for improvement in HTA's operational approach.
32. The Board felt HTA's implementation of the first twelve months of DtR to have been sound, especially given initial uncertainty about the numbers and scope of reports likely to be received, and the nature of activity that they would identify. The Board acknowledged the commitment and resilience of HTA staff, particularly the small Living Organ Donation Team, in meeting at pace the challenge of fulfilling a new regulatory function for which the HTA had received no additional funding in 23/24 and 24/25. It noted the challenges of building new relationships and developing effective interactions with the police and criminal justice system.
33. The Board was satisfied that resources allocated to DtR as a statutory duty and the consequent de-prioritisation and pressures of work elsewhere were being duly monitored and managed through HTA's business planning processes. The Board noticed in-year improvements to the process. For example, an extended deadline for clinical evidence had resulted in better quality evidence and saved time overall. The Board also noted the streamlined decision-making process set out in the HTA's Police Referral and Warrants Policy (as revised at the March board meeting) providing for police referral decisions to be delegated to the Director of Regulation. The Board discussed the value of a target time for completing investigations, but agreed that on balance the significant variations in the complexity of cases, and iteration required to secure appropriate evidence meant that such an indicator would be of limited value.
34. The Board noted the work undertaken by HTA and partners around

awareness-raising. The Board also noted opportunities for further enhanced and targeted public understanding about potential risks of travelling overseas for transplants. The Board welcomed that feedback was being sought from the agencies with which HTA engaged on DtR, and highlighted the importance of closing feedback loops to support continuous improvement. In particular, feedback to clinicians and representative bodies and network about the outcomes of their reports was essential. The Board also noted that during 2025-26, in line with its statutory duties and commitment to transparency, the HTA would add relevant DtR data to its corporate reporting schedule (with due consideration of patient confidentiality and safeguarding of ongoing investigations). While no reports had been received from Wales and Northern Ireland during the first twelve months, the Board noted that there had been targeted engagement in those nations and in Scotland. It agreed that the proposed introduction of a similar duty to report in Scotland (under The Human Tissue (Supply of Information about Transplants) (Scotland) Regulations 2025) provided the opportunity for the HTA to undertake further UK-wide communication and engagement programme with clinicians.

35. Lynne Berry thanked Board members for their comments and asked the Executive to note members' comments in progressing this work.

3.2 HTA Strategy 2024-27: our review of year 1

36. Louise Dineley introduced paper HTA 18-25 reflecting on the first year of HTA's Corporate Strategy, including successes, learning, and insight from delivery to date, and potential ways that this experience might shape and inform HTA's future delivery against four strategic priorities: Approach to Regulation; Use of Information; Building Trust and Confidence; and Efficient and Effective.
37. The Board discussed the increasing range of methods used to assess compliance with regulatory standards, including Evaluated Self Assessments; Evidential Compliance Assessments (to be discussed at item 3.3); and unannounced inspections. The Board noted that HTA was finalising a 12-month report into the latter, but that early indications were positive, and the programme had continued into 2025-26. It had been found that unannounced inspections in the Post Mortem sector not only provided for a truer-to-life picture of practices as actually undertaken, they were also generally well received by licensed establishments.
38. The Board also discussed the potential for developing or adopting innovative tools and support for staff, including the deployment of AI. It noted that although HTA had in 2024-25 been focussed on optimising existing ICT capability, some piloting of additional AI tools within Data, Technology and

Development directorate had been carried out, and that HTA was working with other ALBs around the risks and opportunities of AI applications. HTA would continue to monitor developments in the areas of Big Data and AI, and seek to escalate its response as required over the strategy term.

39. Overall, the Board was content with progress. It thanked staff for their work in activating the strategy in 2024-25 and setting the groundwork for its continued implementation over the next two years. The Board noted and supported the next steps set out, and looked forward to future updates.

*[*Secretary's note: para. 9 of the final published version of paper HTA 16-25 was corrected after the meeting to clarify that ESA stands for Evaluated Self-Assessment]*

3.3 Evidential Compliance Assessments (ECA) trialled in the PM sector during 2024-25

40. Nicolette Harrison spoke to paper HTA 19-25, which briefed the Board on HTA's new regulatory approach to risk assessment, ECAs, which had been trialed in the Post Mortem sector. HTA would consider further trialing this approach in other sectors as part of a strategy of refining its approach to regulation, through innovation and continuous improvement.
41. The Board noted the background information and methodology in the paper and considered the reported outcomes and proposed next steps. The Board:
- a) Acknowledged ECA's function as both a useful addition to the HTA's compliance programme, and an assessment tool providing assurance on and effective oversight on key regulatory risks.
 - c) Noted that while the exercises had taken more resource than anticipated (particularly around the scrutiny and moderation of material received) ECAs remained significantly less resource intensive for both HTA and the licensed establishments than an inspection.
 - d) Felt that this was a good example of how the HTA could be innovative and adaptable, while maintaining regulatory rigour.
 - e) Asked for more detailed information about the main areas of non-compliance, and the remedial action taken with those licences identified to be fast-tracked for follow-up. This could be provided after the meeting (Action: **Nicolette Harrison**)
 - f) Noted the distinction between shortfalls in evidence of good practice, and demonstrable non-compliance. It noted the exploratory nature of the question set – including some relatively straightforward questions – which sought to identify actual practice.

- g) Noted that ECAs had generally been received well by establishments, with some DI's indicating that findings had been used to support business cases for upgrades to existing security systems.
42. The Board supported staff conclusions that the ECA approach was a useful regulatory tool, that raised awareness in licensed establishments of critical risks and standards around security and access to mortuaries. It reinforced the role and responsibility of the DI and licensed establishments in responding to those areas of risk. The Board was therefore pleased with the outcome of the ECA programme in the Post Mortem sector and that applicability to other sectors or targeted thematic areas would be considered via the Business Planning process for 2026-27 as part of the Innovation in Inspection project.
43. The Board thanked staff for the update and for their work across this important area. Insight from the ECAs would be likely to resonate with the conclusions of Phase 2 of Sir Jonathan Michael's Inquiry.

Item 3.4 - Responses to questions submitted by members of the public

44. Members of the public had been given the opportunity to ask general questions of the Board. Lynne Berry reported that one question had been asked relating to whether the HTA collected bodies for use in medical training. She thanked the questioner for highlighting this important issue.
45. Louise Dineley provided a response. She emphasised that the education and training of medical professionals benefited from the generosity of those who donate bodies for use after their death. People who donate their body contributed in a vital way to training by medical schools. Such donations were highly valued by staff and students alike. She clarified that the HTA did not itself collect or receive bodies or other human materials: rather it licensed and inspected the organisations that did so. The HTA was only able to provide general information about the types of donation possible. Information about body donation to medical schools was available on the Human Tissue Authority (HTA) website (including a body and brain donation information pack which provides information on body, brain or tissue donation for anatomical examination, research or education and training, along with information about how to contact medical schools). HTA staff would follow up with the enquirer to highlight this information. **Action: Private Office**
46. Board members noted that this was an area of significant public interest, and felt that HTA's signposting role was important. It asked HTA staff to have this in mind in their regular engagement with medical schools.

4. Governance items

Item 4.1 – Review of Board Standing Orders, Committee Terms of Reference and supporting documents

47. Lynne Berry introduced paper HTA 20-25 which set out proposed amendments to the Standing orders of the Board, the Members' code of Conduct, and Committee Terms of Reference for the Board's agreement.
48. Notwithstanding the importance of these documents, the Board agreed that the proposed amendments were primarily updates, clarifications and removal of duplication, with no fundamental changes to the HTA's governance arrangements. The draft RemCo and ARAC Terms of Reference had been reviewed and approved in principle separately by those Committees.
49. The Board therefore **AGREED** the amendments presented, and that the revised documents be adopted and published, with Private Office empowered to make minor administrative changes as appropriate and necessary.

5. Closing Administration

Item 5.1 - Forward plan

50. The Board noted the Forward Plan of corporate meetings and related activity (HTA 21-25). It concurred that the HTA would need to respond in an agile way to events, and in-year amendments to the plan were likely.

Item 5.2 - Any Other Business

51. Board members expressed thanks to Morounke Akingbola, departing Head of Finance and Governance and a key member of the HTA team for 16 Years. The Board also thanked Gary Crowe, whose second full term as a Board member expires at the end of August. His sterling service as a Board member and Chair of ARAC had been much appreciated by members and staff.
52. Board members felt that papers for the meeting had been well-written and supported effective oversight of HTA's work. They asked SMT to thank staff who had contributed directly and indirectly to the meeting, and more generally for their commitment to fulfilling the HTA's mission over the past year.
53. With no further items raised, the meeting closed. Members would reconvene in the afternoon for development and briefing sessions. The next formal meeting of the HTA Board was scheduled for 18 September 2025.