# Seventy-ninth Meeting of the Human Tissue Authority

**Date**  
4 May 2017  

**Time**  
13:30 – 16:30  

**Venue**  
Viceroy Suite, Grosvenor Hotel  
101 Buckingham Palace Road, SW1W 0SJ

## Morning Session:
- Coffee meeting with HTA colleagues (09:30 – 10:40) HTA Office  
- Transfer to Grosvenor Hotel  
- Post-mortem session (11:00 – 13:00) Grosvenor Hotel

## Agenda

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<table>
<thead>
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<tbody>
<tr>
<td>1</td>
<td>Welcome and apologies</td>
</tr>
<tr>
<td>2</td>
<td>Declarations of interest</td>
</tr>
</tbody>
</table>
| 3 | Minutes of 9 February 2017 | HTA (12/17)  
HTA (C12/17)  
| 4 | Matters arising from 9 February 2017 | Oral |
| **Regular Reporting** |   |
| 5 | Chair’s Report | Oral |
| 6 | Chief Executive’s Report | HTA (13/17)  
| 7 | Delivery Report – Quarter Four 2016/17 (year-end) | HTA (14/17)  
| 8 | Development Report – Quarter Four 2016/17 (year-end) | HTA (15/17)  
| 9 | Deployment Report – Quarter Four 2016/17 (year-end) | HTA (16/17)  
| 10 | White space for non-agenda items | Oral |
| **Policy Issues** |   |
| 11 | Paper: European Union Directives on Coding and Import Update | HTA (17/17)  
| 12 | Governance: Authority Standing Orders Update | HTA (18/17)  
| 13 | Any other business |   |

Meeting close
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting.
# Minutes of the seventy-eighth meeting of the Human Tissue Authority

**Date**  
9 February 2017

**Venue**  
Viceroy Suite, Grosvenor Hotel  
101 Buckingham Palace Road  
London, SW1W 0SJ

## Present

<table>
<thead>
<tr>
<th>Members</th>
<th>In attendance</th>
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| Sharmila Nebhrajani, OBE (Chair)  
Dr. Hossam Abdalla  
Amanda Gibbon  
Prof. Andrew (Andy) Hall  
William (Bill) Horne  
Glenn Houston  
Prof. Penney Lewis  
Prof. Dame Sally Macintyre  
Bishop Graham Usher  
Dr. Lorna Williamson, OBE | Allan Marriott-Smith (Chief Executive)  
Vicky Marshment (Director of Policy, Strategy and Communications)  
Richard Sydee (Director of Resources)  
Caroline Browne (Head of Regulation – Post-Mortem)  
Nicholas Baré (Head of Corporate Policy and Strategy) |

## Apologies

<table>
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<tr>
<th>Apologies</th>
<th>Observers</th>
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| Prof. Anthony Warrens  
Dr. Stuart Dollow | Jeremy Mean (Department of Health)  
Rob Watson (Head of Regulation – Human Application)  
Laura-Jade Heseltine (Regulation Officer) |
| Sarah Bedwell (Director of Regulation)  
Rumku Basu-Owen (Department of Health)  
Roger Wallis (Department of Health) | |
<table>
<thead>
<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
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<tbody>
<tr>
<td>Item 1</td>
<td>Welcome and apologies</td>
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<tr>
<td>1.</td>
<td>Sharmila Nebhrajani (the Chair) welcomed Members, attendees and observers to the seventy-eighth meeting of the Human Tissue Authority.</td>
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<td>2.</td>
<td>The Chair advised that Caroline Browne (Head of Regulation – Post-Mortem) would attend the meeting to present Item 15 – Cryopreservation [paper HTA (11/17)].</td>
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<td>3.</td>
<td>The Chair noted that this was the first time Jeremy Mean (Deputy Director - Population Health) from the Department of Health (DH) would observe an Authority meeting.</td>
<td></td>
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<td>4.</td>
<td>Rob Watson (Head of Regulation – Human Application) and Laura-Jade Heseltine (Regulation Officer) from the HTA, would also observe the meeting.</td>
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<tr>
<td>5.</td>
<td>Apologies were received from Authority Members Anthony Warrens and Stuart Dollow. Rumku Basu-Owen (DH) and Roger Wallis (DH) also sent apologies.</td>
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<tr>
<td>Item 2</td>
<td>Declarations of interest – Oral</td>
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<tr>
<td>6.</td>
<td>The Chair thanked Members for recently submitting updates to their relevant interests, which appear in a register of Authority Member’s declarations of interest on the <a href="#">HTA website</a>.</td>
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<tr>
<td>7.</td>
<td>The Chair asked Members to declare any personal or pecuniary interests that they may have in regard to the meeting’s agenda.</td>
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<td>8.</td>
<td>The Chair declared that she was the also the Chair of the Steering Group for the Understanding Patient Data Task Force. The Group is considering the recommendations of the Calidicott Review, and therefore has an interest in how the HTA responds to the Audit and Risk Assurance Committee’s Caldicott review’s recommendations, discussed in Item 4 – Matters Arising (paragraph 18 in these minutes).</td>
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9. No further declarations were made.

### Item 3 Minutes of 1 November 2016 – HTA (01/17)

10. Ahead of the 9 February 2016 meeting, comments for the 1 November minutes were provided by Lorna Williamson, Bill Horne, Glenn Houston and Stuart Dollow.

11. With the exception of these incorporated updates, the minutes were accepted as an accurate record of the meeting.

### Item 4 Matters arising from 1 November 2016 – Oral

12. The Chair noted that actions from the 1 November 2016 meeting would be addressed by the Executive during relevant items in the meeting.

13. Completed items not addressed during the meeting included:

   a. Action Seven: The findings and result of the fees structure consultation were published in December 2016
   b. Action 10: The HTA’s filming guidelines were published on its website in December 2016
   c. Action 11: The filming guidelines were communicated to Ofcom and the Care Quality Commission in December 2016
   d. Action 14: The HTA policy for handling complaints about maladministration and inappropriate conduct was updated and finalised after feedback from Members was incorporated.

14. The Chair invited Jeremy Mean to update the Authority on DH matters. Jeremy Mean reported that he had begun his new HTA related role at the Department in September and was managing an entirely new sponsorship team. A new colleague, Rumku Basu-Owen has broadly taken on the responsibilities of Jeff Porter, while Roger Wallis (based in Leeds) has taken on the responsibilities of Patrick Irwin. Both Jeff and Patrick left the Department in January. As part of the Department’s 2020 restructure, it has brought
all London staff onto one site, with 500 fewer colleagues (-30%) following the reorganisation.

15. The Chair invited Amanda Gibbon to update the Authority on audit matters. Amanda Gibbon provided an update on three audit related meetings that had taken place since the 1 November 2016 Authority meeting.

16. On 8 November 2016, the HTA’s Audit and Risk Assurance Committee (ARAC) discussed the findings of the Enquiries Management internal audit. It also carried out a deep dive review on workforce risks and the HTA’s People Strategy, which addresses these risks.

17. On 16 November 2016, Amanda Gibbon and Allan Marriott-Smith attended the DH’s Audit and Risk Committee meeting. Issues discussed included cyber security, information governance relating to the Caldicott Review, risk interdependencies across DH bodies, as well as cryopreservation and taphonomy. The meeting allowed the Department to consider broader risks in the context of the HTA’s remit.

18. On 8 February 2017, ARAC met to review progress with the Living Organ Donation internal audit, which was deemed complete. Final versions of the People and Workforce audit and Enquiries Management audit reports were agreed. The Committee carried out a deep dive review on how the HTA maintains public confidence through its regulatory approach and assurance. It also reviewed its arrangements to address Caldicott Review recommendations, concerning living organ donation patient data.

19. Amanda Gibbon reported that a new joint Head of Internal Audit, Jeremy Nolan, had been appointed for the HTA and the Human Fertilisation and Embryology Authority (HFEA). He is employed by the Government Internal Audit Agency.

20. The Chair invited Bill Horne to update the Authority on the Welsh Transplant Advisory Group, which met in Cardiff on 6 December 2016. Bill Horne reported that the Group discussed ongoing issues following the introduction of the
Welsh deemed consent organ donation legislation and had taken the opportunity to share the HTA’s new filming guidelines with the Group. Bill Horne reported that he had also represented the HTA at an event in Cardiff marking the first anniversary of the introduction of the deemed consent legislation.

<table>
<thead>
<tr>
<th>Item 5</th>
<th>Chair's Report</th>
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<tr>
<td>21.</td>
<td>The Chair highlighted meetings of note that she had attended since 1 November 2016.</td>
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<td>22.</td>
<td>The Chair spoke at the Nuffield Council on Bioethics on 14 November 2016, for its 25th anniversary, noting that there was a high level of interest in living organ donation cases.</td>
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<td>23.</td>
<td>On 22 November 2016, the Chair, and HTA colleagues attended the Independent Assessors’ Conference, which detailed change in the living organ donation landscape, HTA policy developments and trends and challenges with organ donation.</td>
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<td>24.</td>
<td>The first HTA teleconference for Members to discuss organ and marrow donation panel cases was held on 30 January 2017. During the teleconference, chairs of panels summarised cases where it was felt that other Members would benefit from discussing the learning points taken from the cases. It was noted that sharing these learning points would assist in delivering Recommendation 1 from the Item 6 – Board Effectiveness Internal Audit Report [paper HTA (02/17)].</td>
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<td>25.</td>
<td>The Chair and Chief Executive were due to meet Lord Prior on 9 November 2016, which was rearranged for 1 March 2017. In the intervening period, Lord O’Shaughnessy has taken up the position of Under Secretary of State for Health. The scheduled meeting is planned to go ahead with the new Minister.</td>
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</table>
| 26.    | The Chair advised that a dedicated training budget has been put in place for Members for 2017/18. This will assist Members to address any development needs identified in upcoming appraisal meetings for 2016/17 performance. In addition to accompanying Regulatory Managers on site HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
inspections, Members should consider how their development needs could best be met. Bill Horne highlighted the value of the course that ARAC Members attend at the Civil Service College where he had also attended recent training on, “Accountability and Governance for Arm’s Length Bodies”, which had been very useful.

**Action One:** Provide the Authority with learning points from the 30 January teleconference for organ donation panel cases.

**Action Two:** Consider how learning points from teleconferences for organ and marrow donation panel cases could be brought together to build an anonymised training resource for Members.

<table>
<thead>
<tr>
<th>Item 6</th>
<th>Board Effectiveness Internal Audit Report – HTA (02/17)</th>
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<tr>
<td>27.</td>
<td>The Chair presented this item and introduced the report.</td>
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<td>28.</td>
<td>This draft version of the internal audit report into Board Effectiveness, prepared by PwC, sets out four recommendations on how the Authority can improve its effectiveness as a Board. The Chair thanked those Members who completed the self-assessments and had follow up meetings with the auditors.</td>
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<tr>
<td>29.</td>
<td>The report did not highlight any significant weaknesses that may affect the Authority’s effectiveness. It identified one medium and three low priority recommendations, which the Chair is currently reviewing. During quarter four, the Executive will draw up an action plan to respond to the recommendations.</td>
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<td>30.</td>
<td>Members discussed Recommendation Two – regarding flexibility in the appointment process of Members – mindful of the collective memory that established Members contribute to the Authority’s governance.</td>
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<td>31.</td>
<td>Jeremy Mean noted that the Department is sympathetic to receiving requests for re-appointment of non-executive board members, understanding that Boards in the healthcare system take time to bed-in. The Department</td>
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</table>
will take a balanced approach to a mix of new appointments and retention of currently serving Members.

32. It was noted that the Authority should consider how established Members could support recently appointed Members.

33. It was also noted that ARAC Members would need to carefully consider where value for money could be achieved concerning HTA internal audits in 2017/18. It was suggested that Authority Members could identify priorities areas for future internal audit at its September strategy awayday.

34. The Authority noted the content of this report.

**Action Three:** Consider how established Authority Members can share their institutional memory with recently joined Members.

**Action Four:** At its September strategic awayday, the Authority Members will identify priority areas for future internal audits.

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<tr>
<th>Item 7</th>
<th>Chief Executive’s Report – HTA (03/17)</th>
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<td>35.</td>
<td>Allan Marriott-Smith presented this item and introduced the report.</td>
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<td>36.</td>
<td>The Chief Executive reported that concerning Risk Four on the strategic risk register – failure to utilise our capabilities effectively – the HTA now has a fully staffed Executive function and is building capacity, following the agreement of the Authority to employ two additional Regulatory Managers at its November meeting. Ten candidates will be interviewed during February. There was one resignation in the period; the Head of Business Technology. Richard Sydee is carefully considering the skills and experience that the new role-holder will require, before advertising the role.</td>
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<tr>
<td>37.</td>
<td>Allan Marriott-Smith invited Caroline Browne to provide Members with an overview of work being carried out by the University of Huddersfield to establish a taphonomy</td>
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</table>
centre in the United Kingdom. Taphonomy is the research of decomposition, where bodies are left and studied in various situations to better determine the time of death. The University’s Vice Chancellor will consider a business proposal and ethics approval application in March.

38. Taphonomy does not conform to the scheduled purposes, and licencing requirements set out in the Human Tissue Act (the “Act”). HTA and Department colleagues will meet with Professor John Cassella (Forensic Science Education – Staffordshire University) in mid-February to discuss the University of Huddersfield’s plans.

39. Members discussed the ramifications of how extending the HTA’s regulatory remit in this way and the impact on its resources. The Chair highlighted previous instances where the HTA had taken a lead in debates where it has not legal locus, such as the disposal of foetal remains. Members requested that an update on taphonomy be provided at their May 2017 meeting.

40. Allan Marriott-Smith invited Jeremy Mean to provide an update on progress with the publication of the HTA’s triennial review. Jeremy Mean reported that it was still the Department’s intention to publish the review alongside that of the HFEA, when a date is confirmed in the House of Commons.

41. Allan Marriott-Smith drew Members’ attention to the HTA’s log of possible amendments to the Act and associated regulation, noted at paragraphs 21-25. While the log remains an operational document, Members are welcome to review its contents for strategic oversight. Should the possibility of legislative change become an option, the Executive will bring the log to the subsequent Authority meeting, supported by a paper and recommendations.

42. The Authority noted the content of this report.
**Action Five:** Provide an update on taphonomy at the May 2017 meeting.

**Action Six:** Members to receive a paper on proposed legislative change as and when necessary.

**Action Seven:** Members to receive an organisation chart, including length of service.

**Item 8 Delivery Report – Quarter Three – HTA (04/17)**

43. Vicky Marshment presented this item and introduced the report in Sarah Bedwell’s absence.

44. Vicky Marshment provided Members with an updated version of the communications section of the report, which clarified quarterly references. The updated details will be included in the pack of February papers available on the HTA website.

45. It was noted that communication statistics from newsletter non-open rates would be used to help the HTA to improve quality for Independent Assessors, alongside other information, such as conference attendance and report quality.

46. Vicky Marshment updated Members on the commercial organisation noted in the November Delivery Report [Item 7 – HTA (43/16)] at paragraph 33. During the quarter, HTA colleagues met with the National Association of Funeral Directors (NAFD) to discuss a regulatory approach, regarding this subject. Based on this meeting, the HTA will not carry out any further work to develop a regulatory approach until the NAFD has consulted its membership on issues raised, and reported back to the HTA on its findings.

47. Details were provided to Members on the ongoing Investigation 01/17 (paragraphs 9-10), in which a non-HTA licensed organisation was carrying out activities that may require a licence. The organisation in question has agreed to stop carrying out these activities while the HTA investigation is carried out. To advance the investigation, HTA colleagues will meet with other regulators to consider,
in particular, whether the single surgical procedure exemption is relevant in this case.

48. Members discussed how the Executive were applying the recently reviewed policy for referring breaches of human tissue legislation [Item 13 – HTA (09/17)], in reference to the Investigation 05/17, discussed in paragraphs 18-20. Vicky Marshment noted that the Executive was mindful that Members should be provided with adequate reporting to assure them that the updated policy is effectively delivering outcomes, without Members needing to review the Executive’s operational activity.

49. Members discussed the serious adverse events and reactions reports (SAEARs), and the HTA reportable incidents reports (HTARI) and raised, in particular, the incidence of accidental body damage in mortuaries. It was noted that accidental damage to bodies had been addressed in a recent HTA publication, Regulation of the Post-Mortem Sector 2014-16: What we have learned. A risk assessment in the report sets out the most common mitigating actions that have been up taken by mortuaries, to minimise the risk of incident reoccurrence.

50. The Authority noted the content of this report.

**Action Eight:** Provide Members with details of the Executive’s consideration of factors for a police referral concerning Investigation 05/17.

**Action Nine:** On an ongoing basis, provide Members with details of all police referrals for breaches of human tissue legislation.

**Action 10:** Provide Members with a copy of, Regulation of the Post-Mortem Sector 2014-16: What we have learned.
## Development Report – Quarter Three – HTA (05/17)

| Item 9 |  
|---|---|
| 51. Vicky Marshment presented this item and introduced the report. |
| 52. During the quarter, the licensing fees project was largely completed. The HTA’s analysis of the responses to the consultation and approved fee model for the 2017/18 year were published on the HTA’s website. Work is now underway to ensure that systems are ready to accommodate necessary changes to the fee structure for April 2017 invoicing. |
| 53. Preparation to set 2018/19 fees is also underway. The Executive is considering what data the HTA currently collects and how it is evaluated, to develop a proportionate approach to assessing whether the resources used to complete regulatory activity are adequately reflected within the fees model. |
| 54. The project to implement the HTA’s updated Codes and Standards is on target to be completed by the implementation date of 3 April 2017, when they come into effect. During the quarter, the HTA called on Designated Individuals to take part in webinars, to ensure that they are well prepared for implementation. The first webinar for the post-mortem sector (Code B) took place on 8 February 2017, and received positive feedback. Webinars for other Codes will take place until early March. Activity to update governance documents and develop relevant application forms continues. A report on the implementation will be presented to the Stakeholder Group in October 2017. |
| 55. The project to implement European Union Directives on Coding and Import / Export, is currently rated as outside of tolerance. This reflects uncertainty around the timetable for the consultation on the draft regulations, transposition into UK law and their implementation. At the time of this meeting, the Department and HTA were waiting on clearance from the Prime Minister’s Office to begin a four-week consultation. |
| 56. The Authority noted the content of this report. |
Action 11: Update Members on the progress on the consultation, transposition and implementation of the Coding and Import / Export Directives at their May 2017 meeting.

**Item 10 Deployment Report – Quarter Three – HTA (06/17)**

57. Allan Marriott-Smith presented this item and introduced the report, with assistance from Richard Sydee.

58. There has been little change to the HTA’s medium to long-term accommodation plans, which provides some certainty for 2018/19 budget planning. During the quarter, NHS Property Services began reviewing office space needs for the Department of Health and its arm’s length bodies, for the coming three years.

59. Outstanding debts, shown at Table Two, are not considered to be at an unexpected level, though there are five debtors, which have debts that have not been settled since quarter two, 2016/17. Richard Sydee will write to these NHS bodies, indicating that the HTA will escalate these debts to the small claims court, should they not be settled promptly.

60. In response to a query, Richard Sydee identified an adverse variance of -5.22% on the Resources Directorate Summary (at Annex D), as a currently unused legal contingency budget, which the Executive has agreed as prudent to maintain.

61. Allan Marriott-Smith noted that he had undertaken to report to the Authority, following the November 2016 update on the HTA People Strategy. The current strategy will roll forward into the 2018/19 year, and will reflect a fundamental review of how the organisation delivers its goals, based on any changes to its regulatory model.

62. The Chief Executive also noted that good progress was being made to implement the recommendations of the workforce internal audit. Recommendation One - to consider additional tiers to the resource structure, so as to allow more opportunity for progress - is currently being
reviewed, to consider if this would be practical for the Regulation Manager cadre.

63. The Authority noted the content of this report.

<table>
<thead>
<tr>
<th>Item 11</th>
<th>HTA Codes of Practice – Lay Guidance – HTA (07/17)</th>
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<tbody>
<tr>
<td>64.</td>
<td>Vicky Marshment presented this item and introduced the paper.</td>
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<tr>
<td>65.</td>
<td>The HTA’s updated Codes of Practice will come into effect on 3 April 2017. To support the technical Codes, the HTA is developing lay guidance, with input from a public panel and the Care Quality Commission’s online community. These documents are intended to make the updated Codes accessible to the widest possible audience.</td>
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<tr>
<td>66.</td>
<td>Members supported the ongoing development of the lay guidance and agreed to provide comments individually.</td>
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<td>67.</td>
<td>Vicky Marshment reiterated that the HTA was carrying out a programme of webinars in February and March, to ensure that Designated Individuals are well prepared for the implementation of the updates Codes. The webinars are being posted on the HTA’s YouTube internet page, to serve an open learning resource for licensed establishments.</td>
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<td>68.</td>
<td>The Authority noted the content of the paper.</td>
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**Action 12: Provide Members with the timetable for webinars.**

<table>
<thead>
<tr>
<th>Item 12</th>
<th>Representations Process – HTA (08/17)</th>
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<tr>
<td>69.</td>
<td>Vicky Marshment presented this item and introduced the proposed updated process.</td>
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<td>70.</td>
<td>The HTA’s process, giving establishments the right to make representations before the Authority imposes licence variations, refusals and revocations, was reviewed by the Authority at its February 2016 and October 2015 meetings. During the quarter, this process was further reviewed, following discussions at the February meeting. Vicky</td>
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Marshment thanked Members who provided input during the development of the recent revisions to the process.

71. Feedback from Designated Individuals was also sought during the development of revisions. Those involved considered that the revisions make a positive difference to the process.

72. Vicky Marshment noted that the aims of the revisions were to reduce the burden on all involved parties, to provide establishments with a sufficiently fair process, and to make a route to appeal accessible and swift.

73. The proposed revisions to the representations process will necessitate changes to the Authority’s Standing Orders. These will be reviewed at the Authority’s May 2017 meeting.

74. Notwithstanding the need to confirm the title of the Process Chair (paragraphs 25-27), the Authority agreed to the proposed changes to the representations process.

**Action 13: Review proposed updates to the Authority’s Standing Orders at its May 2017 meeting.**

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<thead>
<tr>
<th>Item 13</th>
<th>HTA policy for managing and referring potential criminal breaches of human tissue legislation – HTA (09/17)</th>
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<tr>
<td>75.</td>
<td>Allan Marriott-Smith presented this item and introduced the proposed updated policy.</td>
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<td>76.</td>
<td>During the quarter, the Chief Executive sought feedback from Members on the proposed update to the policy that was reviewed at the Authority’s November 2016 meeting. These comments were reflected in the newly updated policy.</td>
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<tr>
<td>77.</td>
<td>Members suggested further minor amendments to be incorporated to the updated policy. Members also reiterated requests relating to Actions Eight and Nine [Delivery Report HTA (04/17)], to understand details behind decisions to make police referrals, to ensure that the policy is effectively delivering desired outcomes.</td>
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78. Subject to these comments, the Authority agreed to the proposed policy for managing and referring potential criminal breaches of human tissue legislation.

**Action 14:** The policy for managing and referring potential criminal breaches of human tissue legislation to be brought to the Authority meeting, following its next use.

<table>
<thead>
<tr>
<th>Item 14</th>
<th>Year-Two Update of the HTA Strategy – HTA (10/17)</th>
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<tr>
<td>79.</td>
<td>Vicky Marshment presented this item and introduced the paper.</td>
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<td>80.</td>
<td>Following the Authority’s strategy awayday in September 2016, HTA colleagues have been developing the year-two update to the HTA’s strategy document, and the related 2017/18 business plan. As a part of this process, the Executive proposed a set of key performance indicators (KPIs) on 26 January, annexed to this paper.</td>
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<td>81.</td>
<td>Vicky Marshment reported that the Executive had decided to include a financial KPI for the 2017/18 year, which is currently being developed.</td>
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<td>82.</td>
<td>Members asked if the indicator for Delivery KPI:3 could not be expressed differently to address the business activity,</td>
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<td>100% of corrective and preventative actions (CAPAs) implemented to address major shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented</td>
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<td>to take regulatory action for all regulatory non-compliances.</td>
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<td>The Executive agreed to review the indicator for this KPI.</td>
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<td>83.</td>
<td>Members also asked the Executive to consider if a safety-based KPI would be appropriate for the HTA.</td>
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<tr>
<td>84.</td>
<td>Members discussed the importance of the licensing and inspection review work programme. Vicky Marshment</td>
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noted that progress against this programme of work, made up of many work strands, would become a standing item in the Development Report.

85. Vicky Marshment confirmed that Members would receive a copy of the final draft text for the strategy document in March, for them to review and comment on.

86. Subject to comments from Members on the final draft strategy text, the Authority delegated sign-off of the final text to the Chair.

| Action 15: Review the indicator for Delivery KPI:3. | VM |
| Action 16: Consider if a safety-based KPI is appropriate. | VM |
| Action 17: Provide Members with a final draft of the strategy text to review by correspondence. | NB |

### Item 15  Cryopreservation – HTA (C12/17)

CONFIDENTIAL MINUTES

### Item 16  Any Other Business – oral

87. The Chair asked Members to raise any other business.

88. Members suggested that in light of discussions throughout the Authority meeting and at the 8 February ARAC meeting, risk tolerance and appetite should be an item for detailed discussion and review at the September strategy awayday. To provide context for the awayday risk session, HTA colleagues will select and develop relevant risk scenarios for the Authority to discuss.

89. No further business was raised.

| Action 18: Develop a risk-based session for the September 2017 Authority strategy awayday. | VM |

The meeting closed at 15:58.
Chief Executive’s Report

Purpose of paper

1. This paper provides an overall assessment of the strategic risks currently facing the HTA as set out in Annex A. The paper also reports on other issues of strategic interest emerging over the quarter that are not reported elsewhere.

Decision-making to date

2. No significant decisions have been made with respect to this report.

Action required

3. The Authority is asked to note the content of this report.

Overview of strategic risks

4. Strategic risks one, two and four (found in Annex A) remained stable or decreased over the quarter. SMT assessed that there was some upward pressure on strategic risk three – Failure to manage expectations of regulation – in recent weeks, while still remaining amber. This is associated both with the announcement of a general election which, at the time of writing, results in some uncertainty about the timing of the passage of the Coding and Import Regulations through Parliament, and a number of issues emerging at the boundaries of our remit over the last six weeks. These are discussed further in the Development Report. There was also some slight upward pressure on strategic risk five – Insufficient financial resource – (although this remained green). This is discussed further in the Deployment Report.
5. As this is the start of a new business year, SMT has also reviewed the strategic risks facing the organisation. It came to the view that strategic risks one to four should remain unaltered, but agreed that strategic risk five should be broadened to consider more widely the external risk factors as well as the impact of poor internal management control on our finances.

Other issues

Living Organ Donation Panel teleconference sessions

6. The first two Members’ teleconferences to discuss issues arising from living donation cases were held on 30 January and 24 March 2017. The aim of these teleconference sessions is to provide a forum for Authority Members to discuss difficult, challenging or interesting living donation cases, so that learning is shared with Members who were not involved with the decision-making. Feedback from Members to date has been very positive and further feedback is welcome to help shape future sessions.

7. SMT has created a central repository of the case summary notes and discussion notes from each teleconference as a future training resource.

8. The next teleconference is scheduled for 30 May 2017.

Managing Member inspection observations

9. Arranging observations for Members has proved to be more challenging than initially anticipated, but progress is being made with two Members now scheduled to attend inspections during quarter one.

10. There are a number of reasons for the delay in arranging observations. We have had a number of new Regulation Managers and have prioritised their training needs so that we can continue to meet our business plan. In addition, some inspections are not suitable for an observer because of their complexity or sensitivity.

11. We would request all Members to be as flexible as possible when arranging to observe an inspection. Members who are able to offer us a range of dates and are able to travel are likely to be offered an earlier opportunity to observe. We recognise that our three-month planning period for an inspection may cause some Members difficulties and, where possible, we will try to schedule an inspection around a Members’ availability. However, this is not always possible, as we also consider establishments’ needs when developing our wider inspection schedule.
Accountability to the Department

12. The HTA met with the Department of Health on 27 January and 27 March as part of its regular accountability arrangements. We outlined our progress against plans and our current assessment of risk. No issues of concern were raised.

13. As part of the end-of-year accountability arrangement, I will meet with Mark Davies on 25 May and the Chair will meet with Clara Swinson on 8 May.

Ministerial meeting

14. The Chair and I met with our new Minister, Lord O'Shaughnessy, the Parliamentary Under Secretary of State at the Department of Health on 1 March. This was an introductory meeting to outline the role of the HTA and to describe the key risks we are managing. Discussion focussed on strategic risk three – *Failure to manage expectation of regulation* – the limitations of the legislation and how we mitigate this risk.

Taphonomy

15. The Executive continues to liaise with Huddersfield University regarding its proposal to develop a taphonomy facility. At present, it is unclear when a firm decision will be reached by the University on whether or not to proceed.

16. To be prepared in the event that a new facility does proceed, Caroline Browne and Christopher Birkett met with colleagues from the Home Office to discuss the risks associated with the activity, how it might be regulated and the risk of it not being subject to regulatory oversight. They are currently preparing a draft options paper ahead of a second meeting with the Home Office in mid-May.

Cryopreservation

17. The HTA wrote to the Department to outline the key issues stemming from the Authority’s cryopreservation discussion on 9 February. As part of this, we agreed to consider what information could be made available for the public and for those working in establishments who may be asked to assist with cryopreservation.

18. To inform the development of this guidance, Barry Fuller, Professor in Surgical Sciences and Low Temperate Medicine at University College London (Royal Free Hospital) delivered a presentation on the history and science of cryopreservation at the HTA office on 4 April.
19. Those present welcomed the discussion. Key points included:

   a. Current cryopreservation research is carried out on living, not dead cells. No research supports the reanimation of dead cells, as whole body cryopreservation suggests may be possible.
   b. Efficacy aside, the practical challenge for hospitals to deal with cryopreservation at the point of death is not inconsiderable.
   c. Nothing in law prevents individuals from pursuing cryopreservation options, but people should be able to source reliable advice in order to make an informed decision.
   d. The HTA will be one source of public information, but any information would need to be considered in partnership with others.

Royal College of Pathologists – Death Investigation Group

20. During the quarter, an HTA representative was invited to become a Member of the Royal College of Pathologists’ (RCPath) Death Investigation Group. The Group advises RCPath’s Council and oversees the delivery of the responsibilities of the College with respect to all matters and issues relating to the investigation of non-forensic deaths by pathologists in the United Kingdom.

21. Set up in December 2016, the Group operates in the context of reduced non-coronial consented autopsy work, and the relative increase in the number of coronial autopsies. The Group acts as a focus for advocacy for non-forensic autopsy pathologists.

22. This is a significant invitation for the HTA and demonstrates our excellent working relationship with the College and the value it attaches to our input.

Competent Authority for Tissues and Cells meeting

23. On 21-23 February, a meeting of European Union (EU) Competent Authorities for Tissues and Cells took place. The meeting was attended by Rob Watson (Head of Regulation – Human Application) and Hazel Lofty (Head of Regulatory Development). This and similar meetings provide the HTA with updates on progress that all Member States are making with regulatory matters concerning tissues and cells. Two issues are of strategic importance to the HTA:

   a. Around half of Member States have yet to transpose Coding and Import Directives into national law. As a result, the United Kingdom, and others, are now at risk of formal infringement proceedings, given that the 29 April deadline for transposition has passed. This represents a financial risk to the Department and a reputational risk for the HTA, regarding its relationship with licenced establishments.
b. The Commission is carrying out an evaluation of EU blood, human tissues and cells legislation. This will define the legislative landscape for the HTA for the coming decade and beyond. Issues raised by the evaluation will no doubt feed into Brexit discussions regarding how the United Kingdom will mirror EU regulations or choose to regulate the use of tissues and cells differently.

**European projects - VISTART and the Joint Action on authorisation of preparation processes in blood and tissues and cells**

24. The VISTART project is an EU Joint Action initiative aiming to promote and facilitate the harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells. It also aims to increase inter-Member State collaboration and confidence in each other’s inspection and vigilance programmes.

25. In 2016/17, the Commission sought nominations from Member States for participation in a new Joint Action initiative on the authorisation of preparation processes in blood and tissues and cells. This initiative will also be central to the United Kingdom’s developing Brexit position, concerning future regulatory harmonisation. The initiative is currently considering:

   a. the definition of serious adverse events and adverse reactions (SAEARs) and the management of reporting;
   b. establishing principles for Competent Authorities for the evaluation and approval of clinical follow-up protocols for newly developed and validating processing methodologies; and
   c. inspection methods across Member States, and developing common approaches for common risks.

**Growth Duty**

26. The Government’s growth duty came into statutory effect on 29 March, under the Deregulation Act 2015. This requires regulators to have regard to the desirability of promoting economic growth, alongside the delivery of protections set out in relevant legislation. The duty applies to most national regulators, which must follow published statutory guidance.

27. This guidance clarifies how regulators can work in accordance with the growth duty. In essence, this is by applying an understanding of:

   a. the general business environment;
   b. their specific business community and individual businesses that they regulate; and
   c. the impact of their activities on businesses.
28. In practice, this is something we already consider when developing policy and taking regulatory decisions, so will not result in a change to how we operate. However, we do need to be aware that this is an area we could potentially be challenged on, and there will be reporting obligations at some point in the future (pending secondary legislation). We are currently updating our corporate documentation to make explicit reference to the growth duty where necessary, and staff training sessions have been planned.

**Critical incident test**

29. We tested our ability to respond to a critical regulatory incident on 9 March. The test was observed by our Internal Auditors and involved staff participating in simulated regulatory incidents. The Internal Auditors will report on the findings of the test at the 18 May Audit and Risk Assurance Committee meeting.

**Internal audit quality management session**

30. The HTA Management Group met with colleagues from our Internal Audit provider (PwC) on 23 March, to discuss and review the controls in place in relation to our licensing and line management activities.

31. The deliverable from this review will be an assurance map for HTA management, using the agreed Quality Governance Framework, which will clearly identify any areas for improvement or further investigation. Internal Auditors will also be presenting assurance reports on this at the 18 May 2017 Audit and Risk Assurance Committee meeting.

**Complaints report**

32. The HTA has received no complaints about the organisation in quarter four.
Overview: Risks reflect the strategy for 2016-19. Our highest risk is failure to regulate appropriately, as this would have a significant impact should it materialise.

Other notable risks: Final delivery of some of one of the HTA’s key projects (Coding and Import) remains in part in the hands of others. The HTA can deliver our part but is not in control of other actions necessary before implementation. Any delays will affect the attitude of our stakeholders and the HTA’s reputation. Further uncertainty is caused by Brexit and the General Election.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Feb 2017</th>
<th>Mar 2017</th>
<th>Apr 2017</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Failure to regulate appropriately (Risk to Delivery a-c &amp; e and Development a-d)</td>
<td>↑</td>
<td>↓</td>
<td>↓</td>
<td>A good regulatory framework and processes are in place and continuous improvement is planned. It is important to identify changes and remain agile to adapt to these. A number of new regulation managers have increased the organisations capability and strengthened our regulatory regime.</td>
</tr>
<tr>
<td>2 - Failure to manage an incident (Delivery, Development and Deployment)</td>
<td>↑</td>
<td>↓</td>
<td>↑</td>
<td>Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 16/17.</td>
</tr>
<tr>
<td>3 - Failure to manage expectations of regulation (Risk to Delivery d)</td>
<td>↓</td>
<td>↑</td>
<td>↑</td>
<td>We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DH and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but appears to the public as if it should be is challenging. Brexit and the General Election means that uncertainty has increased and the HTA faces greater challenges in managing expectations.</td>
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<td>4 - Failure to utilise our capabilities effectively (Delivery a-d) (Development a-d) (Deployment a &amp; c)</td>
<td>↓</td>
<td>↑</td>
<td>↑</td>
<td>We continue to be in a position to use the skills of our newer recruits more fully. With the recent departure of the Head of Business Technology there is a significant gap in operational knowledge and capability around our IT infrastructure, recruitment is underway and a replacement Head will hopefully be in post soon to enable our 2017/18 development plans to be completed. CRM and Portal development went live successfully in mid-October.</td>
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<td>5 - Insufficient financial resources (Deployment b)</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>At the start of the 2017/18 financial year we have a robust expenditure plan in place that will support our delivery plan. There is a minor shortfall in income due to a reduction in licensed activity beyond what was budgeted for and no confirmation at this time that DH will meet the costs of the increased rent costs at 151 Buckingham Palace Road as they did in 2016/17.</td>
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Strategic Objectives:

Delivery – to deliver the right mix of activity to main public and professional confidence
a) To deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to the public
b) To be consistent and transparent in our decision making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing fairly and evenly with those who do not comply with our standards
c) To deliver effective regulation of living donation
d) To inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us
e) To maintain our strategic relationships with other regulators operating in the health sector

Development – to make the right investment in development to continuously improve delivery
a) To reduce regulatory burden where risks to public confidence are lowest
b) To make it clearer how to achieve compliance with new and existing regulatory requirements
c) To make continuous improvements to our systems and processes to minimise wasted or duplicated effort
d) To take opportunities to better inform and involve the public

Deployment – to make the most effective use of our people and resources in pursuit of our goals
a) To manage and develop our people in line with the HTA’s People Strategy
b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
c) To provide a suitable working environment and effective business technology

Risks are assessed by using the grid below.
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
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<th>ASSURED POSITION</th>
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<tbody>
<tr>
<td>1</td>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate</td>
<td><strong>Causes</strong>&lt;br&gt;• Failure to identify regulatory non-compliance&lt;br&gt;• Regulation is not transparent, accountable, proportionate, consistent and targeted&lt;br&gt;• Regulation is not sufficiently agile to respond to changes in sectors&lt;br&gt;• Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IA))&lt;br&gt;• Inadequate adherence to agreed policies and procedures in particular in relation to decision making&lt;br&gt;• Poor quality or out of date policies and procedures&lt;br&gt;• Failure to identify new and emerging issues within HTA remit&lt;br&gt;• Failure to properly account for Better Regulation</td>
<td>3</td>
<td>Ongoing</td>
<td>HTA Strategy 2017 to 2020 clearly articulates the HTA’s regulatory model</td>
<td>3</td>
<td>Preventative</td>
<td>Authority developed and approved the HTA Strategy</td>
<td>HTA Strategy published on 1 April</td>
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<td></td>
<td></td>
<td><strong>Quality management systems</strong></td>
<td></td>
<td></td>
<td>Regulatory decision making framework</td>
<td></td>
<td>Preventative</td>
<td>Reports in Authority of key decisions in Delivery Report</td>
<td>Satisfactory report made in November 2016</td>
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<td></td>
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<td></td>
<td>Annual scheduled review of Strategy</td>
<td></td>
<td>Preventative</td>
<td>Outputs from annual strategy review translate into revised annual Strategy</td>
<td>Last review undertaken in September 2016, next scheduled for September 2017</td>
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<td>Approved HTA Business Plan 2017/18 identifies a balanced programme of regulatory activity and continuous improvement</td>
<td></td>
<td>Preventative</td>
<td>Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department</td>
<td>HFA Business Plan published on 1 April and approved by the Department of Health</td>
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<td><strong>People</strong></td>
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<td>HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</td>
<td></td>
<td>Preventative/controlling</td>
<td>Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates</td>
<td>Management are aware of limitations in the QMS and have further work planned in 2016/17 to address these</td>
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<td></td>
<td>Training and development of professional competence</td>
<td></td>
<td>Preventative</td>
<td>Annual PDPs, RM proposals to SMT</td>
<td>Regulation training plan agreed by SMT in June. Training records added onto Simply Personnel and monthly HR updates presented at SMT</td>
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<td>Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</td>
<td></td>
<td>Preventative/controlling</td>
<td>SMT assessment of skills requirements and gaps as awareness occurs, Recruitment policy</td>
<td>Staffing levels and risks reported quarterly to the Authority</td>
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<td></td>
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<td><strong>Quality management systems</strong></td>
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<td>Strengthening arrangements for managing regulation in response to regulatory incidents - ensuring press office support from MWHK</td>
<td></td>
<td>Preventative</td>
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<td></td>
<td>Implementation of the HTA People Strategy</td>
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<td></td>
<td>Delivery of Licensing and inspection review projects to strengthen our regulatory model (VM) 2017/18</td>
<td></td>
<td>Preventative</td>
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<td>Extension of reporting arrangements to adverse events in the Research sector (DB) Proposals developed by G7 2017/18</td>
<td></td>
<td>Preventative</td>
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<td><strong>People</strong></td>
<td></td>
<td></td>
<td>Delivery of the People strategy road map (AMS) by end of Q1 2017/18</td>
<td></td>
<td>Preventative</td>
<td>People Strategy Progress report produced and March 2016</td>
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<td>Strengthening horizon scanning arrangements (VM) by Q2 2017/18</td>
<td></td>
<td>Preventative</td>
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<td><strong>Other</strong></td>
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<td>Embed Better Regulation initiatives in the regulatory model (VM) by Q1 2017/18</td>
<td></td>
<td>Preventative</td>
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</table>
| 2    | Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:  
- relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)  
- caused by deficiency in the HTA’s regulation or operation  
- where we need to regulate, such as with emergency mortuaries  
- that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)  
Risk owner: Sarah Bedwell | Future, should event occur | 5 3 | Filled identified business-critical roles | 3 2 | X | Preventative | Monthly reports to HTAMG | Last report October 2016 |
|      | Cause | - Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)  
- Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)  
- Failure to work effectively with partners/other organisations  
- Breach of data security  
- IT failure or attack incident affecting access to HTA office | **Preventative** | Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff | X X | Preventative | Policies etc. reviewed annually, training specification and notes after incident reviews | Plan updated and agreed September 2016 |
|      | Effect | - Loss of public confidence  
- Reputational damage  
- Legal action against the HTA  
- Intervention by sponsor | X | Media handling policy and guidance in place, including regular media training for key staff & Members with relevant scenarios, to supplement media release and enquiries SOPs | X | Preventative | Policy reviewed annually, training specifications  
Reports on media issues in Delivery Report | Media policy to be reviewed.  
Deliver report to Authority meeting November - satisfactory |
<p>|      | Availability of legal advice | - Accessible lines to take and key messages for likely scenarios | X | Preventative | Documented, incidents reported to Chair and in Delivery Report | Delivery report to Authority meeting November - satisfactory |
|      | Fit for purpose Police Referrals Policy | - Onward delegation scheme and decision making framework agreed by the Authority | X X | Preventative | Standing Orders and Authority minutes | SO reviewed and agreed in October 2015 |
|      | Regulatory decision making framework | - IT security controls and information risk management | X | Preventative | Reports to Authority of key decisions in Delivery Report | Satisfactory reports made in November 2016 |
|      | Business continuity plan regularly reviewed and tested | - Evaluate test exercise of incident and feedback to all staff (SB) May 2017 | X | Preventative | Critical Incident Response Plan and notes of test, reported to SMT | Test was undertaken in Q4 of 2016/17 |</p>
<table>
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</table>
| 2   | Failure to manage public and professional confidence of human tissue regulatory in particular stemming from limitations in current legislation or misperception of HTA regulatory reach | **Cause**  
External factors  
- No scheduled reviews of Human Tissue Act and associated regulations  
- Rapidly advancing life sciences  
- Potential move away from the UK as base for some regulated establishments/activities due to Brexit and changes in exchange rates | 4 4 | Ongoing | Log of issues known to the HTA with respect to the legislation to inform DH and manage messages | 4 3 | X Monitoring | Dropping log | Stakeholder Group meeting with a variety of stakeholders (including Public Authority Meeting) | Last stakeholder group meeting in October 2016, Authority meeting in November 2016 |
|     | Risk Owner: Vicky Marshment | **Matters which certain stakeholder groups believe require regular review**  
- Scope of relevant materials e.g. waste products  
- Licensing requirements e.g. transplantation research  
- Regulation relating to child bone marrow donors  
- Issues raised by emergence of social media e.g. non-related donors  
- Strengthening of civil sanctions for non-compliance  
- Implementation of the costing and import directives in light of Brexit | | | | | | | | |
|     | | **Matters which stakeholders/public may expect to be inside regulatory scope**  
- Efficacy of clinical treatment from banked tissue  
- Police holdings  
- Products of conception and fetal remains  
- Data generated from human tissue  
- Funeral directors  
- Forensic research facilities  
- Cryopreservation  
- Body stores / Taphonomy  
- Imported material  
- Other  
- Inadequate stakeholder management | | | | | | | | | |
|     | | **Effect**  
- Diminished professional confidence in the adequacy of the legislation  
- Reduced public confidence in regulation of matters relating to human tissue  
- Reputational damage | | | | | | | | |
|     | | **Implementation of triennial review recommendations (March 2017)**  
- Proactive horizon scanning and development of policy in emerging/complex areas June 2017  
- Cryopreservation: sustainability and development of policy to ensure greater clarity on matters inside and outside of regulatory scope were published April 2017. | | | | | | | | |
|     | | **Codes of practice and standards project** - provides greater clarity on matters inside and outside of regulatory scope were published March 2016.  
- Strengthening of civil sanctions for non-compliance | | | | | | | | |
|     | | **Implementation of Functional Review Recommendations**  
- Use of a 15 day to report issue directly to Ministers in England, Wales and Northern Ireland as new issues emerge | | | | | | | | |
|     | | **Legal advice now gives a clearer view of our Schedule 2, s. 20 powers** | | | | | | | | |
|     | | **Consequential changes to reports to the Code of Practice Development Working Group**  
- Circulation of principles within Code A to water stakeholders to be undertaken Quarter 1 2017/18  
- Implementation of Functional Review recommendations | | | | | | | | |
|     | | **Circulation of principles within Code A to water stakeholders to be undertaken Quarter 1 2017/18**  
- Implementation of Functional Review recommendations (March 2017)  
- Codes of practice and standards project - provides greater clarity on matters inside and outside of regulatory scope were published April 2017. | | | | | | | | |
|     | | **Other**  
- Inadequate stakeholder management | | | | | | | | |
### People

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<thead>
<tr>
<th>REF</th>
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</table>
| 4   | Failure to utilise people, data and business technology capabilities effectively | - Lack of knowledge about individuals' expertise  
- Poor job and organisational design resulting in skills being under used  
- Poor line management practices  
- Poor project management practices  
- Poor leadership from SMT and Heads  
- Data holdings poorly managed and unexplained  
- Inadequate business technology or training in the technology available | 2 4 | | | | X 4 3 | I X X | Preventative/Monitoring | GMS reminders on policies due for review, SMT review of all revised policies | Currently in the middle of a regular review cycle |

#### Prevention

- Established annual Performance Development Planning (PDP) process supported by mandated 1-2-1 meetings and mid year review process (1-2-1s and mid year review) Standard objectives for all line managers

#### Monitoring/Detective

- Regular review of HTA organisational structure and job descriptions
- Feedback from HTA people about work, management and leadership

- Data relating to establishments securely stored with the Customer Relationship Management System (CRM)

- Staff training in key business systems

- IT systems protected and assurance received from 3rd party suppliers on protection being up to date

### Effect

- Poor deployment of staff leading to inefficient working
- Disaffected staff
- Increased turnover leading to loss of staff
- Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed
- Poor use of technology resulting in inefficient ways of working
- Inadequate balance between serving Delivery and Development objectives

### Business Technology

- Staff training in key business systems
- IT systems protected and assurance received from 3rd party suppliers

### People

- Strengthen the PDP process by introducing structured 180-degree feedback (AMS) 2017/18
- Range of projects within the People Strategy relating to managing and leading people, in particular more structured management and leadership training and development (AMS) by March 2017

- HTAMG Development schedule to be part of monthly meetings throughout 2017/18

- Plans to be developed (RS) by Q3 2017/18

### Business Technology

- Software specific training needs identified (RS) by Q3 2017/18
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATION</th>
<th>RESIDUAL RISK</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tr>
<td>5</td>
<td>Insufficient financial resources</td>
<td>Fee payers unable to pay licence fees</td>
<td>4</td>
<td>Ongoing</td>
<td>Budget management framework to control and review spend and take early action</td>
<td>3</td>
<td>Preventive</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Budgetary control policy reviewed annually and agreed by SMT</td>
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<tr>
<td></td>
<td>Risk to Deployment objective 6</td>
<td>The number of licenced establishments changes, leading to reduced fee income</td>
<td>4</td>
<td>Ongoing</td>
<td>Financial projections, cash flow forecasting and monitoring</td>
<td>3</td>
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<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Update agreed by the Authority November 2016</td>
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<td>Risk to Deployment objective 6</td>
<td>Management fail to set licence fees at a level that recover sufficient income to meet resource requirements</td>
<td>4</td>
<td>Ongoing</td>
<td>Licence fee modelling</td>
<td>3</td>
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<td></td>
<td>Richard Sydee</td>
<td>Failure to estimate resource required to meet our regulatory activity</td>
<td>4</td>
<td>Ongoing</td>
<td>Rigorous debt recovery procedure</td>
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<td>Update agreed by the Authority November 2016</td>
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<td></td>
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<td>Poor budget and/or cash-flow management</td>
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<td>Ongoing</td>
<td>Reserves policy and levels reserves</td>
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<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
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<td></td>
<td></td>
<td>Unexpected increases in regulatory responsibilities</td>
<td>4</td>
<td>Ongoing</td>
<td>Delegation letters set out responsibilities</td>
<td>3</td>
<td>Preventive</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Delegation letters issued annually</td>
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<td></td>
<td></td>
<td>Unforeseeable price increases / reductions in GIA</td>
<td>4</td>
<td>Ongoing</td>
<td>Prioritisation when work requirements change</td>
<td>3</td>
<td>Preventive</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Agreed business plan, monthly HTAMG and SMT reports</td>
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<tr>
<td></td>
<td></td>
<td>Fees model provides cost/income information for planning</td>
<td>4</td>
<td>Ongoing</td>
<td>Fees model provides cost/income information for planning</td>
<td>3</td>
<td>Preventive</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Annual review of fees model, reported to SMT and Authority</td>
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<td></td>
<td>Annual external audit</td>
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<td>Monitoring of income and expenditure (RS)</td>
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<td>Monitoring</td>
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<td>Monitoring</td>
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<td></td>
<td></td>
<td>Monitoring for changes to DH Grant-in-aid levels and arrangements (RS)</td>
<td>4</td>
<td>Ongoing</td>
<td>Monitoring</td>
<td>3</td>
<td>Preventive</td>
<td>Monitoring</td>
<td>Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH</td>
<td>All</td>
<td>Monitoring</td>
</tr>
</tbody>
</table>

**Insufficient financial resources**

- Fee payers unable to pay licence fees
- The number of licenced establishments changes, leading to reduced fee income
- Management fail to set licence fees at a level that recover sufficient income to meet resource requirements
- Failure to estimate resource required to meet our regulatory activity
- Poor budget and/or cash-flow management
- Unexpected increases in regulatory responsibilities
- Unforeseeable price increases / reductions in GIA

**Effect**

- Payments to suppliers and/or staff delayed
- Compensatory reductions in staff and other expenditure budgets
- Increased licence fees
- Request for further public funding
- Draw on reserves

Leading to:

- Insufficient financial resources (Risk to Deployment objective b)

**Risk Owner:** Richard Sydee
**Authority Report**

**Delivery – Quarter Four 2016/17 (year-end)**

<table>
<thead>
<tr>
<th>Date</th>
<th>4 May 2017</th>
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</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>7</td>
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<tr>
<td>Paper Reference</td>
<td>HTA (14/17)</td>
</tr>
<tr>
<td>Author</td>
<td>Sarah Bedwell</td>
</tr>
</tbody>
</table>

**Strategic objectives (Delivery)**

- To deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to the public.
- To be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our Standards.
- To deliver effective regulation of living donation.
- To inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them, and influence them in matters that are important to us.
- To maintain our strategic relationships with other regulators operating in the health sector.

**Relevant key performance indicators (KPIs)**

- At least 95% of enquiries are answered within 10 working days of receipt, excluding body donation enquiries.
- At least 180 site visits to take place during the business year across all sectors (reported as total site visits year-to-date).
- At least 80% of responding establishments agree with the post inspection survey question "Has the inspection/audit process helped improve the ways in which your organisation works?" (reported quarterly).
- 100% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented.

**Related Strategic Risks**

- Failure to regulate appropriately
- Failure to manage an incident
- Failure to manage expectations of regulation
- Failure to utilise our capabilities effectively

(see paper 13a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the delivery activities of the HTA and to highlight trends and any issues which require consideration by Members.

2. It is provided as a source of assurance on the delivery activities of the HTA, including statistics and background information set out in Annex A. Annex B reports Serious Adverse Events and Adverse Reactions (SAEARs) HTA Reportable Incidents (HTARIs).

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 13 April 2017.

Action required

4. The Authority is asked to note the content of this report.

Directors’ summary

5. Tables Two, Three and Four show a rise in the number of reportable incidents across the post-mortem, human application and organ donation and transplantation sectors. Looking back over previous years, however, the reported incidents for the post-mortem and human application sectors are consistent as the number of incidents reported in 2015/16 were lower than we would expect. There has, however been a rise in the organ donation and transplantation sector, which is not offset by previous years. We have discussed this with NHSBT, which manages the reporting system under a service level agreement. The rise in incidents reported to us is part of a rise in all incidents reported to NHSBT (they require reporting of a wider set of incidents than the statutory requirement). It also appears that the rise in reporting generally is greater, proportionally, than the rise in the number of incidents reportable to us. It appears that this rise reflects better reporting; however, we will continue to monitor this with NHSBT.

6. Since the beginning of March, Northumbria Police have been coordinating an operation in the North East to contact families in relation to tissue that has been retained following police investigations longer than was necessary. They have been deploying Family Liaison Officers to speak with families, to explain what happened and to give them the options on what happens to the tissue now (i.e. burial, cremation, sensitive disposal). This operation is ongoing.
7. We were called as a respondent in a matter that was considered at a Directions hearing at the Court of Protection. We had no involvement in the issues which led to the Hearing.

8. Members were provided with a confidential briefing at the time and were updated at the panel teleconference held on 24 March. The judgment was handed down on 12 April, which can be viewed [here](#). The applicant’s case was struck out, with the applicant and notified persons ordered to pay costs to the HTA.

**Critical shortfalls**

9. There were no critical shortfalls during quarter four.

**Investigations**

**New investigations**

10. There have been no new investigations in quarter four.

**Update on investigation reported in previous Delivery report (HTA 04/17)**

**Investigation 07/16**

11. In previous reporting, we included an investigation about a product intended for human application that is available for sale. The Designated Individual (DI) raised concerns that the products may contain animal products that have been subject to recall. This investigation is still ongoing, updates will be provided in the quarter one Delivery Report.

**Investigation 09/16**

12. In the previous Delivery Report, there was an investigation into an enquiry regarding services offered by an establishment, where an activity was being carried out on licensed premises, but not under the governance of the licence. As a result, all activities were stopped.

13. The investigation remains active and the agreed action is to let the Medicines and Healthcare products Regulatory Agency to take the lead, as this is a medicinal product.

**Investigation 10/16**

14. In previous reporting, we included an investigation where the relative of a deceased woman was contacted by a mortuary to explain that blocks and slides taken during her
post-mortem examination were still being stored when they should have been returned to the next of kin.

15. Arrangements were made for the blocks and slides to be returned to the family. A formal complaint was made to the Trust by the relative. The HTA also received a Freedom of Information Act request regarding this investigation, which is detailed at paragraph 42.

16. We notified the relative that we had received the investigation report from the Trust, which includes the steps they had taken as a result of the investigation. The HTA is satisfied that a thorough investigation was carried out and that effective actions were taken. We also provided advice to the Trust to help them strengthen their systems further, to mitigate the risk of a similar future incident.

17. **Non-routine site visit inspections**

18. There were no non-routine site visit inspections in quarter four.

**Police referrals**

19. This report will now include:

   a. details of the cases considered by SMT that were potential breaches of human tissue legislation;
   b. factors in favour of referral;
   c. factors against referral; and
   d. the decisions made.

**Police referral 01/17**

20. In December 2016, the HTA was provided with a brief intelligence report by the National Crime Agency, which raised concerns about a British citizen sending funds to an account overseas. The funds were being transferred to a bank account that had been linked to an email address associated with the buying and selling of organs.

21. The HTA has no powers to investigate this case. SMT made a decision to refer the case to the relevant Police force for investigation.

22. An investigation was undertaken and the Police were satisfied that the person involved had not tried to purchase an organ and was not involved in the buying or selling of human organs. Indeed, the individual who transferred money overseas appears to have been the victim of fraud.
23. In February 2017, a European Union (EU) Competent Authority in another Member State made us aware of a website, which appeared to offer a British matching donor service in exchange for a fee.

24. Factors in favour of referring this case to the Police included:

   a. the alleged offence has the potential to damage public confidence in the use of human tissue;
   b. referral to the Police for investigation would have a positive impact on maintaining public and/or professional confidence in the use of human tissue;
   c. the alleged offence may have been deliberate; and
   d. the alleged offence or other offences under human tissue legislation are likely to be continued or repeated.

25. There were no factors against making a referral.

26. SMT therefore decided to refer this case to the Police who in turn referred this on to the country in which the company offering the service is registered. The investigation is ongoing and we are liaising with the relevant Member State. We will update Members with further details at the Authority Meeting.

Legal notices

27. We issued three sets of Directions in quarter four to three establishments in the Human Application sector, which prevent them from procuring tissues or cells for human application until we have conducted site visit inspections. For more information please see the ‘Regulatory decision meetings’ summary below.

Regulatory decision meetings

28. Three regulatory decision meetings (RDMs) were held in quarter four.

29. The RDMs were convened to discuss our approach to establishments in the human application sector, which hold licenses, but do not currently undertake any licensed activities. We had invited the establishments to revoke their licences but they do not wish to do so. In practice, inspecting these establishments adds little value as they are not undertaking any activity and could not meet the requirements of any CAPA plan, which might be put in place to deal with shortfalls against standards.
30. The establishments are not currently undertaking any activity because the Advanced Therapy Medicinal Products supplier has ceased to offer the service the establishments have been provided. They cannot therefore continue with any activities until a new supplier is in place. In addition, there is little funding available for the treatment.

31. We issued Directions to the establishments preventing them from undertaking activities under the licences until the HTA has undertaken an inspection. The Directions require the establishments to give us notice of their intention to undertake licensable activities.

32. The Directions were issued on 30 March and will remain in force until inspections are conducted, or the establishment(s) revokes their licence(s).

Reconsiderations, representations and appeals

33. No reconsiderations, representations or appeals were considered during quarter four.

Other regulatory activity

34. A referral was made to the Health and Safety Executive for consideration regarding a post-mortem suite floor, which had a number of large cracks on the surface. These cracks were causing water to build-up during cleaning and therefore affecting the overall decontamination of the area.

35. Although this was acknowledged to be a health and safety risk to staff working in the area, and had been on the associated Trust’s risk register, on inspection, it was discovered that there were no plans to have the necessary work undertaken.

Enquiries

General enquiries

36. During quarter four, we recorded 869 general enquiries, compared to 796 in the previous quarter. The enquiries included:

a. 540 from members of the public about body donation (365 were received via email or phone, and in the post, and 175 via the website). This compares to 503 in the previous quarter.

b. 190 from professionals about licensing or other areas of our regulatory work, compared with 148 in the previous quarter.

37. Of these enquiries, 439 were received via the website, compared to 263 last quarter. Other enquiries are usually received by phone.
The HTA sets itself a KPI of responding to 95 percent of general enquiries in ten working days. Of enquiries received during quarter four, 95 percent were closed in our case management system within ten working days, 93 percent in the previous quarter. Over quarter four, four percent of enquiries were responded to within twenty working days, with the average time taken in quarter four standing at five days. The cases that fell outside ten working days generally tended to involve concerns raised with us about establishments.

**Freedom of Information Act (FOIA) requests**

We had six FOIA requests in quarter four, compared to five in the previous quarter. We publish FOIA responses on our [website](#).

We received three requests relating to reported SAEARs and HTARI cases in 2016. In response to the three requests, we released the names of establishments, where the incidents / events / reactions occurred, their classifications, as well descriptions and dates. This generated limited media coverage.

The remaining requests related to information on:

- BACs payments and direct debit software suppliers;
- directed altruistic donations; and
- an HTARI report and the HTA’s response to the report, details of which are provided below.

Regarding the request for an HTARI report, and the HTA’s response to it, the HTA declined the request for the report. In doing so it relied on the Section 31 exemption. This is a qualified exemption, for “the exercise by any public authority of its functions for any certain specified purposes”. In this case “ascertaining whether circumstances which would justify regulatory action in the pursuance of any enactment exist or may arise”.

In this instance we did, however, decide to release an appropriately redacted copy of the HTA’s response to the licence holder in question. The response outlined the HTA’s expectations of remedial action that the licence holder must take as a result of the reported HTARI.

It remains HTA policy to assess whether the Section 31 exemption applies when any request is made for detailed information relating to a HTARI because of the potential impact that release may have on full disclosure of incidents by establishments (for example, for fear of adverse publicity) which in turn could become a risk to public safety.
Stakeholder engagement

Codes and Standards Implementation project

45. In quarter four, the following engagement with stakeholders on the Codes and Standards project took place:

a. five bespoke Codes and Standards emails to all establishments;
b. twelve webinars on the Codes and Standards, involving 357 individuals; and
c. a new page on the HTA website, collating the newsletter and webinar information.

EU Coding and Import Directive consultation

46. On Friday, 10 March, the Department of Health launched a consultation on the Coding and Import Directives on www.gov.uk. We notified establishments of this, and of the HTA draft guidance to the consultation the following Monday. This has since been followed up with a reminder email, and newsletters advertising two relevant webinars, which were recorded in March. The Department’s consultation closed on 7 April.

Joint Health Research Authority / HTA research on public sentiment and ethics

47. The HTA, the Health Research Authority, the Medical Research Council and other stakeholders have come together to draw up a research proposal to investigate what the public think about how tissue is used in research, with the HTA focus largely being on public sentiment around consent, particularly dynamic consent.

48. The business case for the joint research has been agreed and submitted for funding matching with Sciencewise, and a list of members for the project’s Oversight Group has been proposed. We are currently waiting to hear from the Department for Business, Energy and Industrial Strategy, regarding access to the framework of public engagement suppliers.

HTA Response to the Scottish Consultation on Organ and Tissue Donation and Transplantation - a consultation on increasing numbers of successful donations

49. The HTA submitted a response to the Scottish Government’s consultation on two ways to potentially increase the number of deceased organ donation and tissues donors - by seeking to increase numbers of referrals and by seeking to increase the number of times when donation is authorised to proceed.

50. Our response is available here.
HTA response to the Care Quality Commission’s consultation on changes to the way they regulate health and adult social care services

51. The HTA submitted a response to the Care Quality Commission's consultation on its next phase of regulation.

52. With shared areas of interest, and an existing Memorandum of Understanding, the HTA looks to strengthen existing relationships for the benefit of both regulators and establishments.

53. Our response is available here.

Histopathology Working Group survey

54. During March, we produced a self-assessment survey seeking views on the effectiveness of the HTA’s Histopathology Working Group (HWG) from its members. The survey’s aim was to provide assurance to the Authority, and member organisations, about the operation of the Group in relation to five core areas:

a. **The functions of the group**: Is HWG fulfilling its stated functions.

b. **Its objectives**: Are the Group’s objectives still appropriate and is the role of members to help achieve the objectives clear.

c. **The skills and membership**: Does the Group’s membership have the appropriate mix of skills and expertise to enable it to perform its functions well.

d. **Its operation**: Is the current format and frequency of meetings sufficient for the Group to fulfil its functions.

e. **Communication**: Does the Group communicate effectively with member organisations and other sector stakeholders.

55. In addition, the survey invited views on the role of the Chair and secretariat service.

56. On the whole, respondents confirmed that the Group works effectively, in maintaining oversight of the post-mortem sector and in informing HTA policy development.

57. The Group is due to discuss the results of the survey at the next HWG meeting in May.
Engagement with establishments

58. As well as specific newsletters about the Coding and Import Directives and the HTA’s updated Codes and Standards, the following newsletters were sent to establishments in quarter four:

- 17 January – Independent Assessor Bulletin;
- 23 January – Professional Newsletter;
- 28 February – Public Newsletter;
- 7 March – Independent Assessor Bulletin;
- 22 March – Professional Newsletter; and
- 27 March – Save the Date Newsletter: HTA Summer Conference.

Establishment button

59. The HTA continues to work on the development of an “establishment button” that HTA-licensed establishments can add to their website to indicate that they are licensed by us. The button will link through to their establishment page on the HTA website, which includes basic information like inspection reports. By making this feature available, we hope it will increase professional and public confidence in their activities. By widening access to licence statuses and reports, this would also increase awareness of the HTA as well as the transparency of our regulatory activities.

60. During the quarter, the HTA carried out customer relationship management system (CRM) testing to determine how to best accommodate establishments with multiple licenses (e.g. NHS Trusts) to avoid them having to add a different button for each of their licences.

61. We continue to encourage establishments to add the button where practical, to provide feedback, but a full roll out - which would include a self-service facility – will not happen until after the CRM changes later in the year.
Delivery KPI narrative

Performance against 2016/17 KPIs

62. One KPI is marked as red, as 93% of enquiries in the quarter were answered within 10 working days (rather than 95%). Two cases were mistakenly left open in the CRM system by error. The figure would have been 95% is this was not the case.

63. All other Delivery KPIs for quarter four are within target or tolerance and marked as green.

2017/18 KPIs

64. The HTA’s 2017/18 business plan sets out six KPIs for Delivery. Five of these have been retained from 2016/17 and one new KPI has been added. One KPI from 2016/17 (KPI:2 – Seek feedback from establishments after each inspection and analyse and report the results each quarter) has been removed. The 2017/18 KPIs are:

a. KPI:1 – Undertake a risk based inspection / audit programme (continued from 2016/17)
   Indicator: At least 210 site visits to take place during the business year across all sectors (year-to-date)

b. KPI:2 – Take appropriate action for all regulatory non-compliance (continued from 2016/17)
   Indicator: 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly)

c. KPI:3 – Make appropriately evidenced decisions to agreed quality standards (continued from 2016/17)
   Indicator: 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly)

d. KPI:4 – Make appropriately evidenced decisions within agreed timeframe (continued from 2016/17)
   Indicator: 100% of panel cases turned around within ten working days (average reported monthly)
e. **KPI:5 – Respond to enquiries in a timely way (continued from 2016/17)**

Indicator: At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)

f. **KPI:5 – Ensure human tissue is used safely (new)**

Indicator: Report provided to the Authority annually (in May / June) on a series of measures, which provide an overview of safety in the regulated sectors.
Annex A – Statistics and background information

Regulation

Table One: Site visits (including licence application assessment visits (LAAVs))

<table>
<thead>
<tr>
<th>Type of site visit</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
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</thead>
<tbody>
<tr>
<td>Routine inspection</td>
<td>39</td>
<td>29</td>
<td>32</td>
<td>36</td>
<td>136</td>
<td>164</td>
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<tr>
<td>LAAV - new application</td>
<td>4</td>
<td>3</td>
<td>6</td>
<td>5</td>
<td>18</td>
<td>15</td>
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<tr>
<td>Satellite site inspection</td>
<td>8</td>
<td>10</td>
<td>11</td>
<td>17</td>
<td>46</td>
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<td>CAPA follow up</td>
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<td>0</td>
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<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Non-routine inspection</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total sites visited</strong></td>
<td><strong>51</strong></td>
<td><strong>43</strong></td>
<td><strong>50</strong></td>
<td><strong>58</strong></td>
<td><strong>202</strong></td>
<td><strong>234</strong></td>
</tr>
</tbody>
</table>

Licensed Establishment inspections by year

- **LAAV - new application**: 3, 17, 15, 18
- **Satellite site inspection**: 45, 47, 46
- **CAPA follow up**: 0, 1, 2, 1
- **Non-routine inspection**: 4, 6, 6, 1

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
65. In 2014/15, mortuaries licenced by the HTA admitted around 330,000 bodies, and performed over 100,000 post-mortem examinations. The number of reported HTARIs in context is very low.

### Table Two: HTARIs in the post-mortem sector

<table>
<thead>
<tr>
<th>HTARI Classification</th>
<th>Q4 2016 / 17</th>
<th>Q3 2016 / 17</th>
<th>Q2 2016 / 17</th>
<th>Q1 2016 / 17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
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<tbody>
<tr>
<td>Classification yet to be finalised / allocated</td>
<td>0 13</td>
<td>N/A</td>
<td>N/A</td>
<td>13</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Accidental damage to a body</td>
<td>13 7</td>
<td>10 7</td>
<td>37</td>
<td></td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination</td>
<td>0 0</td>
<td>1 0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family</td>
<td>0 0</td>
<td>1 1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family</td>
<td>2 0</td>
<td>0 1</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposal or retention of an organ against the express wishes of the family</td>
<td>0 0</td>
<td>1 0</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>1 2</td>
<td>1 0</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services</td>
<td>1 0</td>
<td>0 0</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>1 0</td>
<td>1 0</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major equipment failure</td>
<td>0 0</td>
<td>3 3</td>
<td>6</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent</td>
<td>0 0</td>
<td>2 0</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-mortem examination of the wrong body</td>
<td>1 0</td>
<td>0 1</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Release of the wrong body</td>
<td>6 2</td>
<td>1 2</td>
<td>11</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>0 0</td>
<td>2 2</td>
<td>4</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious security breach</td>
<td>2 1</td>
<td>2 0</td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viewing of the wrong body</td>
<td>4 0</td>
<td>2 2</td>
<td>8</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>10 4</td>
<td>11 6</td>
<td>31</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>41 16</strong></td>
<td><strong>36 25</strong></td>
<td><strong>118</strong></td>
<td><strong>102</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table Three: SAEARs in the human application sector

66. Given the nature of regulated activities carried out in the human application sector, it is difficult to calculate a total number of activities to establish a denominator to compare with numbers of events and reactions.

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event linked to Distribution</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to End use</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Event linked to Materials</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to Preservation</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Processing</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Event linked to Procurement</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>21</td>
<td>9</td>
</tr>
<tr>
<td>Event linked to Storage</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Testing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Transportation</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to Other process</td>
<td>7</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>5</td>
<td>7</td>
<td>4</td>
<td>3</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
<td>21</td>
<td>21</td>
<td>93</td>
<td>60</td>
</tr>
</tbody>
</table>

SAEARS in the human application sector by year

The diagram shows the number of SAEARs by type and year, with bars indicating the total counts for each category across different years.
Table Four: SAEARs in the Organ Donation and Transplantation sector

67. During quarter four, a total of 1,013 organs were successfully transplanted and 1,206 organs were retrieved from 595 patients (England, Wales, Northern Ireland and Scotland).

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events</td>
<td>10</td>
<td>13</td>
<td>4</td>
<td>10</td>
<td>37</td>
<td>22</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>18</td>
<td>10</td>
<td>18</td>
<td>63</td>
<td>36</td>
</tr>
</tbody>
</table>

Table Five: Bone marrow and PBSC cases where the donor lacks capacity/competence

<table>
<thead>
<tr>
<th></th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvals</td>
<td>25</td>
<td>16</td>
<td>14</td>
<td>14</td>
<td>69</td>
<td>55</td>
</tr>
</tbody>
</table>
Table Six: Living organ donation cases

<table>
<thead>
<tr>
<th>Type of case</th>
<th>TOTALS</th>
<th>Number of cases considered</th>
<th>Approvals by the Living Donation Assessment Team</th>
<th>Approvals by Authority panels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 16/07</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDAT Panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4 16/07</td>
<td>233</td>
<td>19</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Q3 16/17</td>
<td>217</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Q2 16/17</td>
<td>208</td>
<td>2</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Q1 16/17</td>
<td>216</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>16/17 Total Year</td>
<td>874</td>
<td>21</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>15/16 Total Year</td>
<td>886</td>
<td>0</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>
Communications

Social media

68. In quarter four, the HTA’s Twitter account had 1,589 followers, up from 1,503 in the previous quarter. Our engagement rate decreased to 1.3% from 1.5% during quarter three, with a peak rate of 4.1%.

69. On average, HTA tweets were seen by 545 people per day, down from 715 in quarter three. Our impression rate this quarter was down from last quarter due to high-profile coverage the HTA received regarding the cryopreservation case in November 2016.

Table Seven:

<table>
<thead>
<tr>
<th>Month</th>
<th>Impressions</th>
<th>Profile Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>17.5K</td>
<td>1,573</td>
</tr>
<tr>
<td>February</td>
<td>13.8K</td>
<td>1,811</td>
</tr>
<tr>
<td>March</td>
<td>16.2K</td>
<td>1,693</td>
</tr>
</tbody>
</table>

70. Tweets with the highest reach and engagement in quarter four were about:

- **g. Corporate**
  - Publication of recordings from our Codes of Practice training webinar series on the new [HTA YouTube channel](#).

- **h. ODT**
  - Promoting World Kidney Day and sharing HTA kidney donation approval statistics.

- **i. Human Application**
  - Launch of Department of Health’s consultation on the EU Directives on Coding and Import of tissues and cells.

- **j. Anatomy**
  - Channel 4’s broadcast of the first TV advertisement of live surgery.

- **e. ODT**
  - Sharing living organ donation Frequently Asked Questions, following the broadcast of BBC’s ‘Hospital’ (episode six), which featured a case of paired and pooled donation.

71. There are 671 Facebook ‘likes’ on the HTA page, up from 652 in quarter three. The HTA also had 451 followers for its LinkedIn company page, up from 437 in quarter three.

72. In March, we created an HTA YouTube channel to promote and share recordings of the presentations from the Codes of Practice training webinar series. Since the channel’s launch, we have had a total of 530 views of the Codes videos. We will also be...
publishing recordings of the Coding and Import Directives webinar sessions on YouTube in due course.

**Digital communications and publications**

73. In quarter four, we published the ‘draft guidance on the coding and import of tissues and cells for human application’ document. The guidance was prepared for those working in the human application sector, in order to provide them with key information regarding the two new EU Directives, that are being transposed into British law. The guidance document is currently in draft format, pending the feedback we receive from the Department of Health’s consultation, which ended on 7 April.

Table Nine: Digital users

<table>
<thead>
<tr>
<th></th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users</td>
<td>53,204</td>
<td>50,568</td>
<td>41,093</td>
<td>54,361</td>
<td>199,226</td>
<td>165,032</td>
</tr>
<tr>
<td>Page views</td>
<td>217,912</td>
<td>206,910</td>
<td>185,555</td>
<td>170,670</td>
<td>781,047</td>
<td>729,300</td>
</tr>
<tr>
<td>Pages viewed per session</td>
<td>3.05</td>
<td>3.04</td>
<td>3.28</td>
<td>3.14</td>
<td>3.13</td>
<td>3.38</td>
</tr>
<tr>
<td>Average session duration</td>
<td>00:02:50</td>
<td>00:02:48</td>
<td>00:02:58</td>
<td>00:02:45</td>
<td>00:02:50</td>
<td>00:02:56</td>
</tr>
<tr>
<td>Online enquiries</td>
<td>460</td>
<td>270</td>
<td>298</td>
<td>368</td>
<td>1,396</td>
<td>1,448</td>
</tr>
<tr>
<td>eNewsletter signups</td>
<td>519</td>
<td>341</td>
<td>324</td>
<td>331</td>
<td>1,515</td>
<td>938</td>
</tr>
</tbody>
</table>

74. The highest viewed pages are:

Table 10: Page views

<table>
<thead>
<tr>
<th>Highest viewed pages</th>
<th>Q4 2016/17</th>
<th>Q3 2016/17</th>
<th>Q2 2016/17</th>
<th>Q1 2016/17</th>
<th>2016/17 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body donation FAQs</td>
<td>12,896</td>
<td>15,597</td>
<td>15,703</td>
<td>15,557</td>
<td>59,753</td>
</tr>
<tr>
<td>Medical school search</td>
<td>16,397</td>
<td>15,355</td>
<td>13,161</td>
<td>12,127</td>
<td>57,040</td>
</tr>
<tr>
<td>Donating your body info</td>
<td>16,121</td>
<td>12,836</td>
<td>6,381</td>
<td>5,481</td>
<td>40,819</td>
</tr>
<tr>
<td>Guidance for professionals</td>
<td>5,009</td>
<td>6,023</td>
<td>6,335</td>
<td>5,480</td>
<td>22,847</td>
</tr>
</tbody>
</table>

\[^1\] Data first collected in 2016/17
75. The most frequently clicked top menu items on the front page are:

   k. FAQs – 19,649;
   l. guidance for professionals – 16,141; and
   m. guidance for the public – 9,552.

76. This suggests that the majority of visitors to the HTA website are professional stakeholders, but with a significant number of visitors who are members of the public, looking to find out more about what the HTA does.

**Newsletters**

77. The HTA sent out a professional newsletter in March and an Independent Assessor bulletin in January. The HTA public newsletter was sent out in February.

78. Since January, we have been issuing a series of newsletters that focus on the updated Codes of Practice and Standards. The rationale behind these publications is to share key information and guidance to help establishments prepare for implementation of the new Codes. We have circulated a total of five newsletters in the run up to the launch of the Codes and we have been distributing these to Designated Individuals, Corporate Licence Holders and Persons Designate. The last issue will be circulated on 3 April.

79. The government average is for 24% of subscribers to open newsletters.

**Table 11: Professional newsletter**

<table>
<thead>
<tr>
<th></th>
<th>Number of recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-16</td>
<td>2900</td>
<td>0.00%</td>
</tr>
<tr>
<td>Oct-16</td>
<td>3000</td>
<td>5.00%</td>
</tr>
<tr>
<td>Nov-16</td>
<td>3100</td>
<td>10.00%</td>
</tr>
<tr>
<td>Dec-16</td>
<td>3200</td>
<td>15.00%</td>
</tr>
<tr>
<td>Jan-17</td>
<td>3300</td>
<td>20.00%</td>
</tr>
<tr>
<td>Feb-17</td>
<td>3400</td>
<td>25.00%</td>
</tr>
<tr>
<td>Mar-17</td>
<td>3500</td>
<td>30.00%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>35.00%</td>
</tr>
</tbody>
</table>
80. We will continue to monitor and test these emails to consistently achieve high open rates.

81. Despite a relatively large amount of news around the areas we regulate - especially in relation to organ donation and scientific advancements - the HTA was only approached in relation to a minority of cases.
Media coverage

82. During quarter four, coverage which directly mentioned the HTA was limited to a handful of subjects. These included:

n. Stories from the annual FOIA request for information on the previous calendar year’s HTARIs, with one fairly minor national article and some local coverage. This is a yearly occurrence which to date has failed to make much of an impact. There was also one story on another HTARI, separate from the FOIA coverage.

o. We were contacted by a Scottish news outlet who had some questions around cryopreservation. They were sent our way as the Scottish Government is awaiting the outcome of HTA work in this area before making taking any policy positions themselves on this.

p. There were a number of other miscellaneous articles on cryopreservation during the quarter, not featuring the HTA, but indicative of the position this story still holds in the public consciousness and the potential for further national coverage should another human interest story come to light, or potentially when we publish any guidance on cryopreservation.

q. The other piece which cited the HTA was a broader on how the Human Tissue Act has impacted those working in research, and referenced the upcoming launch of our updated Codes and Standards.
### Annex B – SAEARs / HTARI details

#### Human Application – Serious Adverse Events

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Process Event Linked To</th>
<th>Description of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-36865-S3B2</td>
<td>Procurement</td>
<td>Femoral head procured and stored without a licence. Misunderstanding about nature of current licence. Licence now revoked.</td>
</tr>
<tr>
<td>CAS-37273-F8Y5</td>
<td>Storage</td>
<td>Fill valve in liquid nitrogen storage tank malfunctioned resulting in overfilling of tank - no loss of stored tissue. New tank commissioned and all tissues transferred into new tank.</td>
</tr>
<tr>
<td>CAS-37340-V8P5</td>
<td>Storage</td>
<td>Loss of traceability of cord blood unit - unable to find unit in storage and there is no record of disposal.</td>
</tr>
<tr>
<td>CAS-37406-J2V7</td>
<td>Procurement</td>
<td>Apheresis machine failed during stem cell collection; apheresis abandoned as no back up machine available.</td>
</tr>
<tr>
<td>CAS-30124-ZPJ2</td>
<td>Procurement</td>
<td>Microbial contamination of apheresis stem cell collection due to an infected Hickman line.</td>
</tr>
<tr>
<td>CAS-37378-B3Y4</td>
<td>Storage</td>
<td>Use of stored skin, which should have been disposed of - no impact on recipient.</td>
</tr>
<tr>
<td>CAS-35951-V0X1</td>
<td>Storage</td>
<td>Skin being stored outside HTA licence without knowledge of DI and without proper procedures.</td>
</tr>
<tr>
<td>CAS-37786-S7N9</td>
<td>Storage</td>
<td>Damage observed in bag containing frozen stem cells - donor re-harvested.</td>
</tr>
<tr>
<td>CAS-37304-D0N6</td>
<td>Procurement</td>
<td>Contaminated bone marrow procurement; will be released under concession and recipient provided with prophylaxis.</td>
</tr>
<tr>
<td>CAS-37696-F7C4</td>
<td>Processing</td>
<td>An incorrectly sized piece of amnion distributed for end use. No impact on recipient as another unit of tissue of the correct size was available.</td>
</tr>
<tr>
<td>CAS-37701-Z3C7</td>
<td>Storage</td>
<td>Leak in bag of stem cells observed. Staff retrained to ensure appropriate sealing and double bagging of stem cell harvests.</td>
</tr>
</tbody>
</table>
### Human Application – Serious Adverse Reactions

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Donor or Recipient</th>
<th>Description of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-36555-Q6V7</td>
<td>Recipient</td>
<td>Failure of second adipose tissue implant resulting in necrosis; unable to confirm that it is linked to quality of implanted adipose tissue implanted.</td>
</tr>
<tr>
<td>CAS-36944-S0V0</td>
<td>Recipient</td>
<td>Recipient developed pulmonary oedema along with anaphylaxis following transfusion of cryopreserved stem cells. Could be due to DMSO toxicity or fluid overload.</td>
</tr>
</tbody>
</table>

### Organ Donation and Transplantation – Serious Adverse Events

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Type</th>
<th>Brief description of incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-36236-N3H7</td>
<td>ODT Event</td>
<td>New clinical information received post donation – organs transplanted.</td>
</tr>
<tr>
<td>CAS-36338-C9C0</td>
<td>ODT Event</td>
<td>Insufficient perfusion fluid for perfusion– loss of organ for transplant.</td>
</tr>
<tr>
<td>CAS-36697-Q0J9</td>
<td>ODT Event</td>
<td>Incorrect microbiology result – organ transplanted.</td>
</tr>
<tr>
<td>CAS-36590-D7C9</td>
<td>ODT Event</td>
<td>Surgical damage – loss of organ for transplant.</td>
</tr>
<tr>
<td>CAS-37417-N3Y2</td>
<td>ODT Event</td>
<td>Surgical damage – loss of organ for transplant.</td>
</tr>
<tr>
<td>CAS-37568-M4R8</td>
<td>ODT Event</td>
<td>Prolonged cold ischaemic time – loss of organ for transplant.</td>
</tr>
<tr>
<td>CAS-37761-H0K3</td>
<td>ODT Event</td>
<td>Surgical damage – loss of organ for transplant.</td>
</tr>
</tbody>
</table>
Organ Donation and Transplantation – Serious Adverse Reactions

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Donor or Recipient</th>
<th>Incident type</th>
<th>Brief description of Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-37421-G0Z4</td>
<td>Recipient</td>
<td>ODT Reaction</td>
<td>Surgical repair of organ – organ transplanted.</td>
</tr>
<tr>
<td>CAS-36557-J1F0</td>
<td>Recipient</td>
<td>ODT Reaction</td>
<td>Surgical repair of organ – organ transplanted.</td>
</tr>
<tr>
<td>CAS-36778-G8D6</td>
<td>Recipient</td>
<td>ODT Reaction</td>
<td>New clinical information received post donation – organ removed following implantation.</td>
</tr>
</tbody>
</table>
## Post Mortem HTA Reportable Incidents

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Classification</th>
<th>Brief summary of HTARI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-32024-48VF</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>Clerical error led to tissue being stored for longer than required.</td>
</tr>
<tr>
<td>CAS-33029-B0Q2</td>
<td>Disposal or retention of a whole fetus or fetal tissue</td>
<td>Failure in communication led to accidental disposal of a fetus by cremation rather than burial.</td>
</tr>
<tr>
<td>CAS-33753-T8G1</td>
<td>Post-mortem examination of the wrong body</td>
<td>Human error led to post-mortem examination of the wrong body.</td>
</tr>
<tr>
<td>CAS-34312-M6L4</td>
<td>Accidental damage to a body</td>
<td>Human error led to minor accidental damage caused during PM examination.</td>
</tr>
<tr>
<td>CAS-34555-Y9F1</td>
<td>Accidental damage to a body</td>
<td>A process error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-34825-J4M6</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Staff action resulted in unauthorised access to the body store area.</td>
</tr>
<tr>
<td>CAS-35297-B2R2</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error led to the brakes not being correctly applied to a mortuary trolley.</td>
</tr>
<tr>
<td>CAS-35417-C3K8</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-35418-G4C9</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Failure to follow procedures led to loss of traceability of pregnancy remains from A&amp;E to mortuary.</td>
</tr>
<tr>
<td>CAS-35610-F2K9</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Human error resulted in removal of tissue without consent.</td>
</tr>
<tr>
<td>CAS-35652-Y3F6</td>
<td>Viewing of the wrong body</td>
<td>Human error led to viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-35703-N1K1</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error led to a funeral director not being informed that a cannulae was left in situ.</td>
</tr>
<tr>
<td>CAS-36000-J6W2</td>
<td>Major equipment failure</td>
<td>Electrical failure led to unrestricted access to the mortuary.</td>
</tr>
<tr>
<td>CAS-36021-K9G3</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage during a PM examination.</td>
</tr>
<tr>
<td>CAS-36053-B8Q7</td>
<td>Major equipment failure</td>
<td>Storage fridge failure, no deterioration of bodies.</td>
</tr>
<tr>
<td>CAS-36314-C6V5</td>
<td>Accidental damage to a body</td>
<td>Accidental damage to body when admitting into fridge.</td>
</tr>
<tr>
<td>CAS-36722-H1B4</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-36918-N9R1</td>
<td>Release of the wrong body</td>
<td>Due to human error, the wrong body was released to funeral directors.</td>
</tr>
<tr>
<td>CAS-37207-V5N0</td>
<td>Accidental damage to a body</td>
<td>Due to human error, a body was placed in the freezer instead of the fridge by mistake. There was no damage to the body.</td>
</tr>
<tr>
<td>CAS-37256-X4W4</td>
<td>Viewing of the wrong body</td>
<td>Human error led to viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-37294-Z8V2</td>
<td>Accidental damage to a body</td>
<td>Accidental damage to body when admitting into fridge.</td>
</tr>
<tr>
<td>CAS-37295-T7T4</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-37507-C5C6</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Delay in disposal of fetal tissue due to administration error.</td>
</tr>
<tr>
<td>CAS-37574-K3R4</td>
<td>Loss of an organ</td>
<td>Human error led to inadvertent disposal of a small section of tissue.</td>
</tr>
<tr>
<td>CAS-38142-K7S7</td>
<td>Accidental damage to a body</td>
<td>Equipment failure led to accidental damage of a body.</td>
</tr>
<tr>
<td>CAS-35819-D8C4</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-36439-Z6F3</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-36671-H4Q9</td>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family</td>
<td>Human error lead to accidental retention of a fetus</td>
</tr>
<tr>
<td>CAS-37588-R5Y5</td>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family</td>
<td>An administrative error led to a small number of blocks and slides being retained longer than they should.</td>
</tr>
</tbody>
</table>
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
# Authority Report

## Development – Quarter Four 2016/17 (year-end)

<table>
<thead>
<tr>
<th>Date</th>
<th>4 May 2017</th>
<th>Paper Reference</th>
<th>HTA (15/17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>8</td>
<td>Author</td>
<td>Victoria Marshment</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<td>Author Contact</td>
<td><a href="mailto:victoria.marshment@hta.gov.uk">victoria.marshment@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

### Strategic Objectives (Development)

- a. To reduce regulatory burden where risks to public confidence are lowest
- b. To make it clearer how to achieve compliance with new and existing regulatory requirements
- c. To make continuous improvements to our systems and processes
- d. To take opportunities to better inform and involve the public

### Relevant KPIs (marked as red, amber, green, black or blue)

- To undertake a review of the HTA fee structure and set fee levels for 2017/18 (project complete)
- To deliver a project to implement EU Directives on Coding and Import.
- To deliver a project to HTA's successfully release revised Codes of Practice (project complete)
- To deliver a project to implement the HTA's revised Standards and Codes.
- To develop a plan for Designated Individual (DI) relationship development. (rolled into 17/18)

### Related Strategic Risks (marked as red, amber or green)

1. Failure to regulate appropriately
2. Failure to manage an incident
4. Failure to utilise our capabilities effectively

(see paper 13a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the development activities of the HTA and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the development activities of the HTA.

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 13 April 2017.

Action required

4. The Authority is asked to note the content of this report.

Directors’ summary (Sarah and Vicky)

5. Colleagues across the HTA should be proud of the launch of the updated Codes of Practice and Standards, which was the culmination of three years’ work. A post implementation review (PIR) will be undertaken in the summer, seeking input from both staff and colleagues working at licensed establishments. In regards to this work, we are keen, as part of the PIR, to establish our approach for updating these documents in future (in the normal run of things) and the frequency at which will update them.

6. The consultation on the Coding and Import Directives began in early March. While there remain challenges and risks associated to this project (see paper European Union Directives Update [HTA (17/17)], the start of consultation facilitated greater engagement with affected establishments and moved this work on considerably. This will continue to be a project which features prominently on our risk registers until well into quarter three 2017/18 (if current timetables are realised). However, we have greater control of impacting factors than we have done previously, albeit we are still dependant on the Regulations passing through the Parliamentary approval process.
Project updates

Core 2016/17 projects

7. The three projects below were considered core during 2016/17.

Fees

8. The 2017/18 fees project is now complete. Licence fees were published on our website in December 2016, but a number of system changes were implemented through quarter four to enable 2017/18 licenses to be issued and to ensure fees could be calculated and invoiced correctly.

9. This work is now complete and invoices for 2017/18 licence fees were sent on 20 April. A PIR paper has been prepared and will be shared with the HTA's Management Group (HTAMG). This paper contains a number of recommendations around our approach to internal communications and ensuring all interested parties are engaged in this work from project commencement.

Codes and Standards Implementation

10. This project's status is currently rated in tolerance.

11. During the quarter, a final push was made to launch the HTA's updated Codes and Standards, which was made up of three strands.

   a. **Communications** - The HTA delivered a plan to assist establishments with being aware of upcoming changes and being prepared for implementation. This was led through newsletter content and online webinars, to engage directly with Designated Individuals (DIs) and other with an interest. A set of lay guidance is currently being finalised, which was seen by the Authority in draft form at its February meeting. The lay guides are currently being reviewed by the Public Access Group, at Newcastle University.

   b. **Customer Relationship Management (CRM)** – Changes were prepared to the portal and CRM requirements to ensure that the HTA’s systems are ready to work with the new Codes and Standards. While these changes were not completely made by 3 April, backup systems are in place to manage a small number of new applications that will be received in April, before system updates are operational.

   c. **Document management** – Colleagues have piloted system to manage reviews of corporate documents that needed to be updated for the Code and Standards launch. The review and update of these 80 documents, has provided a solid test
case for how other HTA corporate documents can be reviewed and managed in the coming quarters.

12. In order to complete this project, a PIR will be carried out over the summer (as mentioned above), which will be reviewed at the Stakeholder Group at its October meeting. This review will consider how the project functioned, feedback from stakeholders, and whether the new Codes and Standards are effectively operating from the perspective of Regulation Managers.

European Union (EU) Directives on Coding and Import

13. The project status is currently rated as red to reflect the impact that delays to the draft legislation and consultation have had on the implementation timetable.

14. Consultation on Regulations to amend the Human Tissue (Quality and Safety for Human Application) Regulations 2007 commenced on 10 March. The four week targeted consultation closed on 7 April. The Department of Health will consider any required changes to the draft legislation. The HTA continues to engage with the sector and has held two webinars during the consultation period in addition to answering ad-hoc enquiries from establishments.

15. The other main work streams are:

   a. refining our guidance and interpretation of the requirements in order to inform HTA Directions;
   b. preparing for the required HTA systems changes;
   c. development of a process for reissuing import licences; and
   d. continued stakeholder engagement and communications.

16. The timetable for implementation remains exceptionally challenging, both for establishments and for the HTA. The Department of Health are committed to having Regulations in force by summer 2017.

17. More detailed information can be found in the European Union Directives Update [HTA (17-17)].
Additional 2016/17 projects

18. In the final quarter of 2016/17, the following projects were considered to be of importance.

Building our relationship with licenced establishments programme

19. This work (previously referred to as the DI project) has been scoped over the past year, and a high-level programme plan has been agreed by the HTA Management Group.

20. This programme of work will be formed of a number of projects, the first of which will involve putting together a training package for DIs and others working at licensed establishments. Detail of the projects currently identified as part of this programme can be found at Annex A.

21. To support this programme of work, a programme board will meet monthly and we would value input from an Authority Member (or more than one Member on a rotation basis) to support the oversight of this work. We will also seek user involvement in the programme board.

Public engagement

22. Since the last Development Report, we have:

   a. Appointed a dedicated Public Engagement Officer in the Communications Team, who will be working to develop our public engagement plan.
   b. Consulted with external public stakeholder on our lay guides to the new Codes and Standards – these will be published in April 2017 once all feedback has been evaluated and incorporated.
   c. Commissioned an independent research agency to undertake a public evaluation to measure and investigate the public’s level of awareness, understanding, and interest in the work of the HTA. This work will play a fundamental role in shaping how we target our public engagement plans to areas the public are most interested in and / or concerned about. The pilot focus group took place at the end of March, with the rest of the field work coming in April and May, and the final report in late May or early June.
   d. Begun an online forum to share with members of the public, both directly and through partner organisations, who might be interested in joining our online panel to feedback on elements of our work.
   e. Put plans in place for establishing the online forum for professional and public stakeholders, which along with our planned website survey post-April, will inform both our digital offering to the public, and help us to build an online community to act as another engagement channel.
Licensing and inspection review

23. As reported in the previous Development Report, two projects were approved to begin in the 2016/17 business year, however, progress with these projects is largely dependent on resources required for the Import and Coding project. These are:

a. Improving our risk-based approach in the human application sector – This project has not yet started due to resources deployed on Coding and Import Directives and other policy work. This project has been included as a KPI for 2017/18 (see below).

b. Improving the efficiency and effectiveness of the licence application and assessment process – This project is underway and consensus has been reached on the revised approach. The revised process is likely to be fully implemented in quarter one 2017/18.

24. Information on the work flowing from the licensing and inspection review, and the indicative timelines for completion, is included at Annex B.

Development KPI narrative

25. All Development KPIs are within tolerance with the exception of Development KPI:2:

a. PROJECT: To deliver a project to implement EU Directives on Coding and Import (covered above), marked red.


2017/18 KPIs

26. The HTA’s 2017/18 business plan sets out three KPIs for Development. These are:

a. KPI: 7 – PROJECT: Deliver a project to implement EU Directives on Coding and Import (continued from 2016/17)
   Indicator: Project red-amber-green (RAG) status remains amber or green during the course of the project (reported monthly)

b. KPI:8 – PROGRAMME: Deliver a licenced establishment relationship management programme as per plan specification
   Indicator: To deliver the programme as agreed by HTA Management Group
   Elements of programme RAG status remain amber or green (reported monthly)

c. KPI:9 – PROJECT: Assessment of risk in Human Application sector and update of processes to reflect this
   Indicator: Project red-amber-green (RAG) status remains amber or green during the course of the project (reported monthly).

Projects scheduled to start in the next six months

<table>
<thead>
<tr>
<th>Project</th>
<th>Brief description</th>
<th>Start date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development KPI</td>
<td>PROJECT: Assessment of risk in the human application sector and update of processes to reflect this</td>
<td>Q1</td>
</tr>
<tr>
<td>Delivery PI</td>
<td>PROJECT: Undertake Disclosure and Barring Service checks for Accredited Assessors</td>
<td>Q1</td>
</tr>
<tr>
<td>Delivery PI</td>
<td>PROJECT: Organise the HTA’s annual event and produce the annual review publication</td>
<td>Q1</td>
</tr>
<tr>
<td>Development PI</td>
<td>PROJECT: Establish appropriate horizon scanning functions at the HTA</td>
<td>Q1</td>
</tr>
<tr>
<td>Development PI</td>
<td>PROJECT: Reviewing how the HTA’s stakeholder and sector groups operate to identify best practice and standardise processes that could improve remit delivery and efficiency</td>
<td>Q2</td>
</tr>
<tr>
<td>Deployment PI</td>
<td>PROJECT: Deliver recommendations from the enquiries audit</td>
<td>Q2</td>
</tr>
</tbody>
</table>
### Annex A – Building our relationship with licenced establishments programme

#### Programme outline

<table>
<thead>
<tr>
<th>Title</th>
<th>Priority</th>
<th>Overview</th>
<th>Work stream/aim</th>
<th>Resource</th>
<th>Status</th>
<th>Completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training package</td>
<td>High</td>
<td>This is the request we have had made repeatedly of us when we have spoken about this work, there is definite demand for an online training offering. Some work has been done on this already so we are not starting from a blank sheet of paper.</td>
<td>- Delivering compliance and improvement through licensed establishments</td>
<td>Policy, Strategy and Communications lead, with input for Regulation</td>
<td>In progress</td>
<td>End quarter one</td>
</tr>
</tbody>
</table>
| Online forum              | High     | The online forum will give us a mechanism to interact with those working at establishments in a flexible and controlled way, while also supporting communication between establishments. | - Input to processes, policies and projects  
- Delivering compliance and improvement through licensed establishments  
- Sharing learning and best practice | Policy, Strategy and Communications and Resources lead, with input from Regulation                   | In progress | End quarter three   |
| Licensed establishment event/s | Medium  | Again, there has been demand for the opportunity to meet face-to-face and for the content of the day to be in part driven by establishments.                                                        | - Delivering compliance and improvement through licensed establishments  
- Sharing learning and best practice | Policy, Strategy and Communications lead, with input from Regulation                                     | Not yet started | Plan in place by end quarter two |
| Input to projects, policies and process changes | Medium  | Documentation and relevant systems to be amended to ensure this is part of the process. Use of programme board and the internal communications stream below to embed this. | - Input to processes, policies and projects  
- Delivering compliance and improvement through licensed establishments  
- Sharing learning and best practice | Policy, Strategy and Communications | Not yet started | End quarter two     |
We have established engagement groups for the post-mortem and transplant sectors, as well as the broader stakeholder group. There has been discussion as to whether a group for private tissue banks would be a valuable addition and provide a mechanism for us to support this sub-sector to higher levels of compliance. We may also wish to consider a review of what we have and what we need more widely in terms of groups, and both the stakeholder group and HWG have recently undertaken reviews.

| New groups | Medium | We have established engagement groups for the post-mortem and transplant sectors, as well as the broader stakeholder group. There has been discussion as to whether a group for private tissue banks would be a valuable addition and provide a mechanism for us to support this sub-sector to higher levels of compliance. We may also wish to consider a review of what we have and what we need more widely in terms of groups, and both the stakeholder group and HWG have recently undertaken reviews. | • Input to processes, policies and projects  
• Delivering compliance and improvement through licensed establishments  
• Sharing learning and best practice | Policy, Strategy and Communications lead, with input from Regulation | In progress | Scoped by end quarter two |

| RM (relationship manager) role | Low | This is currently being scoped and could valuably form a work package of this programme. | • Delivering compliance and improvement through licensed establishments | Regulation | In progress | Scoped and decision made by end quarter one |
# Annex B – Licensing and inspection review

## Indicative timetable

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Title</th>
<th>Priority</th>
<th>Overview</th>
<th>Actions</th>
</tr>
</thead>
</table>
| LIR-03-13-17 | Human Application (HA) Risk                | High     | Human application inspections need to be better targeted at risk, to ensure limited resource is deployed most effectively. Existing assessment and compliance processes (e.g. Preparation Process Dossiers (PPD)) should be integrated into risk profiling to tailor inspections. Need improved regulatory oversight of licensable activities carried out under third party agreements in the HA sector. | - Examine inspection metrics, process, planning and assessment parameters, and existing methods of risk assessment  
- Improve data collection to better understand satellite/third party activity and inform action taken |
|               |                                             |          |                                                                                                                                             |                                                                                                                                            | In progress For strategic awayday in October                                                                                           |
| LIR-06        | Human Tissue (HT) Act Risk                  | High     | Scope to improve transparency about how we determine risk in different HT Act sectors and establishments, and linking risk to inspection scheduling.                                                                 | - Review assessment of risk in different HT Act sectors, decision making process and factors informing 'risk-based' inspection scheduling  
- Identify how risks could be mitigated with most effective use of resource  
- Develop clear public guidance and methods to improve communication of this to internal/external stakeholders |
|               |                                             |          |                                                                                                                                             |                                                                                                                                            | Preliminary work underway End quarter four                                                                                               |
| LIR-12        | Licensing Policy Work                       | Medium   | Remedy gaps and inconsistencies in policies and guidance on hub - satellite arrangements, cross-sector licensing and change of premises. Licences in post-mortem and human application sector also doing research work. | - Revision of relevant documents where inconsistencies present  
- Improve oversight of developments in activity taking place under a license, and horizon scanning of future developments to plan required amendments  
- Assess impact on fees and other policies |
<p>|               |                                             |          |                                                                                                                                             |                                                                                                                                            | Not yet started TBC                                                                                                                     |</p>
<table>
<thead>
<tr>
<th>LIR-09</th>
<th>Human Application (HA) Licensing Policy</th>
<th>Medium</th>
<th>Level of risk differs between HA areas and licensing can be disproportionate, but some legislative constraints. Need for clarification of technical aspects of regulation.</th>
<th>Identify opportunities for legislative change or amending licensing policy to reduce regulatory burden, in line with Growth Duty and Deregulation Act 2015, and where there is overlap with other regulators</th>
<th>Not yet started</th>
<th>TBC</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIR-10</td>
<td>Policy on use of Directions and Conditions</td>
<td>Medium</td>
<td>The use of Directions and legal notices is currently considered on a case-by-case basis, and is not governed by an overarching policy. There is a risk that this could create inconsistencies, and there is a lack of transparency for stakeholders. The current system for centrally recording Directions and legal notices relies heavily on individuals keeping local records and requires improvement.</td>
<td>• Create clear guidance and a framework on Directions and legal notices, with powers set out • Review process of logging and revoking Directions</td>
<td>In progress</td>
<td>End quarter three</td>
</tr>
<tr>
<td>LIR-14</td>
<td>Review of LAAV policy and process</td>
<td>Medium</td>
<td>Current policy for carrying out a licensing application assessment visit (LAAV) is not risk based, meaning a site visit may not be the best use of resources in all cases. Policy and procedural gaps for managing shortfalls found during the application process.</td>
<td>• Review license application process, use of a LAAV, and assess whether resource could be more effectively utilised by risk-based licensing assessment</td>
<td>In progress</td>
<td>To SMT May - implemented by end quarter two</td>
</tr>
<tr>
<td>LIR-15</td>
<td>Designated Individual (DI) training</td>
<td>Medium</td>
<td>The HTA does not currently provide any formal training for Designated Individuals (DIs). Work to improve online resources is ongoing, which could be expanded upon.</td>
<td>• Combined with licensed establishment work</td>
<td>In progress</td>
<td>End quarter one</td>
</tr>
<tr>
<td>LIR-16</td>
<td>Quality Management System</td>
<td>Medium</td>
<td>The existing quality management system requires further development. Elements of a quality management system exist but are managed discretely by different areas of the business and would benefit from clearer linkage.</td>
<td>Develop quality management system to focus more on: • management of processes and systems rather than individual SOPs; • better measurement of outcomes, analysis of data and information; • clearer links between identified risks and business plan activities; • improved internal audit and feedback of results.</td>
<td>In progress</td>
<td>Project planned for 2017/18</td>
</tr>
</tbody>
</table>
| LIR-18 | Joint working with other regulators/ accreditation bodies | Medium | There are areas where joint working with other regulators and accreditation bodies could potentially reduce regulatory burden for licensed establishments. | • Work with stakeholders to identify areas where improved cooperation across sectors between HTA and other regulators or accreditation bodies could reduce regulatory burden
• Determine feasibility and rationale for advancing these and for improving transparency between regulators | In progress | Some progress - some more formal oversight required |
| LIR-19 | Representations process | Medium | Current Representations process is overly burdensome for both HTA and licensed establishments, and perceived to be unfair. | • Revise Representations process to make it shorter, less burdensome in terms of cost and time, and easier to navigate | In progress | Agreed by Authority in Feb - implemented early quarter two |
| LIR-05 | Inspection Timetable Review | Low | Inspection timetable could benefit from greater emphasis on observation of practice, and include use of round table discussion where appropriate. | • Development of policy, guidance and training on inspections, including on observing practice if policy determines it appropriate
• Update internal documents to reflect guidance | In progress | |
| LIR-01 | Public Engagement | Low | The Authority and HTA executive team have both identified a need to further engage members of the public more widely in our regulation. | • Identify and implement ways in which public engagement can inform our licensing and inspection processes and wider regulation
• Improve transparency of licensing and inspections process to improve public understanding and confidence | In progress | Ongoing - research results at summer event |
<p>| LIR-07 | Integration of inspection monitoring into CRM | Low | Current inspection process is managed and monitored manually using an Excel spreadsheet. This can be prone to error, is cumbersome and could be developed to improve management reporting process. | • Work to use CRM to replace Excel spreadsheet complete | Completed | |</p>
<table>
<thead>
<tr>
<th>LIR-08</th>
<th>Use of portal to issue licence certificates</th>
<th>Low</th>
<th>System for issuing new licenses, receiving and processing licence variations is very resource intensive, relying on manual data entry and multiple email exchanges.</th>
<th>• Completed as part of CRM work following new portal integration</th>
<th>In progress</th>
<th>Ongoing</th>
</tr>
</thead>
</table>
| LIR-02-11 | Post inspection CRM process | Low | Improve system for recording, reporting and following-up inspection findings by Regulation Managers to make it less burdensome. Current system is very manual and administratively onerous, requiring repetitive data entries into CRM, inspection reports and CAPA plans. CRM requires changes to improve functionality, user experience and management reporting. | • Largely addressed by CRM project - revised CAPA plan and Site Visit entity completed  
• Remaining improvements and measures for success have been logged in Plan.io which will be considered quarterly for action and priorities | Completed |
| LIR-04-20 | Shared Learning | Low | Improve sharing of learning between inspectors across sectors. Consistently and routinely feedback and share learning from serious adverse event and reaction reporting to licence holders | • Formalise the schedule for sector inspection summary and HTARI/SAEARs reports  
• Develop method to feedback learning from inspections and SAEARs/HTARIs to stakeholders as routine practice | In progress | Ongoing - SAEARs report due this year |
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting.
### Authority Report

**Deployment – Quarter Four 2016/17 (year-end)**

<table>
<thead>
<tr>
<th>Date</th>
<th>4 May 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>9</td>
</tr>
<tr>
<td>Paper Reference</td>
<td>HTA (16/17)</td>
</tr>
<tr>
<td>Author</td>
<td>Allan Marriott-Smith</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
</tr>
</tbody>
</table>

**Author Contact**

allan.marriott-smith@hta.gov.uk

### Strategic objectives (Deployment)

- a) To manage and develop our people in line with the HTA’s People Strategy
- b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- c) To provide a suitable working environment and effective business technology

### Relevant KPIs (marked as red, amber, green, black or blue)

- Attrition rate measured monthly on a rolling annual basis. Assessed as red if more than 18%
- Percentage of Regulation Managers with more than one year of service. Assessed as red if less than 85%
- Number of vacancies reported monthly. Assessed as red if three or more
- 80% of staff attending training courses agree that the skills and knowledge gained will be useful for knowledge, performance, career development or general wellbeing
- To review HTA salary bands and report outcome to the HTA Remuneration Committee by end May 2016 (Completed)
- A structured approach to leadership development is in place and accessible to staff during 2016/17

### Related Strategic Risks (marked as red, amber or green)

- 2 Failure to manage an incident
- 4 Failure to utilise our capabilities effectively
- 5 Insufficient financial resources

(see paper 13a/17 for detailed information)
Purpose of paper

1. To provide the Authority with standardised information on the deployment of HTA resources and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the deployment of HTA resources.

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 13 April 2017.

Action required

4. The Authority is asked to note the content of this report.

Director’s summary (Allan)

5. The People Strategy has been updated in line to reflect the progress made since it was first published and to reflect the comments of staff and the recommendations of Internal Audit.

6. Staff turnover and length of service continue to present some risks to the continuity of delivery of high quality regulation. We were, however, successful in our recruitment activity in quarter four, finding high-quality candidates to fill vacant roles.

7. Our draft year-end position, ahead of audit and final adjustments, is a surplus of £54k against operating expenditure of £4,515k.

People

People Strategy

8. SMT reviewed the five recommendations proposed during the review of the People Strategy that was conducted in December 2016 as part of our Internal Audit programme. Actions have been put in place to address four of these recommendations. The fifth recommendation was allocated to the Heads of Regulation, who are currently reviewing the viability of stratification within the Regulation Manager role and are due to report to SMT in May.

9. In line with previous discussion with the Authority, the People Strategy has been updated in light of the audit recommendations stemming from the staff survey and
feedback sought from the staff forum. This Strategy covers the period to the end of 2017/18 and was published at the end of March.

All staff away morning

10. On 27 March, the quarterly all-staff away morning was held. This was also attended by Roger Wallis from the Department’s Sponsorship Team.

11. Items covered during the morning included a review of the business plan priorities for 2017/18. Interactive sessions were included to help individuals identify where they contribute to the achievement of our operational objectives and to demonstrate that individuals will contribute across one or more of the Delivery, Development and Deployment strands. This session also provided a basis for setting focused personal objectives for 2017/18.

12. Colleagues were given a demonstration of the HTA’s Wiki, which will now become the organisational home-internet page and will provide a repository for capturing intelligence on work-related topics that may have longer term significance for the organisation.

13. Colleagues also contributed to an interactive session ahead of the HTA’s upcoming public engagement research, and were updated on the developing programme of establishment engagement. Details of both can be found in the Development Report.

14. Changes to the HTA’s Risk Management Policy and Strategy, following the 9 February Audit and Risk Assurance Committee meeting were also shared.

Gender pay gap reporting

15. During quarter four, we attended a workshop with the Department of Health on the introduction of gender pay gap reporting legislation. As an organisation with less than 250 employees, the HTA is not required by legislation or by the Department of Health to publish statutory calculations on an annual basis. We will however include information on gender pay within our annual report.

HTA Management Group (HTAMG)

16. In March, HTAMG reviewed its terms of reference. It also agreed to outline proposals for a development programme aimed at increasing the skills and capability of the management team collectively.
Finance

Financial position at 2016/17 year-end

17. **Annex A** shows the summarised financial position for the year ending 31 March 2017. There was an over spend on revenue expenditure of £27k, and £80k more income than budgeted. Together this resulted in £54k more surplus than budgeted.


19. Licence fee income was below budget by £83k, with significant variances within the human application and post-mortem sectors, and smaller shortfalls within the other sectors. These shortfalls are mainly due to changes within NHS Trusts - consolidating licenses, changes in activities and revocations.

20. Grant-in-Aid and other income are both above budget, £98k and £65k higher than original estimates respectively. This is related to the increase in our office rental costs this financial year with Department of Health funding the net cost after deducting the pass through charge to our sub tenants NHS Resolution (formerly NHS Litigation).

21. **Annex C** shows expenditure as at 31 March for staff and non-staff costs. There is an overall overspend of £27k.

22. Staff costs are underspent by £92k due to vacancies in Director, Manager and Officer posts for part of the year.

23. There is an overspend of £118k on non-staff costs. Below are details of the material variances.
Table One: Expenditure variance

<table>
<thead>
<tr>
<th>Budget</th>
<th>£</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel &amp; Subsistence</td>
<td>15,400</td>
<td>Main overspends are within Regulation directorate due to increase in site visits and travel costs</td>
</tr>
<tr>
<td>Training &amp; Recruitment</td>
<td>(16,345)</td>
<td>Recruitment costs are under-spent by £13k with training spend close to budget</td>
</tr>
<tr>
<td>Conference &amp; Project costs</td>
<td>8,997</td>
<td>Stakeholder Engagement cost £24k not budgeted for off-set against underspends in venue hire and project costs</td>
</tr>
<tr>
<td>Other costs</td>
<td>10,896</td>
<td>Staff benefits over budget due to PSA accrual for 16/17</td>
</tr>
<tr>
<td>Accommodation</td>
<td>166,992</td>
<td>Backdated rent increase accrual</td>
</tr>
<tr>
<td>Capital Charges</td>
<td>(73,694)</td>
<td>Reduction in Amortisation due to late capitalisation of Intangible assets</td>
</tr>
<tr>
<td>Other variances</td>
<td>6,245</td>
<td>Various small variance</td>
</tr>
</tbody>
</table>

Forecast outturn

24. The Annex D provides an analysis of expenditure by Directorate. Most Directorates have under-spent due to the reasons detailed above. The Resources Directorate over spend is largely due to the increase in rent for 2016/17.

Other key performance indicators

Debtors

25. As at 31 March, our licence fee gross debtor balance was £40k (£14k in 2015/16) relating to fourteen organisations.

26. Nine of the outstanding fourteen were billed between February and September 2016, with the remainder billed in November and December. Below is a breakdown by sector.

Table Two: Debtors by sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>£ Value</th>
<th>% Value of debt</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>£1,799.99</td>
<td>5%</td>
</tr>
<tr>
<td>BEG</td>
<td>£9,133.30</td>
<td>23%</td>
</tr>
<tr>
<td>Local Authority</td>
<td>£5,100.00</td>
<td>13%</td>
</tr>
<tr>
<td>CGB</td>
<td>£23,826.56</td>
<td>60%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>£39,859.85</td>
<td>100%</td>
</tr>
</tbody>
</table>
**2016/17 Financial accounts**

27. The draft annual accounts have been prepared and the audit commenced on 18 April.

28. The Audit and Risk Assurance Committee will review the accounts and reports at its meeting on 18 May, together with the Audit Completion Report from the National Audit Office (NAO). The Committee inform the signing of the annual report and accounts by the Accounting Officer, before certification by the Comptroller and Auditor General. The report and accounts are then laid before Parliament and published. We expect publication towards the end of June, if possible.

29. Key points from the draft annual accounts will be presented at the Authority meeting.

30. The reports in aggregate are similar to those from last year. We have amended them to reflect the updated Financial Reporting Manual and ensured that the content of the Performance Report and Accountability Report meet requirements. Last year, these reports were the Strategic and Director’s report.

**Budget for 2017/18**

31. A budget of £4.54m has been agreed for 2017/18. £3.35m is expected from the licence fees set. Devolved governments are expected to contribute £116k and NHS Resolution (formerly NHS Litigation) Authority £310k (for rented office space).

32. The Department of Health has agreed both our revenue Grant-in-Aid and capital requirement for a five-year period:

   a. Revenue Grant-in-Aid of £703k has been agreed by the Department of Health. An additional amount of £98k has again been requested to fund the increase in accommodation costs for 2017/18.

   b. The Capital for 2017/18 is £100k, although a higher figure of £250k has been requested to fund Business Plan commitments.

**Financial risks**

33. Financial risks continue to be considered on an ongoing basis. Below is a table of the risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high-level strategic risks that SMT has identified and is managing. The strategic risk five - *insufficient financial resources* – is still considered to be low as the HTA has sufficient reserves in hand, although we are mindful of potential future changes [HTA (13a/17)].
Table Three: Risks and mitigations

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigating actions and controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>A significant under-spend leading to a loss of stakeholder confidence in HTA’s ability to manage resources effectively.</td>
<td>Identification of the likely outturn as early as possible. Consideration of additional work that would add value. Credit unused licence fees to establishments if excessive.</td>
</tr>
<tr>
<td>Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income.</td>
<td>Periodic review of establishments and expected income. Budgets are then managed to reflect income.</td>
</tr>
<tr>
<td>Lack of prompt payment by licence fee payers affects cash flow and operations generally adversely.</td>
<td>Revenue collection is closely monitored and the HTA’s credit control and debt collection procedures used to pursue and recover late payments.</td>
</tr>
<tr>
<td>The HTA is required to undertake additional functions or activities not planned or costed within the approved budget.</td>
<td>The HTA’s financial management arrangements would be used to identify any opportunities that arise to make efficiencies and vire monies from elsewhere to fund any such new spend.</td>
</tr>
</tbody>
</table>

Business technology and working environment

Business technology

34. Portal and customer relationship management (CRM) developments to support new application forms following the introduction of the new Codes continues. These will also double as variations forms in future, which will streamline changes to the process and reduce the burden on both establishments and HTA staff.

35. CRM and portal developments to support the European Union Directives on Coding and Import continue.

36. The risk to the delivery of these Business Plan activities has increased as no Head of Business Technology is currently in post, but this will be mitigated with thorough handover notes and increased supplier involvement. Operational risk six (cyber risk) has been increased to reflect the gap until a new Head of Business Technology is in post and up to speed.
Working environment

37. The data gathering stage of the Department of Health Estates’ review of arm’s length body’s (ALBs) accommodation is complete, with HTA visited by NHS Property Services in March. Recommendations are expected in June on the future accommodations needs of ALBs and how they might be met in the medium-term.

38. HTA staff will soon move to more flexible desk arrangements in order to ensure that we can make the most effective use of the number of desks available at 151 Buckingham Palace Road. The current arrangements, where staff who attend the office more than three days per week have a permanent desk, is leading to difficulties in allocating desks to new starters. In future, teams will have home areas where desks will be allocated at a ratio of 3:4 desks to team members.

39. While there have been no instances where there have been insufficient desks to meet demand, this new approach aims to ensure equity between new and existing staff members and those whose work patterns are less office-centric.

Deployment KPI narrative

Performance against 2016/17 KPIs

40. The attrition rate, measured monthly on a rolling annual basis, was marked as red and was 25.26% at year-end, against and indicative target rate of 18%. One colleague left the HTA in quarter four.

41. Three new Regulation Managers joined the HTA during the quarter. The percentage of Regulation Managers with more than one year of service, was marked as red and was 60% in March, against an indicative target rate of 85%. Twelve out of twenty Regulation Managers have more than one year of service.

42. The KPI related to the introduction of the structured learning and development plan is assessed as green.

2017/18 KPIs

43. The HTA’s 2017/18 business plan sets out six KPIs for Deployment. Two of the KPIs from 2016/17 remain the same, two have been altered, two have been added and two have been removed as they were completed (KPI:5 – Undertake a review of the HTA salary bands to assess market relativity, KPI:6 – Provide access to structured leadership development training programmes). The 2017/18 KPIs are:
a. **KPI:10 – Reduce attrition rates through improved selection and targeted retention measures to retain staff (continued from 2016/17)**
   Indicator: Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly)

b. **KPI:11 – Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff (altered from 2016/17)**
   Indicator: Percentage of Regulation Managers with more than one year of service (high risk if less than 85%) (reported quarterly)

c. **KPI:12 – Lead and advise on best recruitment procedures to maintain organisational capacity and capability (altered from 2016/17)**
   Indicator: Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly)

d. **KPI:13 – Manage all development options offered to staff and evaluate courses to ensure quality delivery and learning effectiveness (continued from 2016/17)**
   Indicator: 80% of staff attending training courses agree that the skills and knowledge gained will be useful for knowledge, performance, career development or general wellbeing (training statistics to be reported quarterly)

e. **KPI:14 – Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees (new)**
   Indicator: Actual income versus budgeted income (reported monthly) Actual spend versus budgeted spend (reported monthly) Actual cash reserves versus required reserve of £1.8m (high risk if deficit is more than 10%) (reported monthly)

f. **KPI:15 – Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees (new)**
   Indicator: Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health Grant-in-Aid and devolved governments income) (reported quarterly) Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly).
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
# Human Tissue Authority

## Summary - Income & Expenditure

For the Twelve Months Ending 31 March 2017

<table>
<thead>
<tr>
<th>Year to Date</th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>£</td>
<td>£</td>
<td>£</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>INCOME &amp; EXPENDITURE SUMMARY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(4,560,528)</td>
<td>(4,480,274)</td>
<td>(80,253)</td>
<td>1.79%</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditure</td>
<td>4,515,787</td>
<td>4,489,218</td>
<td>26,568</td>
<td>0.59%</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(44,741)</td>
<td>8,944</td>
<td>(53,685)</td>
<td>-600.23%</td>
</tr>
<tr>
<td>Exceptional items</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (surplus)/deficit of income over expenditure</td>
<td>(44,741)</td>
<td>8,944</td>
<td>(53,685)</td>
<td>-600.23%</td>
</tr>
</tbody>
</table>

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# Human Tissue Authority

## Member Income Summary

### Annex B

For the Twelve Months Ending 31 March 2017

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Grant In Aid</strong></td>
<td></td>
</tr>
<tr>
<td>GIA</td>
<td>801,000</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td>801,000</td>
</tr>
<tr>
<td><strong>Licence Fees</strong></td>
<td></td>
</tr>
<tr>
<td>Application Fees</td>
<td>53,700</td>
</tr>
<tr>
<td>Anatomy</td>
<td>84,046</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>1,028,275</td>
</tr>
<tr>
<td>Public Display</td>
<td>17,300</td>
</tr>
<tr>
<td>Research</td>
<td>560,679</td>
</tr>
<tr>
<td>Human application</td>
<td>1,244,450</td>
</tr>
<tr>
<td>ODT</td>
<td>271,688</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td>3,260,137</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Other income (Rent)</td>
<td>310,138</td>
</tr>
<tr>
<td>Other income (Secondees)</td>
<td>66,877</td>
</tr>
<tr>
<td>Devolved Assemblies</td>
<td>122,376</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td>499,390</td>
</tr>
<tr>
<td><strong>Total Income</strong></td>
<td>4,560,528</td>
</tr>
</tbody>
</table>
### Human Tissue Authority

**Summary - Expenditure**

**For the Twelve Months Ending 31 March 2017**

#### EXPENDITURE SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff Costs</strong></td>
<td>2,700,135</td>
<td>2,792,114</td>
<td>(91,979)</td>
<td>-3.29%</td>
</tr>
<tr>
<td><strong>Non Staff Costs</strong></td>
<td>1,813,096</td>
<td>1,694,604</td>
<td>118,492</td>
<td>6.99%</td>
</tr>
<tr>
<td><strong>Gross Costs before Exceptional Items</strong></td>
<td>4,513,231</td>
<td>4,486,718</td>
<td>26,512</td>
<td>0.59%</td>
</tr>
<tr>
<td><strong>Exceptional Items</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td><strong>Total Expenditure</strong></td>
<td>4,513,231</td>
<td>4,486,718</td>
<td>26,512</td>
<td>0.59%</td>
</tr>
</tbody>
</table>

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### Human Tissue Authority

**Directorate Summary**  
**Annex D**

**For the Twelve Months Ending**  
**31 March 2017**

<table>
<thead>
<tr>
<th></th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy, Strategy &amp; Communications</td>
<td>537,518</td>
<td>538,219</td>
<td>(701)</td>
<td>-0.13%</td>
</tr>
<tr>
<td>Regulation</td>
<td>1,720,441</td>
<td>1,735,267</td>
<td>(14,825)</td>
<td>-0.85%</td>
</tr>
<tr>
<td>HTA Board</td>
<td>179,379</td>
<td>178,858</td>
<td>521</td>
<td>0.29%</td>
</tr>
<tr>
<td>Resources</td>
<td>1,677,739</td>
<td>1,590,622</td>
<td>87,118</td>
<td>5.48%</td>
</tr>
<tr>
<td>Chief Executive’s Office</td>
<td>400,709</td>
<td>446,253</td>
<td>(45,544)</td>
<td>-10.21%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>4,515,787</td>
<td>4,489,218</td>
<td>26,568</td>
<td>0.59%</td>
</tr>
</tbody>
</table>

**Total Directorate(s) Expenditure**  
4,515,787  4,489,218  26,568  0.59%

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Authority paper

Date 4 May 2017 Paper reference HTA (17/17)
Agenda Item 11 Author Dr. Hazel Lofty

European Union Directives on Coding and Import Update

Purpose of paper

1. To inform the Authority of progress made in implementing the two European Union (EU) Directives relating to the Single European Code and the Import of human tissues and cells.

Decision-making to date

2. This paper was considered by the Senior Management Team (SMT) at its meeting on 20 April 2017.

3. An introduction to the Directives and the HTA implementation project was given to the Authority in July 2015 in the paper, Implementation of EU Coding and Import Directives [paper HTA (32/15)].

Action required

4. The Authority is asked to note the content of this report.

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Background


6. The requirement to implement a Single European Code (SEC) was established in Directive 2006/86/EC – part of the three original Directives referred to as the EU tissue and cells directives (EUTCD), which were transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The aim was to have a unique identifier applied to tissues and cells distributed in the EU, providing information on the main characteristics and properties of those tissues and cells in order to facilitate traceability from donor to recipient and vice versa. Following several years of negotiation, the technical requirements for the coding of human tissues and cells were set out in Commission Directive 2015/565.

7. Similarly, the original EUTCD required that imports of tissues and cells were undertaken by establishments licensed for that purpose and that imports met standards of quality and safety equivalent to those laid down in the Directives. It also called for the introduction of procedures to verify equivalency of the quality and safety. Commission Directive 2015/566 sets out those procedures for verifying the equivalent standards.

8. Both Directives were published in April 2015, with a deadline of 29 October 2016 for transposition into national law, and 29 April 2017 for full implementation of the provisions. In the United Kingdom, both Directives will be implemented via the Human Tissue (Quality and Safety for Human Application) Amendment Regulations 2017 (the Amendment Regulations). Separate Regulations will implement the requirements for tissues and cells used in assisted reproduction for which the Human Fertilisation and Embryology Authority (HFEA), which is the Competent Authority.

9. The HTA set up a project to implement the Directives in quarter one 2015. Members will be aware from updates that the transposition process has been subject to delays in drafting the Amendment Regulations and arranging the consultation.

10. The Directives impact establishments in the HTA’s human application (HA) sector. We estimate that approximately 120 establishments will either need to allocate or apply the SEC, and approximately 43 establishments will need to apply for a re-issue of their import licence. All HA establishments will have an entry in the Tissue Establishment Compendium (see paragraph 17c below).

11. This paper gives an overview of the key changes, the work to be undertaken to finalise implementation of the Directives and areas of risk that remain for the HTA.
Consultation

12. The Department of Health (the Department) conducted a truncated four-week targeted consultation on the draft Amendment Regulations from 10 March – 7 April 2017. In order to support the consultation, the HTA published an accompanying draft guidance document, setting out the requirements for the main HA sub-sectors in order to help establishments understand the changes.

13. During the consultation period, the HTA hosted two webinars to provide further advice and guidance to establishments on the new requirements. Overall, approximately 50 representatives of HA establishments attended the webinars, and feedback received was positive. In addition, we hosted a round-table teleconference for establishments working with haematopoietic stem cells, as there are a number of complex licensing issues for this sub-sector relating to implementation of the Directives.

14. During the consultation, the HTA also facilitated contact with a representative sample of HA establishments (fourteen in total) in order to inform the Department impact assessment that accompanies the draft legislation.

15. Subject to the necessary approvals and parliamentary process, Department is aiming to transpose the Directives by summer 2017.

Policy Areas

16. The drafting of the Amendment Regulations has necessitated close working with colleagues at the Department in order to ensure the requirements of the Directives fit as closely as possible with the existing licensing regime, to ensure implementation is proportionate and any costs which would have to be passed on to establishments via fees are kept to a minimum.

17. There have been a number of policy issues to consider; key areas are outlined in summary below.

   a. Clarification of definitions of import, export and distribution – In order to ensure the new requirements work with existing legislation, the Amendment Regulations clarify the interpretation of these terms in relation to the licensing requirements.

   b. Haematopoietic stem cells – Both Directives allow certain exemptions for haematopoietic stem cells from bone marrow, peripheral blood or cord blood. In order for the exemptions to be effected, the HTA has worked closely with establishments and the Department to propose a proportionate licensing and authorisation framework with the aim of fulfilling the requirements of the Directives without placing undue burden on establishments or affecting clinical supply.
c. **Licence details** – Both Directives require the HTA to be more explicit in setting out the details of the activities that the licence covers, particularly in relation to the tissue types that the establishment is authorised to work with. In order to facilitate this, and ensure a robust framework for subsequent licence variations, the HTA will be amending the standard conditions on HA licences.

d. **Transitional provisions** – The Amendment Regulations contain a number of transitional provisions. For coding, certain exemptions have been extended to account for the delays in transposition to ensure those storing frozen products are not adversely affected. For import, existing licences will automatically transition when the amending Regulations come into force, subject to the HTA having received and assessed the relevant information, and having issued a new licence certificate. In order to facilitate this, the HTA will be accepting applications for re-issue of import licences as soon as practically possible.

### Changes to the HTA licensing framework

18. In addition to the policy issues described above, the Amendment Regulations will necessitate a number of changes to the existing licensing framework. Key changes are summarised below.

19. The Coding Directive relies on information contained in two databases (referred to as ‘Compendia’) held by the European Commission.

   a. The Tissue Establishment Compendium, which gives details of each licensed tissue establishment in each Member State. The HTA is responsible for keeping these details up to date for all UK licensed establishments.

   b. The Tissue and Cell Product Compendium, which lists the applicable codes for all tissue products authorised for distribution within the EU. The HTA will need to apply to the European Commission to have new products added, when required.

20. Key HA licensing documents will also need substantial amendment to reflect the changes. This will include the HA standards, the HTA’s ‘Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment’ and the HA standard licence conditions. In particular, the Amendment Regulations require the HTA to issue directions in relation to how establishments should comply with the requirements of the Directives. Due to the timescale for implementation, the HTA will issue the directions in draft so that establishments have time to prepare in advance of the Amendment Regulations coming into force. We also intend to re-issue our sub-sector specific guidance for establishments following feedback received during consultation.

21. The HTA’s licensing system (CRM) and the HTA portal are being adapted to accommodate the required changes. The changes are primarily related to reflecting
the detail required by the Tissue Establishment Compendium, and the information we are required to receive and assess in relation to imports. Applications to re-issue import licences (as referred to in paragraph 17) will be facilitated via the portal to ensure the process is as streamlined as possible.

22. Information gained during the assessment of import licences will be used to inform the risk based approach to inspections of this sector.

**Strategic risk**

23. The transposition and implementation of the EU Directives into UK law is reflected in the HTA’s strategic risk three – *failure to manage expectations of regulation*.

24. In line with the mitigations set out in the risk register, we have worked closely with our sponsor team at the Department to ensure that the Regulations reflect the intent of the Directives, fit with our licensing framework, are implemented proportionately, and meet the expectations of stakeholders. During this process, we have also strived to raise awareness of existing and potential legislative issues.

25. We have also been proactive in our communication with licensed establishments, to ensure that they can be prepared as possible for implementation. There are a number of technical complexities within the Directives, and clear guidance and directions will be key in enabling establishments to comply.

26. We note the restrictions on communications during a pre-election period and are working with Department to establish how the upcoming general election will impact the passage of the Regulations.

**Operational risks**

27. There are also a number of operational risks identified in relation to this project. This paper summarises the key risks relating to implementation, and how they will be mitigated.

28. Amendments to the standard licence conditions will come into force 28 days after they are issued to establishments, to allow for representations to be made in accordance with the requirements of the Human Tissue Act 2004. We estimate that the risk of establishments operating outside of these licence conditions during this time period is low, given that there is some coverage in existing standard conditions. We estimate that the risk of receiving representations is also low, as these are largely administrative provisions and implement a fair and due process for licence variations.

29. Due to the tight timescale for implementation, the HTA will be requesting applications for re-issue of import licences before the Amendment Regulations come into force in
order that licences can transition to the new licensing framework without a gap. Although we have no powers to compel establishments to make a licence application, their existing licence will cease to have effect when the Amendment Regulations come into force. Therefore, if they wish to continue importing they will need to apply. We are also tracking establishments who have made contact with us, and will proactively contact any importers that we have not heard from.

30. The assessment of information to allow HTA to re-issue import licences may detect significant non-compliance which requires addressing before the licence can be re-issued, or the licence to be issued subject to conditions. There is therefore a risk of challenge relating to any proposed regulatory decision. In order to mitigate this, the HTA will be opening for applications as soon as practically possible in order that we can maximise the timeframe to identify any issues before the Amendment Regulations come into force. We will continue to offer advice and guidance to establishments, and assessments will be undertaken by a small group of trained Regulation Managers to ensure consistency of approach.

31. The delays to drafting and consulting on the Amendment Regulations have resulted in a truncated timetable for implementation. This presents a number of risks for the HTA in relation to pressure on resources and our ability to deliver other work during this period. This has been mitigated as far as possible by adapting the inspection schedule for HA establishments and delaying the start of development activities however all available resource has been deployed.

32. For establishments, the truncated timetable increases the risk of non-compliance. Understandably some establishments have been reluctant to commit resources until more definitive information was made available, which may result in them being under prepared. This is combined with uncertainty relating to exiting the EU, and the cost of implementing systems which may be redundant or need amendment in the future. The Government's position is that whilst we remain a member of the EU, we will continue to implement EU legislation. The HTA will continue to support establishments to be compliant, and will utilise existing risk based and proportionate approaches to ensure that this is achieved.
Authority Standing Orders Update

Purpose of paper

1. To present the Authority with an updated version of the Authority’s Standing Orders, which reflect material and minor changes.

Decision-making to date

2. The senior management team (SMT) approved proposed changes to the Standing Orders at its meeting on 20 April 2017, to present to the Authority at this meeting.

Action required

3. The Authority is asked to review and approve proposed changes to the Authority Standing Orders. An updated version of the Standing Orders with tracked changes can be found at Annex A.

Process

4. The Standing Order at paragraph 105 sets out how the Authority’s Standing Orders can be amended or replaced. Two-thirds of Members must be present at the meeting when changes are considered.
Material changes

5. The following material changes are proposed to the Standing Orders.

Standing Orders 21 and 22

6. In the absence of Chair (for an entire meeting – 21, and temporarily – 22), these Standing Orders set out that the remaining, “Members shall choose one of their number to preside”, though, it does not set out how.

7. It is proposed that for the avoidance of doubt, both Standing Orders are amended to include the words - “by a simple majority vote”.

Standing Order 29

8. We do not require Members to sign their names in an attendance book at Authority and Committee meetings, as their presence is recorded in that meeting’s minutes. Therefore, it is proposed that this Standing Order is removed.

Annex 1: Scheme of delegation of powers to the Chief Executive, Officers and Committees

9. At its February 2017 meeting, the Authority reviewed and agreed to proposed changes to the HTA’s Representation arrangements. To reflect these changes, the following proposals have been made for the Authority to consider. They should be read with reference to pages 21-22 of the Standing Orders.

10. It is proposed that the decision description, “Issuing general directions” is moved from the decision class, “Enforcement decisions (significant regulatory activity)”, to the decision class, “Decisions relating to the licensing of establishments”, as these decisions are not classed as enforcement activity.

11. It is proposed that the decision description, “A notice of proposal being issued to revoke the licence”, be amended to reflect the updated Representation arrangements with, “A notice of a proposal to refuse, revoke, vary or impose conditions on a licence”.

12. It is proposed that the decision description, “Decisions on representations made following a decision to place conditions on a licence or suspend a licence”, be amended to reflect the updated Representation arrangements with, “Decisions made following a notice proposing a decision to refuse, revoke, vary or impose conditions on a licence”.

13. It is proposed that the designation level for this decision description be changed from, “Panel of three members of staff (must not include the original inspectors, decision maker or anyone else involved in the original decision). The Chair must be a Director
of any function or a Head of Regulation”, to, “Decision proposer (Director of any function or Head of Regulation)”, to reflect the updated Representation arrangements.

14. A new decision description is proposed to reflect the updated Representation appeal arrangements. The proposed new decision description is, “Decisions on appeals made following a decision to refuse, revoke, vary or impose conditions on a licence”. The proposed designation level for this decision is, “Panel of five Authority Members”.

15. It is proposed that a decision class “Decisions relating to redress for those affect by our actions”, is removed as it will be replaced by the decision description and delegation level detailed above in paragraph 14, if agreed. This decision class is made up of two decision descriptions, “Reconsiderations” and “Appeals”, which both have the same designation level, “Panel of five Authority Members”.

Minor changes

16. In addition to minor formatting and content amendments, the following minor changes are proposed to the Standing Orders.

Code of Conduct for Members of the Human Tissue Authority

17. Reference to Government advice for non-Executive Board Members to be updated (pages 28, 28 and 34), including for:

   a. openness and accountability (paragraph 11e)
   b. estate management (paragraph 11g)
   c. financial management (paragraph 36).

Appendix 4 and 5 Terms of Reference for the Audit and Risk Assurance Committee, and Remuneration Committee

18. It is proposed that minor changes are made to reflect changes in post titles and version histories.
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
# Table of Contents

- Table of Contents ................................................................. 2
- Introduction ............................................................................. 3
- Interpretation .......................................................................... 3
- Rulings under standing orders ............................................... 4
- Admission of public and press to designated public meetings ........................................................................ 5
- Orders in respect of meetings of the Authority ......................... 5
  - Calling meetings ................................................................. 5
  - Notice of meetings ............................................................ 6
  - Chairing meetings ............................................................. 6
  - Quorum for meetings ......................................................... 6
  - Closed meetings ............................................................... 7
  - Record of attendance ......................................................... 7
  - Notices of motion ............................................................. 7
- Voting ...................................................................................... 8
- Appointment of Members and Chairs ...................................... 9
- Senior Independent Director .................................................. 9
- Resignations .......................................................................... 9
- Review and revocation of Authority or Committee Membership ......................................................... 10
- Arrangements for compiling the agenda of meetings .............. 11
- Agenda, minutes and papers ................................................ 11
- Officers in attendance ........................................................... 12
- Attendance of observers ....................................................... 12
- Co-optees .............................................................................. 12
- Declaration of interests ......................................................... 12
- Orders in respect of delegation and reporting ......................... 14
- Matters of an urgent nature .................................................. 15
- Audit matters ......................................................................... 15
- Corporate seal ....................................................................... 15
- Licensing decisions ............................................................. 16
- Appointment of Committees .................................................. 16
- Appointment of Members to Committees ............................. 17
  - Terms of appointment ...................................................... 17
- Appointment of sub-Committees ......................................... 17
- Appointment of experts, external practitioners to Committees ........................................................................ 17
- Orders in respect of Committees ......................................... 18
- Variation or suspension of standing orders ......................... 18
- ANNEX 1: Schedule of delegation of powers to the Chief Executive, Officers and Committees ................................. 19
- ANNEX 2: Code of Conduct for Members of the Human Tissue Authority ......................................................... 24
Introduction

1. These standing orders are made pursuant to Schedule 2 of the Human Tissue Act 2004 ("the HT Act"). Subject to the provisions of the HT Act and Regulations made under it, these standing orders will regulate the procedure of the Authority and of its Committees as appropriate.

Interpretation

2. Any expression to which a meaning is given in the HT Act or in Regulations made under it shall have the same meaning in these standing orders, unless the context otherwise requires. In addition:

- "the Authority" means the Human Tissue Authority established under section 13 of the HT Act;
- "the Chair" means the Chair of the Authority appointed in accordance with Schedule 2 of the HT Act;
- "Member" means a Member of the Authority (including the Chair) appointed in accordance with Schedule 2 of the HT Act;
- "the Chief Executive" means the Chief Executive Officer of the Authority;
- "the Department" means the Department of Health;
- "Accounting Officer" means the officer responsible and accountable for the resources entrusted to the Authority and who shall be responsible for the stewardship of any and all public funds or assets in the Authority’s possession. For the Human Tissue Authority, the Accounting Officer is the Chief Executive;
- "Committee" means a Committee established by the Authority;
- "Committee Chair" means the Chair of a Committee, as the context requires, whether or not he/she is also a Member of the Authority;
- "Lay Member" means a Member of the Authority who does not have and has not had a professional interest in any of the kinds of activity within the remit of the Authority;

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
“Non–lay Member” means a Member of the Authority who has or has had a professional interest in any of the kinds of activity within the remit of the Authority;

“Officer” means an employee of the Authority. In certain circumstances, “officer” may include a person who is employed by a third party contracted to the Authority who carries out functions on behalf of the Authority; and

“Executive Senior Management Team” means the senior management team of the Human Tissue Authority.

3. In these standing orders, unless the contrary intention appears, words in the singular include the plural and words in the plural include the singular.

Rulings under standing orders

4. The Chair shall, subject to paragraph five below, decide on the application of these standing orders to any proceedings of the Authority.

5. The decision of the Chair under this standing order, or under any other power contained in these standing orders when notified to the Authority shall take effect immediately, unless two Members of the Authority disagree, in which case the Chair’s decision shall be treated as a proposal to be effective only if confirmed by the Authority on a vote. One Member shall be entitled to explain the cause of the disagreement following which the ruling will be put to the vote without further discussion: any alternative decision of the Chair necessary for the proper conduct of business shall be treated in the same way.

6. Where the Chair of the Authority has died, has ceased to hold office or where he/she has been unable to perform his/her duties as Chair owing to illness, absence from the United Kingdom or any other cause, another lay Member nominated by a majority of the Members shall act as Chair until a new Chair is appointed or the existing Chair resumes duties. Reference to Chair in these standing orders shall, so long as there is no Chair to perform his or her duties, be taken to include references to the stand-in Chair.

7. The validity of any proceedings of the Authority shall not be affected by any vacancy in the office of: the Chair; the Members appointed by the National Assembly of Wales, the Member appointed by the relevant Ministers in Wales and Northern Ireland department; any defect in a person’s appointment as Chair or other Member or; the composition for the time being of the Membership of the Authority.
Admission of public and press to designated public meetings

8. Members of the public and representatives of the press may attend designated public meetings of the Authority, as the Authority deems necessary; at least one such meeting will be held in each calendar year. However, they may be excluded from the part of the meeting that deals with business of a confidential nature, or about which publicity would be prejudicial to the public interest.

9. The Chair will give such directions as he/she thinks fit in regard to the arrangements for meetings and accommodation of the public and representatives of the press, such as to ensure that the business of the Authority may be conducted without interruption and disruption. However, the Authority may resolve that the public and press are required to withdraw to suppress or prevent disorderly conduct or other misbehaviour at a meeting.

10. Members of the public, or representatives of the press, shall not record proceedings in any manner whatsoever, other than in writing, or make any oral report of the proceedings as they take place, without the prior agreement of the Authority.

11. Members of the public and representatives of the press are not admitted to meetings of Committees, except by specific invitation.

12. The Authority may set aside time at the end of its agenda for members of the public to ask questions.

Orders in respect of meetings of the Authority

Calling meetings

13. Ordinary meetings of the Authority will be held at such times and places as the Authority may decide.

14. The Chair may call a meeting of the Authority at any time, provided 10 clear calendar days’ notice is given. If a request for a meeting, signed by at least five Members, is presented to the Chair, then the Chair must call a meeting within 21 calendar days of receiving such a request. If the Chair refuses to call a meeting or without so refusing, does not within 21 calendar days after the requisition has been presented to him/her call a meeting, those Members that requested it may call a meeting.

15. Extraordinary meetings of the Authority may be called at any time by the Chair.
16. Extraordinary meetings of the Authority may also be called at the request of a Member, if supported by at least one third of the Members of the Authority.

Notice of meetings

17. The dates of Authority meetings and any Committee meetings of the Authority will be notified to all Members for the forthcoming calendar year.

18. Before each meeting of the Authority, a notice of the meeting which specifies the principal business proposed to be transacted at it and is agreed by the Chair, or by an officer of the Authority authorised by the Chair to agree it on his/her behalf, shall be delivered to each Member via e-mail or post to his/her last known address, at least seven calendar days before the day of the meeting. Supporting papers, whenever possible, will accompany the agenda.

19. The business of the meeting shall not be invalidated where any Member fails to receive notification.

20. At least seven days before each meeting of the Authority, a public notice of the time and place of the meeting, and the public part of the agenda, will be displayed on the HTA website.

Chairing meetings

21. At any meeting of the Authority or its Committees, the Chair, if present, shall preside. If the Chair is absent, the Members present shall choose one of their number to preside by a simple majority vote.

22. If the Chair is absent temporarily on the grounds of a declared conflict of interest, the remaining Members shall choose one of their number to preside by a simple majority vote.

Quorum for meetings

23. No business shall be transacted at a meeting of the Authority unless there is a quorum of at least one third of the Members plus the Chair or the person chairing the meeting. Where the quorum is only one third of the Members, at least two Members, excluding the Chair or person chairing the meeting, will be lay.
24. A quorum of Members must be present throughout the Authority meeting. Should the Chair of the meeting declare there is not a quorum, the meeting shall be adjourned and the remaining business postponed to the next ordinary meeting, unless the Chair of the meeting indicates an earlier date or is able to conduct the business under the urgent action provision (see paragraphs 80–83).

25. If a Member has been disqualified from participating in the debate on any matter and/or from voting on any question by reason of the declaration of interest, he/she shall no longer count towards the quorum. If a quorum is then not available for the discussion and/or decision on any matter, that matter may not be discussed further or voted upon at the meeting. Such a position shall be recorded in the minutes of the meeting.

26. Where the Authority is considering the appointment of a Chief Executive, the Authority is not quorate unless the Chair is present.

27. A meeting of the Authority, as required by Regulation 14(1) of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, will be quorate if three Authority Members are in attendance.

Closed meetings

28. The Authority may convene closed meetings as required. If the Chair is absent, the remaining Members shall choose one of their number to preside. No officers will attend unless requested to do so.

Record of attendance

29. Every Member attending a meeting of the Authority or Committee shall sign their name in an attendance book or on the sheet provided for that purpose, which shall be evidence of their attendance at the meeting.

30. Attendance will also be recorded in the minutes of any meetings.

Notices of motion

31. Any motion proposed must be seconded before it is considered.

32. A Member who wishes to move a motion will send a written notification of this to the Chair at least seven clear calendar days before the meeting. The Chair will insert this notice in the agenda, subject to the notice being permissible under any appropriate Regulations. This does not, however, prevent any motion or amendment
being moved during the meeting, without notice, on any business mentioned on the agenda.

33. When a motion is under discussion, or immediately before discussion, it will be open to a Member to move:

a. an amendment to the motion;
b. the adjournment of the discussion or the meeting item;
c. that the meeting proceed to the next business;
d. the appointment of an ad hoc Committee to deal with a specific item of business;
e. that the motion be now put; and
f. a motion that certain members of the public and representatives of the press be excluded from the meeting.

34. No amendment to the motion will be allowed if, in the opinion of the Chair, the amendment negates the substance of the motion.

35. A motion or amendment, once moved and seconded, may be withdrawn by the proposer with the agreement of the seconder and the consent of the Chair.

Voting

36. The normal practice of the Authority will be to achieve consensus on all issues.

37. When necessary, a question at a meeting will be decided by a majority of the votes of the Chair and Members present and voting on the question. In the case of the number of votes for and against the question being equal, the Chair will have a second or casting vote.

38. All questions put to the vote, at the discretion of the Chair of the meeting, be determined by oral expression or by a show of hands. A paper ballot may also be used if a majority of the Members present so request.

39. At the request of at least one third of the Members present, the voting (other than by paper ballot) on any question may be recorded in the minutes to show how each Member present voted or abstained.
40.39. In no circumstances may an absent Member vote by proxy. Absence is defined by being absent at the time of the vote.

Appointment of Members and Chairs

41.40. Appointment of the Chair and Members of the Authority, as laid out in Schedule 2 of the HT Act, are made by the Secretary of State, or the Minister in the devolved administration governments of Wales or Northern Ireland, for periods of up to three years. Members may be reappointed, and may serve a maximum of two terms.

42.41. The Chair of the Authority is an ex–officio Member of all Authority Committees and should be regarded as additional to any specified maximum Membership.

Senior Independent Director

43.42. The Chair will nominate a Member of the Authority to act as a Senior Independent Director (SID), with this appointment to be ratified by the Authority. The Authority will be responsible for appointing the SID. The SID shall be available for Members to raise concerns with, if those concerns have not been resolved through other channels (such as the Chair or Chief Executive) or where it would be inappropriate to use these established channels. In addition, the SID shall provide a sounding board for the Chair and serve as an intermediary for other board Members as necessary.

44.43. In line with recommendations from the Department of Health regarding Board governance, any concerns regarding the Chair should be raised with the SID. The SID should take responsibility for informing the Director General of Public Health at the Department of Health about any concerns which they believe to have foundation. They should liaise with the Department of Health throughout any investigation and follow-up actions.

45.44. The Chair of the Executive’s HTA’s Staff Forum, who shall also hold the position of Freedom to Speak Up Champion, shall have a direct reporting line to the SID, through which any concerns from members of staff can be raised where it would be inappropriate to use established channels.

Resignations
46. If any Member wishes to resign from the Authority, they must give notice in writing to the Secretary of State and, if applicable, the Minister in the devolved administration from which they are appointed.

47. A Chair of the Authority may resign at any time during their term of office by giving notice in writing to the Secretary of State. Resignation as Chair constitutes resignation from the Authority.

48. In accordance with paragraph 6 of Schedule 2 of the Human Tissue Act 2004, previous service as a Chair or other Member of the Authority does not affect a person’s eligibility for appointment to either office.

Review and revocation of Authority or Committee Membership

49. The Authority may revoke the appointment of any Authority or Committee Member to a Committee or the office of Chair of a Committee.

50. Authority Members will be expected to attend every Authority meeting and every meeting of any Committee of which they are a member. If a Member is not able to attend a meeting, they must provide apologies to the Chair and to the Authority Secretary in advance of the meeting if possible.

51. If a Member does not attend more than two consecutive meetings, the Authority or Committee Chair, as applicable, will arrange a meeting with the Member to discuss their attendance and whether they wish to continue their membership of the Authority or Committee.

52. If a Member’s attendance is approaching the trigger point of three missed Authority meetings, the Chair will schedule a meeting to discuss their attendance and whether they wish to continue their membership of the Authority and/or Committee. The Chair will then write to the Member to outline their future position on the HTA’s Authority.

53. Where required in circumstances other than non-attendance at meetings, the Chair will organise a meeting between the Chair and a Member in order to agree to terminate a Member’s role on the HTA Authority by way of mutual agreement.

54. In accordance with paragraph 9 of Schedule 2 of the Human Tissue Act 2004, a Chair or other Member of the Authority may be removed from office by the Secretary of State if that person is satisfied that he/she:
a. has been absent from meetings of the Authority for six consecutive months, or longer, without the permission of the Authority; or
b. is unable or unfit to carry out his functions as Chair or other Member.

Arrangements for compiling the agenda of meetings

55. Authority or Committee Members wishing to put forward agenda items should notify the Authority Secretary (in the case of the Authority) or the designated lead officer (in the case of a Committee) at least 14 calendar days before the date of the meeting.

56. The Chair, in consultation with the Chief Executive or the Committee Chair, in consultation with the Authority Secretary (in case of the Authority) or the designated officer (for Committees), shall decide whether and when any particular item shall be included in the final published agenda.

57. In the event that the Chair of the Authority or the Chair of a Committee is not willing to include an item on the final published agenda, any Member shall be entitled to have a notice of motion included on the agenda, provided this is submitted in writing to the Authority Secretary or the designated lead officer (for Committees) at least five calendar days before the meeting.

58. It is in the discretion of the Chair of a meeting to allow urgent items not on the published agenda to be discussed at the relevant meeting. The reasons for allowing such action should be indicated by the relevant Chair.

Agenda, minutes and papers

59. The minutes of every Authority or Committee meeting will be submitted to the following meeting and, once confirmed as a correct record, agreed by the Chair of the meeting. Copies are retained for reference and may be available for public inspection. Minutes of confidential discussions will be considered and approved in private session. Any amendment to the minutes shall be agreed and recorded at the following meeting.

60. Copies of the agenda, minutes and papers will be made available to the public for ordinary and at open meetings of the Authority, excluding confidential elements, at and on request from the time they are circulated to Members.

61. Members will receive the minutes of its Committees on request. The circulation of any confidential minutes of the Committees will be at the discretion of the Committee Chair and will not be unreasonably withheld. Any Authority Member who is not on a Committee...
will have a right to consult any confidential minutes of that Committee on approval of the Chair.

**Officers in attendance**

62.61. The Chief Executive and Directors will be in attendance at meetings along with any other officers the Chief Executive deems appropriate.

**Attendance of observers**

63.62. Up to two observers from the Department of Health will normally be invited to attend all meetings of the Authority.

64.63. The Chair may invite observers from other Government Departments and agencies to attend Authority meetings as necessary.

**Co-optees**

65.64. The Authority may co-opt participants to provide specialist skills, knowledge and experience, subject to the agreement of at least one-third of the Members. Co-optees will not be entitled to vote.

**Declaration of interests**

66.65. Each Member is responsible for ensuring that when they attend an Authority or Committee meeting at which a matter in which they have either a personal or material interest is to be discussed or voted upon, the existence and nature of their interest is disclosed at the beginning of that meeting, or when the interest becomes apparent.

67.66. Members may consider themselves as having a material interest in a matter if they have a pecuniary interest, direct or indirect, in any contract, proposed contract or other matter being considered by the Authority. In the case of couples living together, the interest of one partner shall, if known to the other, be deemed also to be an interest of the other.

68.67. A Member has an indirect pecuniary interest in a contract, proposed contract or other matter if:

   a. they, or a nominee of theirs, is a director of a company or other body, not being a public body, with which the contract was made or is proposed to be made or which has a direct pecuniary interest in the other matter under consideration; or
b. they are a business partner of, or are in the employment of, a person with whom the contract was made or who has a direct pecuniary interest in the other matter under consideration.

69.68. However, a Member will not be considered as having a pecuniary interest in any contract, proposed contract or other matter if:

a. they are a Member of a company or other body, but have no beneficial interest in any securities of that company or other body; or

b. they have an interest in any company, body or person with which they are connected as mentioned above (in paragraphs 66-67) which is so remote or insignificant that it cannot reasonably be regarded as likely to influence him/her in consideration or discussion of, or in voting on, any question with respect to that contract, proposed contract or other matter.

70.69. If any Member is in doubt as to whether to declare a material interest, he/she should discuss this with the Chair, Committee Chair or the Chief Executive before the meeting. The final decision as to whether a Member has a conflict of interest lies with the Chair of the Authority or Committee.

71.70. A Member should consider that they have a personal interest in a contract, proposed contract or other matter if the decision being taken is one which a Member of the public with knowledge of the relevant facts would reasonably regard as so significant that it is likely to prejudice the Member’s judgement of the public interest.

72.71. If a Member has a clear and substantial personal or material interest in a specific matter, they should not participate in its discussion or determination and withdraw from the meeting whilst it is being considered.

73.72. Every Member shall make a written declaration in the register of Members’ interests of relevant pecuniary interests, including:

a. main employment or business and any subsidiary employment or business directly or indirectly related to the HTA’s work;

b. any directorship, consultancy or shareholding in any organisation or partnership concerned with the employment or provision of any procedures, education services, research or any other matters within the remit of the Authority; and

c. any contracts with the Authority.
74. Members must make the declaration within one month from the date of their appointment and shall report any material changes to the declaration within one month of such changes.

75. In addition, Members are required to make an annual written declaration of their interests for annual accounting purposes, when requested by the Authority Secretary, or the designated lead officer (for Committees).

76. The Chief Executive shall maintain a register of interests to be kept available at all reasonable hours for public inspection. The register shall be updated at least annually.

Orders in respect of delegation and reporting

76. The Chief Executive is accountable through the Chair to the Members of the Authority and also, as Accounting Officer, through the Permanent Secretary at the Department, to Parliament.

77. The relationship between the Department and the HTA is laid down in the Framework Agreement.

78. The day-to-day management of the HTA is delegated to the Chief Executive by the Authority within the framework for delegation and reporting set out in Annex 1.

79. The Authority may delegate authority to Committees to make decisions and/or take action on its behalf. The Authority may also delegate specific action to the Chair or to the Chief Executive at any time. The Chair of the relevant Committee or the Chief Executive will report to the Authority on the use of any specific delegated authority in a timely manner. A schedule of delegation of powers is set out in Annex 1. The HTA's governance structure is set out at Appendix 3 of Annex 1.

80. The HTA’s Code of Conduct for Members of the Human Tissue Authority (Annex 2) sets out:

a. the HTA's governance structure – Appendix 3;

b. the Terms of Reference for the Audit and Risk Assurance Committee – Appendix 4; and

c. the Terms of Reference for the Remuneration Committee – Appendix 5.

Commented [NB2]: Currently being updated

Commented [NB3]: Reformatted for clarity

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Matters of an urgent nature

81. The Chair of the Authority, the Chair of a Committee and the Chief Executive are authorised to take urgent action in respect of matters which would normally be determined by the Authority or one of its Committees which arise between meetings. Such urgent action will be reported to the next meeting of Authority or Committee together with an explanation for the grounds of urgency.

82. In all cases where the Chief Executive decides to take such urgent action, the Chair of the Authority and/or the Committee Chair will be given the opportunity and the responsibility for deciding whether to call a special meeting to determine the matters at issue.

83. The Authority may appoint two or more Members authorised to act on its behalf on grounds of urgency and whose decision will be reported to the Authority as soon as possible thereafter. Likewise, a Committee may appoint two or more Committee Members authorised to act on its behalf on grounds of urgency and whose decisions will be reported to that Committee as soon as possible thereafter.

84. Consultations with the Chair of the Authority and relevant Committee Chairs will be dealt with by the Authority Secretary in writing, explaining the reason for the urgent action and the necessary background information.

Audit matters

85. The audit service (whether this be internal or external audit) via an audit manager shall report directly to the Chair of the Audit and Risk Assurance Committee between meetings, in the following circumstances:

a. where matters of propriety need to be reported, and to do so through line management would be inappropriate in the opinion of the audit manager; and

b. where circumstances prevent or jeopardise the ability to meet the terms of reference of the audit.

Corporate seal

86. The seal of the Authority shall be kept by the Chief Executive in a secure place.
87. The seal of the Authority shall not be fixed to any documents unless the sealing has been authorised by a resolution of the Authority or of a Committee thereof or where the Authority has delegated its powers.

88. The affixing of the HTA’s corporate seal to a formal contract or other document must be accompanied by the signature of the Chair or another nominated Member of the Authority and the counter-signature of the Chief Executive or his/her nominee.

**Licensing decisions**

89. The Authority hereby delegates authority to appropriately qualified members of staff (normally from the Regulation Directorate) to grant, revoke, vary and suspend licences issued under the Authority’s remit.

90. This power of delegation will also extend to the hearing of representations from applicants against a decision made by a member of staff.

**Appointment of Committees**

91. The Authority may establish or dissolve any Committee for such purpose as it considers appropriate. It will determine the powers of any such Committee.

92. The Chairs of Committees will be appointed by the Authority for a set term which does not exceed the Member’s remaining tenure. The remainder of the term will be reaffirmed at Authority annual meeting. The Committee Chairs will take place as the need arises. Committees shall determine the Membership of any working parties they may establish.

93. In the event of there being a vacancy in a Committee Chair, the Chair of the Authority will propose and the Authority will appoint a new Chair at the next meeting of Authority. The Chair of the Authority is authorised to appoint an interim Chair in cases of urgency.

94. The frequency of Committee meetings will be defined in the Terms of Reference, which must be agreed by the Authority.

95. The Authority will keep under review the structure and remit of its Committees. The current Committee structure and the Terms of Reference for each Committee are set out at Annex 2, Appendices 4 and 5.
Appointment of Members to Committees

Terms of appointment

96. Recruitment of Members to Committees will be through expressions of interest, with personal statements in application. Expressions of interest will be reviewed by the Authority Chair, Chief Executive and Committee Chair, who will jointly decide on appointments.

97. Should an insufficient number of expressions of interest be received to fill an available role, the Authority Chair will appoint the Member who has the most appropriate skills and experience to fulfil the requirements of the role.

98. Authority Members who become members of Committees will be appointed for a set term of three years, which will not exceed their tenure as Authority Members. Authority Members may be reappointed to Committees in accordance with the HTA’s business needs.

99. The Authority may at any time alter a Committee’s Membership

100. The Chair and the Chief Executive have final approval of all Committee appointments.

Appointment of sub-Committees

101. The Authority may delegate authority to a Committee to establish and appoint Members to a sub-Committee. Any such sub-Committee must be chaired by a Member of the Committee and a majority of sub-Committee Members must be Members of the Committee. In establishing a sub-Committee, the Terms of Reference and delegated powers will be determined by the relevant Committee.

Appointment of expert, external practitioners to Committees

102. Committees may co-opt for up to a maximum of one third of the total number of Members of the Committee or invite other participants to contribute to their meetings and consideration of issues. An example of such occasions would be meetings of a Committee to consider a particular issue relating to the Committee’s remit and where expert contributions would enhance the quality of any such considerations.
Orders in respect of Committees

103. Those standing orders contained in the section of the management scheme headed “Orders in respect of meetings of the Authority” also apply to Committees, except where the Committee may agree to vary those orders. Any such variation must be agreed by the Authority.

104. Members of the Authority shall be entitled to attend meetings of Committees of which they are not Members. Members attending meetings of which they are not Members shall be entitled to speak with the permission of the Chair of the meeting but in no case shall they be entitled to vote.

Variation or suspension of standing orders

105. These standing orders may not be amended or replaced otherwise than by a motion passed at a meeting at which at least two-thirds of the Members are present.

106. Notice of a motion to vary these standing orders must be given to all Members of the Authority five calendar days before the meeting.

107. Provided that at least two thirds of Members are present at a meeting including the Chair, any one or more of these standing orders, except the standing orders on declaration of interests in paragraphs 65-75, may be varied or suspended for the duration of that meeting, unless that would contravene any rule of law, legislative provision or direction made by the Secretary of State.

108. With the exception of any standing order which reflects the provisions of the HT Act, the quorum of meetings or the declaration of interests, all or any of these standing orders may be suspended at any meeting provided that at least two-thirds of the Members are in favour. Any Member can move to suspend standing orders.

109. A decision to suspend standing orders shall be recorded in the minutes of the meeting.
ANNEX 1: Schedule of delegation of powers to the Chief Executive, Officers and Committees

Framework of delegation to the Chief Executive and Officers reporting to the Authority on that delegation

1. The Chief Executive will prepare each year a three-year strategic plan and annual business plan for approval by the Authority and agreement between the Authority and the Department. Alongside these plans, the Chief Executive will prepare a budget for the financial year showing proposed expenditure under main headings and against main activities.

2. Once approved by the Authority, the Chief Executive will be responsible for putting these plans into effect and has authority to take such decisions as are necessary relating to the employment of staff and the engagement of financial or other services.

3. The Authority may agree policies in relation to its statutory functions and the Chief Executive will be responsible for ensuring that those policies are followed. The Chief Executive may propose to the Authority policies in relation to any of its functions and once approved by the Authority, shall act in accordance with those policies.

4. The Chief Executive must act within any overall limits and conditions set in relation to the Authority’s expenditure as informed to the Authority by the Department and may:
   a. approve and certify expenditure;
   b. authorise payments and accept receipts;
   c. negotiate, organise and review banking arrangements;
   d. vire money between budgets;
   e. make any arrangements necessary relating to the employment of staff, their terms, conditions and pay; and
   f. sub-delegate his/her powers to Members of the Authority’s staff.

5. These delegated authorities shall be subject to the limits set by the Department of Health effective from 1 April 2009.

6. The Chief Executive will report to the Authority and advise the Authority in a timely manner of all material matters currently or prospectively affecting the HTA and its performance.
7. In particular, the Chief Executive will report each quarter to the Authority on the achievement of key targets set out in the business plan and on the Authority’s expenditure and income against its budget.

8. The Chief Executive will report to the Authority any significant proposal to vary the staffing structure of the HTA.

9. The Chief Executive or other officer authorised by him/her is authorised to apply and authenticate by his or her signature the seal of the Authority.

10. The Authority delegates the power to grant, revoke, vary and suspend licences issued under the Authority’s remit to the Chief Executive who may then delegate decisions to members of staff (usually from the Regulation Directorate).

11. This delegation extends to the hearing of representations from applicants against decisions made by members of staff.

12. The Authority delegates to the Chief Executive the power to assess and make decisions on applications for living organ donation, except those which are retained by the Authority as a result of Regulations and those which it has decided to retain as a matter of policy.

13. The Chief Executive may make any decision delegated by the Authority. Delegation by the Chief Executive to executive members of staff is set out in the Onward Delegation Scheme.

**Framework of delegation to Committees reporting to the Authority on that delegation**

14. A Committee can take decisions on matters contained within its Terms of Reference unless the matter is reserved for decision by the full Authority on the recommendation of that Committee.
### Onward Delegation Scheme

<table>
<thead>
<tr>
<th>Decision class</th>
<th>Decision description</th>
<th>Delegation level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decisions relating to the licensing of establishments</td>
<td>Grant of a licence</td>
<td>Regulation Manager</td>
</tr>
<tr>
<td></td>
<td>Varying a licence</td>
<td>Regulation Manager or Officer</td>
</tr>
<tr>
<td></td>
<td>Extending a licence</td>
<td>Regulation Manager</td>
</tr>
<tr>
<td></td>
<td>Issuing general directions</td>
<td>Director of any function or Head of Regulation</td>
</tr>
<tr>
<td>Post-inspection decision-making</td>
<td>Major and minor shortfalls</td>
<td>Regulation Manager with a Head of Regulation</td>
</tr>
<tr>
<td></td>
<td>Critical shortfalls or collection of major shortfalls</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
<tr>
<td>Enforcement decisions (significant regulatory activity)</td>
<td>Directions being issued requiring specific action to be taken straight away</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
<tr>
<td></td>
<td>Additional conditions being proposed</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
<tr>
<td></td>
<td>A notice of suspension of licensable activities</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
<tr>
<td></td>
<td>A notice of a proposal to refuse, revoke, vary or impose conditions on a licence being issued to revoke the licence</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Decision class</th>
<th>Decision description</th>
<th>Delegation level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decisions on representations made following a notice proposing a decision to refuse, revoke, vary or impose conditions on a licence, a decision to place conditions on a licence or suspend a licence</td>
<td>Panel of three members of staff (must not include the original inspectors, decision maker or anyone else involved in the original decision). The Chair must be a Director of any function or a Head of Regulation. Decision proposer (Director of any function or Head of Regulation)</td>
<td></td>
</tr>
<tr>
<td>Decisions on appeals made following a decision to refuse, revoke, vary or impose conditions on a licence</td>
<td>Panel of five Authority Members</td>
<td></td>
</tr>
<tr>
<td>Issuing general directions</td>
<td>Director of any function or Head of Regulation</td>
<td></td>
</tr>
<tr>
<td>Approval of non-panel cases</td>
<td>Officers</td>
<td></td>
</tr>
<tr>
<td>Refusal of cases</td>
<td>Panel of three Authority Members via a Regulatory Decision Meeting</td>
<td></td>
</tr>
<tr>
<td>Panel cases</td>
<td>Panel of three Authority Members</td>
<td></td>
</tr>
<tr>
<td>Reconsiderations</td>
<td>Panel of three Authority Members not associated with the original decision</td>
<td></td>
</tr>
<tr>
<td>Decisions relating to redress for those affected by our actions</td>
<td>Reconsiderations</td>
<td>Panel of five Authority Members</td>
</tr>
<tr>
<td>Appeals</td>
<td>Panel of five Authority Members</td>
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</tr>
<tr>
<td>Decisions on action following receipt of information from outside the HTA</td>
<td>Post-inspection decisions (where an inspection has been undertaken as a result of the information received)</td>
<td>Regulation Manager with a Head of Regulation</td>
</tr>
<tr>
<td>Enforcement decisions</td>
<td>Regulatory Decision Meeting (Director of any function or Head of Regulation)</td>
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## Decisions on referral to the police

<table>
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<tr>
<th>Decision description</th>
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<tr>
<td>Police referral</td>
<td>Senior Management Team</td>
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## Decisions on the interpretation of our legal remit (policy decisions)

<table>
<thead>
<tr>
<th>Decision description</th>
<th>Delegation level</th>
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<tbody>
<tr>
<td>Policies for external audiences</td>
<td>Senior Management Team</td>
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<tr>
<td>Internal policies</td>
<td>Appropriate Director</td>
</tr>
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## Other decisions of strategic significance

<table>
<thead>
<tr>
<th>Decision description</th>
<th>Delegation level</th>
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<tbody>
<tr>
<td></td>
<td>Senior Management Team</td>
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ANNEX 2: Code of Conduct for Members of the Human Tissue Authority

Code of Conduct for Members of the Human Tissue Authority

Date last reviewed: 30 December 2015  4 May 2017
Next review due: 30 December 2017  4 May 2019
Table of Contents

Introduction ................................................................................................................................. 26
Public service values .................................................................................................................. 26
Relationship with the sponsor department ............................................................................. 27
The role of the Chair ................................................................................................................ 27
Corporate responsibilities of Members ...................................................................................... 28
Delegation .................................................................................................................................. 29
Responsibilities of individual Members ................................................................................... 29
Handling conflicts of interests .................................................................................................. 30
Personal liability of Members ................................................................................................. 32
Openness and accountability ..................................................................................................... 33
Accountability for public funds ................................................................................................. 33
Annual report and accounts ..................................................................................................... 34
The role of the Chief Executive ............................................................................................... 34
Audit Committee ...................................................................................................................... 35
The Authority as employer ....................................................................................................... 35
Appendix 1: The seven principles of public life ...................................................................... 37
Appendix 2: Evidence to select or scrutiny committees ............................................................ 38
Appendix 3: HTA Governance Structure ............................................................................... 39
Appendix 4: Terms of Reference for the Audit and Risk Assurance Committee ....................... 40
Appendix 5: Terms of Reference for the Remuneration Committee ......................................... 46
Appendix 6: Addison rules ....................................................................................................... 50
Introduction

1. This Code of Conduct should be read with the Code of Conduct for Board Members of Public Bodies, which is also referenced in the Terms and Conditions of appointment. All in this Code of Conduct that applies to Members applies to the Chair as well.

2. The HTA is an executive Non-Departmental Public Body (NDPB) of the Department of Health (the Department) and covers England, Wales and Northern Ireland.

3. The Authority will oversee the implementation of the Human Tissue Act, 2004 (HT Act) and will work towards achieving a balance between the rights and expectations of individuals from all stakeholder communities, including: individuals, families, medical practitioners and those involved in research, education, training, pathology and public health surveillance to the population as a whole. The HTA is designated the Competent Authority for the implementation of the European Union Directives for EU Tissue and Cells Directive so far as it is related to tissues and cells and organ donation.

4. Members of the Authority in carrying out their responsibilities shall have due regard to Equal Opportunities generally, the general duty of the Race Relations (Amendment) Act 2000 and the requirements of any other diversity legislation.

Public service values

5. The Authority will, at all times:

   a. observe the highest standards of propriety involving impartiality, integrity and objectivity in relation to the stewardship of public funds and the management of the bodies concerned;

   b. maximise value for money through ensuring that services are delivered in the most economical, efficient and effective way, within available resources, and with independent validation of performance achieved wherever practicable. Value for
money is not the lowest price: it is the optimum combination of whole life costs and quality to meet the user’s requirement;

c. be accountable to Parliament, users of services, individual citizens and staff for the activities of the bodies concerned, their stewardship of public funds and the extent to which key performance targets and objectives have been met; and

d. in accordance with Government policy on openness and responsiveness, comply fully with the Freedom of Information Act 2000.

Relationship with the sponsor department

6. The Secretary of State for Health or the relevant Minister is answerable to Parliament for the policies and performance of all public bodies sponsored by the Department, including their use of resources and the policy framework within which they operate. The respective roles of the HTA and the Department (its sponsor department) are set out in the Management Statement and Financial Memorandum, which specifies the terms on which the HTA receives and spends its funds and conducts its relations with the Department.

The role of the Chair

7. The Chair has particular responsibility for providing effective strategic leadership on matters such as:

   a. formulating the Authority's strategy for discharging its statutory duties;
   b. encouraging high standards of propriety and promoting the efficient and effective use of staff and other resources throughout the organisation;
   c. ensuring that the Authority, in reaching decisions, takes proper account of guidance provided by the responsible Minister or sponsor department;
   d. representing the views of the Authority to the general public; and
   e. providing performance assessments for individual Members when necessary and in line with any Directions issued by the Secretary of State for Health; and
   f. dealing with the appraisal of Members' performance and objective setting.

8. The Chair should ensure that the Authority meets at regular intervals throughout the year and that the minutes of meetings accurately record the decisions taken and, where appropriate, the views of individual Members.

9. Communications between the Authority and the Minister of the sponsor department will normally be through the Chair except where the Authority has agreed that an individual Member should act on its behalf. Nevertheless, an individual Member has the right of access to Ministers on any matter which he or she believes raises important issues
relating to his/her duties as a Member of the Authority. In such cases, the agreement of
the rest of the Authority should normally be sought. The main point of contact between the
HTA and the sponsor department on day-to-day matters will normally be the Chief
Executive or another Member of staff who is authorised by the Chief Executive to act on
behalf of the Authority.

10. The Chair should ensure that all Members of the Authority, when taking up office, are fully
briefed on the terms of their appointment and on their duties, rights and responsibilities.
The Chair and other Members of the Authority should each have a copy of the Code of
Conduct for Members of the Authority; Management Statement and Financial
Memorandum and other relevant background material such as the Chair sees fit. The
Chair should encourage new Members to attend an induction course on the duties of
Members of public bodies or some other suitable form of induction programme.

Corporate responsibilities of Members

11. Members have corporate responsibility for ensuring that the HTA complies with any
statutory or administrative requirements for the use of public funds. Other important
responsibilities of Members include:

a. ensuring that high standards of corporate governance are observed at all times;
b. establishing the overall strategic direction of the organisation within the policy and
resources framework agreed with the responsible Minister;
c. ensuring that the Authority operates within the limits of its statutory authority and any
delegated authority agreed with its sponsor department and in accordance with any
other conditions relating to the use of public funds;
d. ensuring that, in reaching decisions, the Authority has taken into account any
guidance issued by the sponsor department;
e. formulating a strategy for implementing the Freedom of Information Act 2000,
including prompt responses to public requests for information, and meeting other
requirements set out in Public Bodies: A Guide for Departments, Chapter 8: Policy –
Openness and Accountability for openness and responsiveness as set out in part J of Non Departmental Public Bodies: A Guide for Departments.

f. ensuring that the Authority has specific responsibility for sustainable development and operates within the framework of the Sustainable Development Strategy, following the priorities set by the sponsoring department; and

g. ensuring that the Authority manages its estate in line with advice provided by Government Estates Management sustainably in line with the Government’s Framework for Sustainable Development on the Government Estate.

12. The Authority is responsible for the production of a three-year strategic plan. The process of preparing such a document provides an opportunity for agreeing, with the responsible Minister, or officials on his or her behalf, the policy and resources framework within which the Authority will discharge its duties and for determining its key strategic objectives and targets.

Delegation

13. To the extent permitted by the originating legislation or other provisions under which the HTA was established, responsibility for day-to-day management matters should be delegated to staff so far as is practicable, within a clearly understood framework of strategic control. The Authority will put in place internal guidance covering those matters delegated to staff and those reserved for decision by the Authority.

14. The Authority may decide to delegate responsibility for specified matters, where it has power to do so, to individual Members or Committees of the Authority. Decisions taken by individual Members or Committees of the Authority under delegated powers should be recorded in written minutes available to the Authority as a whole.

Responsibilities of individual Members

15. Individual Members should be aware of their wider responsibilities as Members of the Authority. Like others who serve the public, they should follow the Seven Principles of Public Life set out by the Committee on Standards in Public Life. The principles are printed at Appendix 1. The Members must:

a. undertake, on appointment, to comply at all times with the Code of Conduct that is adopted by the HTA and with rules relating to the use of public funds;

b. act in good faith and in the best interests of the Authority;

c. not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote
their private interests or those of connected persons, firms, businesses or other organisations; and to declare publicly any private interests which may be perceived to conflict with their public duties; and

d. ensure that they comply with the Authority's rules on the acceptance of gifts and hospitality.

16. Members are expected not to occupy paid party political posts or hold particularly sensitive or high-profile unpaid roles in a political party. Subject to that, part-time Members are free to engage in political activities, provided that they are conscious of their general public responsibilities and exercise a proper discretion, particularly in regard to the work of the HTA. On matters directly affecting the work of the HTA, Members should not make political speeches or engage in other political activities.

17. The restrictions in paragraph 16 do not apply to Members who are Members of Parliament (MPs) (in those cases where MPs are eligible to be appointed), to local councillors or to Peers in relation to their conduct in the House of Lords. The position of Peers in this regard is covered by a statement made by Lord Addison in 1951 in relation to Peers who are Members of public bodies. See Appendix 6.

18. Failure to meet the requirements of holding public office as set out in the Cabinet Office Code may be grounds for removing a Chair or Member from office if the legal criteria for removal of the person from office are met.

**Handling conflicts of interests**

19. The Chair and other Members must declare any personal or business interests which may conflict with their responsibilities as Authority Members. The Authority, in consultation with the sponsor department, will draw up rules of conduct for Members which ensure that such conflicts are identified at an early stage and that appropriate action can be taken to resolve them.

20. The rules will include the keeping of a register of interests appropriate to HTA activities. The register will, as a minimum, list direct or indirect pecuniary interests which Members of the public might reasonably think could influence Members' judgement. Members are strongly encouraged to register non-pecuniary interests which relate closely to HTA
activities and interests of close family Members and persons living in the same household as the Authority Member.

21. The register of interests will be open to the public and updated regularly. The Authority will ensure that details of how access can be obtained are available widely and include such details in annual reports.

22. In the absence of specific statutory provisions, the common law requires:

a. that Members of public bodies should not participate in the discussion or determination of matters in which they have a direct pecuniary interest and;

b. that when an interest is not of a direct pecuniary kind, Members should consider whether participation in the discussion or determination of a matter would suggest a real danger of bias. This should be interpreted in the sense that Members might either unwittingly or otherwise unfairly regard with favour or disfavour, the case of a party to the matter under consideration. In considering whether a real danger of bias exists in relation to a particular decision, Members should assess whether they, a close family member, a person living in the same household as the Authority Member, or a firm, business or organisation with which the Authority Member is connected are likely to be affected more than the generality of those affected by the decision in question. This would cover, for example, a decision to invite tenders for a contract where a firm with which a Member was connected was significantly better placed than others to win it. This paragraph does not preclude the HTA deciding to issue an indemnity in the terms of paragraph 30 below.

23. Indirect pecuniary interests arise from connections with bodies which have a direct pecuniary interest or from being a business partner of, or being employed by, a person with such an interest. Non–pecuniary interests include those arising from Membership of clubs and other organisations. Close family Members include personal partners, parents, children (adult and minor), brothers, sisters and the personal partners of any of these.

24. Where, in accordance with the above, Members do not participate in the discussion or determination of a matter, they should normally withdraw from the meeting, even if it is held in public. This is because the continued presence of someone who had declared an interest might be thought likely to influence the judgement of the other Members present.

25. In cases where Members are authorised by law to represent a group likely to be affected by HTA decisions, the relevant statutory framework may permit Members to be involved, notwithstanding any direct pecuniary interest that they may have in the decision. However, the possibility that specific statutory provisions may impose restrictions that are stricter...
than those described in paragraph 22-24 for interests that are not of a direct pecuniary kind should not be overlooked and the Authority should obtain legal advice to ensure clarity in their considerations.

26. Whether or not Members are able, in the light of the considerations above, to participate in the discussion or determination of a matter, they must declare as soon as practicable after a meeting begins if they have an interest, pecuniary or other, in a matter being considered. They must also disclose any interests in it of which they are aware on the part of close family members and persons living in the same household as the Authority Member. In addition, Members should consider whether they need to disclose relevant interests of other persons or organisations which members of the public might reasonably think could influence the Member's judgement.

27. Unless it is an exceptional circumstance, the HTA like all executive NDPBs, is required to follow generally accepted accounting practice. Members must facilitate compliance with the need for material transactions with related parties to be disclosed in financial statements. “Related parties” include (in addition to business contacts) close members of the family of an individual, who are defined for the purposes of the standard as those family members, or members of the same household, who may be expected to influence, or be influenced by, that person in their dealings with the reporting entity.

28. The HTA should adopt safeguards to prevent conflicts of interests arising from the acceptance of outside appointments during or after tenure as an Authority Member. Advice can be sought from the sponsoring department’s team.

**Personal liability of Members**

29. Although any legal proceedings initiated by a third party are likely to be brought against the Authority, in exceptional cases proceedings (civil or, in certain cases, criminal) may be brought against the Chair or other individual Members. For example, an Authority Member may be personally liable if he/she makes a fraudulent or negligent statement which results in loss to a third party. Members who misuse information gained by virtue of their position may be liable for breach of confidence under common law or may commit a criminal offence under insider-dealing legislation.

30. However, the Government has indicated that individual Members who have acted honestly and in good faith will not have to meet out of their own personal resources any personal civil liability, which is incurred in execution, or purported execution, of their Authority functions, save where the person has acted recklessly. Subject to its own
specific statutory powers, the HTA will therefore issue to its Members suitable indemnities consistent with this paragraph.

31. Members who need further advice should consult the HTA's Chief Executive.

Openness and accountability

32. Members and their staff should conduct all their dealings with the public in an open and responsible way and ensure full compliance with the Freedom of Information Act 2000. They must make publicly available annual reports, and, where practical and appropriate, will hold open meetings, release minutes of meetings, and invite evidence from Members of the public on matters of public concern. The HTA will seek to follow best practice in making available information to the public and co-operate with other bodies to place relevant information in the public domain. The HTA should consult on a wide range of issues by means of questionnaires, public meetings, or other forms of consultation, whenever possible and in the most appropriate manner. The HTA will make all efforts to adhere to the nine principles of public service delivery.

33. The Authority must ensure it can demonstrate that it is using resources to good effect, with propriety, and without grounds for criticism that public funds are being used for private, partisan or party political purposes. It will act consistently with the nature of the Authority's business and any need for confidentiality on commercial or other grounds, always subject to the rights of Parliament and the Comptroller and Auditor General to obtain information. The Authority will also put in place a well-publicised and easy-to-use complaints procedure which covers both maladministration and failure to provide access to information.

Accountability for public funds

34. Members have a duty to ensure the safeguarding of public funds – which for this purpose should be taken to include all forms of receipts from fees, charges and other sources – and the proper custody of assets which have been publicly funded. They must take appropriate measures to ensure that the HTA at all times conducts its operations as economically, efficiently and effectively as possible, with full regard to the relevant statutory provisions and to relevant guidance in Government Accounting.

35. Members of the Authority are responsible for ensuring that it does not exceed its powers or functions, whether defined in statute or otherwise, or through any limitations on its
authority to incur expenditure. Advice on such matters should be provided by the Authority's Chief Executive and legal advisers.

**Annual report and accounts**

36. As part of its responsibilities for the stewardship of public funds, the Authority must ensure that it includes a full statement of the use of such resources in its Annual Report and Accounts. Such accounts should be prepared in accordance with the Accounts Direction issued by the responsible Minister and such other guidance as may be issued, from time to time, by the sponsor department and the HM Treasury, including Executive Non-Departmental Public Bodies: Annual Reports and Accounts Guidance, the Financial Reporting Manual.

37. Subject to any existing statutory requirements, the HTA should aim to produce an Annual Report and Accounts as a single document and should give it appropriate publicity. If the Annual Report is published separately, it should normally contain at least a summary of the Annual Accounts and, in any case, give details of how to obtain the full accounts. A statement by the auditors should be included in the summary to confirm that it is consistent with the Annual Accounts. It should also state whether the report on the Annual Accounts was qualified and provide details if this was the case.

38. The Annual Report and Accounts should provide a full description of the Authority’s activities; state the extent to which key strategic objectives and agreed financial and other performance targets have been met; list the names of the current Members of the Authority and senior staff; and provide details of remuneration of Members and senior staff in accordance with Treasury guidance. The Annual Report should contain information on access to registers of interests in accordance with paragraph 21 above.

**The role of the Chief Executive**

39. The Chief Executive has responsibility, under the Authority, for the overall organisation, management, and staffing of the HTA and for its procedures in financial and other matters, including conduct and discipline. This involves the promotion by leadership and example of the values embodied in the Seven Principles of Public Life. Members should support the Chief Executive in undertaking this responsibility.

40. The Chief Executive will be designated as the Accounting Officer for the HTA. NDPB Accounting Officers are responsible to Parliament and the Accounting Officer of the responsible department for the resources under their control. The essence of the role is a personal responsibility for the propriety and regularity of the public finances for which they
are answerable; for the keeping of proper accounts; for prudent and economical administration; for the avoidance of waste and extravagance; and for the efficient and effective use of all the resources in their charge. The Accounting Officer has a responsibility to see that appropriate advice is tendered to the Authority. Satisfactory performance of these responsibilities is fundamental to the role of the Chief Executive.

41. More detailed guidance on the role of an Accounting Officer is set out in The Responsibilities of a NDPB Accounting Officer: Public Bodies: A Guide for Departments, chapter 6: Financial Management - Accountability, which covers appearances before the Committee of Public Accounts of the House of Commons. All Members should ensure that they have a copy of this document. The contents of the memorandum apply to the senior full-time official of an NDPB in cases where there is no formally designated Accounting Officer. The Treasury’s handbook, Regularity and Propriety, describes what these concepts mean in a financial context. Although the handbook is intended primarily for Accounting Officers, Members should also familiarise themselves with it.

Audit Committee

42. Unless agreed otherwise with the sponsor department, the Authority will establish an Audit Committee as a Committee of the Authority. The Committee should consist of Members and should be chaired by a lay Authority Member, other than the Authority Chair, and who preferably has experience of financial matters. The Chief Executive, the Director of Resources, and any other officer at the discretion of the Chair, will normally attend all meetings of the Audit Committee, unless, exceptionally, their own performance is being discussed.

The Authority as employer

43. The Authority should ensure:

a. that it complies with all relevant legislation and that it employs suitably qualified staff who will discharge their responsibilities in accordance with the high standards expected of staff employed by such bodies. All staff should be familiar with the HTA’s main aims and objectives;

b. that the organisation adopts management practices which use resources in the most economical, efficient and effective manner;

c. that the HTA’s rules for the recruitment and management of staff provide for appointment and advancement on merit on the basis of equal opportunity for all applicants and staff. In filling senior staff appointments, the Authority should satisfy
itself that an adequate field of qualified candidates is considered, and should always consider the merits of full and open competition; and

d. that its staff, and the Authority’s own Members, have appropriate access to expert advice and training opportunities in order to enable them to exercise their responsibilities effectively (in line with wider Government commitments on training strategies).

44. The Authority should adopt a code of conduct for its staff using the model issued for executive NDPBs by Cabinet Office in August 1996, subject to any modifications that may be necessary – and that are agreed with the sponsor department – to take account of their own particular characteristics and circumstances. The model code covers arrangements enabling Members of staff to raise concerns about propriety with a nominated official or Authority Member of the HTA in the first instance and subsequently, if necessary, with a nominated official in the sponsor department. There should be safeguards to prevent conflicts of interests when staff leave.

45. The Authority has a responsibility to monitor the performance of the Chief Executive and other senior staff. Where the terms and conditions of employment of the Chief Executive and other senior staff include an entitlement to be considered for performance related pay, and where such payments are assessed by an Authority Committee (specifically the Remuneration Committee) comprising of Members, the Committee should ensure that they have access to the information and advice required to make the necessary judgements.
Appendix 1: The seven principles of public life

Selflessness
Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity
Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity
In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merits.

Accountability
Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness
Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty
Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership
Holders of public office should promote and support these principles by leadership and example.
Appendix 2: Evidence to select or scrutiny committees

1. Departmental Select or Scrutiny Committees have an important role in examining the expenditure, administration and policies of the Authority. The Government fully supports this role. Lords Committees and other Committees may also seek evidence from NDPBs from time to time.

2. Authority Members may, on occasion, be invited to give evidence to Select or Scrutiny Committees. When they do so, they should be as helpful as possible in providing accurate, truthful and full information, refusing to provide information only when disclosure would not be in the public interest. This should be decided in accordance with the relevant statutes and Freedom of Information Act 2000. Members should bear in mind in this context the need to respect legitimate Authority confidences.

3. Before giving evidence, Members may find it helpful to see Departmental Evidence and Response to Select Committees (also known as the Osmotherly Rules). This gives general advice on dealing with Select Committees including their powers to summon witnesses and papers and responses to Select Committee reports.

4. Similarly, the Chief Executive of the Authority may be called, as an Accounting Officer, to give evidence to the Public Accounts Committee (PAC). Guidance on giving evidence to the PAC is set out in the Accounting Officer Memorandum which can be obtained from the Treasury Officer of Accounts.

5. Members wishing to give evidence should, as a matter of courtesy, advise their Chair and colleagues and the HTA and its sponsoring department of their intention. They should discuss with them the handling of any oral or written evidence they want to submit and whether they expect to be giving evidence on behalf of the HTA or in a personal capacity. The Select Committee should be advised of the status of the witness.

6. Subject only to a Committee’s power to decide to require the attendance of a witness, the decision on whether to give evidence is solely for the individual concerned. There must be no pressure placed on individuals to deter them, or action taken against them as a consequence of giving evidence to a Select Committee. Any such actions might be regarded as contempt of the House, with potentially serious consequences for those involved.
Appendix 3: HTA Governance Structure

**Groups**

<table>
<thead>
<tr>
<th>Authority Groups</th>
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<tbody>
<tr>
<td><strong>Audit and Risk Assurance Committee</strong></td>
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<tr>
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<td><strong>Regulation Directorate</strong></td>
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**Associated documentation**

- Authority Standing Orders (May 2017)
- Schedule of delegation to the Chief Executive and Committees
- Decision Making Framework
- HTA-TOR-001 Terms of Reference for Audit and Risk Assurance Committee (May 2017)
- HTA-TOR-002 Terms of Reference for Remuneration Committee (May 2017)
- The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006
- HTA-SOP-111 Assessment process for living donor transplant cases
- HTA-SOP-115 Reconsideration of HTA living organ donation decision under Regulation 13
- HTA-TOR-003 Terms of Reference for Advisory Groups
- HTA-TOR-004 Terms of Reference for Senior Management Team (SMT) (November 2016)
- HTA-POL-023 Policy for managing and referring potential criminal breaches of Human Tissue legislation (February 2017)
- HTA-TOR-005 Terms of Reference for HTA Management Group (HTAMG)
- REG-SOP-026 Regulatory Decision Making
- REG-SOP-014 Representations (February 2017)
- REG-SOP-036 Appeals (Reconsiderations)
- HTA-SOP-114 Living Organ Donation Regulatory Decision Making
- REG-SOP-003 Evaluating new licence applications
- REG-SOP-026 Regulatory Decision Making
- HTA-SOP-111 Assessment process for living donor transplant cases
Appendix 4: Terms of Reference for the Audit and Risk Assurance Committee

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<td>May 2017</td>
<td>24 February 2016</td>
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<tr>
<td>Author(s)</td>
<td>Sue Gallone</td>
<td>Next review date</td>
<td>24 February 2016</td>
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<td>Amy Gelsthorpe / Richard Sydee</td>
<td>Distribution</td>
<td>Internal and external</td>
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<tr>
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<td>HTA Authority</td>
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Constitution

1. The Authority has established an Audit and Risk Assurance Committee (known to Human Tissue Authority (HTA) staff as ARAC) to support it in its responsibilities for risk management and governance. The ARAC will achieve this by advising the Authority and the Accounting Officer on the exercise of their responsibilities, ensuring the comprehensiveness of assurances that these responsibilities are being met and reviewing the reliability and integrity of these assurances.

2. The ARAC will make recommendations to the Authority regarding the adoption of the Annual Report and Accounts.

Duties and functions

3. The ARAC will advise the Accounting Officer and Authority on:
   a. the strategic processes for risk, control and governance and the Annual Governance Statement;
   b. the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management’s letter of representation to External Audit;
   c. the planned activity and results of both Internal and External Audit;
   d. adequacy of management response to issues identified by audit activity, including External Audit’s audit completion report;
   e. assurance relating to corporate governance requirements for the HTA;
   f. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (permamently delegated to ARAC by the Remuneration Committee);
g. (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non–audit services from contractors who provide audit services; and

h. where necessary, anti–fraud policies, whistle–blowing processes, organisational culture and arrangements for special investigations.

Rights

4. The ARAC has the following rights:

a. it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);

b. it may procure independent specialist ad–hoc advice, at the expense of the HTA, subject to budgets agreed by the Authority; and

c. it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.

Access

5. Internal and External Audit will have free and confidential access to the Chair of the ARAC. In addition, a confidential session with Internal and External Auditors for ARAC members will be scheduled each year.

Information requirements

6. As appropriate to the meeting the ARAC will be provided with:

a. a report summarising any significant changes to the organisation’s Risk Register;

b. a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;

c. management response to audit recommendations;

d. changes to the Internal Audit Plan;

e. details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;

f. a progress report from the External Audit representative summarising work done and emerging findings; and

g. progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.
7. As and when appropriate the ARAC will also be provided with:

a. the Internal Audit Strategy;
b. Internal Audit’s annual opinion and report;
c. External Audit’s annual report and opinion
d. the draft accounts of the organisation;
e. the draft Annual Governance Statement;
f. a report on any changes to accounting policies;
g. a report on any proposals to tender for audit functions;
h. a report on co-operation between Internal and External Audit; and
i. a report on any fraud or financial misdemeanour and any whistleblowing.

Reporting to the Authority

8. The Authority will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.

9. The ARAC will formally report back (either verbally or in writing) to the Authority after each of its meetings.

10. The ARAC will provide the Authority with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.

Reviewing effectiveness

11. The ARAC will use the National Audit Office’s self-assessment checklist for Audit Committees in order to undertake annual reviews of its own effectiveness and agree actions for improvement. The ARAC will report the results of the review to the Authority.

Recruitment and membership

12. The ARAC will be chaired by a lay Authority Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.

13. All other members of the Committee should be Authority Members, but not Authority Chair. Including the ARAC Chair, there will be a minimum of three Authority Members and a maximum of five Authority Members on the Committee at any time.
14. At least one Authority Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.

15. Recruitment of Authority Members to the ARAC will be through ‘expressions of interest’ with personal statements in application. The applications will be reviewed by the Authority Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Authority Chair will appoint the Member who has the most appropriate skills and experience to the role.

16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as Authority Members. It should be noted that Authority Members may be reappointed to the ARAC in accordance with the HTA’s business needs.

17. Members of the ARAC must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

18. A minimum of two members of the ARAC (excluding the ARAC Chair) will be present for the meeting to be deemed quorate.

19. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting if possible. If a member does not attend more than two consecutive meetings the Committee Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.

20. Authority Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.

21. If the ARAC Chair is not present at a meeting, an alternative Authority member will be co-opted to chair that meeting.

22. The Chair of the Authority may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. An Authority Member
who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.

23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.

24. Up to two observers from the Department of Health will normally be invited to attend meetings of the Committee.

25. The ARAC may ask any other officials of the Authority to attend to assist it with its discussions on any particular matter.

26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

Frequency of meetings

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the Authority.

28. The Chair of the ARAC may convene additional meetings as they deem necessary.

29. External Audit may request a meeting of the Committee if they consider one necessary.

30. The Accounting Officer or the Authority may ask the ARAC to convene further meetings to discuss particular issues on which the Committee’s advice is sought.

Secretariat responsibilities

31. The Director of Resources will nominate a designated lead officer (the Secretary) who will manage the secretariat responsibilities for the Committee.

32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.

33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda,
minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.

34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.

35. The minutes will be approved by the ARAC Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.

36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee’s Chair prior to being sent to the Head of Communications for publication.

Version history

37. These Terms of Reference will be reviewed annually by the ARAC and will be approved by the Authority following that review.

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<th>Approved by</th>
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Appendix 5: Terms of Reference for the Remuneration Committee

Reference number: HTA-TOR-002
Version: 15.016.0
Owner: Resources Directorate
Date approved: 24 February 2015
Next review date: 24 February 2016
 Reviewed by: Sue Gallone, Amy Gelsthorpe, Diane Galbraith
Distribution: Internal and external
Approved by: HTA Authority

Constitution

1. The Authority has established a Remuneration Committee (known to Human Tissue Authority (HTA) staff as RemCo) to agree the remuneration strategy on behalf of the Authority. The Remuneration Committee will achieve this by ensuring that it is compliant with government policy on remuneration in Arm’s Length Bodies (ALBs), and that the needs of the organisation in relation to recruitment and retention are fully considered.

Duties and functions

2. The duties of the Remuneration Committee are to:

a. determine and agree the HTA’s remuneration strategy, taking into account affordability, recruitment and retention, comparability with other ALBs’ remuneration and Government policy on remuneration;

b. approve the annual pay bill for the HTA;

c. approve recommendations for early retirement and any other extraordinary remuneration, including termination arrangements or compensation for all staff;

d. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (delegated to ARAC);

e. determine the remuneration of the Chief Executive within the Government’s policy for remuneration of very senior staff;

f. have regard to the annual civil service pay guidance, the civil service reward principles and all other relevant codes, laws and regulations.
Rights

3. The Remuneration Committee has the following rights:
   a. it may commission independent specialist advice at the expense of the HTA, subject to
      budgets agreed by the Authority;
   b. it will be consulted in advance on the procurement of any external advice being sought
      on its behalf;
   c. it may secure the attendance of outsiders with relevant experience and expertise in
      order to discharge its responsibilities.

Information requirements

4. The Remuneration Committee will be provided with information about pay award proposals
   and any other papers deemed necessary for each meeting.

Reporting to the Authority

5. The Remuneration Committee will formally report back (either verbally or in writing) to the
   Authority after each meeting.

Reviewing effectiveness

6. The Remuneration Committee will draw on the National Audit Office's [self-assessment]
   checklist for Audit Committees as appropriate in order to undertake annual reviews of its
   own effectiveness and agree actions for improvement. The Remuneration Committee will
   report the results of the review to the Authority.

Recruitment and membership

7. The Remuneration Committee will be chaired by the Authority Chair.

8. The Remuneration Committee will be made up of no fewer than three, and no more than
   five, other Authority Members.

9. At least one Authority Member, who is not the Chair, must be a member of both the
   Remuneration Committee and the Audit and Risk Assurance Committee.

10. Recruitment of Authority Members to the Remuneration Committee will be through
    'expressions of interest' with personal statements in application. The applications will be
reviewed by the Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Authority Chair will appoint the Member who has the most appropriate skills and experience to the role.

11. Remuneration Committee members will be appointed for a set term of three years, which will not exceed their tenure as Authority Members. This term may be extended in accordance with business need.

12. Members of the Remuneration Committee must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

13. A minimum of two members of the Remuneration Committee (excluding the Chair) will be present for the meeting to be deemed quorate.

14. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting. If a member does not attend more than two consecutive meetings the Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.

15. Authority Members who are not members of the Remuneration Committee have the right of attendance. Authority Members attending meetings will be entitled to speak with the permission of the Chair of the meeting, but in no case will they be entitled to vote.

16. The Chief Executive, the Director of Resources and the Human Resources Manager will attend meetings of the Remuneration Committee, except when matters relating to their own remuneration are under consideration.

17. The Remuneration Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.
Frequency of meetings

18. The Remuneration Committee will meet at least once per calendar year. These meetings will be scheduled to ensure that deadlines relating to remuneration are met and to facilitate timely reporting to the Authority.

19. The Chair of the Remuneration Committee may convene additional meetings as they deem necessary.

20. The Accounting Officer or the Authority may ask the Remuneration Committee to convene further meetings to discuss particular issues on which the Committee’s advice is sought.

Secretariat responsibilities

21. The Head of HR Human Resources Manager will have secretariat responsibility for the Committee.

22. The agenda, minutes from the previous meeting and any meeting papers for consideration will be distributed to the group one week before each meeting.

23. Minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Members will be required to provide any comments on accuracy of the minutes by email. This will ensure the key areas of discussion and action points are captured accurately.

24. Minutes of the Remuneration Committee are confidential and will not be published on the HTA website.

Version history

25. These Terms of Reference will be reviewed annually by the Remuneration Committee and will be approved by the Authority following that review.

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<th>Date</th>
<th>Comments</th>
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<td>24 February 2015</td>
<td>Updated to ensure factual accuracy, update membership information and add version control.</td>
<td>Amy Gelathorpe-Hill</td>
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<td>Diane Galbraith</td>
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Human Tissue Authority – standing orders revised 27 January 2015
Page 49 of 52
Appendix 6: Addison rules

1. A peer who is a member of a public Authority, whether commercial or non-commercial in character, is not by reason of such Membership debarred from exercising his or her right to speak in the House of Lords, even on matters affecting the Authority of which he or she is a member; and it is recognised that, in the last resort, only the Peer concerned can decide whether he or she can properly speak on a particular occasion.

2. The following guidance (based upon that given by the then Leader of the House Viscount Addison, after consultation and agreement between the parties) may be helpful to Peers, who are considering whether or not to take part in a particular debate.

3. When questions affecting a particular Authority or public Authority in general arise in Parliament the present Minister and the Government of the day generally are alone responsible to Parliament. The duty of reply rests with Ministers only, and cannot devolve upon Members of public Authorities who may also be Members of the House of Lords. There can be no question of Members replacing, or usurping the functions of, Ministers and dealing with matters of Ministerial responsibility. In the Commons, of course, the possibility could not arise, because a Member of the House must resign his/her seat on accepting an appointment of this nature.

4. It is important that, as contemplated in the Statutes and, in the case of the BBC, by the Charter, the Authorities shall be free to conduct their day to day administration without the intervention of Parliament or Ministers, except where otherwise provided. If Members who happen also to be peers were to give the House information about the day to day operations of the Authority or to answer criticisms respecting it, the House would in fact be exercising a measure of Parliamentary supervision over matters of management. It would also be difficult for the responsible Minister not to give similar information to the House of Commons.

5. There is no duty upon the Authority Member to answer questions put to him in debate, and that no criticism should attach to any Authority Member who refrains from speaking in a debate. Nor should the fact that a Member spoke in a particular debate be regarded in any way as precedent for him or any other Member speaking in any other debate.

6. The above applies only to debates relating to public Authorities. Experience acquired as a Member of a public Authority will often be relevant to general debates in which the same contributions do not arise, and the contributions of Members who are peers may be all the more valuable because of that experience.
7. The statement below, taken from the memoranda, best sums up the intentions behind Lord Addison’s Rules.

8. “The House of Lords is a sensible body; and the latitude to speak or refrain from speaking, inherent in a peer, is not likely to cause embarrassment. Indeed, any attempt to lay down a hard and fast rule would be more likely to cause embarrassment.”
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting.