Seventy-first Meeting of the Human Tissue Authority

Date 28 April 2015
Time 10:00 – 16.00
Venue British Dental Association
64 Wimpole Street
London
W1G 8YS

Agenda

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 27 January 2015 HTA (14/15)
4. Matters arising from 27 January 2015
5. Chair’s report
6. Regulatory Activity Report – Quarter Four HTA (15/15)
7. HTA Policy for managing and referring potential criminal breaches of Human Tissue legislation HTA (16/15)
8. Living Donation Activity Report – Quarter Four HTA (17/15)
9. HTA Decision Making Framework HTA (18/15)
10. HTA Codes of Practice and Standards Review Project Update HTA (19/15)
11. Human Transplantation (Wales) Act 2013 - Update HTA (20/15)
12. Strategic risk register – April 2015 HTA (21/15)
14. Strategic Performance Review – Quarter Four HTA (23/15)
15. Communications Evaluation Report – Quarter Four HTA (24/15)
16. Audit and Risk Assurance Committee meeting report - 4 February 2015 HTA (25/15)
18. Staff survey – high level view Oral
19. Any other business

Lunch 1.00 to 1.30
## Authority training and development session 1.30 to 4.00

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<tr>
<td>1.</td>
<td>Review of 2014/15</td>
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<td>2.</td>
<td>Forward look: Business Plan 2015/16</td>
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<td>3.</td>
<td>Post Mortem sector seminar</td>
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Minutes of the seventieth meeting of the Human Tissue Authority

Date 27 January 2015
Venue Mary Sumner House
24 Tufton Street
London
SW1P 3RB

Present

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<th>Members</th>
<th>In attendance</th>
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<tbody>
<tr>
<td>Sharmila Nebhrajani (Chair)</td>
<td>Alan Clamp (Chief Executive)</td>
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<tr>
<td>Hossam Abdalla</td>
<td>Morounke Akingbola (Head of Finance)</td>
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<td>Brian Coulter</td>
<td>Sarah Bedwell (Director of Regulation)</td>
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<td>Susan Dilly</td>
<td>Jenna Khalfan (Head of Communications)</td>
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<td>Amanda Gibbon</td>
<td>Allan Marriott-Smith (Director of Strategy and Quality)</td>
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<td>Rosie Glazebrook</td>
<td>Rachel Noble (Authority Secretary)</td>
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<tr>
<td>Andy Hall</td>
<td>Jessica Porter (Living Donation Manager)</td>
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<td>William Horne</td>
<td>Jill Shepherd (Regulation Manager)</td>
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<td>Suzanne McCarthy</td>
<td>Imogen Swann (Head of Regulation)</td>
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<td>Gurch Randhawa</td>
<td>Amy Thomas (Regulation Manager)</td>
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<td>Catharine Seddon</td>
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<td>Anthony Warrens</td>
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<td>Observers</td>
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<td></td>
<td>Patrick Irwin (Department of Health)</td>
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<td></td>
<td>Jeff Porter (Department of Health)</td>
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Item 1 Welcome and apologies

1. Sharmila Nebhrajani welcomed Members and observers to the seventieth meeting of the Human Tissue Authority.
2. Apologies were received from Sue Gallone, Director of Resources. Morounke Akingbola, Head of Finance, Patrick
Irwin (Department of Health) and Jeff Porter (Department of Health) were welcomed to the meeting.

3. The Chair thanked Members for their participation in the panel assessment training that had taken place prior to the meeting. Allan Marriot-Smith and Jessica Porter were thanked for their contributions to an excellent session.

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<tr>
<th>Item 2</th>
<th>Declarations of interest</th>
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<td>4. Amanda Gibbon had been offered the role of Chair of the steering committee for the UK Clinical Research Collaboration Tissue Directory and Coordination Centre, which was a collaboration between University College London and the University of Nottingham’s Advanced Data Analysis Centre. Although no current conflict was deemed, it was agreed that this would be kept under review.</td>
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<th>Item 3</th>
<th>Minutes of 16 September 2014 [paper: HTA (01/15)]</th>
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<td>Minutes of the 28 October 2014 [paper: HTA (02/15)]</td>
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<td>5. The minutes of 16 September 2014 were adopted subsequent to the following amendments:</td>
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<td>• Paragraph 27: that the first sentence was amended to read, ‘steps were being taken.’</td>
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<td>• Paragraph 37: that the second sentence was amended to read, ‘it would be for the police and the CPS to decide if a jury could be convinced that such a promise had been made.’</td>
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<td>• Paragraph 43: that the sentence was amended to read, ‘outlined in paragraph 27 of the paper.’</td>
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<td>• Paragraph 50: that a paper on cost recovery in tissue banking was added to the rolling action log.</td>
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<td>6. Additionally, Members requested clarification on the steps taken to engage Members in the development of the new website. Alan Clamp reported that an email had been sent to Members in November which provided a link to the new site. It was reported that the general feedback form had not worked in some cases and it was agreed that this would be checked.</td>
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<td>7. The minutes of the 28 October 2014 were adopted.</td>
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<td><strong>Action:</strong> Website feedback link to be checked.</td>
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<td><strong>Action:</strong> A paper on cost recovery in tissue banking would be brought to the July Authority meeting.</td>
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### Item 4  Matters arising

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<td>8.</td>
<td>Alan Clamp reported on the annual Staff Survey which would take place in February/March 2015. Actions arising from the Survey would normally be completed by December of the same year and Members were advised that they would receive a copy of the results of the 2015 Survey at the meeting in April.</td>
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<td>9.</td>
<td>Five staff posts had been vacated since the previous meeting of the Authority: Director of Communications; Executive Assistant to the CEO, SMT and the Chair; Media Officer; Administrative Assistant; and one Regulation Manager. There had been four new starters: three Regulation Managers had been appointed and the Executive Assistant role was also filled. It had been decided that the Director of Communications post (which was filled on a 0.5 whole time equivalent basis) would be abolished, and that the Head of Communications would instead report directly to the CEO. Three outstanding vacancies remained.</td>
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<td>10.</td>
<td>In addition to Authority papers, Members had also received the updated terms of reference for the Audit and Risk Assurance Committee (ARAC), Remuneration Committee (RemCo), Stakeholder Group (SG), Transplant Advisory Group (TAG), and Histopathology Working Group (TAG). Members were advised to submit any comments on the drafts to Rachel Noble.</td>
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<td>11.</td>
<td>It was noted that the process of Members’ appointments to sub-Committees was complete, and the Chair thanked Members for accepting these Committee responsibilities.</td>
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Committee (UKDEC)
- Felicity Harvey, Department of Health
- Sally Cheshire, Chair of the Human Fertilisation and Embryology Authority (HFEA)
- Baroness Pitkeathley, Professional Standards Authority (PSA)
- Doug Brown, Alzheimer’s Society

13. The Chair had also written to the British Heart Foundation, Cancer Research UK and Arthritis Research to request a series of meetings to discuss areas of shared interest. These meetings would take place in the fourth quarter of 2014/15.

14. Recruitment for a new Member for Northern Ireland would commence at the beginning of February 2015, and the Authority would be kept informed of progress with this appointment.

Item 6 Regulatory Activity Report – Quarter Three [paper: HTA (03/15)]

15. Sarah Bedwell introduced the report, which detailed regulatory activity during the third quarter of 2014/15.

16. An update was provided on the ongoing investigations that were reported in paragraphs seven to 10 of the paper. Members were advised that the investigation prompted by a US Food and Drugs Administration (FDA) warning letter would be closed soon and more information on collaborative working with the FDA would be provided during the tissue banking seminar at item 12.

17. The HTA had undertaken an unannounced visit in response to concerns raised by a whistle-blower. The establishment had responded positively and steps had been taken to comply with the Corrective and Preventive Action (CAPA) plan provided. The HTA would continue to monitor the establishment’s progress toward compliance.

18. The Regulation team had been working with an establishment that had been found to be operating without a licence. The establishment had ceased to receive new material for storage for research and the HTA was working with the establishment to bring it up to licensing standard. The HTA’s Senior Management Team (SMT) would make a decision on whether to refer the case to the police at the end of January 2015. Members enquired whether the decision to refer to the police was a matter for Authority discussion, and it was confirmed that this duty was currently delegated to SMT. The Chair reiterated her desire to be notified of any potential referrals to
the police as they arose.

19. The Regulation team had worked closely with the Health Research Authority (HRA) when investigating the unlicensed activity and would continue to do so to ensure that this situation did not recur, and that establishments understood licensing requirements.

20. SMT had identified the need to review the HTA’s policy for considering police referrals and would report back to the Authority on this review at the next meeting.

21. The first line of paragraph 43 would be amended to replace ‘regional’ with ‘Welsh’.

22. The Authority noted the report.

**Action:** SMT to review the police referral policy and liaise with the Association of Chief Police Officers, the Crown Prosecution Service and HRA as necessary.

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<tr>
<th>Item 7</th>
<th>Living Donation Activity Report – Quarter Three [paper: HTA (04/15)]</th>
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<tr>
<td>23.</td>
<td>Allan Marriott-Smith introduced the report, which provided an overview of living donation activity in the third quarter of 2014/15.</td>
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<td>24.</td>
<td>A total of 311 cases had been assessed in quarter three, which included the first case in which the donor and recipient had met through Facebook for the purpose of donation.</td>
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<td>25.</td>
<td>The Executive had met with representatives from Facebook and Twitter to establish what policies were in place to deal with illegal activity, or the promotion thereof, in relation to organ donation. It was reported that organ donation in exchange for reward was not expressly included in the listed crimes within Facebook’s terms and conditions, and, although such activity could be removed from the site, there was little evidence that it was actively policed. Similarly, Twitter had no policy on illegal activity in relation to organ donation, nor were tweets of this nature policed. The site would not allow the promotion of illegal activity, but it would be up to site users to report such tweets before they would be removed.</td>
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<td>26.</td>
<td>Independent Assessor (IA) recruitment and retention figures were being monitored, and it was noted that a programme of reaccreditation would take place in 2015/16. The number of IAs remained consistent, and the Executive would report on this by exception.</td>
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<tr>
<td>27.</td>
<td>The living lung programme at the Harefield Hospital would be operational imminently, with an IA already in place. It was</td>
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confirmed that the majority of lung cases would be scheduled as opposed to being out of hours or emergency cases.

28. Clarification was sought on paragraph 13 of the report, which noted that the living liver programme at the BUPA Cromwell Hospital would ‘primarily cater for privately paying patients from overseas’. Members noted a potential conflict of interest if the IA’s salary was indirectly paid for by patient payments, and it was agreed that the Executive would explore this with the coordinator.

29. The new rota for out-of-hours decision-making would be sent to Members in the coming weeks.

30. The Authority noted the report.

Action: Clarification would be sought on whether the BUPA living liver programme was entirely private or whether NHS patients would be treated.

AMS

Item 8  Update on the review of Codes of Practice and HTA Standards [paper: HTA (05/15)]

31. Allan Marriot-Smith introduced the paper, which provided an overview of the revised proposals for the progress of the review of the HTA’s Codes of Practice and Standards.

32. Following the Authority’s discussion in September 2014, the Executive had drafted an overarching Code of Practice to test whether a single document could fulfil the statutory requirements of the Codes of Practice as set out in section 26 of the Human Tissue Act. Following review of this draft by sector experts and SMT, it was concluded that the model of a single overarching Code (supported by sector handbooks) would be largely unworkable for stakeholders, and that further work was required to determine how best to streamline documents.

33. The proposals had been sent to the Department of Health (DH) for consideration. Patrick Irwin reported that DH lawyers had requested clarification of the proposed section on Standards, policies and guidance, as the preliminary view from DH lawyers was that information on standards must be included in the codes requiring Secretary of State and Parliamentary approval. Members raised some concerns about the Standards’ presence alongside policies and guidance in the proposed third tier of information. It was agreed that this point would be discussed by the internal project group and would be explored further with DH officials.

34. Members were advised that a project board would be
established when advice had been received from DH.

35. The Authority noted the report.

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<th>Item 9</th>
<th>Licensing and Inspection Review [paper: HTA (06/15)]</th>
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<td>36. Sarah Bedwell introduced the paper, which provided an overview of proposals for the Licensing and Inspection Review.</td>
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<td>37. There had been good progress on work packages one to three: the cleaning of the customer relationship management database, the generation of a process map, and the quality assurance of evidence. Significant learning had been drawn from the internal audit and risk mapping exercise, and the Authority and the HTA’s internal management group would maintain an oversight of the project.</td>
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<td>38. The Authority commended and noted the report.</td>
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**Action:** An update on the project would be presented to the Authority at the end of work package two.

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<th>Item 10</th>
<th>Policy on bone marrow and peripheral blood stem cell (PBSC) donation [paper: HTA (07/15)]</th>
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<td>39. Allan Marriott-Smith introduced a draft of the proposed new policy for assessment of PBSC donation cases. The draft policy had been developed in response to apparent limitations in the protection for child donors under the legislation in cases of non-competence.</td>
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<td>40. Members were advised that the most significant changes to practice included a need to establish at interview that the consent decision had been made in the best interests of the donor child, that the donor interview would be used to quality assure the assessment of the competence of the donor child, to explore the child’s wishes with respect to the donation and to discuss the issue of reward. Additionally, clarification of the circumstances under which the court should be approached to assess whether the donation was in the child’s best interests had been provided.</td>
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<td>41. Subject to the approval of the policy, the HTA would need to issue further guidance and commence a process of reaccreditation. It was agreed that the Executive would provide further information to the Authority on the percentage of Accredited Assessors (AAs) who had been trained to work with children.</td>
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<td>42. It was confirmed that ‘best interests’ was the correct legal terminology, and that ‘best’ could not be substituted.</td>
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<td>43. The Authority approved the draft policy.</td>
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### Item 11
Review of Strategic Plan for 2015/16 [paper: HTA (08/15)]

44. Allan Marriott-Smith introduced the paper, which was a near-final draft of the HTA's Strategic Plan for 2015-18. The paper included the Strategic Performance Review 2015/16 which set out the key performance indicators (KPIs), which DH and the Authority would monitor during the coming business year.

45. It was noted that the predicted fees income was higher than the figure approved by the Authority at its meeting in October 2014, as the total number of licenced establishments had increased in the intervening period. Alan Clamp advised that the figure remained below the £3.4m threshold set out in the KPIs, thus a further decision was not required.

46. Members considered the KPIs and questioned whether the target of no more than two staff vacancies at any one time (KPI 3.1) was achievable. It was agreed that this KPI would remain, as the rate of attrition provided a helpful overview of staff turnover.

47. An amendment was proposed to the wording of strategic objective 1b to read “To be 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.” This was agreed.

48. Members were advised that the Plan would be published on 1 April 2015, and that any additional comments should be submitted to Allan Marriott-Smith by the end of February.

49. The Authority approved the report.

**Action:** The Chair would approve the final version for publication after final comments.

### Item 12
Seminar on tissue banking

### Item 13
Authority quarterly review of strategic risk register [paper: HTA (09/15)]

50. Alan Clamp introduced the paper, which provided an overview of key risks. The register was updated in January 2015.

51. It was reported that the risk of large-scale change had been reduced. The inability to carry out its remit remained the HTA’s highest risk, and it was noted that 50 per cent of Regulation Managers and a third of the HTA’s remaining
workforce has been in place for less than one year.

52. The Authority noted the report.

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<th>Item</th>
<th>Financial Report – Quarter Three [paper: HTA (10/15)]</th>
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<td>14</td>
<td>Morounke Akingbola introduced the report, which provided an overview of the HTA’s financial position as at 31 December 2014, nine months into the financial year. It was reported that income had increased by 12 per cent, and that there had been an over-spend of £10k on I.T. and telecoms as a result of the refresh of mobile devices and installation of the leased line for disaster recovery purposes. The collection of debts had progressed well, with only £20k outstanding. The forecast for the end of the financial year was for an under-spend of £173k. Members questioned whether staff made use of the career investment scheme, and it was reported that there was a relatively low uptake. Action: Data on career investment uptake would be provided at the next meeting.</td>
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<th>Item</th>
<th>Strategic Performance Review – Quarter Three [paper: HTA (11/15)]</th>
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<td>15</td>
<td>Allan Marriott-Smith introduced the paper, which provided an overview of progress against KPIs during the third quarter of 2014/15. It was noted that the target of providing responses to 95 per cent of enquiries within 10 days was a stretch target, and Members questioned whether this could be reduced. Sarah Bedwell advised that, although the target would remain fixed, there may be some scope to include an amber rating where enquiries were of sufficient complexity that a 10 day deadline was unachievable. The Authority noted the content of the paper. Action: The Executive would review the basis of red, amber and green ratings as part of the next planning round.</td>
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<th>Item</th>
<th>Communications Evaluation Report – Quarter Three [paper: HTA (12/15)]</th>
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<td>16</td>
<td>Jenna Khalfan introduced the report, which provided performance metrics on the HTA’s communications activity in the third quarter of 2014/15. In total, the HTA had received 26 mentions in the media in quarter three, compared with 49 in the previous quarter.</td>
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Three pieces of negative coverage were received.
61. There had been extensive testing of the new website, which had been launched behind the existing site at the beginning of January. Feedback on the site had been largely positive, and some minor amendments had been made as a result of this exercise. The website would launch fully in February 2015, and Members would receive an update on this at the next meeting.

62. Members commented on the high quality of the new website, and congratulated Jenna and her team for their hard work on its development.

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<tr>
<th>Item 17</th>
<th>Report of the Audit and Risk Assurance Committee (ARAC) meeting held on 6 November 2014 [paper: HTA (13/15)]</th>
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<td>63.</td>
<td>Catharine Seddon provided an overview of the minutes of the most recent ARAC meeting.</td>
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<td>64.</td>
<td>It was noted that two internal audits had taken place, both of which had been satisfactory. A risk management strategy and policy had been developed and would be formally reviewed, and there had been a deep dive on crisis management. A recent test of business continuity plans had taken place, which led to some proposed amendments to the crisis management policy.</td>
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<td>65.</td>
<td>The ARAC Chair recorded her thanks to Jodi Berg and Pamela Goldberg for their contribution to ARAC during their time as Authority Members.</td>
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<td>66.</td>
<td>The Authority noted the content of the report.</td>
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<tr>
<th>Item 18</th>
<th>Any other business</th>
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<td>67.</td>
<td>The Chair and the Authority recorded its thanks to Brian Coulter for seven years of service to the HTA.</td>
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<td>68.</td>
<td>Alan Clamp asked for expressions of interest from Members who wished to attend the National Information Board meeting for ALB Non-Executive Directors (NEDs) which would take place on 12 February 2015, 16.00-17.30.</td>
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The meeting closed at 16.25
Regulatory Activity Report - Quarter Four 2014-15

Purpose of paper
1. This paper provides a high-level summary of how the HTA manages information relating to actual or potential breaches of the regulatory framework, both internally and externally. This report provides information on:

   a. **Critical shortfalls**: any critical shortfalls identified against licensing standards. Critical shortfalls against licensing standards are those considered to be of such significance that the HTA would normally expect licensable activities to cease immediately, until that shortfall was addressed;

   b. **Investigations**: how the HTA deals with information it receives about breaches, including investigation of allegations from external sources, regulatory action panels convened, and management of information through routine and non-routine inspections;

   c. **Legal activity**: legal activity associated with the management of breaches, including issuing legal notices and responding to requests to hear representations or appeals;

   d. **Incidents**: serious incidents reported to the HTA by licensed establishments in the post mortem and human application sectors;

   e. **Preparation Process Dossiers (PPDs)**: details about the number of PPDs assessed for human application establishments involved in processing activity within the required timeframe; and
f. **Other regulatory activity**: this section of the report describes regulatory activities undertaken by the HTA which fall outside of categories (a)-(d) above. This could include, for example, measures which are taken to address failures to comply with General Directions, or taken as a result of repeated regulatory breaches by an establishment.

**Decision-making to date**

2. The Senior Management Team (SMT) reviewed the content of the report and suggested amendments on 16 April 2015.

**Critical shortfalls**

3. In quarter 4 (Q4), no shortfalls against licensing standards were assessed as critical.

**Investigations**

4. One new investigation was opened in Q4. There were two ongoing investigations from quarter 3 (Q3). Of these investigations, one was closed in Q4. An update will be provided in the Regulatory Activity Report in Q1 2015/16 on the remaining open investigation.

**New Investigation**

5. In anticipation of an expansion to its work, a licence application was received from an establishment. During the licence application assessment visit, it came to light that the establishment had been storing small amounts of relevant material for research since 2005 and therefore operating without a necessary HTA licence since the requirements came into force.

6. The reason for this unintended oversight was a misunderstanding of the permissions and licensing arrangements already in place, specifically confusion about the role of MHRA (which has regulated the establishment over the same time period) and an absence of licensing concerns or prompts from their tissue suppliers.

7. As a result of the findings during the Licensing Application Assessment Visit (LAAV), licensable activities were ceased immediately. Further correspondence with the establishment sought additional information to assess the breach and inform a potential police referral. The establishment was made aware that the police referral decision was planned to take place at a specified SMT meeting.

8. SMT considered the breach and decided not to refer to the police on the basis that there had been a misunderstanding about the need for a HTA licence. SMT
agreed that there were no behaviours to suggest an active avoidance of a HTA licence.

9. In terms of compliance with our licensing standards, the establishment worked hard to put right their shortfalls to our satisfaction and is now licensed.

**Update on ongoing investigations**

**Update one**

10. In Q3, the parents of a deceased child raised a concern about genetic testing of tissue samples retained following their child’s post-mortem examination under the authority of the Coroner. The Child Death Review indicated that genetic testing had been carried out after the PM examination and it was not clear if this was at the Coroner’s direction. The hospital where the child was treated prior to death has confirmed to the parents that no genetic testing has been carried out. The HTA has advised the parents to contact the HTA again if any new information comes to light.

**Update two**

11. The quarter one (Q1) 2013/14 RAR refers to a US Food and Drugs Administration (FDA) warning letter about a US company which manufactures acellular tissue products. The FDA’s concerns related to the failure of some items of tissue to meet the company’s release criteria, problems with equipment used for tissue preparation and poor quality management systems. Tissue from the US company is imported into the EU via an establishment in the Netherlands and, from there, is distributed to a UK-licensed establishment.

12. The Q1 RAR reported that the initial HTA review suggests the issues identified by the FDA have been addressed satisfactorily. However, the HTA is awaiting the outcome of the FDA inspection (due to take place in 2014) before a Regulatory Decision Meeting (RDM) can be convened to consider closure of the investigation. The establishment has not yet received a response from the FDA related to the close-out of the April 2013 Warning Letter. The HTA has not received an update from the FDA. As of 1 April 2015, the FDA website status still records no response letter has been posted and a close-out date has not been published.

13. A sector-specific breakdown of investigations during the past six quarters is given in Table 1 (Annex A).
Regulatory Decisions

14. One RDM for three establishments was held during Q4 to consider the need for regulatory action.

15. In January 2015, all establishments licensed for patient treatment under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 were required to submit data relating to the activities they undertook and the tissue types they worked with in the period of 1 January to 31 December 2014. As of 10 March 2015, three establishments had not submitted their data, or had not submitted it in the required format. A RDM was held to determine what regulatory action, if any, should be taken.

Establishment one

16. This establishment had not submitted their data or responded to any email communications about the Annual Activity Data. Following the meeting, an enforcement letter was sent to the Corporate Licence Holder contact. Their data has since been received.

Establishment two

17. This establishment submitted their data in a Word document rather than through the HTA Portal. No regulatory action was taken, but the Designated Individual (DI) was contacted for an explanation as to why they had not submitted their data through the Portal, as requested. We are still awaiting a response to our request.

Establishment three

18. This establishment had difficulty submitting their data as their licence was revoked in 2014 and the site was re-licensed as a satellite site under another licence. No regulatory action was taken. Instead, the HTA provided advice on the dates the licence was active and the data the establishment was required to submit. We have now received the data.

19. A sector-specific breakdown of RD Meetings convened during the past six quarters is given in Table 2 (Annex A).

Non-routine site-visit inspections

20. There were two non-routine site visit inspections conducted in Q4, both in the Post Mortem sector.
Non-Routine Inspection one

21. The first non-routine inspection was undertaken to follow-up on a major shortfall identified during a routine inspection, carried out in January 2014. The non-routine inspection found that the establishment had addressed the major shortfall but identified further areas of non-compliance which are being addressed.

Non-Routine Inspection two

22. The second establishment had recently refurbished their licensed premises. The non-routine inspection focused on assessing the licensed premises against the Premises, Facilities and Equipment standards. The establishment was found to have met all standards.

23. A sector-specific breakdown of non-routine inspections during the past six quarters is given in Table 3 (Annex A).

Referrals

Referral one

24. A member of the public contacted the HTA for information on the handling of fetal tissue of less than 24 weeks gestation by a hospital. A Regulation Manager provided advice on the HTA’s expectations for the sensitive disposal of fetal tissue following pregnancy loss and a copy of the recently-released guidance. The member of the public was also advised to contact the Northern Ireland Ombudsman if they wished to make a complaint.

Referral two

25. The DI for a licensed Post Mortem establishment contacted the HTA in relation to delays in disposing of specimens from ectopic pregnancies. The local crematorium declined to accept ectopic pregnancy specimens between 2008 and 2013, causing a delay in their disposal. At the time the DI contacted the HTA, there were 294 specimens awaiting disposal. The local crematorium has since agreed to accept these remains for cremation and the DI confirmed in October 2014 that the remains had been released for cremation. Following investigation into this issue, the HTA referred this matter onto the Care Quality Commission (CQC).

Referral three

26. We were contacted by a member of the public regarding post mortem tissue blocks and slides from a deceased relative. Many of the individual’s concerns related to communication with HM Coroner’s Office, and hence were outside our remit. We provided the person with information on how to take forward their
concerns in that respect. Regarding the blocks and slides, we contacted the relevant PM establishment to confirm whether it was aware of the case, and whether it was currently storing the blocks and slides. The establishment confirmed on both points. Following completion of coronial processes, the blocks and slides were returned to the deceased person’s family, in line with their wishes.

**Licence application assessment visits (LAAVs)**

27. In Q4, there were four LAAVs conducted; three of which relate to licence applications for the research sector. The remaining LAAV related to a licence application for the human application sector. In two LAAVs, no issues were raised which would prevent the licences being issued. The remaining establishments have been issued a Corrective and Preventive Action (CAPA) plan with the expectation that once these issues are addressed, they will be offered a licence.

**Legal notices**

28. There were no legal notices issued in Q4.

**Representations or appeals**

29. There were no representations or appeals in Q4.

**HTA Reportable Incidents (HTARIs) reported in the post mortem sector**

*HTARIs reported in Q4*

30. There were 40 HTARI notifications received in Q4. This is an increase on Q3 (32 notifications). A further six incidents were reported but were classified by the HTA as non-reportable incidents and an additional case was reported but re-classified as a “near miss”.

31. In Q4, 32 (80%) HTARI notifications were received within five working days of the incident being discovered. The notification rate within the correct timeframe can be compared with 94% in Q3, 79% in Q2 and 89% in Q1. The remaining late reports were received between seven and 24 working days after the incident was discovered. The late reporters were reminded of the importance of reporting within five working days.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

Table 1: Number of HTARIs in the PM sector reported to the HTA in Q4

<table>
<thead>
<tr>
<th>Number of HTARIs</th>
<th>HTARI category</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Accidental damage to a body</td>
</tr>
<tr>
<td>7</td>
<td>Any other incident that could result in adverse publicity that may lead to damage in public confidence</td>
</tr>
<tr>
<td>3</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>
</tr>
<tr>
<td>1</td>
<td>Disposal or retention of an organ against the express wishes of the family</td>
</tr>
<tr>
<td>3</td>
<td>Major equipment failure</td>
</tr>
<tr>
<td>2</td>
<td>Post Mortem examination conducted was not in line with the consent given or the Post-mortem examination proceeded with inadequate consent</td>
</tr>
<tr>
<td>10</td>
<td>Release of the wrong body</td>
</tr>
<tr>
<td>1</td>
<td>Serious security breach</td>
</tr>
</tbody>
</table>

32. A breakdown by category of HTARIs during the past six quarters is given in Table 5 (Annex A).

**Ongoing HTARIs from previous quarters**

33. A HTARI is considered closed when the HTA is satisfied that the incident has been thoroughly investigated by the establishment, and appropriate corrective and preventive actions have been taken, or are in the process of being implemented.

34. The HTA normally expects to receive an establishment’s internal investigation report within two months of the initial HTARI notification. There are 15 outstanding HTARIs from Q3. All cases have been followed up.

**Serious adverse events and adverse reactions (SAEARs) reported in the human application sector**

**24 hour reporting requirement for SAEARs**
35. It is mandatory for a licensed establishment to give initial notification of a SAE or SAR to the HTA within 24 hours of the discovery of the event or reaction. The HTA reinforces the 24-hour reporting requirement when it inspects establishments in the human application sector. Of the 30 SAEARs reported in Q4, the HTA received notification within:

- 24 hours of discovery in 22 instances (73%). This can be compared with 85% for Q3, 75% for Q2 and 67% for Q1 (2014/15), and
- 10 days of the date of discovery in another five instances (17%).

36. Of the SAEARs reported outside of the 24 hour period, three were reported within 48 hours and one was reported within three days of the date of discovery. The remaining two SAEARs were reported five, 11, 32 and 37 days after the date of discovery.

<table>
<thead>
<tr>
<th>Number reported</th>
<th>Activity/type of SAEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Distribution</td>
</tr>
<tr>
<td>1</td>
<td>Materials</td>
</tr>
<tr>
<td>2</td>
<td>Preservation</td>
</tr>
<tr>
<td>2</td>
<td>Processing</td>
</tr>
<tr>
<td>5</td>
<td>Procurement</td>
</tr>
<tr>
<td>6</td>
<td>Storage</td>
</tr>
<tr>
<td>1</td>
<td>Testing</td>
</tr>
<tr>
<td>0</td>
<td>Transportation</td>
</tr>
<tr>
<td>3</td>
<td>Other&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>1</td>
<td>Donor reaction</td>
</tr>
<tr>
<td>5</td>
<td>Recipient reaction&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Table 2: Numbers of serious adverse events and adverse reactions in the human application sector reported to the HTA in Q4. <sup>1</sup>SAEs in this category relate to infected material (three cases), infusion (two cases), thawing of sample and quality assessment. <sup>2</sup>The SARs in this category relate to two cases of delayed engraftment and contribution to recipient death and transmitted bacterial infection.
### Ongoing SAEARs reported in previous quarters

37. There are 16 outstanding SAEARs from Q3 2014/15 and eight outstanding SAEARs from Q2 2014/15. All establishments have been contacted for follow-up reports.

### SAEARs reported in the organ donation and transplant (ODT) sector

38. NHS Blood and Transplant (NHSBT) notified the HTA of eight ODT SAEARs (seven SAEs and one SAR) during Q4. Three of these notifications were made to NHSBT within 24 hours of the event being discovered. The remaining notifications were made between two and 22 days after the event or reaction was discovered.

39. A breakdown of ODT SAEARs during the past six quarters is given in Table 7 (Annex A).

### Preparation Process Dossiers

40. The HTA has a performance indicator to ensure that a decision is reached on at least 90% of Preparation Process Dossiers (PPDs) within 20 working days of receipt of the completed dossier, or any additional information requested by the HTA.

41. A ‘decision’ is intended to be either PPD authorisation, the issuing of a request for additional information, or rejection of the PPD if this is deemed to be the most appropriate course of action. Where PPDs are incomplete, this should be communicated to the establishment within 20 working days, with the timeline for a decision restarting upon submission of the additional information by the establishment.

42. In Q4, the PPD Working Group made a total of 12 formal decisions. All decisions were made within 20 working days of receipt of the completed dossier or any additional information requested by the HTA.

### Other regulatory activity

43. In Q4, the HTA did not issue a regulatory alert.

### Action

44. Members are asked to note the content of this report.
Annex A

Sector-specific breakdowns of numbers of investigations, RD Meetings, non-routine inspections, legal notices issued and appeals heard, and HTARIs / SUIs in the previous six quarters.

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/15 Q4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14/15 Q3</td>
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<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14/15 Q2</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
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<tr>
<td>13/14 Q4</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q3</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q2</td>
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<td>1</td>
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<td>0</td>
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</tbody>
</table>

Table 1: Numbers of investigations

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<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
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</thead>
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<td>14/15 Q4</td>
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<td>0</td>
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<td>0</td>
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<td>1</td>
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<td>0</td>
</tr>
<tr>
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</table>

Table 2: Numbers of RD Meetings.

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<th>Research</th>
<th>Anatomy</th>
<th>ODT (audit)</th>
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<td>0</td>
</tr>
<tr>
<td>14/15 Q3</td>
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<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>14/15 Q2</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14/15 Q1</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q4</td>
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<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>13/14 Q3</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 3: Numbers of non-routine inspections

1 Refers to Case Review Meeting held in place of an RDM as RDMs can only be held where an establishment holds, or held at relevant times, an HTA Licence.
2 One Additional RD meeting held at the end of Q3 was not reported until Q4.
Table 4: Numbers of legal notices issued.

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/15 Q4</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>14/15 Q2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14/15 Q1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q4</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q3</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13/14 Q2</td>
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<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>Category</td>
<td>14/15 Q4</td>
<td>14/15 Q3</td>
<td>14/15 Q2</td>
<td>14/15 Q1</td>
<td>13/14 Q4</td>
<td>13/14 Q3</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>Accidental damage to a body ¹</td>
<td>13</td>
<td>11</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</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>3</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</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 ²</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Disposal or retention of an organ against the express wishes of the family</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Major equipment failure</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</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>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Post-mortem examination of the wrong body</td>
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<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Release of the wrong body</td>
<td>10</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Serious security breach</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Viewing of the wrong body ²</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Any other incident that could result in adverse publicity that may lead to damage in public confidence</td>
<td>7</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total number of HTARIs in quarter</strong></td>
<td>40</td>
<td>32</td>
<td>24</td>
<td>18</td>
<td>37</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 5: Numbers of HTARIs in the PM sector reported to the HTA in the past six quarters. ¹ Category extended in December 2011 to include accidental damage to a body which was not scheduled for a PM examination. ² HTARI category introduced in December 2011.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

<table>
<thead>
<tr>
<th>Event</th>
<th>14/15 Q4</th>
<th>14/15 Q3</th>
<th>14/15 Q2</th>
<th>14/15 Q1</th>
<th>13/14 Q4</th>
<th>13/14 Q3</th>
<th>13/14 Q2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement</td>
<td>5</td>
<td>7</td>
<td>9</td>
<td>3</td>
<td>2</td>
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<td>Processing</td>
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<td>3</td>
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<td>Distribution</td>
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<td>Transportation</td>
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<td>4</td>
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<td>Materials</td>
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<td>7</td>
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<td>4</td>
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<tr>
<td>Donor reaction</td>
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<td>0</td>
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<td>1</td>
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<tr>
<td>Recipient reaction</td>
<td>5</td>
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<td>11</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total number of SAEARs during that quarter</strong></td>
<td><strong>30</strong></td>
<td><strong>27</strong></td>
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Table 6: Numbers of SAEARs in the human application sector reported to the HTA in the past six quarters.

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Table 7: Numbers of SAEARs in the organ donation and transplantation sector reported to the HTA in the past six quarters.
Authority paper

Date 28 April 2015  Paper reference HTA (16/15)

Agenda item 7  Author Allan Marriott-Smith

Policy for managing and referring potential criminal breaches of Human Tissue legislation

Purpose of paper

1. The purpose of this paper is to provide the Authority with a copy of the HTA’s current policy for managing and referring possible criminal breaches of Human Tissue legislation. The Authority requested sight of the policy at its meeting on 28 January.

Background

2. SMT agreed a formal policy for managing referrals to the police, based on the indicative factors approach in February 2012. The version provided at Annex A is the version that was approved by SMT following the policy’s last use on 26 February 2015. As the HTA does not have cause to use the policy very frequently, it is assessed following each use and updated as necessary.

3. This version of the policy is the one that would currently apply if a decision on police referral were required.

4. In April the Government replaced the Association of Chief Police Officers (ACPO) with the National Police Chiefs’ Council (NPCC). As the HTA policy is supported by a protocol for referrals agreed with ACPO, we will also need to establish whether the same arrangements will apply with the NPCC. This will provide the opportunity for a more fundamental review of the policy. In addition, Bill Horne has provided the Executive with a number of very helpful suggested improvements to the policy which will also be incorporated as part of this review.
Decision making to date

5. This version of the policy was approved in February 2015, and this paper was approved for submission to the Authority by SMT at its meeting on 16 April 2015.

Proposed amendments

6. For indicative purposes, the proposed amendments will clarify:

- the distinction between licensing offences and other offences under the Act;
- the delineation of the HTA’s regulatory powers and the investigatory powers of the police and the relationship between the two – in particular with respect to evidence standards required under the Police and Criminal Evidence Act;
- the HTA’s position with respect to the timing of a referral e.g. balancing the duty of proportionality with the risk of evidence of any criminal activity being compromised;
- the HTA’s approach to possible criminal activity occurring in Scotland;
- the status and use of any revised protocol established with the NPCC.

7. The Executive will seek a full external legal review of the policy.

Action

8. The Authority is asked to provide any comments on the policy in advance of the review.
Policy for managing and referring potential criminal breaches of Human Tissue legislation

Purpose

1. This policy sets out how the HTA manages and refers alleged breaches of the Human Tissue Act 2004 (“the Act”) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (“the Regulations”) to the police where those breaches may amount to criminal offences. The criminal offences under the Act and the Regulations are set out in Appendix 1.

2. The policy underpins a draft protocol agreed with the Association of Chief Police Officers of England, Wales and Northern Ireland (ACPO), the Crown Prosecution Service (CPS) and the National Policing Improvement Agency (NPIA).

Background

3. The Human Tissue legislation sets out a range of criminal offences. Some become lawful through the licensing structure operated by the HTA. In the licensing structure, the HTA has the power to identify poor practice and to require improvement. In doing so, the HTA has statutory power to carry out inspections, investigations, and has power to enter premises and seize documents. In some situations, regulatory action may be sufficient to deter or avoid any potential criminal breach of the Human Tissue legislation.
4. Other potential criminal offences may be capable of being remedied through powers given for HTA direction, for example, the legal powers given to the HTA to authorise DNA testing.

5. Human Tissue legislation also creates criminal offences associated with organ transplantation, specifically the trafficking in human organs. Any such offences will most likely have been committed by private individuals as opposed to establishments within the HTA’s licensing regime. They cannot, therefore, be addressed through regulatory proceedings. In these cases, the decision for the HTA will be how far any such breaches should be investigated internally, and whether such breaches should be referred to the police for investigation and possible referral to the CPS.

6. In the course of its regulatory activity the HTA can potentially uncover evidence suggesting offences may have been committed under other legislation e.g. human trafficking offences. This policy covers police referrals in situation where no other agency has the responsibility for investigating such offences.

7. The HTA has power to search any premises, not just licensed premises; where there are reasonable grounds to believe that any offence is being or has been committed under the Human Tissue legislation.

8. The police have powers under the Police and Criminal Evidence Act 1984 to combat crime; these are supported by Codes of Practice relating to the exercise of those powers.

9. The CPS seeks to take forward prosecution of cases where there is a high chance of success, and ensure that public resources are targeted at prosecuting cases that are in the public interest.

10. Some offences under the Human Tissue legislation require the consent of the Director of Public Prosecution (DPP) in order to prosecute (see paragraph xx). For practical reasons, the involvement of the CPS will be required for these offences.

Principles

11. The fundamental principle underpinning this policy is that the HTA will carry out its own regulatory investigation into any alleged criminal activity as far as is possible under the Human Tissue legislation, and taking into account the principles of good regulation and the Regulator’s Code. The HTA does not normally conduct an investigation in a manner which would provide evidence to the standards required for a criminal court. The HTA, should, therefore liaise
closely with the police at an early stage where it believes that a potential criminal prosecution is necessary for the purposes of public protection.

12. In cases where it is alerted to the possibility that a potential criminal offence may have been or is being committed, the HTA will conduct a regulatory investigation, where relevant, using its powers under the Human Tissue legislation, including its powers of entry and seizure. The exception to this is where the HTA believes that a potential criminal prosecution is necessary for the purposes of public protection. In those cases the HTA will liaise closely with the police whilst conducting the regulatory investigation.

13. Even where there is clear evidence of a criminal offence, the Authority retains discretion not to refer a case for investigation by the police. However, the manner in which that discretion is exercised is crucial. As a public body, the Authority’s decisions are subject to scrutiny by means of Judicial Review to consider whether the Authority’s discretionary powers have been exercised irrationally or without consideration of relevant factors or after taking into account irrelevant factors. Decision-making, therefore, needs to be properly reasoned.

14. There is also a need for the Authority’s decisions to be consistent. This does not mean, however, that the Authority should decide to refer every case in which there is an alleged criminal breach of a particular section of the Act or Regulations to the police. Regulatory bodies often strive to achieve consistency whilst retaining a degree of flexibility by articulating and reasoning decisions around a list of indicative factors.

15. In adopting this ‘indicative factors’ approach for decisions on whether to refer a case to the police for potential prosecution under the Act, or Regulations, lists of factors have been proposed which may point in favour of or against referral.

16. Accordingly, the absence of relevant evidence should not be a reason which prevents the Authority from making a referral.

**HTA decision making process**

17. The HTA’s [decision making framework](#) sets out the principles of decision making within the HTA and the level of decision making required for police referrals.

**Notification of potential offence**

18. The Authority may receive notification of a potential offence from a number of sources including:
- intelligence gained from someone in an establishment or in the sector
- inspection processes
- notification from a member of the public
- notification by the police

**The role of the Director of Regulation**

19. The Director of Regulation has responsibility for oversight of all potential criminal cases which relate to offences under licensing provisions. When information is received to the effect that a criminal offence may have been committed this will be managed initially by the Director of Regulation through the HTA’s regulatory processes, where it is possible to do so. The aim of this is to seek to establish the facts of the case and to gather enough information to reach a decision about whether the activity identified appears to be a criminal offence, or one which can be managed using regulatory tools. The Director of Regulation will inform the CEO of the potential criminal offence at the earliest opportunity.

20. In circumstances where the HTA believes a criminal offence has been committed, the Director of Regulation will decide whether the case should be remitted to SMT for a decision on police referral. This includes cases where the evidence does not relate to a licensed establishment (where there is no other action that the Authority can take other than to consider referral to the police). Where the case is not referred to SMT for decision the Director of Regulation will inform SMT of the nature of the case and the reasons for the decision.

**Where other regulatory action is possible**

21. Where a potential offence arises in relation to licensed activity, the regulatory process may result in regulatory action being taken. This may include the need for an urgent inspection or, in extreme cases, action to suspend the licence concerned or make Directions placing restrictions on existing activities pending consideration of an application for variation. After an initial decision has been made in relation to the need for regulatory action, the Director of Regulation can, via the Regulatory Decision Making process, consider the indicative factors in determining whether the matter should be referred to the Senior Management Team.

22. The Director of Regulation’s decision on the regulatory action taken may also impact on whether the case is referred to the Senior Management Team for further consideration. By way of example, the Director of Regulation may conclude that there was an isolated failure, which was not deliberate and is unlikely to be repeated. The Director may feel that measures taken by the
establishment, either of its own volition, or as a result of imposition of Directions or a licence condition, provides sufficient public protection for the future. In these circumstances the Director of Regulation may form the view that referral to the police is unnecessary and to not refer the decision to the Senior Management Team. The Director of Regulation’s decision will be notified to the Senior Management Team, either for formal ratification, or simply for information purposes. This information may be invaluable to the Senior Management Team when exercising its discretion in future cases.

23. In any event, it is suggested that the Director of Regulation’s decision is reasoned by reference to the indicative factors and recorded, along with reasons for the decision. If a clear breach of the Act or the Regulations has been identified, the establishment concerned should normally be informed that the breach has been noted and that it will form part of the establishment’s licensing history when considering the need for regulatory action on any future occasion. Repetition in the future may invoke more severe regulatory action and may also cause a shift in the balancing of factors in favour of referral to the police.

24. It is possible that there may be a case where the HTA recommends some immediate regulatory action and that a decision to refer to the police is delayed to take into account the response to the regulatory action. The Director of Regulation is best placed to review the position in the light of the response to the regulatory action.

The role of the Director of Strategy and Quality

25. The Director of Strategy and Quality has responsibility for oversight of all potential criminal cases which relate to trafficking and transplantation offences. When information is received to the effect that a criminal offence may have been committed this will be managed initially by the Director of Strategy and Quality through the HTA’s regulatory processes, where it is possible to do so. The aim of this is to seek to establish the facts of the case and to gather enough information to reach a decision about whether the activity identified appears to be a criminal offence. The Director of Strategy and Quality will inform the CEO of the potential criminal offence at the earliest opportunity.

26. In circumstances where the HTA believes a criminal offence has been committed, the Director of Strategy and Quality will remit the case to SMT for a decision on police referral.
The Senior Management Team

27. The Senior Management Team discussion and decision should always include the Chief Executive and, where licensable activities are involved, the Director of Regulation. A legal adviser may provide legal advice as appropriate.

28. The Senior Management Team will consider the information available by reference to the indicative factors set out below. SMT may defer making a decision until additional evidence is gathered.

29. Where a decision is made, a record should be made of this in the SMT minutes, whether it is to refer the case to the police or not, and the reasons for it. The Chair will be informed of a decision to refer in advance of the referral and a report made to the Authority at the next practicable Authority meeting.

Indicative factors in deciding whether to refer to the police

Factors in favour of referral

30. The following may be regarded factors in favour of referral to the police:

- The offence has the potential to damage public confidence in the use of human tissue
- The offence poses a high risk to public safety
- Referral to the police or a criminal prosecution would have a significant positive impact on maintaining public confidence.
- The person concerned is or was in a position of authority or trust for example a licence holder of designated individual
- The available information suggests that the person concerned was a ringleader or an organiser of the events
- The available information suggests that the offence may have been deliberate or that steps have been taken to conceal the facts related to the offence or to mislead anyone concerning the facts related to the offence (including the falsification of any information in any document)
- The available information suggests that the offence was carried out by a group
- There are grounds for believing that the offence or other offences under the 2004 Act is likely to be continued or repeated, for example, by a history of recurring conduct
- The offence was committed despite a warning being given that the conduct may amount to an offence or that a licence was required
- The offence continued over a significant period of time
Factors against referral

31. The following may be regarded as public interest factors against referral to the police:

a) The offence has limited potential to damage public confidence in the use of human tissue
b) The offence poses a low risk to public safety
c) The person concerned has been subject to criminal penalty relating to these events in the UK or abroad
d) The person concerned acknowledged the breach of the Act to the Authority and/or the person concerned has not attempted to conceal the matter
e) The breach was an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment (this must be balanced against the seriousness of the offence)
f) It appears that the offence was committed was not deliberate and occurred as a result of a genuine mistake or misunderstanding (this must be balanced against the seriousness of the offence)
g) There has been a long delay since the offence occurred (this must be balanced against the seriousness of the offence, whether the delay has been caused in part by the defendant and whether the offence has only recently come to light.)

A reasoned approach

32. When considering the indicative factors, the proper approach is not simply to add up the number of factors on each side. It is necessary to decide how important each factor is in the circumstances of each case and go on to make an overall assessment.

Recording decisions

33. Any decision made by the Senior Management Team should be recorded. The record of the decision should include a summary of the available information, the decision of the Team and the reasons for the decision, by reference to the indicative factors.

Process for referral to the police

34. Any HTA decision to make a referral to the police (whether the police are requested to assist an inquiry, or take on an inquiry) will be made without undue delay. The basis of that decision to refer will have been that, in the view of the HTA, evidence has emerged giving rise to a reasonable suspicion that
criminality exists, especially where the criminality appears to be of the kind likely
to cause harm to people.

35. Where the HTA becomes aware that a potential criminal activity may have taken
place or is taking place, the HTA will refer the matter to the police and will send:

a) a summary of the alleged offence;
b) a plan of action for the HTA investigation, where the matter is one that falls
   within its regulatory remit;
c) an explanation of where the matter may fall outside the HTA’s remit. This
   may cover cases where the limits of investigatory powers do not allow the
   HTA to interview under caution, for example;
d) details of the named member of HTA staff to liaise with police on that case.

36. The HTA will conduct an impact assessment of the referral of all cases to the
police. This will inform case management to minimise disruption to service
delivery, communication and maintenance of public confidence. The HTA will
update this impact assessment on a fortnightly basis, and send a further copy to
the police after every referral.

37. The subsequent decision as to who should undertake the investigation will be
coordinated, and made without undue delay. Given the highly specialised nature
of this work, whether the police take it on, or whether it is undertaken jointly,
there needs to be effective mechanisms for liaison, sharing of information and
allocation of specific roles.

38. Section 5 (consent), section 32 (commercial dealings in transplantation) and
section 33 (restrictions on living organ donation) of the Human Tissue Act 2004
have offences that require the consent of the DPP for prosecution. Where the
HTA becomes aware of this type of alleged offence, the HTA will alert the CPS
in each of these cases at the same time a referral is made to the police. Given
that there will be few opportunities for individual police forces to develop any
expertise in relation to Human Tissue legislation; the HTA will ensure that at the
time of any such referral, the Special Crime Division of the Crown Prosecution is
notified.

39. Effective management of the investigation by the HTA will ensure agreed roles
and responsibilities, with communication between the signatory organisations
continually maintained. An investigation may require liaison with any other
enforcing authority that may have an interest. Milestones will be agreed and
monitored, and policy and key decisions recorded.

40. The parties will agree on:
a. the approach to be taken;
b. how evidence is to be disclosed between the parties;
c. how interviewing witnesses is to be co-ordinated;
d. how instructing experts is to be co-ordinated;
e. a strategy for keeping the public, witnesses, and other interested parties such as coroners, informed of developments in the investigation;
f. a communication strategy to take account of sensitivities of the public; and
g. those involved in the issue, and to encourage consistency of approach in reporting.

41. In certain large scale investigations, it may be beneficial to form a strategic liaison group to ensure effective inter-organisational communication, and to share relevant information and experiences.

42. At the conclusion of its own regulatory investigation, the HTA will decide the appropriate time to formally refer a matter to the police and will send:

   a. a summary of the alleged offence
   b. a regulatory investigation report signed by the Chief Executive
   c. details of the regulatory action taken by the HTA
   d. a chronology of events
   e. a checklist of all retained documents, with confirmation this is subject to any legal requirements on privacy and data protection.
   f. HTA impact assessment
   g. whether this case has also been notified to the CPS

43. There are three exceptions to this approach, and they concern situations where it may be more appropriate for the police to conduct an investigation directly. The three situations are:

   a. clear evidence of harm to people resulting from apparent criminal activity;
   b. an outrage to public decency about which the HTA may be notified;
   c. any other case where the police request to assist or take on the inquiry.

44. During an investigation, the police may require formal statements from HTA members of staff or other types of information. These will be requested through the named contact at the HTA.

45. The police may also require expert evidence from the HTA. Where such a request is made, the police and HTA will rely on the Guidance Booklet for Experts (see Related documents).

46. If the police have agreed to investigate a case referred to them by the HTA, then CPS will provide advice and assistance to the police during the investigation. In
In the event that a police file is duly submitted, CPS will review that file in accordance with the Code for Crown Prosecutors. If the test therein is satisfied, CPS will prosecute the case.

47. In cases of an alleged criminal offence where either, (a) it has not been referred by the HTA to the police; or (b) it has been referred to the police, but the police have decided it is not a matter for prosecution, then CPS’s involvement will be confined to those offences where the DPP’s consent to prosecute is required (sections 5, 32 and 33). In those cases, the HTA will investigate the offence and will submit to the Special Crime Division of CPS a file of evidence (and supporting information) of a sufficiency to enable an informed decision to be reached by the CPS lawyer whether consent to prosecute should be granted. Where the DPP’s consent is granted, CPS will prosecute the case, as the HTA does not have power to prosecute.

48. The CPS should take into account the consequences for any bereaved of the decision whether or not to prosecute, and of any views expressed by the public. The public announcement of the decision will be made according to the agreed media strategy.

Review and audit

49. The parties will review the operation of the protocol annually and consider the need for changes to the arrangements. Where relevant, any changes to the protocol will be reflected in this policy.

50. Between scheduled reviews, there may also be a need to revise both this policy and the protocol.

Related documents

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Appendix 1

Offences under the Human Tissue Act 2004

1. Various offences are created by the Human Tissue Act, 2004 (the Act). A summary of the offences is provided below.

a) Consent
   - Section 5(1): Prohibition of Activities without consent;
   - Section 5(2): Making of a false representation in relation to activities requiring consent;
   - Section 5(3): Storage of body for use for anatomical examination without the relevant signed certificate;
   - Section 5(5): Use of body for anatomical examination without the death of the person being registered; and
   - Section 8(1): Restriction of activities in relation to donated material.

b) Licensing
   - Section 25(1): Breach of licence requirement unless there is a reasonable belief that the activity is not a licensable activity or that the individual acts under the authority of a licence;
   - Schedule 5 Paragraph 8 Enforcement Offences: failure without reasonable excuse to comply with Paragraph 1(1) (Production of Statutory Records for Inspection) or Paragraph 6(3) (Inspector’s Supplementary Powers) or intentional obstruction of the exercise of an inspector’s rights under Schedule 5 (see Schedule 2 paragraph 1 for further explanation).

c) Anatomical specimens
   - Section 30: Possession of anatomical specimens away from licensed premises, subject to exceptions (see Schedule 2 paragraph 2 for further explanation);
   - Section 31: Possession of former anatomical specimens away from licensed premises (see Schedule 2 paragraph 3 for further explanation).

d) Trafficking / Transplantations
   - Section 32: Prohibition of commercial dealings in human material for transplantation (see Schedule 2 paragraph 4 for further explanation);
   - Section 33: Restriction on transplants involving live donors (see Schedule 2 paragraph 5 for further explanation);
Section 34(3): Failure to comply with the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 in relation to the supply of information about transplant operations or knowingly or recklessly supplies information which is false or misleading in a material respect.

e) DNA analysis

- Section 45: Non-consensual analysis of DNA, subject to exceptions (see Schedule 2 paragraph 6 for further explanation)

2. It is important to note that proceedings for offences under Sections 5, 32 or 33 of the Act (see above) may not be instituted except by or with the consent of the DPP (or in the case of Northern Ireland, the DPP for Northern Ireland).

3. Section 49 of the Act envisages the prosecution of individuals and corporate bodies. Section 49(1) provides that where an offence under the HT Act is committed by a body corporate and is proved to have been committed with the consent or the connivance of or to be attributable to any neglect on the part of:

   a) any director, manager, secretary or other similar officer of the body corporate, or
   b) any person who was purporting to act in such capacity,

he (in addition to the body corporate) commits the offence and will be liable for prosecution.

4. An offence can also be committed by neglect.

Offences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

5. In addition to offences created by the Act, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) creates offences which are summarised below. Offences under the Regulations may be committed by a person, body corporate or Scottish partnership.

- breach of requirement to hold a licence or to act under a third party agreement;
- breach of confidentiality requirement; and
- enforcement offences.
Authority paper

Date  28 April 2015  Paper reference  HTA (17/15)
Agenda item  8  Author  Jessica Porter

Living Donation Activity Report – Quarter Four

Purpose of paper

1. This report provides high level information on the activity of the Strategy and Quality Directorate in respect of its living donation responsibilities. This is referred to as the work of the Living Donation Assessment Team (LDAT) in order to differentiate from the other responsibilities of the Directorate which are reported elsewhere.

2. The team has responsibility for the systems which enable the consideration and decision making on living organ donations; and the systems for consideration and decision making on bone marrow donations from those who lack capacity or competence to consent to the donation.

Action

3. The Authority is asked to note the contents of the report and provide any comment.

Decision-making to date

4. SMT reviewed the content of the report and suggested amendments at its meeting on 9 April 2015.
**General activity**

5. The HTA considered and approved 222 cases of living organ donation in Quarter Four (Q4). Additionally, the LDAT considered and approved 21 bone marrow donation cases. Further detail on the types of cases is available on page 5.

6. Clinical teams will, on occasion, decide not proceed with a donor and recipient pair, either in the short term or permanently. This is referred to as a halted work up. The HTA has asked for cases to be reported to us where the reason for halting a work up is associated with matters within the HTA’s regulatory remit (e.g. the clinical team believe the donor is being placed under duress). The HTA also collects information about cases where the work up is halted and the referral to the HTA withdrawn as a result of a matter raised in the IA interview. One halted work up was recorded in Q4.

7. A TAG meeting was held on 17 March, the first time the Group had met since new Members of the Authority were formally appointed.

8. KPI 1.6 (all panel cases to be turned around in 10 working days) was missed on one occasion during March. The reasons for this are set out in the Quarter 4 Strategic Performance Review paper HTA (23/15).

**Potential donor: Adult lacking capacity donating peripheral blood stem cells (PBSC)**

9. Extensive advice and guidance has been provided to a bone marrow unit in Scotland where an adult lacking capacity is the most suitable donor of PBSCs for his sibling.

10. This will be the first adult donor lacking capacity that the HTA has been called upon to assess. This case is made slightly more complicated by the fact that the legislation in Scotland is markedly different in this area to the rest of the UK.

11. Legal advice has been sought by the Trust concerned and the HTA provided specific advice and guidance to the Accredited Assessor about what the interviews and report to the HTA must cover.

12. An update will be provided in the next LDAR.
Enquiries

13. Enquiry 1 – A transplant unit contacted the HTA for advice on whether it would be appropriate for them to implement a minimum age requirement for potential non-directed altruistic donors. A response was sent clarifying the legal position that capacity and the right to make autonomous decisions are the key considerations, as opposed to a blanket age restriction.

14. Enquiry 2 - The LDAT received several phone calls this quarter from transplant units enquiring about how best to decide whether a pair should be referred to the HTA as directed or non-directed altruistic. Individual advice and guidance was provided in each case.

15. Enquiry 3 - The HTA was also asked by a Living Donor Coordinator what to do when a donor changes their mind between the point of IA assessment and surgery regarding their decision about what they would like to happen to their organ in event it cannot be transplanted. We advised that the surgeon must act on the current wishes of the donor but that the HTA should always be notified to ensure records are updated to reflect current wishes.

Legal Advice

16. During Q4 we have sought and received further legal advice in relation to the HTAs role in the assessment of bone marrow and peripheral blood stem cell donations from children lacking competence to consent and adults lacking capacity to consent.

17. Following a meeting with Counsel, we finalised our policy which has been published internally. A project is now underway to issue revised guidance to professionals working in the field of bone marrow and PBSC donation. This will involve all Accredited Assessors undergoing refresher training.

Engagement with Independent Assessors

18. An IA training day was held in February in Manchester and 11 new IAs were accredited.

19. One IA bulletin was issued in Q4 which addressed a number of issues including the publication of improved IA Guidance, the Council of Europe Convention against Trafficking in Human Organs, requirements for referral letters and donor declarations, information that must be provided on duress, coercion and reward, and guidance on social media advertising.
Working with stakeholders

20. The Living Donation Manager and Living Donation Officer visited the Manchester team of Living Donor Coordinators (along with those from Salford and Preston) to provide a general overview of on-going work and to share useful information. Discussions were held around the pressures faced by units when patients requiring an organ transplant advertise for a donor or share their stories on social media sites.

21. The Living Donation Manager attended the Competent Authority (organs) meeting in Brussels.

22. The Living Donation Manager and Chief Executive attended the International Conference on the fight against Trafficking in Human Organs held in Santiago de Compestela, Spain. One of the aims of the Conference was to share the views, concerns and approaches of professionals and organisations that participate in the fight against trafficking in human organs across Europe and the rest of the world.

23. At the same conference, the Council of Europe Convention against Trafficking in Human Organs was opened for signature. Fourteen countries signed the convention, including the UK, Poland, Belgium, Norway, Moldova, Albania and Greece, with many others expected to follow.

24. The HTA Guidance to transplant teams and Independent Assessors document was re-issued at the end of March. This was to incorporate substantive changes that were not included in the June 2014 edition. This includes information on trafficking and guidance for units including a definition of trafficking and the indicative signs the clinical community should be looking for, clarity on the evidence of relationship that donors and recipients could and should provide in each type of case and an entirely new annex, designed to help support IAs with interview techniques and report writing skills.

Media activity

25. During Q4, we provided a number of statistics to journalists covering the topic of living donation more broadly.

26. We also provided a great deal of information to documentary makers and liaised with them about best practice. As a result the HTA will be updating its
media and filming guidelines to support units that are being approached, or would like to work with, documentary makers.

27. Living donation stories more generally were featured in The Mirror, The Westmorland Gazette and Cambridge News. There was a specific article about the issue of people trafficking featured in The Daily Mail.

**Action**

28. Members are asked to note the content of this report.
Living organ donation cases approved in Q4 2014/15

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<th>Directed liver lobe</th>
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Bone marrow cases approved in Q4 2014/15

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HTA Decision Making Framework

Purpose of paper

1. The purpose of this paper is to provide the Authority with a revised version of the HTA Decision Making Framework for approval. A copy of the Framework is provided as Annex A to this paper.

Background

2. The Authority last approved the HTA Decision Making Framework at its meeting on 22 January 2013. The Framework is reviewed biannually, as part of the ongoing programme of review for HTA governance documents.

3. Amendments have been made reflect the changes to the delegation of decision making in living organ donation cases. These were requested by the Authority during living organ donation panel training on 27 January 2015.

4. Panel cases are those which must be assessed by a panel of three Authority Members, either as a matter of law, or as a matter of HTA policy. The detailed description of what constitutes a panel case is set out in the Policy for the assessment of living organ donation cases (HTA-POL-102). The relevant extract is presented in Annex B.

5. Non-panel cases, which are assessed by appropriately trained executive members of staff\(^1\), are by definition all the cases not assessed by a panel. The

\(^1\) A sample of the decisions made by the Executive is moderated on a quarterly basis to ensure consistency and quality. Living donation decision making, more generally, will be subject to internal audit in quarter one of 2015/16.
great majority of these cases are directed kidney donations between family members.

6. Amendments have also been made to reflect decision making delegations for regulatory decisions. These are necessary to ensure cover is in place when the Director of Regulation is absent.

Decision making to date

7. SMT reviewed the proposed amendments to the Framework at its meeting on 15 April 2015, and recommended that the revisions be adopted by the Authority.

Action

8. The Authority is asked to adopt the revised version of the framework.
Annex A

Human Tissue Authority (HTA) Decision-making Framework

In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed). Human Tissue Act 2004, s.38 (2).

Description

1. In carrying out its statutory responsibilities, the HTA is required to make decisions on a wide variety of issues on a daily basis. To ensure that the HTA is transparent, accountable, proportionate, consistent, and targets its regulatory activity only at cases in which action is needed, a framework is required to assist the Authority in its decision making and to provide a standard against which the decisions taken can be judged.

Purpose

2. The purpose of this document is to set out:

   a) the scope of decisions which need to be controlled within the framework
   b) the delegation scheme for decision making, to ensure that decisions in the HTA are taken in line with statutory requirements, and at the right level of seniority
   c) the principles which underpin decisions covered by the framework.

Background

3. The Human Tissue Act 2004 (the Act) sets out the legal framework for the storage and use of human organs and tissue from the living and for the
removal, storage and use of human organs and tissue from the deceased. The Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland - the Human Tissue (Scotland) Act 2006. The HTA is the UK Competent Authority for the EU Tissue and Cells Directives - European laws that have been implemented in the UK via the Quality and Safety Regulations, and the EU Organ Donation Directive implemented in the UK via the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

4. Responsibility for superintending the Human Tissue Act rests with the Authority (the Chair and Authority Members) [s.15(c)]. The Authority is able to appoint such staff as it sees fit [Schedule 2(11)] and may delegate any of its functions to any member of staff [Schedule 2(21)(b)].

5. The Act and associated regulations preclude the delegation of certain decisions (for example, in relation to reconsiderations of licensing decisions) and in other circumstances the Authority has taken a decision to retain decision making responsibility as a matter of policy (for example, certain living donation cases).

6. The Standing Orders of the Authority set out the delegation of functions to the Chief Executive (see Annex A).

Scope of decisions controlled within the framework

7. This framework covers the following decision categories:

a) decisions relating to the initial licensing of establishments

b) post inspection decision making

c) enforcement decisions (significant regulatory activity)

d) living organ donation decisions

e) decisions relating to redress for those affected by our action

f) decisions on action following receipt of information from outside the HTA

g) decisions on referral to the police

h) decisions on interpretation of our legal remit (policy decisions)
i) other decisions of strategic significance as defined in the Crisis Management Plan. That is to say, any other decision where HTA action; failure to act; or acting on the receipt of information received:

i. could pose a risk to life, the public interest or public protection
ii. could have a major detrimental impact on the integrity of the HTA as a regulator
iii. could result in serious criticism or loss of faith – directly or indirectly – in us by our key stakeholders, including the Department of Health or other government departments, the public or the sectors that we regulate.

8. While this framework sets out the principles which should underpin HTA decision making, it does not provide a ‘how to’ guide for making decisions in every circumstance. More detailed guidance notes exist to assist delegated decision makers in coming to a view about the correct course of action in each particular decision class. (Directors in the relevant business areas are responsible for ensuring that these are in place and subject to regular review).

9. In a similar vein, this framework does not set out the process by which decisions are made, but does mandate the need for standard operating procedures which describe the decision making processes to be followed in each decision category. Again, Directors in the relevant business area have the responsibility to ensure that these are in place.

**Delegation scheme for decision making**

10. In order to function, the Authority must delegate decision making to the Executive. The scheme of delegation ensures that decisions are taken at the appropriate level of accountability relative to the likely risks associated with the decision.

11. Delegation in the HTA comes from the top down. Directors are responsible for putting in place mechanisms to assure the quality of decisions which are delegated within their Directorates.

12. All delegated decision makers also have a responsibility for ensuring that their decisions are consistent with this policy and any local guidance relating to the decision. Delegated decision makers also have a duty to ensure that where they have any doubt whether or not decision making is within their remit, then this would be discussed with their line manager in the first instance.
13. The delegation scheme is attached at Annex B.

Principles which guide decision making covered by this framework

14. It is neither possible, nor desirable, to set out what decision should be made in every circumstance. The range of decisions to be made, and the complexity of the information on which a decision will be based, limit the scope for introducing clear cut decision rules. It is, however, possible to set out the principles which should be applied when making a decision so that there is consistency in how decisions are reached.

15. Decision making should take account of these principles and should be reflected in more detailed guidance which supports decision making for particular classes of decision.

16. **Law** – decisions should be in line with public law principles. That is to say we must have the legal powers to make the decision; we must act reasonably and follow fair procedures.

17. **Better regulation** – this framework should be accounted for in our decisions. That is to say we should be accountable for our decisions and they should be transparent, consistent, proportionate and targeted.

18. **Good practice** - decisions should be taken in line with our policies, procedures and guidance. They should be based on adequate evidence and properly informed. This includes accounting for the views of Authority Members and the appropriate stakeholders where necessary. Decisions should be properly documented.

19. **Strategic focus** – decisions should be consistent with or contribute towards the delivery of our strategic aims and high level business objectives. At the highest level, the decision should contribute to the safe and ethical use of human tissue, with proper consent.

20. **Risk awareness** – decisions should be appropriately risk-assessed. This should cover:

   a) an assessment of the risks associated with a departure from the standards we expect of our stakeholders

   b) an assessment of the risks associated with the decisions we make, including their impact on those immediately affected and their stakeholders.
Further implications

21. Legal advice must be built into decision making processes where this is necessary.

22. Appropriate risk assessment tools need to be used to guide decision making.

23. Arrangements for record keeping must be factored in to decision-making processes.

Revision history

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<td>0.2</td>
<td>Redraft with SGr and SB comments.</td>
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<td>10-01-2013</td>
<td>0.3</td>
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<tr>
<td>28-01-2015</td>
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<td>Amendments at bi-annual review and to reflect the adjustment to the delegation to decision making in living organ donation cases requested by the Authority at panel training in 27 January 2015.</td>
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Decision Making Framework Annex A – Standing Orders Extract

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 decision 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.
## Decision Making Framework Annex B - Onward Delegation Scheme

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<td>Regulation Manager or Officer</td>
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<td>Post-inspection decision-making</td>
<td>Major and minor shortfalls</td>
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<td>Enforcement decisions (significant regulatory activity)</td>
<td>Critical shortfalls or collection of major shortfalls</td>
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<td>additional conditions being proposed</td>
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<td>a notice of suspension of licensable activities</td>
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<td>Decisions on representations made following a decision to place conditions on a licence or suspend a licence</td>
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### Annex B Extract from HTA-POL-102

**Decision making in living donation case assessment**

1. The Authority has a legal obligation to assess all cases that are referred to it. While some cases can be delegated to the Executive for decision, other cases are assessed by a panel of three Authority Members (panel cases). The Authority currently distinguishes two types of panel case:
a) Panel cases by law as described in Regulation 12
b) Retained panel cases, where the Authority has decided to retain decision making responsibility and not delegate to the HTA executive

2. Panel cases by law comprise situations where:

a) The donor is a child
b) The donor is an adult lacking capacity to consent
c) Paired donations (definition 1 below)
d) Pooled donations (definition 2 below)
e) Non-directed altruistic donations (definition 3 below)

3. Retained panel cases are further divided into three sub-categories:

a) Certain directed altruistic donation cases. The HTA defines these as cases which fulfil two conditions (a) the donation is being directed to a specific individual and (b) there is no evidence of a qualifying genetic or pre-existing emotional relationship between the donor and recipient. (These cases tend to be characterised by a third party (either a person or other mechanism) bringing the donor and recipient together for the purpose of transplantation). Of these cases, the Authority retains decision making in situations where the donor is travelling from overseas.
b) Economic dependence donation cases. These are cases where the donor has no qualifying relationship with the recipient or is a friend of long standing and has some form of economic dependence on the recipient. For example, an employee or a tenant.
c) Cases which enter the regulatory decision making process. These are cases where, having made an initial assessment of the IA report, the Executive believes that rejecting the case is a possibility.
Definitions

1. Paired donations means an arrangement under which transplantable material is removed from a donor ("D") for transplant to a person who is not genetically related or known to D, and transplantable material is removed from another person for transplant to a person who is genetically related or known to D.

2. Pooled donations means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable material from D is transplanted to the wife of another person ("E"), transplantable material from E is transplanted to the partner of a third person ("F") and transplantable material from F is transplanted to D’s son.

3. Non-directed altruistic donation means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him.
HTA Codes of Practice and Standards Review Project Update

Purpose of paper

1. The purpose of this paper is to provide the Authority with an update on the Codes of Practice (CoP) and Standards Review project. The paper describes the progress made with the project since the Authority meeting in January and seeks views on a number of predominantly structural issues. Members are not at this stage being asked for substantive comment on the drafting as there will be an opportunity to do so in the next stage of the project.

Action

2. Annex A (pages 6-35) to this document provides the first stage draft of Code A. Authority Members are asked primarily for views on the principles section of this Code.

3. Annex B (pages 36-61) presents the first stage draft of Code B (Post Mortem). Members are asked to consider the draft and provide feedback on the structural aspects of the Code and its relationship with Code A.

4. Annex C (pages 62 onwards) provides the draft Standards for the Post Mortem Sector for comment.
Background

5. The CoP and Standards Review project will review the standards and guidance provided to licenced establishments and the guidance provided to clinicians, Independent Assessors and Accredited Assessors operating in the HTA-regulated aspects of transplantation. The objectives for the project are to:

- One - ensure that the CoP and standards reflect our current interpretation of the law and current regulatory practice
- Two - review the HTA’s standards, using recent inspection data, to ensure that the standards are fit for purpose. To set a template for future reviews of the standards using inspection data
- Three - introduce the Principles underpinning our regulation to the Codes
- Four - streamline information, to ensure a user-friendly experience for stakeholders – making our regulatory requirements clearer and minimising regulatory burden where possible
- Five - structure these documents in a way which enables the HTA to edit content which does not require approval by the Secretary of State more frequently, thus ensuring that licenced establishments have access to regularly updated guidance

Decision-making to date

6. In January 2015, the Authority considered a paper on the revised proposals for the CoP review. The Authority accepted the conclusion that a single Code supported by handbooks for each sector would not be in the best interests of stakeholders. There was acceptance of a model of core of information relevant to all sectors in a single document (currently referred to as Code A) supported by separate supplementary Codes for each sector.

7. In February, the Project Team participated in a workshop to agree the scope, structure and timeline for the project and to agree a more detailed specification for the structure and content of the Codes. This paper outlines the key conclusions of these discussions.

8. SMT agreed the content of this paper for submission to the Authority at its meeting on 9 April.

Project scope

9. The Project Team agreed that the CoP and Standards Project should only extend to Codes produced under the Human Tissue Act 2004. This means that the Codes and Standards will only provide practical guidance on activities
undertaken under the Act and its associated regulations. Excluded from scope is any guidance the HTA provides relating to EU legislation, although complementary projects will be undertaken at a later date.

CoP structure and content

10. In discussion, the Project Team reached the conclusion that the distinction between the guidance that sits inside a sector-specific Code of Practice, and that which is presented in guidance handbooks that could be updated without Ministerial and Parliamentary approval was artificial and unhelpful. Ultimately stakeholders want a single reference source which provides them with the practical guidance that allows them to comply with the legislative requirements in the most straightforward way possible. For example, by packaging together the content from Code A, Code B and the Post Mortem sector-standards, a single source is available for those operating in the Post Mortem sector.

11. In discussion, the Executive reached the conclusion that the need for a reference source for each sector, that is easy to navigate, will be of greater importance than the benefits of updating content outside of the Ministerial and Parliamentary approval mechanisms. The result is that more information than the bare statutory minimum will need to be included in each sector Code. This in turn means that project objective five will not be pursued as it will run counter to the interests of our stakeholders. The HTA will pursue an approach of providing supplementary advice as circumstances change (as at present) and anticipate moving to a more frequent (probably triennial) review and Parliamentary approval cycle for the Codes.

12. The structure proposed by the Project Team will streamline the current nine Codes to seven (currently designated by letter to avoid confusion with the existing Codes).

- Code A: Guiding principles and the fundamental principles of consent
- Code B: Post Mortem
- Code C: Anatomical examination (including import/export)
- Code D: Public display (including import/export)
- Code E: Research (including import/export)
- Code F: Transplant – organs
- Code G: Transplant – bone marrow and peripheral blood and stem cells (PBSCs)

13. The guidance on disposal of relevant material from the current Code 5 and information on import and export from the current Code 8 will be tailored to the sectors to which it is relevant in the sector Codes.
14. It is yet to be decided how guidance for those operating in Scotland in the transplantation of organs and PBSCs will be handled. The Executive will be discussing this matter with colleagues in Scotland on 19 May.

Project timeline

15. The project is currently progressing to schedule, with the following key deadlines in place:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 May 2015</td>
<td>First stage of drafting complete</td>
</tr>
<tr>
<td>28 August 2015</td>
<td>Second stage of drafting complete</td>
</tr>
<tr>
<td>1 September 2015</td>
<td>Public consultation opens</td>
</tr>
<tr>
<td>27 October 2015</td>
<td>Public consultation closes</td>
</tr>
<tr>
<td>January 2016</td>
<td>Final sign off of CoP by Authority</td>
</tr>
<tr>
<td>16 February 2016</td>
<td>Deadline for Ministerial review</td>
</tr>
<tr>
<td>1 April 2016</td>
<td>Publication of revised codes and standards</td>
</tr>
</tbody>
</table>

16. During the first stage of drafting, sector experts will review and amend the existing CoP and standards for early review by the Project Team. Authors will keep a full record of changes to clearly illustrate how the Codes have evolved, and the Project Team and Project Board will discuss and agree the proposed changes.

17. Following the meeting of the Authority, comments made on the structure of the drafts will be fed back to authors and will inform further revisions to the documentation. Alongside this, the Executive will organise a seminar for further detailed discussion of the proposed changes to the CoP which will form the baseline for the second stage of drafting.

18. The second stage will focus on refining the drafts in preparation for consultation in August. SMT will discuss a full revised package of drafts at its meeting on 25 June, with the Authority receiving further revised documentation in preparation for its meeting in July. During this period, the Executive will present the drafts for legal review, and the Project Board will maintain an oversight of this process.

Project Governance

19. The Project will be managed on a day-to-day basis by Rachel Noble supported by Amy Gelshorpe-Hill. The outputs from the project will be produced by a Project Team drawn from across the HTA.
20. A Project Board has been established to maintain an oversight of the project. Members of the Board are:

- Alan Clamp, CEO (Senior Responsible Officer) (Customer)
- Allan Marriott-Smith and Sarah Bedwell (Senior Suppliers)
- Amanda Gibbon, Catharine Seddon and Suzanne McCarthy (Senior Users)
- Rachel Noble (Project Manager)

21. The Board will meet on a monthly basis throughout the lifetime of the project. The primary role of the Authority Members sitting on the Project Board as senior users is to ensure the Executive is properly accounting for the HTA’s stakeholders’ needs and the impact of the new Codes on them.

22. More specifically they will seek assurance that:

- the opinions of critical friends have been sought in the pre-consultation stage
- the consultation itself will achieve sufficient coverage
- the post-consultation drafts adequately reflect user views
- the final Codes will be effectively communicated – including addressing any training needs

23. All Authority Members will have the opportunity to comment on drafts of the Codes at various stages. The Authority will be asked to approve the consultation document and draft Codes for consultation. It will also be asked to approve the consultation response and the final Codes for submission for Ministerial and Parliamentary approval.

24. The Project Board will tend to operate on an exception basis, discussing only matters where the project is not delivering to the agreed plan and on risks which have become issues.

**Progress report**

25. Members will be provided with an oral or written update on the progress of the project at each Authority meeting.

**Next steps**

26. The Authority will be invited to a seminar in early May to provide background to the key changes in the draft Codes.

27. The Authority will be asked for comments on the end of first stage drafts during May
Annex A

Draft Code A: Guiding principles and the fundamental principles of consent

The Human Tissue Authority

1. The Human Tissue Authority (HTA) is a regulator set up in 2005 following events in the 1990s that revealed a culture and practice in hospitals of removing and retaining human organs and tissue without consent. The HTA was established by the Human Tissue Act 2004 (HT Act), which addressed this issue, but also updated and brought together other laws that related to human tissue and organs.

2. The HTA regulates, through licensing, Post Mortem examination, anatomical examination, public display of tissue from the deceased and the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training. We also assess applications for organ and bone marrow donations from living people.

3. The HTA has a regulatory remit, defined in statute. The HTA’s codes of practice provide guidance on activities within the scope of this remit. Whilst it can advise on matters outside its remit, the HTA has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.

Guiding principles

4. The HTA’s existence and approach are founded on four guiding principles. These principles are implicit in the Human Tissue Act and actively inform our overall approach to regulation, our Codes of Practice and licensing standards. Anyone undertaking activities falling within the remit of the HTA must have due regard to these principles. The HTA believes that these principles should inform the actions of anyone involved in using materials originating from people.

5. **Consent.** Removal, storage and use of human tissue should be built on a foundation of valid consent or authorisation which has been sought sensitively. This is the fundamental principle at the heart of the Human Tissue Act, and is explored in detail in section xx of this Code.

6. **Integrity** in the treatment of human tissue and bodies. This means:
• human tissue or bodies of the deceased should be used in accordance with the expressed wishes of donors or their relatives
• the dignity of the donor should be respected at all times
• there should be mechanisms in place to protect bodies and human tissue from harm
• privacy and confidentiality of the individual should be maintained
• disposal of human tissue should be sensitively managed and appropriate to the nature of the material
• disposal of human tissue from the deceased should be in line with the wishes of the deceased person’s family
• Where human tissue is imported, importers should endeavour to ensure that the tissue is sourced from a country that has an appropriate ethical and legal framework

7. **Professionalism** in the management of human tissue and bodies. This means:

• Practitioners should work with proper skill, care and training, in accordance with good Practice and other relevant professional guidance
• Practitioners’ work should be subject to a system of governance that ensures the appropriate storage and use of human tissue and which safeguards the dignity of the deceased
• Premises, facilities and equipment should be clean, secure and subject to regular maintenance
• Proper and accurate records and information should be maintained to ensure full traceability of human tissue and bodies of the deceased

8. **Candour** in matters pertaining to the use of human tissue and bodies. This means:

• Communication with a donor, or person providing consent, should be open, honest, clear and objective
• All information provided should be understandable and sufficient to meet the needs of the individual
• Serious incidents involving human tissue should be subject to rigorous investigation to ensure that lessons are learned and the risk of reoccurrence is minimised
• Establishment should adopt a policy of openness and transparency when dealing with serious incidents.
About the Codes of Practice

9. HTA Codes of Practice give practical guidance to professionals carrying out activities covered by the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.

10. This document is part of a suite of Codes produced by the HTA and contains information that is applicable to everyone undertaking activities covered by the HT Act and its associated Regulations.

11. The HTA has published seven Codes of Practice:
   - Code A: Guiding principles and the fundamental principles of consent
   - Code B: Post Mortem
   - Code C: Anatomical examination (including import/export)
   - Code D: Public display (including import/export)
   - Code E: Research (including import/export)
   - Code F: Transplant – organs
   - Code G: Transplant – bone marrow and peripheral blood and stem cells (PBSCs)

12. In combination, Code A and the relevant sector-specific Code provide practitioners operating in that sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

13. The Codes are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA’s website.

14. A number of other organisations have also produced guidance on issues in the HTA’s remit. Where this has been produced in collaboration with the HTA, it is available on our website. The HTA’s Codes of Practice and other guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other guidance and legislation relevant to their activities.

Code structure

15. This Code is divided into two sections. Section One explains the importance of consent as the fundamental principle underpinning the HT Act.
16. Section Two provides guidance on the statutory requirements for consent and is divided into three parts:

- Part One: General provisions
- Part Two: Tissue from the deceased
- Part Three: Tissue from the living

17. All those involved in the removal, storage and use of human tissue from the deceased or the living should take into account the general provisions on consent set out in Section Two, Part One.

18. There are different consent requirements which apply when dealing with tissue from the deceased and tissue from the living; these are set out in Parts Two and Three. Parts Two and Three are further divided into consent requirements for adults and for children.

**Status of this code**

19. This Code of Practice was approved by Parliament on xx April 2016 and was brought into force by Directions dated xx April 2016.

**Legislation and the Human Tissue Authority**

20. The Human Tissue Act 2004 (HT Act) covers England, Wales and Northern Ireland with the exception of the provisions relating to the use of DNA, which also apply to Scotland. The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006.

21. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) implement the European Union Tissue and Cells Directives (EUTCD). The HTA is the Competent Authority in the UK under the Q&S Regulations, which cover the whole of the UK, including Scotland.

22. The HTA is also the Competent Authority in the UK for the implementation of the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Directive). The requirements of the Directive are transposed into UK law via the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q & S Organs Regulations).

23. The HTA Codes of Practice do not extend to providing advice relating to the requirements of European Directives (this is provided elsewhere). They do,
however provide advice on matters where there is an interface between legislation stemming from Europe and domestic legislation.

24. The HTA’s remit in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 (Ref: NHS HDL (2006) 46) and the relevant Codes of Practice. Relevant guidance from Wales and Northern Ireland is referenced throughout the Codes.

25. On 1 December 2015, an opt-out system for organ donation after death will become operational in Wales, following the passage of the Human Transplantation (Wales) Act 2013. The HTA has drafted a Code of Practice to provide advice and guidance on the Human Transplantation (Wales) Act. At the time of drafting this Code of Practice, the Code of Practice on the opt-out system in Wales had not yet gained Parliamentary or Welsh Assembly approval. A copy of the draft document is available on the HTA website.

26. The Code of Practice on the Human Transplantation (Wales) Act 2013 should not be relied on until the law becomes operational on 1 December 2015. Up until that time, the HTA’s Code of Practice 2 is the relevant document.

Scotland

27. The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act) has authorisation as its fundamental principle and specifies where authorisation is needed for the use of human tissue for certain purposes. While provisions of the HT (Scotland) Act are based on authorisation rather than consent, these are essentially both expressions of the same principle. Establishments in Scotland, storing and using tissue and cells for human application or undertaking organ donation and transplantation activities should read this code on consent for guidance on good Practice, but must comply with the authorisation provisions of the HT (Scotland) Act. Where we refer to coroner in this code, in Scotland we mean Procurator Fiscal. Where we refer to Mental Capacity Act 2005 in this code, in Scotland the relevant legislation is the Adults with Incapacity (Scotland) Act 2000. Where we refer to Trusts in this code, in Scotland the relevant terminology is NHS Board.
Section One - The fundamental principles of consent

28. The guidance outlined in this section highlights the importance of consent, which underpins the HT Act. The following issues are central to the application of the consent provisions of the HT Act.

i. the legal concept of consent
ii. is consent required?
iii. appropriate consent
iv. valid consent
v. limits on consent
vi. duration of consent
vii. withdrawal of consent.

The legal concept of consent

29. New paragraph which describes the legal status of consent, that is to say that it is not defined in the Act itself but the concept of valid consent is established in common law. The Human Tissue Act describes specific circumstances under which consent as established in common law is required.

Is consent required?

30. Consent under the HT Act relates to the purposes for which material might be removed, stored or used. These purposes are set out in Schedule 1 of the HT Act and are called scheduled purposes.

31. In broad terms, the HT Act and the HTA’s Codes of Practice require that consent must be in place to:

i. store and use dead bodies
ii. remove, store and use relevant material from a dead body
iii. store and use relevant material from the living.

32. Appendices A and B set out in detail the purposes for which consent is required for under the Human Tissue Act.

33. Anyone removing, storing or using material in circumstances for which the HT Act requires consent must be satisfied that consent is in place. New material about licensing and licensing standards relating to consent.

34. Consent to treatment and examination is covered by the common law and the Mental Capacity Act (MC Act) 2005 where appropriate. Trusts should have local
policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health's guidance. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government's Reference guide to consent for examination and treatment. The Department of Health, Social Services and Public Safety (DHSSPS) (Northern Ireland) has published its own Reference guide to consent for examination, treatment or care.

35. There are certain exceptions to the provisions set out in the HT Act for coroners and criminal justice purposes. Further information can be found on the HTA website.

**Appropriate consent**

36. The HT Act is clear about what constitutes ‘appropriate consent’. Appropriate consent is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative or (in the absence of either of these) the consent of a person in a 'qualifying relationship' with them immediately before they died.

37. Those in a qualifying relationship are found in the HT Act in the following order (highest first).

i. spouse or partner (including civil or same sex partner) The HT Act states that, for these purposes, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship

ii. parent or child (in this context a child may be of any age and means a biological or adopted child)

iii. brother or sister

iv. grandparent or grandchild

v. niece or nephew

vi. stepfather or stepmother

vii. half-brother or half-sister

viii. friend of long standing.

38. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person high up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but others in the family wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs xx and xx should be observed in line with this principle. If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased
person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person's body or tissue for scheduled purposes.

39. While the HT Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other family members - this may include people not on the list, for example, an aunt or uncle.

40. Relationships listed together, for example ‘brother or sister’, are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.

41. Where there is a conflict between those accorded equal ranking, then this needs to be discussed sensitively with all parties (see also paragraphs 84-85 which provide further guidance on handling difficult situations), whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead.

42. A person's relationship shall be left out of account if:

i. they do not wish to deal with the issue of consent
ii. they are not able to deal with the issue
iii. in relation to the activity for which consent is sought, it is not practical to communicate with that person within the time available if consent in relation to the activity is to be acted on
iv. This means a person may be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, declines to deal with the matter or is unable to do so, for example, because they are a child or lack capacity to consent. In such cases, the next person in the hierarchy would become the appropriate person to give consent

Valid consent

43. The giving of consent under the HT Act is a positive act. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

44. This code sets out guidance for practitioners on how to make sure appropriate consent is valid. All consent must be valid in the context of the HT Act. It is important to respect the consent given, regardless of its scope or duration
45. For consent to be valid, the person should understand what the activity involves and, where appropriate, what the risks are. When seeking consent, healthcare professionals or other suitably experienced people should ensure that it is appropriate for the intended purpose.

46. To ensure that the removal, storage or use of any tissue is lawful, it is important to establish clearly that consent has been given. Consent may be expressed in various ways, and does not necessarily need to be in writing, unless the HT Act requires it to be. Obtaining valid consent presupposes that there is a process in which individuals, including their families where appropriate, may discuss the issue fully, ask questions and make an informed choice.

47. A person's agreement or refusal to consent to the removal, storage or use of tissue for purposes under the HT Act must not affect the investigation or treatment that they receive.

48. Possible new material on information provided by commercial organisations.

**Limits on consent**

49. Consent may be limited in a variety of ways. The HT Act does not prevent an individual placing limits on their consent via the imposition of conditions. For example to particular research studies or to donate specific organs.

50. Consent may be generic or specific. Generic consent typically only applies to research. If conducting research on samples of tissue, it is good practice to request generic consent because this avoids the need to obtain further consent in the future. It is still important however that the consent is valid. Further guidance on consent to research is included in the Code of Practice on Research on the HTA website.

51. The extent to which such conditions can be acted on are a matter of law and/or policy for those undertaking activities for scheduled purposes covered by the HT Act. In support of its public sector equality duty, the HTA advises that those undertaking activities for scheduled purposes covered by the HT Act must do so in line with Article 14 of the European Convention on Human Rights (ECHR). This has the effect that any conditions which offend against these principles cannot be acted on.

52. Where any conditions attached to consent cannot be acted upon, a person providing consent would need to be aware of this and willing to put these conditions aside, for valid consent to be in place. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a
persisting condition on consent could or would not be fulfilled, as valid consent would not be in place.

53. With regard to directed deceased donation, the HT Act does not prevent a person from providing consent subject to the condition that a deceased donor organ is directed to a specific individual. The extent to which such a condition can be acted on is a matter for NHS Blood and Transplant (NHSBT) which has legal responsibility for organ allocation.

Duration of consent

54. Consent may differ in its duration. It may be enduring or time-limited.

55. Enduring consent means that it remains in force unless consent is withdrawn. A person may, however, specify a time limit for how long they wish their consent to remain in force. In both cases, the decision should be clearly documented in the patient's records, the laboratory records or both (see section on format of consent, paragraphs xx for further detail).

Withdrawal of consent

56. Consent may be withdrawn at any time whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear, for example, for potential recipients if the donated tissue is for clinical use. Withdrawal of consent cannot be effective where tissue has already been used.

57. If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for a particular scheduled purpose (e.g. research), this does not necessarily mean that the sample or samples have to be removed or destroyed. However, the samples may no longer be stored or used for the particular purpose for which consent has been withdrawn. In addition, if someone withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

Consent requirements further guidance

The HTA produces more detailed guidance on the application of the consent principle in practical situations, the consent requirements imposed by the Act for different purposes and the process of seeking and recording consent as part of its guidance to each licensed sector.
Section Two - Consent requirements

58. This section is divided into three main parts:

i. Part 1: General provisions
ii. Part 2: Tissue from the deceased
iii. Part 3: Tissue from the living.

59. All those involved in the removal, storage and use of human tissue from the deceased or the living should take into account the general provisions set out in Part 1. There are different consent requirements which apply when dealing with tissue from the deceased and tissue from the living; these are set out in Parts 2 and 3. Consent requirements for the living fall under the HT Act, except for the removal of tissue which is a common law matter.

Section Two - Part 1: General provisions

60. Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:

i. Does the activity require consent? For tissue from the deceased, consent is required for all scheduled purposes (paragraph xx). Consent is not required under the HT Act for storage and use of tissue from the living in some circumstances (paragraphs xx)

ii. Who may give consent? (paragraphs xx)

iii. Has sufficient written or verbal information been provided for the person giving consent to make a properly considered decision? (paragraphs xx)

iv. How will the consent be given and recorded? (paragraphs xx)

v. When is written consent required? (paragraphs xx)

vi. Is consent needed for more than one purpose? (paragraphs xx)

vii. If a child is involved, are they competent to consent and have they expressed particular wishes or views? (paragraphs xx)

viii. If an adult lacks capacity to consent, how should the provisions of the MC Act be applied? (paragraphs xx)

ix. What are the exceptions to the consent provisions of the HT Act? (paragraphs xx)

x. What are the consent implications for fetal tissue? (paragraphs xx)

When to seek consent

61. Consent is often sought in a clinical setting for treatment, research, or following the death of a patient. But this is not always the case. The following paragraphs refer generally to clinical settings, but apply equally to other circumstances.
62. Where possible, it is good practice to seek the person's consent to the proposed procedure in advance. Sufficient time should be allowed for questions and discussion.

63. Equally, discussions with families may often take place in hospital before a person's death. They may know the person's wishes in respect of, for example, donating organs for transplantation. It should be made clear to them, however, that knowing and understanding the dying person's wishes is different from giving consent on their behalf following their death (see paragraphs xx for further guidance).

64. The seeking and obtaining of consent from patients before death or from those close to them after their death requires sensitivity. This is especially true for donations for transplantation, Post Mortem examinations and the retention of tissue and organs for research. Further guidance is set out in the Codes of Practice on Post Mortem examination and Donation of solid organs for transplantation.

**Who may seek consent?**

65. It is usually the responsibility of the healthcare professional to seek consent from the person concerned, the person with parental responsibility, or a partner, relative or close friend (see paragraph xx for hierarchy of qualifying relationships).

66. It is important to have procedures in place which clearly set out the responsibilities of all those involved in the process of seeking valid consent. Where these are already in place, establishments should review them to ensure they meet the requirements of this code.

67. **Good Practice example:** Eye banks have formal agreements in place with specialist nurses for organ donation who obtain consent from donor families on their behalf. The system clearly sets out the responsibilities of the parties involved and documents the procedure for recording consent. This ensures that valid consent is obtained by appropriately trained staff in accordance with the HT Act and Codes of Practice.

68. Seeking and obtaining consent is a sensitive issue. Staff seeking consent should have a good understanding of the activities they are seeking consent for. They should also be in a position to answer questions. Healthcare professionals should obtain the support and guidance of their managers to develop the necessary skills in the implications and essential requirements of seeking consent.
69. Even if consent is not sought in a clinical setting, the person seeking consent should still be appropriately trained to ensure that the consent is valid.

70. Seeking consent may be assigned to someone else, as long as they are suitably trained. In particular, they should know enough about the proposed procedure, the intended use of the tissue and the risks involved, for the subject to make an informed decision. For example, a Specialist Nurse for Organ Donation or an appropriately trained member of a bereavement services team (see paragraph xx) could be involved in the consent-seeking process.


**Format of consent**

72. The HT Act does not specify the format in which consent should be given or recorded, except for anatomical examination or public display which must be in writing (see sector-specific Codes). The information required and the manner in which consent is obtained and recorded may vary depending on the particular circumstances.

73. Written consent serves as evidence of consent, but a signature on a form will not of itself make the consent valid (see section on valid consent, paragraphs xx). Systems or protocols should be in place to ensure that the process is correct and that the decision has been properly recorded. Trusts seeking to update existing consent forms or develop new protocols should ensure that they comply with this code and other relevant HTA guidance.

74. **Good Practice example:** An establishment obtains verbal consent via the telephone from the deceased persons' relatives for the donation of tissue (bone, skin, eyes, and heart valves) for transplantation. The family is provided with information about the donation process and the subsequent uses of the tissues and given the opportunity to ask questions, to ensure that valid consent is given. The establishment documents the consent in the donor's records, audio records the consent conversation with the family if possible, and follows up with a letter of confirmation.
75. When consent is obtained but it is not in writing, this should be clearly documented in the patient's records, the laboratory records or both. The record should detail when consent was obtained and the purposes for which the consent was given.

76. A decision recorded on the NHS Organ Donor Register (ODR) constitutes the consent, or refusal, of the person. It is advised the decision recorded on the ODR is shared with family and friends to establish whether the person had made a different decision subsequently.

Religion, belief and culture

77. Attitudes towards the use of tissue and especially towards Post Mortems may vary widely among cultures and religions. All healthcare professionals should be sensitive to this. However, each case and decision is an individual and personal one, and should be treated as such. Trusts and other establishments should ensure that their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes.

Communication

78. Consent is valid only if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person interviewed (e.g. because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.

79. Under the MC Act, efforts should be made to provide information that is appropriate in terms of culture and language when assessing capacity, see chapter 3 of the MC Act Code of Practice (for further information on adults who lack capacity to consent see paragraphs xx).

Use of documentation

80. Information leaflets and consent forms are useful and recommended for:

   i. Post Mortem examination
   ii. anatomical examination
   iii. organ and tissue donation

81. Patient information sheets should be provided about research projects and these are also usually required by ethics committees approving research projects. The
Health Research Authority (HRA) has issued guidance on developing model consent forms and information sheets for research establishments to use when obtaining consent.

82. Establishments should provide appropriate information on the activities for which they are seeking consent. The information might be in the form of leaflets or information sheets, or might be contained within the consent form. Many establishments, including Trusts, have policies on consent that include the use of standard documentation. Such documentation should make reference to the HT Act and the role of the HTA and be reviewed to ensure that it is consistent with this code, as well as the requirements of the Clinical Negligence Scheme for Trusts, the relevant Department of Health Consent guidance and consent guidance from the Welsh Assembly Government and DHSSPS (Northern Ireland).

83. Where appropriate, information should be available in widely spoken languages and in a variety of formats, such as video or DVD, audiotape or Braille and in line with other legislation, such as the Equality Act 2010. Wherever possible, professional translators trained in translating for the bereaved and in maintaining confidentiality should be used.

84. Good Practice example - Some researchers have provided information about their research study via a computerised programme whereby the donor gives consent electronically. The computer programme allows information to be displayed in large font or listened to via audio play-back. The programme allows donors to submit questions by email or via a dedicated contact number. The patient information leaflet may be printed at the donor's request. The establishment also provides the information in hard copy to those who do not have computer access.

Existing holdings

85. The consent requirements of the HT Act are not retrospective. This means it is not necessary to obtain consent for material that was held for use for a scheduled purpose when the HT Act came into force on 1 September 2006.

86. Although there are no statutory requirements to obtain consent for the storage or use of tissue that is an existing holding, this does not mean that all such human tissue can be used freely and without regard to issues of consent or other ethical considerations. If practical, the consent of the participant should be sought and the views of the deceased person or of their family (if known) should be respected, as long as the method of disposal is legal.
87. Under the HT Act, consent is not required for carrying out research on existing holdings of human tissue and organs (see paragraph xx). Although it does not have an explicit role in the ethical approval of research on such material, the HTA endorses the guidance produced by the Health Research Authority (HRA).

88. Although existing holdings are exempt from the consent provisions in the HT Act, the HTA's licensing requirements may still apply where material is being stored or used for a scheduled purpose.

**Use of images**

89. The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the HT Act. However, the HTA requires Designated Individuals to put systems in place to ensure suitable Practices are carried out, which may include systems to prevent the inappropriate use of images.

90. The HTA endorses the guidance on images provided by the General Medical Council (GMC) in its publication *Making and using visual and audio recordings of patients*.

**Section Two - Part 2: Tissue from the deceased**

91. Under the HT Act, consent is needed for the removal, storage and use of material from the deceased for all scheduled purposes as listed below:

   i. anatomical examination  
   ii. determining the cause of death  
   iii. establishing, after a person's death, the efficacy of any drug or other treatment administered to them  
   iv. obtaining scientific or medical information, which may be relevant to any person including a future person  
   v. public display  
   vi. research in connection with disorders, or the functioning, of the human body  
   vii. transplantation  
   viii. clinical audit  
   ix. education or training relating to human health  
   x. performance assessment  
   xi. public health monitoring and  
   xii. quality assurance  

(see appendix A)
92. Although consent is not required for a coroner’s Post Mortem, consent is required under the HT Act for the continued storage or use of tissue, for scheduled purposes, once the coroner’s purposes are complete (see paragraphs xx). See the code of Practice on Post Mortem examination for further guidance.

Who may give consent?

Adults

93. Where an adult has, whilst alive, given valid consent for any particular donation or the removal, storage or use of their body or tissue for scheduled purposes to take place following their death, then that consent is sufficient for the activity to be lawful.

94. If those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their nominated representative, see paragraphs xx) has explicitly consented, the healthcare professional should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes (see the Code of Practice on donation of solid organs for transplantation).

95. The emphasis in these difficult situations should be placed on having an open and sensitive discussion with those close to the deceased where the process is explained fully to them. Healthcare professionals should also consider the impact of going ahead with a procedure in light of strong opposition from the family, despite the legal basis for doing so. For example, in these circumstances, healthcare professionals may consider that carrying out an anatomical examination would be too distressing for relatives, despite the deceased person having consented to this whilst alive.

Nominated representatives

96. If a deceased adult, before death, had neither consented to, nor specifically refused, any particular donation or the removal, storage or use of their body or tissue for scheduled purposes, those close to them should be asked whether a nominated representative was appointed to take those decisions.

97. A nominated representative may be empowered to consent to the carrying out of a Post Mortem examination and to the removal, storage or use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.
98. The appointment of a **nominated representative** and its terms and conditions may be made orally or in writing. The HT Act sets out the requirements for a valid appointment. The appointment of a **nominated representative** may be revoked at any time.

99. If the deceased person appointed more than one nominated representative, only one of them needs to give consent, unless the terms of the appointment specify that they must act jointly.

100. The nominated representative's consent cannot be overridden by other individuals, including family members. It is advisable, nevertheless, to ensure that appropriate consultation and discussion takes place between all those involved.

101. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practical to communicate with the **nominated representative** within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a ‘qualifying relationship’ (see paragraphs xx).

**Qualifying relationships**

102. If the deceased person, before their death, had not indicated their consent (or refusal) to Post Mortem examination, removal, storage or use of their body or tissue for scheduled purposes, or appointed a nominated representative, then consent may be given by someone who was in a ‘qualifying relationship’ with the deceased person immediately before their death. Those in a **qualifying relationship** are listed in the **HT Act in descending order**.¹

- i. spouse or partner (including civil or same sex partner) The HT Act states that, for these purposes, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.
- ii. parent or child (in this context a child may be of any age and means a biological or adopted child)
- iii. brother or sister
- iv. grandparent or grandchild
- v. niece or nephew
- vi. stepfather or stepmother
- vii. half-brother or half-sister
- viii. friend of long standing

¹ The qualifying relationships in Scotland are different and are set out in the HT (Scotland) Act.
103. Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person high up the list refuses to give consent, it is not possible to act on consent from someone further down the list. For example, if a spouse refuses but others in the family wish to give consent, the wishes of the spouse must be respected. However, the guidance in paragraphs xx should be observed in line with this principle.

104. If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person's body or tissue for scheduled purposes.

105. While the HT Act is clear about the hierarchy of consent, the person giving consent should be encouraged to discuss the decision with other family members.

106. Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just one of them, provided they are ranked equal highest. For example, if the deceased person has no spouse or partner, but has several children, the consent of only one child is required.

107. Where there is a conflict between those accorded equal ranking, then this needs to be discussed sensitively with all parties (see also paragraphs xx which provide further guidance on handling difficult situations), whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead.

108. In applying the principles set out above, a person's relationship shall be left out of account if:

   i. they do not wish to deal with the issue of consent
   ii. they are not able to deal with the issue
   iii. in relation to the activity for which consent is sought, it is not practical to communicate with that person within the time available if consent in relation to the activity is to be acted on
   iv. This means a person may be omitted from the hierarchy if they cannot be located in reasonable time for the activity in question to be addressed, declines to deal with the matter or is unable to do so, for example, because they are a child or lack capacity to consent. In such cases, the
next person in the hierarchy would become the appropriate person to give consent.

**Children**

109. **Under the HT Act**, a child is defined as being under 18 years old. A child aged 12 and over, who is able to make their own decisions can give [authorisation for their organs or tissue to be donated](#).

110. The position of a child who, before they died, was competent to reach a decision and gave consent for one or more scheduled purposes to take place after their death, is no different from that of an adult. Their consent is sufficient to make lawful the removal, storage or use of tissue for that purpose. In the Gillick case, the court held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them fully to understand what was involved. The principle of ‘Gillick competence’ does not exist in Scottish law. Since there are extra sensitivities to take into consideration where the deceased donor is a child, the situation should be managed accordingly.

111. If a child consents to a procedure, then this consent carries over into adulthood unless they withdraw their consent.

112. In the case of [anatomical examination](#) or public display, written, [witnessed consent is required from the child](#). Those with parental responsibility at the time of the child’s death cannot agree to the use of their body after death for these purposes.

113. In some cases, it may be advisable to establish with the person who had parental responsibility for the deceased child, whether the child was competent to make the decision. A person who has parental responsibility will usually, but not always, be the child's parent. Clearly, in any case where a child has consented to the use of their body or tissue, it is essential to discuss this with the child's family.

114. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that the appropriate consent will be that of a [person with parental responsibility for the child](#). The consent of only one person with parental responsibility is necessary.

115. The issue should be discussed fully with relatives and careful thought should be given as to whether to proceed if a disagreement arises between parents or

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2 Under the HT (Scotland) Act, a child is defined as being under 16 years old.
other family members. Any previously stated wishes of the deceased child should be considered, taking into account their age and understanding. Further guidance is included in the code of Practice on donation of solid organs for transplantation and code of Practice on Post Mortem examination.

116. If there is no person with parental responsibility (e.g. if the parents have also died, perhaps at the same time as the child), then consent should be sought from someone in a qualifying relationship, (see section on qualifying relationships, paragraphs xx). Under the HT Act, children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

Providing information about the process

117. When seeking consent from a nominated representative or from a person in a qualifying relationship, full and clear information should be provided about the purpose for which consent is being sought. This should allow them to make a properly considered decision. This information should include the nature of the intended activities and the reasons for them.

118. Healthcare professionals need to tailor the information they provide to each specific situation, as some people may insist on in-depth detail, whereas others would prefer to consent having only had the basics of the procedure explained to them. Trust policy should set out a minimum amount of information for healthcare professionals to provide, see the HTA's Directions 001/2006 which set out requirements for establishments licensed under the Q&S Regulations. Some people will want more detail than others about, for example, Post Mortem procedures and this information should be provided in accordance with their wishes (see the code of Practice on Post Mortem examination). Further information may be found in the sections on the duration of consent, paragraphs 41-42 and use of documentation, paragraphs 69-73.

119. The way in which the options are discussed with the deceased person's family is extremely important. They should be approached with sensitivity and given:

- honest, clear, objective information
- the opportunity to talk to someone of whom they feel able to ask questions
- reasonable time to reach decisions (about a hospital Post Mortem and about any donation of organs or tissue)
- privacy for discussion between family members, if applicable
- support if they need and want it, including the possibility of further advice or psychological support.
**Disclosing information about the deceased**

120. Care should be taken regarding the possible disclosure of information, such as genetic information (see section on consent and the use of DNA, paragraphs xx) or HIV status, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members. Healthcare professionals will have to make a decision based on the individual circumstances of each case about whether it is appropriate or not to disclose information about the deceased's medical history, as well as any other sensitive information that the Trust may hold (about the deceased), that the family may not necessarily be aware of. In making decisions, healthcare professionals will have to have regard to their duty of patient confidentiality and may have to consider the provisions of the [Data Protection Act 1998](https://www.legislation.gov.uk/ukpga/1998/29). In certain circumstances, it may be necessary to share sensitive information with the family if the results of the activity have the potential to affect them or other relatives. For further guidance see [GMC guidance on confidentiality](https://www.gmc-uk.org/confidentiality) and the [Department of Health's guidance on confidentiality](https://www.gov.uk/government/publications/confidentiality-after-death) which deals with disclosing information after a patient has died. See also the [Welsh Assembly Government's guidance on confidentiality](https://www.gov.wales/topics/protection-information-life-death/confidentiality-after-death/).

**Written consent**

121. Written, witnessed consent is always needed for [anatomical examination](https://www.npsa.nhs.uk/advice-and-guidance/consent/anatomical-examination/) and for public display of bodies or body parts (see the [Codes of Practice on anatomical examination](https://www.hpa.org.uk/hpafiles/hpa/wellbeing/anatomical_examination/consent_anatomical_examination.pdf) for detailed guidance).

122. Written consent should be obtained wherever possible for all other activities involving the deceased. If verbal consent is obtained, this should be clearly documented in the patient's records (see paragraph xx).

123. Model consent forms are available for Post Mortem and anatomical examination on the HTA's website. In Northern Ireland, HSC Trusts and other relevant organisations should use the standardised consent forms agreed with the DHSSPS. HTA [model consent forms](https://www.hpa.org.uk/hpafiles/hpa/wellbeing/anatomical_examination/consent_anatomical_examination.pdf) provide a suggested format for Trusts obtaining consent for the above purposes. The forms are not prescriptive due to local variations in Practice and may be adapted as necessary, providing they comply with the HT Act and the Codes of Practice. Consent forms are only one part of the consent process and should be completed after appropriate discussion and more detailed explanation where necessary.

**Seeking consent for multiple activities**

124. When someone has died, healthcare professionals may wish to seek consent for more than one scheduled purpose. For example, if a [Post Mortem](https://www.hpa.org.uk/hpafiles/hpa/wellbeing/anatomical_examination/postmortem.pdf)
examination is to be carried out, some tissue samples could also usefully be obtained for research purposes. In this case, it would be appropriate to seek the relevant consent to both activities. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking consent on repeated occasions. Research is one example (for further guidance about tissue to be used for research see paragraphs xx).

125. Where consent has been given for the use of tissue or organs after death for transplantation, separate consent is required for its storage and use for research purposes. In such cases, the necessary consents should ideally be sought in a single consent process and recorded in the same place.

126. In the case of Post Mortem tissue, and unless authorised by a coroner, all storage and use for scheduled purposes requires consent. But, if consent to the storage or use of Post Mortem samples by whoever originally consented to their storage or use is withdrawn, this must be respected for any samples that are still held. Healthcare professionals should discuss with the person concerned how the samples should be returned to them or disposed of, and tell them about any samples that may have already been used or disposed of.

Section Two - Part 3: Tissue from the living

127. Under the HT Act, consent from the living is needed for storage and use of tissue for:

   i. obtaining scientific or medical information which may be relevant to any person including a future person
   ii. public display
   iii. research in connection with disorders, or the functioning, of the human body (but see paragraphs xx, and
   iv. transplantation.

128. Under the HT Act, consent from the living is not needed for storage and use of tissue for:

   i. clinical audit
   ii. education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
   iii. performance assessment
   iv. public health monitoring
   v. quality assurance.

(See Appendix A)
129. Consent to treatment and examination is covered by common law and the MC Act where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health’s guidance. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government’s Reference guide to consent for examination and treatment. The DHSSPS (Northern Ireland) has published its own Reference guide to consent for examination, treatment or care. See also the GMC guidance on consent and decision making in Consent: patients and doctors making decisions together.

130. Tissue may be taken in a variety of circumstances, for example:

i. in the course of diagnostic procedures, e.g. taking a blood or urine sample, tissue biopsy, cervical screening, etc

ii. in the course of treatment, e.g. removing tissue (organs, tumours, etc.) during surgery

iii. when removed specifically for the purpose of research.

131. Although consent for treatment and examination is dealt with under the common law and consent for scheduled purposes is dealt with under the HT Act, the consent for each activity may be obtained at the same time. It is still important to explain clearly the activity for which consent is being obtained, including the risks and wider implications. Further guidance on this issue in respect of obtaining consent for donation may be found in the code of Practice on donation of solid organs for transplantation.

Who may give consent?

Adults who have capacity to consent

132. If an adult has the capacity to make the decision in question, then only they are permitted to give consent.

133. Surplus tissue is often an important source of material for research and consent procedures may include an agreement to its use. The HT Act makes it lawful to dispose of surplus tissue. See the code of Practice on disposal of human tissue for further guidance.

Adults who lack capacity to consent

134. The HT Act does not specify the criteria for considering whether an adult has capacity to consent.
135. Under the **MC Act** a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

iv. understand the information given to them that is relevant to the decision
v. retain that information long enough to be able to make the decision
vi. use or weigh up the information as part of the decision-making process
vii. communicate their decision by any means.

136. Full guidance on how the MC Act defines capacity and how it should be assessed is given in chapter 4 of the **MC Act code of Practice**.

137. The provisions of the **MC Act** should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the [Office of Public Guardian website](https://www.justice.gov.uk) and in the **MC Act code of Practice**. There is separate guidance for Wales and for Northern Ireland. The **Adults with Incapacity (Scotland) Act 2000** governs adults who lack capacity in Scotland.

138. The MC Act governs decision-making on behalf of adults (aged 16 and over) who lack capacity if unable to make a decision in relation to a matter at the relevant time because of an impairment of, or disturbance of, the mind or brain, whether permanent or temporary (see paragraph xx. For the purposes of the MC Act, unlike the HT Act, an adult is a person aged 16 or over. The MC Act only applies to persons aged 16 or over.

139. There are detailed provisions contained in the **MC Act** concerning decisions made on behalf of adults lacking capacity. All decisions must be made in the person's best interests, as laid out in chapter 5 of the **MC Act code of Practice**. Also, certain categories of people have a legal duty to have regard to the MC Act code of Practice, when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in chapter 6.

140. The **MC Act** defines persons who lack capacity, see chapter 4 of the **MC Act code of Practice**, and contains a set of key principles and a checklist to be used in ascertaining best interests, see chapter 5 of the **MC Act code of Practice**. The first core principle of the MC Act is that an adult must be assumed to have capacity to make a decision for themselves, unless it is established that they lack capacity to make the particular decision at the time the decision needs to be made.

141. It should therefore always be assumed that an adult has the capacity to make a decision unless there is reason to believe otherwise.
Individuals may sometimes temporarily be unable to make a decision, for example people affected by trauma, illness or shock. It may therefore not be appropriate to seek consent at that time and in some cases it may be necessary to put off the decision until the person has the capacity to make it, as laid out in the MC Act. See chapter 4 of the MC Act code of Practice for further guidance.

Some adults may have capacity to make decisions about some matters, but not others. The MC Act requires that care should be taken to ensure that patients are given every opportunity, and support where needed, to make their own decisions, see chapter 3 of the MC Act code of Practice.

A person must not be treated as unable to make a decision unless all practicable steps to help them do so have been taken without success, nor must they be treated as being unable to make a decision merely because they make an unwise decision.

The ability of adults with learning difficulties, or with limited capacity to understand should not be underestimated. Where appropriate, someone who knows the individual well, such as a family member or carer, should be consulted, as they may be able to advise or assist with communication.

Since the MC Act came into force a person aged 18 or over may make a Lasting Power of Attorney (LPA). This allows for an attorney to make certain decisions in circumstances where the person no longer has capacity. One type is a personal welfare LPA, which provides for the appointment of a person to make certain healthcare decisions on their behalf. Where an LPA exists, it is good Practice to check the detail to see if the attorney has the authority to make the decision in question. Detailed guidance on the role of the attorney is set out in chapter 7 of the MC Act code of Practice.

Storage or use of tissue from adults who lack capacity to consent is permitted in certain circumstances specified in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

Children

Under the HT Act, a child is defined as being under 18 years old. Under the HT (Scotland) Act, a child is defined as being under 16 years old. A child aged 12 and over, who is able to make their own decisions can give authorisation for their organs or tissue to be donated.

Children may consent to a proposed medical procedure or the storage and use of their tissue if they are competent to do so. In the Gillick case, the court
held that a child was considered competent to give valid consent to a proposed intervention if they had sufficient intelligence and understanding to enable them fully to understand what was involved. The concept of Gillick competence does not exist in Scottish law. The legal position on obtaining consent to treatment is set out in the Department of Health's guidance. Consent documents for Wales can be found at on their website and the DHSSPS (Northern Ireland) has published its own Reference guide to Consent for examination, treatment or care.

150. If a child consents to a procedure, then this consent carries over into adulthood unless they explicitly withdraw it.

151. **Under the Children Act 1989, a person who has parental responsibility** for the child may consent on their behalf only if the child has not made a decision either way; and the child:

   viii. is not competent to do so; or
   ix. is competent to do so, but is unwilling to make that decision.

152. **A person who has parental responsibility will usually, but not always, be the child's parent.** See also the GMC guidance 0-18 years: guidance for all doctors.

153. Where there is any dispute between persons with parental responsibility or any doubt as to the child's best interests, the matter should be referred to court for approval. The need to refer cases to court does not apply to Scotland. For further guidance on court approval in cases of potential donation, see the Codes of Practice on Donation of solid organs for transplantation and code of Practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.

154. Even if the child is competent to consent, it is good Practice to consult the person who has parental responsibility for the child and to involve them in the process of the child making a decision. However, it should be emphasised that, if the child is competent, the decision to consent must be the child's. Information about a competent young person should only be disclosed to the person with parental responsibility for the child with the child's consent. It is also essential to make sure that a child has consented voluntarily and has not been unduly influenced by anyone else.

**Steps to take**

155. To give consent, the individual (or the person with parental responsibility) should understand the nature and purpose of what is proposed and be able to make an informed decision. They should be told of any 'material' or 'significant'
risks inherent in the way the sample will be obtained, how the tissue will be used and any possible risks or implications of its use, e.g. genetic tests. If the person concerned is not a patient, and is volunteering samples purely for research, the general principles of providing appropriate information still apply (see paragraphs 33-38 on valid consent).

156. Healthcare professionals should try to find out about the individual's needs and priorities when telling them about their options. Some people may not be interested in knowing the full details about the proposed use of the tissue and it is good Practice to record this in the notes. People should nevertheless have all their options explained to them and be provided with an appropriate level of information. See GMC guidance on Consent: patients and doctors making decisions together.

157. If identifiable tissue is to be used for research, donors should be informed about any implications this may have. For example, they may be contacted by researchers, given feedback, or be asked for access to their medical records. Donors should be asked whether the consent they are giving is generic (for example, for use in any future research project, or specific). If it is the latter, detailed information about the research project should be provided, in line with good Practice. Researchers will need to consider how they deal with tissue samples in the event of a later loss of capacity. There are certain safeguards which need to be in place where research involving adults who lack capacity is concerned (See the code of Practice on research for further detail).

158. Donors should be told if their samples will or could be used for research involving the commercial sector. They should be given appropriate information on the range of activities and researchers which may be involved, and whether these include commercial establishments. The HTA also advises that is good Practice that donors are provided with adequate information upon giving consent, should their samples be exported for use abroad (see the code of Practice on import and export of human bodies, body parts and tissue for further information).

Powers deeming consent to be in place

159. Section 7 of the HT Act allows the HTA to dispense with the need for consent in certain circumstances, as set out in paragraph xx.

160. The HTA has the power to deem consent to be in place for relevant material from someone who is untraceable, or who has not responded to requests for consent to use of their material, if that material could be used to provide information relevant to another person. This may be important where information could be obtained about the treatment and diagnosis of the applicant. The HTA
has prepared guidance on the implementation of these provisions in relation to DNA analysis (see paragraphs xx on Consent and the use of DNA).

Fetal tissue

161. The law does not distinguish between fetal tissue and other tissue from the living; fetal tissue is regarded as the mother's tissue. Consequently, fetal tissue is subject to the same consent requirements under the HT Act as all other tissue from the living (see section on tissue from the living, paragraphs xx). However, because of the sensitivity surrounding pregnancy loss, it is good Practice to always obtain consent for the examination of fetal tissue and for its storage or use for all scheduled purposes.

162. It is also good Practice to obtain consent for research on non-fetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is non-identifiable.

163. It should be noted that the reference to fetal tissue within this code does not include stillbirths (babies born dead after 24 weeks gestation), or neonatal deaths (babies or fetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Obtaining consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for gaining consent for use of the tissue of the deceased (see paragraphs xx). It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.

164. It is recognised that, in the absence of specific legal requirements, guidance on the use of fetuses and fetal tissue for research has been derived from the 1989 Review of the Guidance on the Research Use of Fetuses and Fetal Material, also known as the Polkinghorne Guidelines. A number of aspects of the Polkinghorne Guidelines are outside the remit of the HTA and of this code of Practice. However, it should be noted that guidance within the Polkinghorne guidelines which recommended that in the context of giving consent, women should not know the purpose for which the fetus would be used, or whether it would be used at all, is now superseded by guidance within this code on valid consent, which must be based on the person's understanding of what the activity involves (see section on valid consent paragraphs 33-38).

165. Pregnancy remains of less than 24 weeks gestation are considered to be the mother’s tissue. The HTA has published guidance on the disposal of pregnancy remains, which reflect the very sensitive nature of these; this can be found here.
1. **Appendix A**
   Existing Appendix A from Code 1

2. **Appendix B**
   Existing Appendix B from Code 1
Annex B

Draft Post Mortem Sector Code

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Introduction

2. Post-mortem (PM) examination in all its forms is important for informing relatives\(^3\), healthcare professionals and other interested parties about the cause of death. It may also inform individuals about possible acquired or genetic diseases that may need treatment and care. More generally, PM examination is considered by clinicians to be important in improving clinical care, maintaining clinical standards, increasing understanding of disease, identifying the spread of infectious diseases and supporting research and training.

3. The HTA’s remit is to ensure that PM examinations are undertaken with appropriate consent or under the authority of the coroner, and on suitable premises licensed for that purpose. It is also to ensure that PM examination and the removal and retention of any organs or tissue samples, including those processed into wax blocks and microscope slides, comply with the requirements of the HT Act.

4. This code applies to those directly involved in performing PM examinations – pathologists and anatomical pathology technologists (APTs). It may also inform the practice of others such as coroners authorising PM examinations, their officers, who are in direct contact with relatives, bereavement staff and funeral directors.

Scope of this code

5. The HTA regulates, through licensing, establishments which carry out full, limited and minimally invasive PM examinations. This includes PM activity undertaken in emergency mortuaries. Further information on emergency mortuary licensing is available on the HTA’s website.

6. The licensing requirements do not apply to establishments where only non-invasive PM examinations are undertaken (for example CT scanning and CT coronary angiography); these will already be subject to the hospital’s own systems of governance and operational standards (see paras xxx-xxx). Nor do they apply to premises where bodies not subject to PM examination are stored prior to release for burial or cremation. However, much of the guidance contained in this code may be taken to apply equally to these activities.

7. The guidance on consent in this code applies to the storage and use of a body after death for the scheduled purposes defined in the HT Act, including

\(^3\) Throughout this code, the term ‘relatives’ should be taken to include partner and, in cases where there are no relatives, close friends of the deceased person.
determining the cause of death. This includes full, limited, minimally invasive and non-invasive PMs. Establishments should have suitable procedures in place for ensuring proper compliance with the HT Act and observing the good practice set out in the HTA’s codes of practice, which includes ensuring that the bodies of the deceased and tissue taken from them are treated with respect, and the dignity of the person is maintained.

8. The code contains guidance on how to communicate with the relatives of people whose death has required a PM examination, whether or not ordered by the coroner. It also makes reference to the licensing standards that professionals working within licensed establishments are expected to meet.

9. The code seeks to ensure that:

- those engaged in activities regulated under the Human Tissue Act 2004 are aware of statutory and regulatory requirements
- the guiding principles of consent, integrity, professionalism and candor inform and underpin the conduct of these activities
- relatives of the deceased person understand the reasons for the PM examination, the processes involved, and their rights in the decision-making process
- where possible, the wishes of the deceased person and their relatives are known, understood and taken into account
- tissue is only retained following PM examination with consent, or the authority of the coroner, or for criminal justice purposes
- there is good communication between all parties involved.

10. This code should be read in conjunction with code A, Guiding principles and the fundamental principles of consent, which sets out the principles which govern the conduct of activities within the HTA’s remit and which informs the content of this and the other codes. Those involved carrying out post mortem examinations, should also familiarise themselves with the HTA’s licensing standards on PM examination.

**Structure and navigation**

11. As most PM examinations are conducted under the authority of HM Coroner, the first part of the code gives information about these in the context of human tissue legislation.

12. Then there is a section on hospital PM examinations, which sets out the legal requirements in relation to consent, the information that should be provided to relatives of the deceased and how this should be conveyed.
13. The later sections of the code cover a range of topics such as training and support for staff, tissue and organ donation, the removal of PM tissue for use for Scheduled Purposes under the HT Act and storage. Finally, at the end of the code, there is a brief section explaining the HTA’s licensing standards.

**Status of this code**

14. This Code of Practice was approved by Parliament on xx April 2016 and was brought into force by Directions dated xx April 2016.

**Using the code**

15. Throughout the code, the word ‘must’ applies to all legal requirements derived from primary and secondary legislation – for example, the requirement to hold a licence to store human tissue for use for a scheduled purpose – and to the HTA’s licensing standards. We use the word ‘should’ when providing advice on how to meet these requirements.

16. Establishments are expected to follow the guidance contained in the codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a code of practice is not in itself a criminal offence under the HT Act but the HTA will consider carefully any breach of a code of practice and in doing so may take appropriate regulatory action.

17. The code places emphasis on consent and communication. Consent should be seen as part of a process in which individuals and their relatives may discuss the issue fully, ask questions and make an informed choice. At all times, relatives should be treated with respect and sensitivity to help them take important decisions at a difficult time. The standards expected when seeking consent are referred to in this code, but are explored in much greater detail in the HTA’s licensing standards.

**The coroner’s post-mortem examination**

18. PM examinations under coronial authority enable coroners to carry out their statutory functions to determine the identity of the deceased person and the cause of death. Coroners are empowered to authorise a PM examination following any sudden death of unknown cause or unexpected death.

19. A PM examination and the removal and storage of tissue samples to determine the cause of death do not require consent from the relatives if these activities have been authorised by the coroner. This includes the removal of samples
outside of the mortuary environment, for examples in cases of sudden infant death syndrome, where samples may be taken from a deceased infant in the Accident and Emergency Department of the NHS hospital.

20. Although the consent of relatives is not required, the reasons for the PM examination, why the coroner is involved and the process that will be followed should be explained to them. As coroner’s PM examinations are primarily undertaken to identify the cause and circumstances of death, it should be explained to relatives that the results may be limited in scope.

21. As a minimum, the relatives should be given information about when and where the examination is to be performed. They should be given contact details for the coroner’s officer, should they have questions about the process.

22. Relatives of the deceased have the right to be represented at the PM examination by a medical practitioner. The PM examination may be observed by healthcare professionals, police, paramedics and others as part of their training, with the consent of the coroner.

23. In some cases, where it is the wishes of the family, a CT scan or other form of imaging may be used. The coroner will decide what type of examination is necessary, with the assistance of the pathologist, after there has been a thorough external examination of the body. The family should be informed of the limitations of imaging and that despite the use of imaging a conventional post mortem examination may still be required.

24. For further information about coroners’ PM examinations, including the provision of the PM report, see the Ministry of Justice (MoJ) Guide to Coroner Services.

RetentionPolicy to determine the cause of death

25. Under The Coroners (Investigations) Regulations 2013, the pathologist must notify the coroner in writing of any material they have retained, setting out why they believe it relates to the cause of death or the identity of the deceased. The pathologist may suggest various retention periods. The coroner, in turn, must notify the pathologist of how long the material must be kept. This period must not exceed the time to discharge the coroner’s functions (these rules do not apply in Northern Ireland).
26. The coroner must also notify the relatives that material has been retained, how long it will be retained for and the options for dealing with the material once it is no longer required for the coroner’s purposes (see paras xxx – xxx below). A coroner’s officer (in Northern Ireland, referred to as a coroner’s liaison officer) will usually make contact with the family; however, the coroner’s officer may not always be the best person to speak to relatives about the PM examination and the issue of retention and, depending on the nature of the case and their concerns, relatives may need access to people with specialist knowledge to talk through any questions they may have. In any event, the person giving information to the family should have knowledge of the HT Act.

**Disposal following coroners’ post-mortem examinations**

27. Once the coroner’s authority has ended, it is not lawful to use or store tissue for a scheduled purpose set out in the HT Act without consent. Nor is it lawful to store tissue for a scheduled purpose without a licence, subject to certain exemptions. The Coroners Regulations place an obligation on the coroner to inform the family what their options are once the coroner’s authority has ended. It is important that the family understand the options available to them to enable them to make a fully informed decision. The three options are:

- disposal of the material by burial, cremation or other lawful means by the pathologist;
- return of the material to relatives to make their own arrangements; or
- further retention of the material with appropriate consent for use for medical research or other purposes, in accordance with the HT Act.

Establishments should have a policy that governs the disposal of tissue when this is the decision of the relatives.

28. *Example – an establishment has worked with the local coroner to produce an information leaflet about the relatives’ options for disposal or retention of tissue following a PM examination. This document reflects the establishment’s disposal policy and associated restrictions, e.g. it notes that local crematoria will not accept blocks and slides, so therefore this option is not available for this type of material. The leaflet provides information for relatives to help inform their decision, explaining, for example, that the cremation of organs will not produce any ashes and that returning the material to the body may cause a delay to funeral arrangements. The document also contains useful contacts at the establishment storing the material, the local crematoria and the burial grounds.*

29. When the coroner has communicated the family’s decision to the pathologist or establishment holding the material, the pathologist should act on this information
as soon as possible following the expiry of the coroner’s authority. Problems arise when relatives do not, or cannot, communicate their decision about what they wish to happen to the tissue. This creates uncertainty about the lawfulness of retention beyond expiry of the coroner’s authority. Therefore, coroners should, when advising families about the options for disposal, ask the family to make a decision by the time that appropriate forms are issued by the coroner releasing the body for burial or cremation.

30. Example – A coroner’s investigation has included a PM examination. The coroner’s officer has attempted to discuss the disposal of tissue removed during the PM examination with the family, but they have said they are too upset by their bereavement to contemplate the question. Despite their bereavement, they still have to decide about their options for funeral arrangements. The coroner’s officer respectfully and sensitively obtains a specific decision on the disposal / retention options when they discuss the procedure relating to various funeral options. The decision is then communicated immediately to the pathologist who takes the appropriate action as soon as possible following the expiry of the coroner’s authority.

31. Good communication between coroners and pathologists is essential in order to ensure that tissue is not stored indefinitely without consent. The HTA recommends that a nominated person is identified to handle the communications channels between the pathology department and the coroner’s office and, where necessary, the family. The nominated person should ensure that decisions are passed to and within the pathology department and there is no uncertainty about tissue disposal or retention when the coroner’s authority has expired. The HTA has published a model communication flowchart to support good communication between coroners and pathologists.

32. If the family do not, or cannot, communicate their decision about what they wish to happen to the tissue, the nominated person should advise that the tissue will be held for three months by the pathology department from the time the coroner’s authority ends, pending notification of a decision by the family. It should be made clear that if no decision is communicated within that time, the tissue will be disposed of. In such situations, the nominated person should inform the pathology department that the family have not made a decision, and at the end of the three month period, the tissue should be disposed of respectfully (see paras xxx below).

33. It is also important that the family understands what may be involved if they consent to the continued retention and use of the tissue for medical research or other purposes, and that this is communicated to and within the pathology department. In these cases, appropriate consent should be obtained in line with
the provisions set out in code 1 (see sections on nominated representatives and qualifying relationships).

34. Relatives should not be led to believe that tissue will definitely be used for medical research, as this may affect the choice they make.

**Working in collaboration**

35. Establishments should work closely with the coroners authorising PM examinations undertaken on their premises. A protocol should be established between the two parties identifying the roles and responsibilities of each and flexible enough to meet relatives' needs sensitively.

36. The coroner should inform the establishment of the relatives' decision about the options for the continued retention or disposal of retained material and, where a decision has been made, this should be documented. This information should be supplied before the coroner’s authority ceases. In any event, where tissue has been retained, the establishment should receive notification from the coroner when the investigation has closed and should act on the wishes as soon as possible after they have been received.

37. Laboratories that carry out specialist analysis for the coroner such as toxicology, which are not based in a hospital environment, should also be informed when the coroner’s authority has expired to avoid them storing samples unnecessarily and without consent. This includes organs sent for specialist examination.

**Criminal investigations**

38. If a person dies in circumstances which are considered ‘suspicious’ or where homicide is suspected, the coroner will authorise a Home Office registered forensic pathologist to perform a forensic post-mortem examination in order to ascertain the identity of the deceased, the cause and circumstances of death and to allow the collection of evidence. During the post-mortem examination, tissue and or organs may be removed from the body by the pathologist for the purpose of further investigation such as toxicology, histology and examination by other experts.

39. Consent is not required to retain material for the purposes of a criminal investigation, nor does material taken for this purpose need to be held on licensed premises. Such material is subject to the requirements of police legislation relating to the seizure and retention of evidence. Where material is held under the authority of the police, or joint authority of a coroner and the
police, the section 39 exemptions of the HT Act apply [include link].

40. Material taken or retained under police authority only is not subject to the provisions of the HT Act. However, section 7.8.6 of _The Forensic Science Regulator’s guidance (building on Home Office guidance) on legal issues relating to forensic pathology_ advises the police, where practical, to dispose of the material in compliance with the HTA’s requirements.

41. Following a police investigation, the police will make a decision as to whether to continue retention of the tissue. If retention is no longer required, the tissue will be offered to the coroner as it may be relevant to the coronial inquiry. If the coroner does not require the tissue, the police will dispose of it. If the coroner does require the material, it must then be held on licensed premises.

42. Material held by the police or the coroner which is historic and has not been appropriately disposed of should be subject to review, with the relevant party, to determine whether its continued use is necessary; if it is not, it should be disposed of in line with the guidance contained in this code.

The hospital post-mortem examination

43. Following a death where a medical certificate of cause of death (MCCD) has been issued, the treating clinician may wish to request a PM examination to investigate further the cause of death, to improve knowledge of the disease or effectiveness of the treatment given. Where it can be issued, it is not acceptable to withhold the issue of an MCCD in order to refer a death to the coroner. Occasionally, a family may request a PM examination following the death of a relative.

44. Consent must be sought for full, limited, minimally invasive and non-invasive PM examinations, and the benefits and limitations of each of these should be explained.

45. Where consent has not been given by the person in life, consent for a hospital PM examination may be given by the deceased person’s nominated representative (if there is one), a person in a qualifying relationship (see paras xx-xx) or, in the case of a child, those with parental responsibility.

46. Consent must be given before the PM examination is undertaken to ensure proper compliance with the HT Act. Therefore, before the PM examination begins, the pathologist must check that it has been properly consented to, either by the deceased person before they died or their relatives.
47. Consent is valid only if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating (e.g. because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.

48. Model consent forms for hospital PM examination of an adult are available on the HTA’s website. The forms are not prescriptive, due to local variations in practice, and may be adapted as necessary, providing they comply with the HT Act and the codes of practice. Consent forms are part of the consent process and should be supplemented with further discussion and more detailed explanation where necessary. In Northern Ireland, HSC Trusts and other relevant organisations should use the standardised consent forms agreed with the DHSSPS. Forms are available for adults and children older than 28 days, for early miscarriages less than 12 weeks gestation and for intrauterine deaths greater than 12 weeks gestation and neonates up to 28 days. Accompanying information leaflets for each of these forms are also available.

49. During the PM examination, tissue or whole organs (e.g. the heart) may be removed for further examination to determine the cause of death. In practical terms, this means that consent to the PM examination and consent to the removal, storage and use of organs and tissue to help determine the cause of death are two separate decisions.

50. Tissue or organs may also be retained for future use for other scheduled purposes such as research or education and training. Separate consent should be obtained for the removal and future storage and use of organs and tissue (including blocks and slides) for scheduled purposes.

51. A signed copy of the consent form should be included in the deceased’s medical record. A copy of the consent form should also be given to the person giving consent.

**Religion, culture and language**

52. Attitudes towards PM examination, in particular the removal of organs and tissue and their use after death, differ greatly and the individual needs of each family must be considered. For example, for religious or other reasons, a family may prefer a CT scan to an invasive PM examination, or they may wish for the funeral to take place as soon as possible; these requests should be discussed sensitively and openly, with every effort made to meet the family’s requirements without compromising the clinical outcome. If the outcome is likely to be compromised,
an explanation of how and why will be required.

**Who may seek consent for hospital post-mortem examinations?**

53. Anyone seeking consent for hospital PM examinations should have relevant experience and a good understanding of the procedure. They should have been trained in dealing with bereavement and in the purpose and procedures of PM examinations and they should ideally have witnessed a PM examination. Those involved may include a member of the medical team involved in the care of the patient prior to their death, and may also include someone closely aligned to pathology such as an APT or a specialist nurse.

54. It is usually the responsibility of the deceased person’s clinician to raise the possibility of a PM examination, knowing the medical problems and the unresolved aspects that merit investigation. However, there may be several options for who actually discusses the PM examination with the relatives and a team approach is common. Responsibility for obtaining consent should not be delegated to untrained or inexperienced staff.

55. Due to the very small number of hospital PM examinations that are now carried out, staff seeking consent may not have the opportunity to undertake this task on a regular basis and therefore there is a risk it may not be undertaken effectively. The establishment should provide staff members with a documented consent procedure, ensuring that the information provided to relatives, and the manner in which consent is sought, are consistent.

56. Wherever possible, it is good practice for consent to be obtained by a person with whom the relatives have established a relationship. If the consultant in charge has not had close dealings with the patient’s family during the last illness, relatives may find it helpful to have someone present whom they know and trust.

57. Example – Some Trusts use trained bereavement officers or APTs to seek consent for PM examination, supported by the treating clinicians and pathologists. By nominating a small number of trained people and ensuring that they are regularly involved with seeking consent for post mortem, the Trust can manage ongoing training effectively.

58. Whichever approach is taken, the hospital should have a named individual who can provide support and information to the relatives.

59. Before the discussion with relatives, the responsible clinician should consider obtaining advice from a pathologist on which, if any, tissue is likely to be retained, for how long and for what purpose. Thereafter, the pathologist undertaking the
PM examination should be available for a discussion with the relatives if they wish for further information.

60. The pathologist conducting the PM examination may feel that conditions imposed by relatives calls into question or limits the value of the PM examination. In such cases, the pathologist should advise relatives of these limitations or, if necessary, that the investigation will not be carried out because it would be uninformative. This eventuality should be explained to relatives at the time of discussion. However, pressure should not be exerted on them as this would render invalid any consent given.

61. Although healthcare professionals may recognise the need to obtain a speedy decision in order to maximise the benefit from a hospital PM examination, it is important that they do not convey to relatives any sense of being rushed. Before the PM examination, relatives may want to spend as much time as possible with the family member who has died and it is important to try to ensure that they have this time. However, if more information or better results might be obtained from an early examination, this should be explained.

62. Consent may be given over the phone or, after a telephone conversation, by email. In these cases, checks should be made to ensure that the appropriate person has consented (see paragraphs xxx-xxx). The content of the telephone conversation should meet the requirements of paragraph xx and be documented. Pathologists must satisfy themselves that the consent was appropriate and valid before proceeding with a PM examination.

63. Once a decision has been made to proceed with the PM examination and consent has been given, the family should be given the opportunity to change their minds or to change the scope of the PM examination. The time relatives have to reflect on their decision and the point up to which they may withdraw their consent should be clearly stated and should not be less than 12 hours. The HTA recommends 24 hours.

Who may give consent for a hospital post-mortem examination?

64. Appropriate consent in the HT Act, means:

- the consent of the deceased person (if a decision to, or not to, consent was in place immediately before death)
- where (i) above does not apply, the consent of a nominated representative appointed by the deceased person to deal with this issue
- where (i) and (ii) above do not apply, the consent of someone in a ‘qualifying relationship’ to the deceased person immediately before that
person died. More information on qualifying relationships and other aspects of consent is contained in code 1.

65. Whilst it may be legally possible to carry out activities with the consent of the highest-ranking qualifying person (where no decision was made by the deceased person and there is no nominated representative), consideration should be given to the possibility of this causing distress and resentment in other family members if there is disagreement.

66. Where the deceased is a child (for the purposes of the HT Act, below the age of 18), consent may be given by them before they died (if competent to reach a decision to consent); this is, however, rare in practice. In these cases, consent can be given by a person with parental responsibility for them immediately before they died; or in the absence of a person with parental responsibility, a person in a ‘qualifying relationship’ to them at that time (see code 1). A person who has parental responsibility will usually, but not always, be their parent.

67. In relation to PM examination of a baby or young child, the Stillbirth and neonatal death charity (Sands) has published detailed guidance on communication with women or couples regarding all areas of pregnancy loss which may be found on the Sands website.

68. Fetal tissue is considered in law to be the mother’s tissue but it is good practice to seek consent for examination of pregnancy remains, regardless of gestational age. (Include reference to new guidance).

69. Women who have been the victim of a violent attack which has resulted in the loss of their unborn child need expert support to help them decide whether or not to consent to a PM examination of their baby, as this cannot be authorised by the coroner. A multi-agency approach, including liaison with the police, will be necessary.

**Discussing the post mortem with the family**

70. The way in which a PM examination is discussed with the deceased person’s relatives is extremely important. They should be given:

- honest, clear, objective information
- the opportunity to talk to someone of whom they feel able to ask questions
- reasonable time to reach decisions (for example about the retention or donation of tissue)
- privacy for discussion between family members, if applicable
• emotional or psychological support if they need and want it (support may be available from an organisation with which a relative is already in touch, particularly if they have been a long-term carer of the deceased person)
• the opportunity to change their minds, within an agreed time limit.

71. Discussions should be face-to-face if possible, so that all necessary issues and questions are addressed and all parties are clear about what is agreed. A comfortable, private room should be used.

What the discussion should cover

72. Relatives should be offered full and clear information about the purpose of the PM examination, the range of choices available to them, the potential uses for any material retained and the disposal options.

73. Whilst putting the needs of relatives first, those providing the information should aim to include the following in the discussion:

• a basic explanation of what happens in a PM examination, including the removal, storage and use of organs and tissue and the various purposes for which tissue might be kept; this should include organs, parts of organs and tissue in various forms, such as frozen sections and samples held in paraffin wax after fixing and processing
• details of where and when the PM examination will take place
• the benefits of a PM examination, the questions to be addressed in this case and the possible outcome
• the possible alternatives to a full PM examination (making clear the limitations to these, and the benefits of a full PM examination)
• information about tests needed (e.g. histology, toxicology, genetic testing) and whether these might cause delays to determining the cause of death
• an explanation of the need for any images to be made (including photographs, slides, X-rays and CT scans)
• when, to whom and how the results of the investigation will be made available and explained;
• options for what will happen to any material removed (including tissue blocks and slides) after the PM examination
• the potential benefits of the continued storage or use of tissue and organs for the family and options for use for a scheduled purposes such as research or teaching, and the potential storage period
• whether there are particular uses which relatives would wish to exclude from any general consent given
• the timing of burial or cremation so that, where possible, any material removed can be reunited with the body if relatives so wish
• the time period in which they can change their mind.

74. They should be provided with factual information that may be taken away if they want it. Consideration should be given to the demographics of the local community when producing printed information. For example, there may be a need to produce information in different languages.

75. At the end of the meeting, relatives should be provided with a record of the discussion and of the agreement reached.

76. Relatives should also be provided with the name, telephone number and/or email address of a contact person (for example, the hospital’s bereavement adviser), so they may ask further questions later. Ready access to general information, for example via a hospital website may also be helpful to them.

77. When discussing the PM examination or retention of tissue, some relatives may wish to know in considerable detail what will be done to the body, organs or tissue. In such cases the procedure should be explained with careful use of language, but honestly and fully. Others will not want as much or even any detail, and this should be respected; however, sufficient information should be provided to ensure that valid consent is in place.

78. It should be explained to the relatives that medical students, doctors and other healthcare professionals may observe the PM examination or a demonstration of the findings for educational purposes and to develop their professional skills. Relatives should be given the opportunity to request that observers are not present. Anyone observing the PM examination must respect the confidentiality of information relating to the deceased person.

Information to be given to relatives after a hospital post-mortem examination

79. Relatives should be told when the results are likely to be available and given the option of an appointment that will allow them to discuss the results with the clinician responsible for the deceased person’s care, the pathologist or other specialist clinician where that would be helpful.

80. Example – In one Trust where consent is delegated to specialist nurses, the family are offered the option of receiving the results in writing. The results letter is drafted by the nurse, and shared with the pathologist and clinician before the final version is sent to the person who gave consent. The letter contains details of how to contact the clinician for a meeting if there are any further questions.
81. Some relatives will not want to know the results of the PM examination or will not want to discuss them in detail. Their wishes should be respected. However, they should be offered the opportunity to discuss the results at a later date.

82. There may be occasions where the deceased person expressed a specific wish before death that information should not be shared with relatives and this should be respected as far as possible.

83. Care should be taken regarding the possible disclosure of information, such as genetic information or the presence of an infectious disease, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members. Healthcare professionals will have to make a decision, based on individual circumstances, about whether it is appropriate to disclose medical history or any other sensitive information about the deceased that the family may not be aware of. In making decisions, healthcare professionals will have to have regard to their duty of patient confidentiality and may have to consider the provisions of the Data Protection Act 1998. In certain circumstances, it may be necessary to share sensitive information with the family if the results of the PM examination have the potential to affect them or other relatives. For further guidance see GMC guidance on confidentiality and the Department of Health’s guidance on confidentiality which deals with disclosing information after a patient has died. See also the Welsh Assembly Government’s guidance on confidentiality.

84. Although in general, information about deceased patients should be treated in confidence, in these circumstances the relatives’ legitimate wish for relevant information should be met with proper care and sensitivity, subject to any expressed wishes of the deceased person and any legislative restrictions on disclosure.

85. For parents who have suffered pregnancy loss or the death of a baby, the pathology results may raise many issues which it is important for them to discuss as a couple. These issues may require further discussion with other healthcare professionals, such as a genetic specialist. Parents should be offered the chance to have such a meeting. If they do not feel ready to take up that offer immediately, they should be provided with contact details so that they may contact them again at a later date. They should also be told who to contact (and how) if they have questions later on, and given details of national and local support organisations.

86. Subject to the parents’ agreement, the report should also be given to the deceased child’s GP or treating clinician, and to the mother’s GP in the case of a
neonatal death or stillbirth.

**Training and support for staff**

87. Staff involved with seeking consent should be trained in how to obtain consent and the establishment should hold training records to demonstrate this.

88. Training and support should be offered to others involved with liaising with relatives, such as coroners' officers and APTs. Training should ensure that they have sufficient knowledge of bereavement management and the procedures involved in the PM examination, as well as the statutory framework of the HT Act.

89. **Example – Establishments seeking to develop training might consider a web-based training module for staff. By working through the relevant sections of the HT Act and the code of practice they can ensure that the key issues are covered. The module might include sections on what constitutes appropriate and valid consent, who is able to seek consent and also give it (i.e. those in 'qualifying' relationships), cultural / religious considerations, the provision of information about the PM examination itself and the retention, storage and disposal of material, and what is documented and where. It might also reference the HT Act so that people know obtaining valid consent is a legal requirement, not just good practice.**

90. Trusts and coroners’ services should ensure that staff are given the necessary training and support to identify and meet the widest possible range of needs and wishes. Relatives may not always know what is traditional or customary within the community when a death occurs and may wish for time to talk to other family and community members. However, each case and decision is an individual and personal one, and should be treated as such.

91. The development of local joint protocols between healthcare establishments and their coroner/s may provide opportunities for considering training needs and development opportunities in liaison with other relevant bodies such as the police, local authority and Local Safeguarding Children Boards.

**Tissue or organ donation** To include references to deemed consent in Wales

92. The procurement of tissue for human application is governed by the requirements of the Q&S Regulations. Procurement may only be undertaken under the authority of a licence from the HTA or a third party agreement instigated by a licensed establishment. Further information on the Q&S Regulations and tissue retrieval is available on the HTAs website.
93. The procurement of solid organs and composite tissues for transplantation is governed by the requirements of the Quality and Safety of Organs Intended for Transplantation Regulations 2012. Procurement must be undertaken under the authority of the appropriate licence from the HTA. Further information about organ and composite tissue retrieval is available on the HTA’s website.

94. Many people, prior to their death, have made a decision to consent or not to consent to organ or tissue donation. All efforts should be made to allow those who wish to donate organs or tissue to do so and explanations should be given where it is not possible. For further guidance, see the code of practice on donation of solid organs for transplantation.

95. The HT Act makes clear that where an adult made a decision to consent to organ donation taking place after their death, then that consent is sufficient for the activity to be lawful.

96. In cases of potential deceased donation, the transplant coordinator or delegated person should be approached at an early stage and asked to determine whether the deceased person had consented to donate their organs after death. This should be done before the relatives are approached. Trained staff should determine whether the deceased person had given consent for organ donation by checking relevant sources, such as the Organ Donor Register. If no records are held, an approach should be made to the deceased person’s relatives by a transplant coordinator or a member of the team who cared for the person, or both together, to establish any known decision of the deceased person to consent (or not) to donation.

97. Once it is known that the deceased person consented to donation, the matter should be discussed sensitively with their relatives. They should be encouraged to recognise the wishes of their relative and it should be made clear, if necessary, that they do not have the legal right to veto or overrule the deceased person’s wishes. There may nevertheless be cases in which donation is considered inappropriate and each case should be assessed individually.

98. Organ retrieval will take place before a PM examination, whereas tissue retrieval may take place prior to or following a PM examination, depending on the tissues involved and any time restraints. However, to avoid contamination of the tissue to be donated for transplantation, it is preferable for the retrieval to precede the PM examination.

99. Where organ or tissue retrieval is a possibility (and it should be made clear that where this involves tissue rather than whole organs, the tissue will be stored until it may be used), the person talking to the relatives should make early contact with
the local transplant coordinator for advice, as outlined in paragraph XX above. In
addition, there should be documented arrangements for access to mortuary
premises by tissue retrieval teams.

100. Authorisation from the coroner will be required in addition to consent from the
relatives if the coroner is investigating the reason for the deceased’s death.

101. For guidance on arrangements between coroners and transplant coordinators
on taking steps for organ preservation, see the code of practice on donation of
solid organs for transplantation.

Removal of PM tissue for use for scheduled purposes

102. Removal of tissue samples from the body of a deceased person for use for a
scheduled purpose is an activity that must take place on licensed premises,
unless the removal is for police purposes. Removal may take place in locations
other than the mortuary, for example in the A&E department in cases of sudden
infant death syndrome, or in operating theatres where tissue is removed for use
for research during a transplant operation. Establishments must ensure that they
have the necessary licences in place to ensure that the activity of removal is not
taking place in breach of regulatory requirements.

Storage of bodies and tissue blocks and slides, including existing holdings

103. The storage of bodies in mortuaries must preserve the dignity of the
deceased, provide for adequate security to ensure bodies are safe from harm
and breaches of confidentiality and ensure that risks of errors in identification are
mitigated. Storage arrangements must be sufficient to meet demand, including at
peak times, and there must be effective contingency arrangements to ensure
that capacity issues do not present an increased risk to bodies in storage. This
includes in relation to long-term body storage.

104. Tissue blocks and slides may be useful for the purposes of audit, teaching,
research and quality assurance. It may also be useful to keep them in case they
are useful for future diagnosis of relatives. The HT Act does not make any special
exemptions from the consent requirements for storing blocks and slides. Nor
does it envisage the storage of material for no purpose. Therefore, specific
consent must be obtained to store and use tissue (including blocks and slides) for
any of the scheduled purposes listed in the HT Act.

105. Blocks and slides for use for scheduled purposes must be stored on licensed
premises. Exceptions to this are storage of tissue from the body of a deceased
person for:
• use for research which is ethically approved, by a recognised research ethics committee (or for which such approval is pending); and
• the sole purpose of analysis for a scheduled purpose (excluding research) where the material has come from, and is to be returned to, a licensed premises following analysis.

106. These exemptions have been described under the HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

107. An existing holding is material that was being stored for use for a scheduled purpose when the HT Act came into force on 1 September 2006.

108. Existing holdings are not subject to the consent provisions of the HT Act, but must be stored on licensed premises.

109. If any NHS Trusts have collections of existing holdings that are considered by clinicians to be valuable for teaching, they should review the usefulness of the collection on a regular basis and, where items are found not to be of value, they should be disposed of (see paras xxx below). To include guidance from Sir Ian Kennedy in relation to BCH.

Disposal of post-mortem tissue

110. Dignified treatment and separate disposal are the minimum considerations when disposing of post mortem tissue. This means disposal should be carried out separately from clinical waste, but not that each tissue sample necessarily needs to be disposed of individually. Arrangements for respectful and sensitive disposal should be made at local level. The establishment may wish to hold a simple but respectful ceremony.

111. Establishments must have a disposal policy and procedures which ensure tissue is disposed of in accordance with the wishes of the deceased person or their relatives. Staff should be familiar with these arrangements, including what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. They may wish to discuss it with relatives or community members before making their choice.

112. Attitudes towards disposal may vary widely among cultures and religions. Staff should be sensitive to this, being aware that choices are for the individual or
relative to make. Establishments should ensure that their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes.

113. If the wishes are to reunite organs and tissue with the body before burial or cremation, the establishment should have a system of checking that any retained tissue is accounted for before the body is released to the family. If there is tissue not accounted for, the establishment should have a clear procedure for the course of action to be followed. Efforts should be made to keep the relatives informed throughout the process.

114. **Example** – One establishment’s procedure includes placing a written notice on the shroud of the deceased person if any tissue has been removed at post mortem, which states the disposal wishes of the relatives. The member of staff who is responsible for releasing the body is required to check the records and ensure that tissue has been reunited with the body as requested. To include other examples obtained from HTARIs

115. If for any reason retained tissue cannot be reunited with the body before it is released for burial or cremation, the establishment should have a procedure that ensures the relatives are informed and that there is prompt and appropriate disposal.

116. The deceased person or their relatives may have expressed wishes for the tissue samples to be retained for future use or made their own arrangements for disposal. Such requests should be considered on a case-by-case basis by the holding establishment, assessing the risks involved. Sufficient information about the disposal options should be given to allow informed choices to be made. The establishment should make a decision based on its understanding of the risk associated with releasing the material in question. If someone has given consent to the storage of tissue, they should be offered the option of allowing the establishment to dispose of the material after its further examination or use.

117. Relatives may enquire about tissue that was taken during post-mortem examination some time later. It may be that tissue has been subsequently disposed of in accordance with this guidance. If this is the case, the relatives should be given full information in a sensitive manner. For more information about communicating with relatives in relation to coroners’ post-mortem examinations see the Ministry of Justice (MoJ).

118. Suitable arrangements should be made with third parties carrying out specialist examination of tissue to ensure that all tissue is sent back to the
originating establishment for disposal or return to the body, or that the third party is provided with instructions for disposal or a copy of the consent for retention.

119. Where existing holdings include identifiable tissue that has been retained at post-mortem examination on a coroner's behalf to establish cause of death, the coroner's office must be consulted before disposal may take place. This is necessary to confirm that the coroner has satisfactorily completed their investigation into the case and is content for the material to be disposed of (see paragraphs 54–60 for further guidance).

120. Where human tissue disposal is contracted to another establishment, the responsibility for compliance with the codes of practice and the HT Act lies with the department contracting such services. It may therefore be advisable to have third party agreements or SLAs in place as part of this process.

**Disposal options**

121. Currently, basic disposal options are incineration, cremation or burial. The HTA’s role is to empower establishments to make decisions locally about the most suitable methods of disposal in each case. The HTA encourages establishments to have a disposal policy that they might make available to the public (see paragraphs xx–xx). Establishments should be open about their processes so relatives have the information required to make an informed choice.

122. Where an organ has been removed at post-mortem examination, the establishment may offer to store the body until the organ can be returned to it. This may not always be practical as there may be a long delay; in these cases, the consequences should be explained to relatives. Where a body is released without an organ, it is important that relatives are made aware that this is the case.

123. Relatives may want a funeral director of their choice to collect tissue or an organ after the release of the body, and to make their own arrangements for cremation or burial. Second funerals and burials of this nature may have significant emotional (and financial) implications. These should be discussed sensitively with those involved.

124. If the deceased person has been buried or cremated, and relatives ask for the remaining tissue to be returned later, this should be released:

- preferably to funeral directors acting for those who have legitimate responsibility for the disposal of the body
- with authoritative confirmation of the identity of the tissue or organ
• with confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

125. There is no legal rule preventing the release of stored material directly to relatives, but the proposed method of disposal must be lawful and safe. This may not always be easy to establish. The establishment must act in accordance with any relevant legislation to ensure the recipient, or burial or cremation authorities, are aware of any hazards associated with the tissue and its fixative and confirm they can handle them appropriately. For example, formalin (commonly used as a fixative) can cause an allergic disease of the lungs and is a low-grade carcinogen.

126. Because of the potential health hazards, releasing tissue directly to relatives for its indefinite storage is generally not advisable. Establishments should make an assessment based on the risks involved and the possible consequences of releasing the material. Further guidance on disposal options is set out below.

Incineration

127. Tissue removed from the deceased for use for scheduled purposes may be incinerated after use; care should be taken to ensure that this method is appropriate to the nature of the tissue.

Burial

128. An establishment wishing to bury tissue from the deceased should consult the local burial authorities to establish what level of service they can provide. If the establishment wishes to bury this material and a service is not available locally, they may wish to contact other service providers further afield as appropriate.

129. The HTA recognises that local circumstances vary and is mindful of the practicalities involved in securing separate incineration. Where practical, human tissue that is incinerated should be bagged separately from clinical waste. It is not necessary for each tissue sample to be disposed of individually.

130. Relatives may want to be reassured about the suitability of burial or other arrangements. They should be told what the establishment may provide, and that any additional requirements will be at their own expense.

Cremation
131. Although there is no legal barrier to cremating tissue blocks, crematoria have discretion about what they may accept. Crematoria have particular concerns about material on glass slides because of health and safety issues.

132. Cremation of human tissue is possible under the Cremation (England and Wales) Regulations 2008 providing that:

- the death of the person was duly registered;
- an application for the cremation of the tissue has been made by an appropriate person on the proper forms; and
- a certificate on release of body parts has been provided by the holder or, if not possible to provide such a certificate, other evidence that the body parts were removed in the course of a post-mortem examination.

133. The Cremation (England and Wales) Regulations 2008 do not apply to Scotland. It should also be noted that different cremation legislation applies in Northern Ireland and that responsibility for this legislation lies with the Department of the Environment (NI).

Disposal of pregnancy remains

134. Pregnancy remains of less than 24 weeks gestation are considered to be the mother’s tissue. The HTA has issued separate guidance on the disposal of pregnancy remains, which reflect the very sensitive nature of these.

HTA Licensing standards

135. The HTA has developed licensing standards with which the establishment must demonstrate compliance. The standards were developed in consultation with representatives from the sector, and reinforce the intention of the HT Act that consent is paramount when engaged in activities involving the use of human tissue, that the bodies of the deceased and tissue taken from bodies should be treated with respect and that the dignity of the person should be maintained. The standards reflect the guiding principles set out in code A and provide the operational detail of how establishments should meet the requirements of the HT Act and the codes of practice.

136. Mortuaries around the UK vary enormously in age and condition and the HTA recognises that in some cases staff are working in difficult circumstances. In extreme cases, the HTA will take regulatory action to prevent PM examinations taking place in premises considered to be unsuitable. However, this is an undesirable outcome which has implications for service delivery, affecting both the service provider and the families of the deceased. The HTA seeks to work
with establishments through its inspection process, to help them make improvements where they can be made. The HTA takes a proportionate and risk-based approach and will take into account the constraints on establishments, where scope for improvement has been exhausted.

137. The person with statutory responsibility under the HT Act to supervise the licensed activities, the Designated Individual (DI), has a duty to ensure that suitable practices are carried out by those working under the licence, that the premises are suitable and that the conditions of the licence are complied with. By ensuring that the establishment is meeting the HTA’s licensing standards, the DI will be meeting their statutory responsibility.

138. The HTA standards are grouped under the headings of consent; governance and quality systems; traceability; and Premises, facilities and equipment. They focus on the internal systems and processes that are in place to support staff in the delivery of high quality services, and are particularly relevant to staff working in mortuaries, which are the focus of the HTA inspection programme for this sector.

139. The HTA’s licensing standards are available at xxxxxx.
## Annex C

### Draft HTA Licensing standards for the Post Mortem Sector

#### Consent

<table>
<thead>
<tr>
<th>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA’s codes of practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA’s codes of practice.</td>
</tr>
<tr>
<td>b) There is a documented standard operating procedure (SOP) detailing the consent process.</td>
</tr>
</tbody>
</table>

**Guidance:** this should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post mortem examination.

<table>
<thead>
<tr>
<th>c) There is written information for those giving consent.</th>
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<tbody>
<tr>
<td>Guidance:** information on consent should be available in different languages and formats, or there is access to interpreters/ translators. Family members should be given the opportunity to ask questions.</td>
</tr>
<tr>
<td>d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use).</td>
</tr>
<tr>
<td>e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.</td>
</tr>
<tr>
<td>f) The deceased’s family are given an opportunity to change their minds and is it made clear who should be contacted in this event and the timeframe in which they are able to change their minds.</td>
</tr>
<tr>
<td>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</td>
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</tbody>
</table>

**Guidance:** this may be based on the HTA’s model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post mortem examination and for the retention and future use of tissue samples.

| C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent |
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention.

*Guidance: refresher training should be available (e.g. annually); attendance at consent training should be documented.*

b) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

### Governance and quality systems

**GQ1 All aspects of the establishment’s work are governed by documented policies and procedures**

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These include:

i. post-mortem examination, including the responsibilities of APTs and Pathologists and the management of high risk cases

ii. practices relating to the storage of bodies, including long term storage

iii. practices relating to evisceration and reconstruction of bodies

iv. record keeping

v. receipt and release of bodies, which reflect out of hours arrangements

vi. lone working in the mortuary

vii. viewing of bodies, including those in long-term storage, by family members and others such as the police

viii. transfer of bodies internally, for example for MRI scanning

ix. transfer of bodies and tissue (including blocks and slides) off site or to other establishments

x. movement of multiple bodies from the mortuary to other premises, for example in the event that capacity is reached

xi. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person’s family

xii. health and safety, in line with HSE guidance

*Guidance: individual SOPs for each activity are not required. Some SOPs will cover more than one activity.*

**Evisceration should not be undertaken by an APT unless the body has been examined by the pathologist who has instructed the APT to proceed.**

**It is good practice to obtain the family’s permission for any ‘cosmetic’ adjustments made during reconstruction, or other invasive procedures, prior to release of bodies, for example, sewing the deceased’s mouth to close it or the removal of a pacemaker. Bodies in long-term storage should be checked periodically.**

b) Policies and SOPs are reviewed regularly, ratified and version controlled; only
the latest versions are available for use. 

**Guidance:** governance documents should be reviewed every 1-3 years or in the event of changes resulting from, for example, an untoward incident.

c) There is a system for recording that staff have read and understood the latest versions of these documents.

d) Deviations from documented SOPs are recorded and monitored.

e) All areas where activities are carried out under an HTA licence are incorporated within the establishment’s governance framework.

**Guidance:** for example, maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in SIDS cases. There should be an identified Person Designated in areas of the establishment remote from the main premises.

f) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.

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**GQ2 There is a documented system of audit**

a) There is a documented schedule of audits. 

**Guidance:** as a minimum, the schedule should include a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

**Guidance:** staff should be made aware of the outcomes of audits and where improvements have been identified.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

**Guidance:** audits of stored tissue should include samples held under the authority of the police, where applicable.

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**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills**

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

**Guidance:** this includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage. 

Anatomical Pathology Technologists should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible.

b) Staff are assessed as competent for the tasks they perform.
c) Staff have annual appraisals.
d) Staff are given opportunities to attend training courses, either internally or externally.

*Guidance: attendance by staff at training events should be recorded.*
e) There is a documented induction and training programme for new mortuary staff.

f) Visiting / external staff are appropriately trained, and receive an induction which includes the establishment’s policies and procedures.

*Guidance: the qualifications and competency of locum staff should be assessed prior to them commencing work.*

Contractors, visiting and temporary staff should be required to read relevant standard operating procedures and sign to confirm their understanding.

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GQ4 There is a systematic and planned approach to the management of records

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

*Guidance: records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.*

b) There are documented SOPs for record management, which include how errors in written records should be corrected.

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GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

*Guidance: HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.*

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candor when dealing with serious incidents.

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GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

*Guidance: risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA’s reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years.*

b) Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

### Traceability

**T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

<p>| | |</p>
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</table>
| **a)** | Bodies are tagged/labelled upon arrival at the mortuary.  
*Guidance: the condition and labelling of bodies received in body bags should always be checked and their identity confirmed; they should be labelled on the wrist and/or toe; body bags should not be labelled in place of the body.* |
| **b)** | There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).  
*Guidance: body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, who it was released to. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage, which are subsequently returned before release to the funeral director.* |
| **c)** | Three identifiers are used to identify bodies and tissue (e.g. post mortem number, name, date of birth/death), including at least one unique identifier.  
*Guidance: identification details should not be written on bodies.* |
| **d)** | There is system for flagging up same or similar names of the deceased. |
| **e)** | Identity checks take place each time a body is moved, whether inside the mortuary or from the mortuary to other premises.  
*Guidance: mortuary white boards containing the names of the deceased give potential for error if wiped clean (e.g. when visitors attend for reasons of confidentiality) and should not be relied upon as the sole source of information about the locations of bodies.* |
| **f)** | Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability; full identification checks should be made when they are placed back into normal storage.  
*Guidance: mortuary white boards containing the names of the deceased give potential for error if wiped clean (e.g. when visitors attend for reasons of confidentiality) and should not be relied upon as the sole source of information about the locations of bodies.* |
| **g)** | There are procedures for releasing a body that has been in long term storage |
and is therefore not in the current register.

g) Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:
   i. material sent for analysis on or off-site, including confirmation of arrival
   ii. receipt upon return to the laboratory or mortuary
   iii. the number of blocks and slides made
   iv. repatriation with the body
   v. return for burial or cremation
   vi. disposal or retention for future use.

Guidance: consent information which covers retention/disposal of tissues should be made available to the other site as appropriate.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. to the lab or another establishment), including record-keeping requirements.

   i) Guidance: formal written agreements with funeral directors are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA’s codes of practice.

   a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner’s or police authority ends or consented post-mortem examination is complete.
   b) There are effective systems for communicating with the Coroner’s Office, which ensure tissue is not kept for longer than necessary?
   c) Disposal is in line with the wishes of the deceased’s family.

Guidance: organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution; clinical waste bags or household bin bags should not be used for this purpose.

Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.

   d) The method and date of disposal are recorded.
<table>
<thead>
<tr>
<th>Premises, facilities and equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PFE1</strong> The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue</td>
</tr>
</tbody>
</table>
| a) The premises are clean and well maintained.  
  b) There are documented cleaning and decontamination procedures and a schedule of cleaning.  
  c) The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).  
  **Guidance**: relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.  
  d) Security arrangements prevent unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access. |
| **PFE2** There are appropriate facilities for the storage of bodies and human tissue |
| a) There is sufficient capacity for storage of bodies, organs and tissues, which takes into account predicted peaks of activity.  
  b) Fridge and freezer units are in good working condition and well maintained.  
  c) Fridge and freezer units are alarmed and the alarms are tested regularly.  
  d) Temperatures of fridges and freezers are monitored on a regular basis.  
  e) There are documented contingency plans in place should there be a power failure or inadequate numbers of refrigerated storage spaces during peak periods.  
  **Guidance**: where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.  
  f) Bodies are shrouded or in body bags whilst in storage.  
  g) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies. |
| **PFE3** Equipment is appropriate for use, maintained, validated and where appropriate monitored |
| a) Items of equipment in the mortuary are in a good condition and appropriate for use:  
  i. fridges / freezers  
  ii. hydraulic trolleys  
  iii. post mortem tables  
  iv. hoists |
v. saws (manual and/or oscillating)

b) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

*Guidance: Maintenance records may be held by the mortuary or centrally by the Trust, e.g. the Estates Department.*
Human Transplantation (Wales) Act 2013 - update

Purpose of the paper
1. This paper provides an update on progress towards the implementation of the Human Transplantation (Wales) Act 2013 (to be referred to throughout the paper as the 2013 Act) and the HTA’s role in superintending compliance with the Act.

Action
2. The Authority is asked to approve the proposals for superintending the 2013 Act outlined in paragraphs 14 to 16.

3. The Authority is asked to note:
   - the updates on changes to the Organ Donor Register (ODR)
   - the passage of the Section 150 Order to permit the use in England and Northern Ireland of organs and tissue removed under the deemed consent provisions in Wales
   - the timeline for approval of the supporting legislative package compromising three sets of Regulations, alongside the HTA’s Code of Practice on living and deceased organ and tissue donation for transplantation - Wales
   - the latest position in Scotland and Northern Ireland contained in Annex A.
Decision-making to date

4. SMT agreed the content of this paper for submission to the Authority at its meeting on 9 April.

Update on changes to the Organ Donor Register

5. In preparation for the implementation of the 2013 Act on 1 December 2015, changes are being made to the Organ Donor Register (ODR), which will enable those ordinarily resident in Wales to register a decision not to donate their organs.

6. Individuals will be able to record one of three possible decisions:
   a. Yes, I want to donate all/some of my organs
   b. No, I do not want to donate
   c. I would like to appoint/nominate a representative to make a decision for the purpose of organ donation only

7. NHS Blood and Transplant (NHSBT) will migrate existing entries to the new register in May 2015 and from 1 June, individuals ordinarily resident in Wales will be able to contact NHSBT to record a decision to opt-out of organ donation. A public information campaign which will explain the changes to the register will be launched in July. Patients who register with a new general practitioner and who are not already on the ODR will be able to join through their GP from June 2015.

8. The revised ODR registration options will apply across the whole of the UK.

Section 150 Order

9. Following debates in the House of Lords on 4 March and the House of Commons on 11 March, the UK Government passed a Section 150 Order\(^1\) which will allow organs and tissues that have been donated in Wales under deemed consent to be transplanted in England and Northern Ireland.

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\(^1\) Section 150 of the Government of Wales Act 2006 empowers the Secretary of State to make ‘consequential provisions’ amending other legislation following laws made by the Assembly
Superintending the 2013 Act

10. On 1 December 2015, the HTA will assume responsibility for superintending the 2013 Act. In preparation for this, discussions have taken place between the HTA, NHSBT, and Welsh Government on the potential scope of the superintending function.

11. The Authority should note that the superintending function is established within the 2013 Act and is distinct from our responsibilities under EU legislation for licensing establishments to ensure the quality and safety of tissues and cells used to treat patients and the quality and safety of organs that are intended for transplantation. The 2013 Act will have an impact on the way the HTA licences and inspects against consent standards for establishments in Wales after 1 December 2015 and activity is underway within the HTA to ensure this transition happens smoothly.

12. ‘Superintending legislation’ is not a protected legal term, and no clear definition of the function exists. Ministers and Welsh Government officials have expressed no fixed perspective on how the superintending function should evolve.

13. As there is likely to be a reasonable degree of interest in the experience of deemed consent in Wales, it would seem appropriate that the HTA take active, but light touch, measures to be able to take a view on the effect of the new legislation if required.

14. At its meeting in December, the Welsh Government’s Organ Donation Project Board received an overview of the proposals for superintending from the HTA. The presentation outlined an approach to superintending which would:

- assess evidence of the volume and characteristics of cases where consent had been deemed
- establish the number of organ donations that result from the application of deemed consent
- establish the volume of cases where deemed consent provisions have not been used where it would have been legitimate to do so, and
- establish any evidence of deemed consent being used where express consent was required.

15. The baseline data for superintending will be collected by NHSBT through an updated Potential Donor Audit (PDA) form, which will be completed in Wales...
for every patient who dies on a critical care area (ICU, ED) below the age of 80, regardless of the outcome of donation.

16. NHSBT will produce reports on this data on a monthly basis to be submitted to the HTA. It is proposed that the HTA assesses the data provided against the parameters outlined in paragraph 14, providing a regular report to the Welsh Government.

17. Although the superintending data will contribute to an impact assessment of the effectiveness of the changes to legislation, it is currently not proposed that the HTA will play an active role in evaluation.

**Code of Practice - Wales, Regulations and draft timetable for legislative approval**

18. The HTA has consulted on and published a Code of Practice to provide practical guidance on the 2013 Act. This Code will require Parliamentary approval for it to come into effect on 1 December 2015, and the HTA is working with Welsh Government on this process.

19. The passage of the Code through the Welsh Assembly will take place at the same time as the passage of three sets of Regulations which the Welsh Government consulted on in Autumn 2014\(^2\). The Regulations consulted on were:

- **The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015.** These Regulations are made under section 7 of the Act and define which organs and tissue cannot be donated under deemed consent provisions
- **The Human Transplantation (Appointed Representatives) (Wales) Regulations 2015.** These Regulations are made under section 8 of the Act and describe people who may not act as an appointed representative
- **The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015.** These Regulations are made under section 9 of the Act and relate to activities involving materials from living adults who lack the capacity to consent. The Regulations maintain the current position for such individuals

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\(^2\) The HTA did not submit a response to this consultation, but will work with Welsh Government to assess any implications on the draft Code of Practice
20. It is anticipated that the approval process for the Code and Regulations will commence in September 2015, to the following draft timeline, with actions taken forward by colleagues in Welsh Government:

   a. 11 September 2015 – write to Secretary of State and Welsh Ministers to seek approval for the Code
   b. 14 September 2015 (TBC) – lay the subordinate legislation package of three sets of Regulations and the draft Code of Practice before the National Assembly for Wales
   c. 6 October 2015 – Code is laid before Parliament

21. Between now and 1 December 2015, the HTA will continue to attend Welsh Project Board meetings, and the Authority will be kept up to date with progress towards implementation.
Annex A – Updates on organ and tissue donation in Scotland and Northern Ireland - Private Members’ Bills

Proposed Organ and Tissue Donation (Scotland) Bill

- The Bill was proposed by Anne McTaggart, Member of Scottish Parliament for Glasgow (Labour)
- The Bill proposes an amendment to the law on human transplantation, including by authorising (in certain circumstances) the posthumous removal of organs and tissue from an adult who had not given express consent
- Only five per cent of people in Scotland oppose organ donation in principle
- 41 per cent of the population are on the ODR
- If passed, the law would apply to those ordinarily resident in Scotland aged 16 and over
- Between 2007/8 and 2012/13, Scotland achieved a 74 per cent increase in rates of deceased organ donation, and a 36 per cent increase in transplant using deceased donor organs
- 38 people in Scotland died in 2013/14 whilst awaiting a transplant
- Scottish Government is keen to see outcomes of the change in Welsh legislation before implementing a change

Organ Donation – record of debate (Hansard) Northern Ireland

- The Bill was proposed by Jo-Anne Dobson, Member of Legislative Assembly for Upper Bann (Ulster Unionist Party)
- The Bill proposes a move to a soft opt-out system for organ donation, with family consent at its heart
- Public consultation undertaken in 2013 which received 1366 responses
- 82 per cent of consultation respondents agreed with a proposed change in law
- If passed, the law would apply to those ordinarily resident in Northern Ireland aged 18 and over
Authority Paper

Date 28 April 2015  Paper reference HTA (21/15)
Agenda item 12  Author Sue Gallone

Strategic risk register – April 2015

Purpose of paper

1. This paper presents the latest strategic risk register for April 2015.

Action

2. Members are invited to review the strategic risk register (Annex A) to ensure key risks are captured and are being managed.

Decision-making process to date

3. This paper is for information and the contents have not required any decisions to be made. The Senior Management Team (SMT) has reviewed the risk register and is content.

Background

4. Members are provided with a quarterly update of the strategic risk register, to assure themselves that risks are being managed properly.

5. The Audit and Risk Assurance Committee also review risk management at its meetings three times per year. The Committee’s role is to seek assurance that risks are controlled and flag up any gaps to the Authority. The Committee reviewed the risk register which was updated in January at its meeting on 4 February.
6. SMT review and update the strategic risk register monthly. The last review was on 31 March.

Risk register

7. The last version of the strategic risk register presented to the Authority was the January 2015 update. There were no changes to risk levels in the last two months of the year. The risk of inability to carry out our statutory remit remains amber. Having sufficient experienced staff is likely to be an ongoing issue. Vacancies are being filled promptly, training is provided and procedures are in place for staff to follow but ongoing turnover keeps the risk at this level.

8. For 2015/16, and following discussion at the Authority event in October 2014, a new risk 2 has been included: Failure to meet public or professional expectations of human tissue regulation resulting from limitations in current legislation or misperception of HTA regulatory reach. The risk is rated amber and we are working with stakeholders, including the Department of Health, to manage it.

9. The previous risk 2, failure to manage change, has decreased as the HTA is in a more stable period. Aspects of this are reflected in other strategic and operational risks, rather than this continuing to be a risk in its own right.

10. The focus of the previous risk 3, inability to manage a major event, has changed. This risk has been broadened to reflect the sorts of incidents we may face and clarify the risks. The level remains the same.

11. All risks have been comprehensively reviewed and actions updated, in line with the strategic and business plans. In particular, the Codes of practice work, licensing and inspection review and Customer Relationship Management database improvement project are reflected. The level of other risks remains the same.

12. SMT is content that the strategic risk register is complete and are prepared to tolerate the level of risk identified.
Overview:

The overall level of risk the HTA faces has not changed. Two risks have changed in line with our review against the new strategic plan. The previous risk 2, managing change, is less significant for us now and has been incorporated into other strategic and operational risks. The focus of the previous risk 3, major events, has changed and has been broadened to reflect the sorts of incidents we may face. Failure to deliver our statutory remit and expectations of regulation are the key strategic risks. Turnover is a key factor in the risk of failure to deliver our statutory remit. Attrition is 23% over the last year (target 18%) and the current vacancy rate is 4% (target is no more than 5%).

Other notable risks:

The Codes project will impact on capacity in all areas of the HTA. We are mindful of post-election changes. There will be a change of Chief Executive in the summer of 2015.

<table>
<thead>
<tr>
<th>Risk</th>
<th>February 2015</th>
<th>March 2015</th>
<th>April 2015</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Statutory remit</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>Risk remains amber due to staff turnover and the resulting experience level of staff. Staff training is in place but more stability (less turnover) is required to reduce this risk. Turnover is an ongoing factor due to the profile of staff at the HTA, limited opportunities in a small organisation and ongoing dissatisfaction with pay levels and pension contribution increases. Maternity leave is a factor too. The vacancy rate was 4% at end of February (target is no more than 5%) the attrition rate was 23% (target is no more than 18%), similar to previous months.</td>
</tr>
<tr>
<td>2 – Expectations of regulation</td>
<td></td>
<td></td>
<td>⇧</td>
<td>This new risk could have a high impact and we continue to communicate carefully to manage it.</td>
</tr>
<tr>
<td>3 – Incident management</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>This risk broadened in April 2015. Processes are in place to prevent and manage the various types of incidents.</td>
</tr>
<tr>
<td>4 – Financial resources</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>This risk is stable. We are mindful of potential future financial constraints from Government and the possibility of more debtors as other organisations are constrained.</td>
</tr>
<tr>
<td>5 – Relationship management</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>Relationships remain good and there is evidence of confidence in the HTA in feedback and survey results.</td>
</tr>
</tbody>
</table>

Risks are assessed by using the grid below:

- **Impact**
  - 5. Catastrophic
  - 4. Significant
  - 3. Moderate
  - 2. Minor
  - 1. Almost None

- **Likelihood**
  - 1. Rare
  - 2. Unlikely
  - 3. Possible
  - 4. Likely
  - 5. Almost Certain
<table>
<thead>
<tr>
<th>Ref</th>
<th>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>
<th>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 1   | Inability to carry out our statutory remit (strategic aim 1) Risk Owner: Alan Clamp | - Inability to regulate and inspect all sectors in line with business plan objectives  
- Inability to deliver sufficient advice and guidance  
- Inability to meet statutory requirements in HA sector  
- Reduced confidence in staff from regulated sectors & increased likelihood of challenge to decisions  
- Strategic plan and business plan in place and reviewed regularly  
- Ongoing review of performance and priorities  
- Contingency plans (as outlined in recruitment policy)  
- Training and development of professional competence  
- Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors  
- Staff retention measures, including annual staff benefits statement, actions on issues identified in staff surveys  
- Ongoing advertisement on NHS jobs for secondments to HTA  
- Quarterly accountability meetings with DH  
- Updated Codes of Practice following phase 1 review  
- CRM development and support contract  
- Business continuity plan | 5 4 | Ongoing Chief Executive gap from June 2015 Further turnover of Authority members at end 2015/16 | 4 3 | - Review and implement recommendations from staff (AC lead) Ongoing  
- Further improvement of HR provision via the HTA People Strategy (AC) September 2015  
- Put in place back-up arrangements for regulatory decision making (SB) By end May 2015  
- Reaccreditation of AAs (AMS) By end Q1 2015/16  
- Licensing and inspection review - implementation of actions from phase 1 and phase 2 work (SB) June 2015  
- CRM improvement project (SG) By end 2015/16 | Same | Contingency plans would focus strictly on meeting legislative requirements. |
<table>
<thead>
<tr>
<th>Ref</th>
<th>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>
<th>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 2   | Failure to meet public or professional expectations of human tissue regulation resulting from limitations in current legislation or misperception of HTA regulatory reach (strategic aim 2) | Causes External factors  
- No scheduled review of Human Tissue Act and associated regulations  
- Rapidly advancing life sciences  
Matters which certain stakeholder groups believe require review  
- Scope of relevant material 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  
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  
- Imported material  
Effects  
- Diminished professional confidence in the adequacy of the legislation  
- Reduced public confidence in regulation of matters relating to human tissue  
- Reputational damage | 4 | Ongoing | 4 | Log of issues known to the HTA with respect to the legislation to inform DH and manage messages  
- Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope  
- Active management of issues raised by the media – including the development of the HTA position on issues  
- Regular reporting to DH sponsorship team on matters which risk public and professional confidence  
- Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance) | 4 | Seek Ministerial support for legislative review in the next Parliament (AC) May 2015  
- Explore potential for secondment from HTA to DH to support a review (AC) Ongoing 2015  
- Increased use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge (AC) Ongoing 2015  
- Completion of licensing review to clarify remit (SB) By end Q1 2015/16  
- Codes of practice and standards project – provides greater clarity on matters inside and outside of regulatory scope (AMS) April 2016  
- Public information on cord blood banking (SB) July 2015 | Same | --- |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Risk Description</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>
<th>Source of Assurance</th>
<th>Assured Position</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</td>
<td>• 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)</td>
<td>Insufficient capacity and/or capability</td>
<td>5 3</td>
<td>Future, should event occur</td>
<td>3 2</td>
<td>Take actions from business continuity plan test</td>
<td>Monthly reports to HTAMG</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• caused by deficiency in the HTA’s regulation or operation</td>
<td>• Multiple incidents</td>
<td>Resource plan in place</td>
<td></td>
<td></td>
<td></td>
<td>Incident handling actions following crisis management training</td>
<td>Matters raised by Directors by email or at SMT – SMT minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• where we need to regulate, such as with emergency mortuaries</td>
<td>• Lack of leadership</td>
<td>Crisis management policy, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td></td>
<td></td>
<td></td>
<td>Reports to Authority and minutes of Authority meeting;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• that causes business continuity issues (All strategic aims)</td>
<td>• Poor decision making</td>
<td>Media handling policy and guidance in place, including regular media training for key staff &amp; Members with relevant scenarios, to supplement media release and enquiries SOPs</td>
<td></td>
<td></td>
<td></td>
<td>Monthly strategic performance review reports to Authority</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Risk owner: Sarah Bedwell</td>
<td>• Lack of clear regulatory processes to ensure compliance with standards</td>
<td>Accessible lines to take and key messages for likely scenarios</td>
<td></td>
<td></td>
<td></td>
<td>Regulatory Activity Report</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Acting in an unlawful manner</td>
<td>Availability of legal advice</td>
<td></td>
<td></td>
<td></td>
<td>Living Donation Activity Report</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Innovation in living organ donation</td>
<td>Mutual support from HFEA, CSC to support risk awareness</td>
<td></td>
<td></td>
<td></td>
<td>Communications Evaluation report</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Ineffective knowledge management</td>
<td>Fit for purpose Police Referrals Policy</td>
<td></td>
<td></td>
<td></td>
<td>SIRO annual review and report</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Poor horizon scanning</td>
<td>Decision making framework and onward delegation scheme agreed by the Authority</td>
<td></td>
<td></td>
<td></td>
<td>Internal audit reports</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Failure to work effectively with partners/other organisations</td>
<td>Communication on role on living lung donation for use when required</td>
<td></td>
<td></td>
<td></td>
<td>Same</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Breach of data security</td>
<td>IT security controls and information risk management</td>
<td></td>
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<td></td>
<td></td>
<td>• IT failure or attack</td>
<td>Business continuity plan regularly reviewed and tested</td>
<td></td>
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<tr>
<td>Ref</td>
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</tbody>
</table>
| 4   | Insufficient financial resources (underpins delivery of all strategic aims and directly impacts on 4) | Cause  
• Fee payers unable to pay  
• Licence fee structure doesn't bring in sufficient fee income  
• Establishments change leading to loss fee income  
• Changes to Grant-in-aid  
• Increase in regulatory responsibilities  
• Need to ‘do more with less’  
• Increased costs  
• Poor budget and/or cash-flow management  
• Reduction in reserves  
Effect  
• Payments delayed  
• Reductions in staff and other expenditure  
• Increased licence fees  
• Request for further public funding | 4 4 Rent review in 2015/16  
Post-election CSR?  
Resources likely to be tighter by second half of 2015/16 | • Budget management framework to control and review spend and take early action  
• Financial projections  
• Cash-flow forecasting and monitoring  
• Licence fee modelling  
• Rigorous debt recovery procedure  
• Reserves policy and levels of reserves  
• Delegation letters set out responsibilities  
• Prioritisation when work requirements change  
• Fees model provides cost/income information for planning | 3 2 | • Monitoring of income and expenditure (SG)  
Ongoing  
• Discussion with DH about cover for rent increase in 2015/16 (SG)  
Ongoing  
• Horizon scanning for changes to DH Grant-in-aid levels and arrangements (SG)  
Ongoing | • Monthly finance reports to SMT and quarterly to Authority  
• Annual external audit  
• Audit and Risk Assurance Committee review and minutes  
• Quarterly reports to DH  
• Agreed business plan | Same |
<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>
<th>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Inadequate relationship/stakeholder management (strategic objective 2)</td>
<td><strong>Cause</strong>&lt;br&gt;• Insufficient capacity/capability to communicate&lt;br&gt;• Lack of engagement of Authority members and staff in communications&lt;br&gt;• Inconsistent communication&lt;br&gt;• Ineffective knowledge management&lt;br&gt;• Failure to explain our regulatory action and rationale for decisions&lt;br&gt;• Failure to engage professional bodies and Government departments&lt;br&gt;• Perception of insufficient professional expertise on Board and in support of Executive&lt;br&gt;• Ineffective regulatory processes&lt;br&gt;• Failure to act in a lawful manner&lt;br&gt;• Joint working with other organisations may impact adversely on HTA approach</td>
<td><strong>Effect</strong>&lt;br&gt;• Complaints to HTA and/or government&lt;br&gt;• Poor regulatory compliance&lt;br&gt;• Reputational damage&lt;br&gt;• Reduction in public and professional confidence</td>
<td><strong>4</strong></td>
<td><strong>ongoing</strong></td>
<td><strong>4</strong></td>
<td><strong>ongoing</strong></td>
<td><strong>3</strong></td>
<td><strong>2</strong></td>
<td><strong>Communications evaluation reports to Authority meetings, and meeting minutes</strong>&lt;br&gt;• Feedback from and minutes from Histopathology Working Group and Transplant Advisory Group&lt;br&gt;• Feedback from surveys (stakeholder evaluation completed every 3 years and ad hoc surveys)&lt;br&gt;• Stakeholder Group feedback and minutes&lt;br&gt;• Feedback report to Authority (every six months)</td>
</tr>
</tbody>
</table>
Authority paper

Date 28 April 2015  Paper reference HTA (22/15)

Agenda item 13  Author Sue Gallone

Financial report - March 2015

Purpose

1. This paper provides an update on the HTA’s financial position as at 31 March 2015.

2. The report provides commentary on the following areas:
   - financial position and performance indicators at year end
   - plans and progress for 2014/15 financial accounts
   - budget for 2015/16
   - financial risks

Action

3. The Authority is asked to note the financial position at year end of 31 March 2015.

Decision making process to date

4. This report was discussed at the Senior Management Team on 16 April.

Financial position at year end

5. Annex A shows the summarised financial position for the year ending 31 March 2015. There was an underspend on revenue expenditure of £122k, and £101k more income than budgeted. Together with exceptional items, this resulted in £208k more surplus than budgeted.
6. **Annex B** provides a more detailed breakdown of income generated to 31 March 2015.

7. Licence fee income is £59k more than expected. This is due to an increase in licence fee income in particular from the Research sector and income from applications for licences exceeding expectations.

8. Other income is £42k above budget, due to rental income that has continued beyond the original period expected.

9. **Annex C** shows expenditure as at 31 March 2015 for staff and non-staff costs. There is an overall underspend of **£107k**, after exceptional adjustments.

10. Staff costs are underspent by **£91k** due to vacancies and lower employer pension contributions being paid as fewer staff are in the pension scheme than expected.

11. There is an underspend of **£16k** on non-staff costs. This includes an exceptional adjustment of £4k – a repayment by a member of staff who left to the career investment scheme. Below are details of other significant variances.

<table>
<thead>
<tr>
<th>Expenditure Variances</th>
<th>£</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel &amp; Subsistence</td>
<td>7,457</td>
<td>Main underspends within Regulations and Members travel. Smaller under-spends across other Directorates.</td>
</tr>
<tr>
<td>Training &amp; Recruitment</td>
<td>2,583</td>
<td>Recruitment costs are overspent by £31k but training is underspent by £29k, in particular as there has been little uptake of the career investment scheme* this year.</td>
</tr>
<tr>
<td>Conference &amp; Project costs</td>
<td>10,508</td>
<td>Most of these came in under-budget.</td>
</tr>
<tr>
<td>Accommodation</td>
<td>9,769</td>
<td>Mainly due to higher costs for rates than expected.</td>
</tr>
<tr>
<td>IT &amp; Telecoms</td>
<td>(33,604)</td>
<td>Spend within Telephones is higher than expected due to refresh of mobile devices and installation of leased line for disaster recovery purposes. Additional IT work on the Customer Relationship Management (CRM) system and the accounting system has also been required.</td>
</tr>
<tr>
<td>Legal &amp; Professional</td>
<td>39,725</td>
<td>Lower spend on legal fees than expected.</td>
</tr>
</tbody>
</table>

*Details to be provided at meeting, as requested in January 2015*
12. **Annex D** provides an analysis of expenditure by directorate. Directorates are under-spending due to the reasons detailed above. The Chief Executive’s directorate shows a small overspend, which is mainly due to recruitment costs.

**Other key performance indicators**

**Debtors**

13. As at 31 March our licence fee gross debtor balance was **£15k** relating to **10** organisations.

**Outstanding debtors by period (or Financial Years)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sector</th>
<th>No. est</th>
<th>£ value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>#</td>
<td>£</td>
</tr>
<tr>
<td>2013/14</td>
<td>BEG</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>2014/15</td>
<td>BEG</td>
<td>1</td>
<td>2,944</td>
</tr>
<tr>
<td>2014/15</td>
<td>BEG</td>
<td>1</td>
<td>1,750</td>
</tr>
<tr>
<td>2014/15</td>
<td>BEG</td>
<td>1</td>
<td>1,600</td>
</tr>
<tr>
<td>2014/15</td>
<td>NHS</td>
<td>1</td>
<td>869</td>
</tr>
<tr>
<td>2014/15</td>
<td>CGB</td>
<td>6</td>
<td>7,899</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>10</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>15,112</strong></td>
</tr>
</tbody>
</table>

14. The very small debt from 2013/14 will be added to further fees charged to this establishment.

15. The first two 2014/15 debtors are paying by instalments and will have repaid fully by June.

16. The next two debts will be paid by May and the final one was invoiced in March.

**2014/15 financial accounts**

17. The annual accounts and reports are being drafted at the time of writing and the audit commenced on 27 April.

18. The Audit and Risk Assurance Committee will review the accounts and reports at their meeting on 2 June, 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.

19. Key points from the draft annual accounts will be presented at the Authority meeting.
20. The reports in aggregate have a similar scope and requirements as last year. We have developed them to reflect the updated Financial Reporting Manual and ensured that the content of the Strategic Report and Directors Report meet requirements. Last year, these reports cross-referred to information in other reports.

Budget for 2015/16

21. A budget of £4.33m (net of secondment recoveries) has been agreed for 2015/16. £3.38m is expected from the licence fees set. Devolved administrations are expected to contribute £115k and NHS Litigation Authority £99k (for rented office space). Revenue Grant-in-aid of £740k has been agreed by the Department of Health (DH).

22. DH has also been asked to agree that we can spend the remaining £10k, of the £60k provided in 2014/15, on the development of the new website in 2015/16. We have also requested a capital budget for 2015/16 of up to £100k for the CRM upgrade.

Financial risks

23. 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 of 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.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Link to the HTA’s strategic risks</th>
<th>Mitigating actions and controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>A significant under-spend leading to a loss of stakeholder confidence in the HTA’s ability to manage resources effectively</td>
<td>Inadequate relationship management</td>
<td>Identification of the likely outturn as early as possible. Credit of unused licence fees to establishments</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>Insufficient financial resources</td>
<td>HTA undertake a periodic review of establishments and expected income. If insufficient income is projected, budgets would need to be managed to reflect income, be supplemented</td>
</tr>
<tr>
<td>Risk</td>
<td>Link to the HTA’s strategic risks</td>
<td>Mitigating actions and controls</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>--------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lack of prompt payment by licence fee payers adversely affects cash flow and operations</td>
<td>Insufficient financial resources</td>
<td>Revenue collection is closely monitored and the HTA’s credit control and debt collection procedures is used to pursue and recover all 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>Insufficient financial resources, Inability to carry out its statutory remit</td>
<td>The HTA’s financial management and governance arrangements will be used to identify any opportunities that may arise to make efficiencies, offset budgetary pressures and vire monies from elsewhere to fund any such initiatives or costs. Costs are closely monitored</td>
</tr>
</tbody>
</table>
## Human Tissue Authority

Summary - Income & Expenditure  
Annex A

For the Twelve Months Ending 31 March 2015

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals £</td>
</tr>
<tr>
<td>Income</td>
<td>(4,366,659)</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>4,144,079</td>
</tr>
<tr>
<td></td>
<td>--------------</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(222,580)</td>
</tr>
<tr>
<td>Exceptional items</td>
<td></td>
</tr>
<tr>
<td>Internal adjustments</td>
<td>(4,125)</td>
</tr>
<tr>
<td>Rebate(s)</td>
<td>19,181</td>
</tr>
<tr>
<td></td>
<td>--------------</td>
</tr>
<tr>
<td>Total Exceptional Items</td>
<td>15,056</td>
</tr>
<tr>
<td></td>
<td>--------------</td>
</tr>
<tr>
<td>Net (surplus)/deficit of income over expenditure</td>
<td>(207,523)</td>
</tr>
</tbody>
</table>
### Human Tissue Authority

**Member Income Summary**

**Annex B**

For the Twelve Months Ending 31 March 2015

<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>
</tbody>
</table>

- **Grant In Aid**
  - GIA: 739,000
  - Sub-Total: 739,000

- **Licence Fees**
  - Application Fees: 48,100
  - Anatomy: 80,367
  - Post Mortem: 1,082,850
  - Public Display: 15,575
  - Research: 657,449
  - Human application: 1,123,596
  - Licence Fees - ODT: 279,575
  - Sub-Total: 3,287,511

- **Other**
  - Other income (Rent): 98,904
  - Other income (Secondees): 125,485
  - Other income (Interest): 372
  - Devolved Assemblies: 115,387
  - Sub-Total: 340,147

- **Total Income**
  - 4,366,659

---

08/04/15
04:36 PM
### Human Tissue Authority

**Summary - Expenditure**

**Annex C**

For the Twelve Months Ending 31 March 2015

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
<td>Variance</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EXPENDITURE SUMMARY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff Costs</td>
<td>2,669,229</td>
<td>2,760,439</td>
<td>(91,211)</td>
<td>-3.30%</td>
<td></td>
</tr>
<tr>
<td>Non Staff Costs</td>
<td>1,474,850</td>
<td>1,505,212</td>
<td>(30,361)</td>
<td>-2.02%</td>
<td></td>
</tr>
<tr>
<td><strong>Gross Costs before Exceptional Items</strong></td>
<td>4,144,079</td>
<td>4,265,651</td>
<td>(121,572)</td>
<td>-2.85%</td>
<td></td>
</tr>
<tr>
<td><strong>Exceptional items</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal adjustments</td>
<td>(4,125)</td>
<td>0</td>
<td>(4,125)</td>
<td>#DIV/0!</td>
<td></td>
</tr>
<tr>
<td>SoHO V&amp;S accrual released</td>
<td>19,181</td>
<td>0</td>
<td>19,181</td>
<td>#DIV/0!</td>
<td></td>
</tr>
<tr>
<td><strong>Total Exceptional Items</strong></td>
<td>15,056</td>
<td>0</td>
<td>15,056</td>
<td>#DIV/0!</td>
<td></td>
</tr>
<tr>
<td><strong>Total Expenditure</strong></td>
<td>4,159,135</td>
<td>4,265,651</td>
<td>(106,516)</td>
<td>-2.50%</td>
<td></td>
</tr>
</tbody>
</table>

08/04/15
04:50 PM
# Human Tissue Authority

## Directorate Summary

**For the Twelve Months Ending 31 March 2015**

<table>
<thead>
<tr>
<th>Service Area</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>Communications and Public Affairs</td>
<td>220,889</td>
<td>286,297</td>
<td>(65,408)</td>
<td>-22.85%</td>
</tr>
<tr>
<td>Regulation</td>
<td>1,564,726</td>
<td>1,588,771</td>
<td>(24,045)</td>
<td>-1.51%</td>
</tr>
<tr>
<td>Strategy and Quality</td>
<td>330,780</td>
<td>354,549</td>
<td>(23,769)</td>
<td>-6.70%</td>
</tr>
<tr>
<td>HTA Board</td>
<td>165,763</td>
<td>179,496</td>
<td>(13,733)</td>
<td>-7.65%</td>
</tr>
<tr>
<td>Resources</td>
<td>1,427,134</td>
<td>1,428,784</td>
<td>(1,649)</td>
<td>-0.12%</td>
</tr>
<tr>
<td>Chief Executive's Office</td>
<td>434,787</td>
<td>427,754</td>
<td>7,033</td>
<td>1.64%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>4,144,079</strong></td>
<td><strong>4,265,651</strong></td>
<td><strong>(121,572)</strong></td>
<td><strong>-2.85%</strong></td>
</tr>
<tr>
<td>Exceptional adjustments</td>
<td>(4,125)</td>
<td>0</td>
<td>(4,125)</td>
<td></td>
</tr>
<tr>
<td>SoHO V&amp;S accrual released</td>
<td>19,181</td>
<td>0</td>
<td>19,181</td>
<td></td>
</tr>
<tr>
<td><strong>Total Directorate(s) Expenditure</strong></td>
<td><strong>4,159,135</strong></td>
<td><strong>4,265,651</strong></td>
<td><strong>(106,516)</strong></td>
<td><strong>-2.50%</strong></td>
</tr>
</tbody>
</table>

08/04/15 04:57 PM
Authority paper

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**Date** 28 April 2015  
**Paper reference** HTA (23/15)

**Agenda item** 14  
**Author** Amy Gelsthorpe-Hill

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**Strategic Performance Review – Quarter Four**

**Purpose of paper**

1. To inform Members of progress against key performance indicators (KPIs) during quarter four of 2014/15.

**Action**

2. Members are asked to note the content of this report.

**Decision-making process to date**

3. The Human Tissue Authority’s Management Group has reviewed the content of this paper as part of its monthly monitoring of business plan delivery. The papers were approved for submission by SMT at its meeting on 16 April.

**Background**

4. The Authority has agreed to monitor a set of KPIs that demonstrate whether the HTA’s strategic aims are being delivered.

5. This is an exception-based report; KPIs which are not listed individually were reported green for the month in question.

**Regulation Directorate**

6. All KPIs for the Regulation Directorate were within tolerance and reported as green for January, February and March.
Strategy and Quality Directorate

7. All KPIs for the Strategy and Quality Directorate were within tolerance and reported as green for January and February.

8. Performance against KPI 1.6, which states that 100% of panel cases are turned around within 10 working days, was red for March at 92%. Of the 13 panel cases turned around in March, one case was approved on day 12.

Resources Directorate

9. Performance against KPI 4.1, which states that the average licensing fee would increase by no more than 3% from 2014/15 level or that fees set would generate no more than £3.4m in revenue, was achieved and completed in October 2014. The Authority agreed proposals for 2015/16 fees that would bring in approximately £3.4m at its meeting on 28 October.

10. There are no further KPIs for the Resources Directorate.

Communications and Corporate Support Directorate

11. Performance against KPI 2.4, which states that ‘at least 95% of enquiries are answered within 10 working days of receipt, excluding body donation enquiries’, was red for January at 93%. The KPI was green for February and March, at 96% and 95% respectively, meaning the KPI was green for the quarterly Communications Report. Enquiries that took longer than 10 working days related to investigations, concerns raised about establishments or enquiries that needed third party information.

12. KPI 3.2 states that the HTA’s attrition rate should be no more than 18%, measured monthly, on a rolling annual basis. It was reported as red for January, February and March, with a rolling monthly attrition rate of 25%, 23% and 23% respectively against a rolling annual attrition rate target of 18%.

13. The Chief Executive Officer, Living Organ Donation Manager, Website and Communications Officer and an Administration Assistant tendered their resignations in quarter four.

14. The Living Donation Manager elected not to return from maternity leave. A fixed term maternity cover contract had been recruited to through a competitive process and was filled by an internal candidate. This contract was converted to permanent; therefore no recruitment is required for this role.
15. The Personal Assistant to the Senior Management Team moved to the new role of Executive Assistant on 12 January.

16. The following new staff appointments have been made in quarter four:
   
   a) the Administration Assistant post was filled and the new post holder started on 30 March
   b) the Personal Assistant to the Senior Management Team post was filled and the new post holder started on 7 April
   c) the Communications Officer post was filled and the new post holder started on 27 April

17. Recruitment for the Chief Executive Officer is currently underway and interviews are provisionally due to be held in the first week of June.

18. The job title and description for the Website and Communications Officer role had been reviewed and amended in accordance with the tasks involved in the role and business need. Recruitment for the Website and Design Officer was underway and interviews were held on 15 April.
Communications Evaluation Report – Quarter Four

Purpose of paper

1. This report forms the evaluation strand of the HTA’s communications strategy. Its purpose is to provide regular and consistent performance metrics on the HTA’s communications activity, specifically media, digital communications, stakeholder engagement and enquiries.

2. This report evaluates communications activity from 1 January – 31 March 2015 (Q4).

Action

3. Authority Members are asked to note the content of this paper.

Decision-making process to date

4. SMT reviewed the content of the report on 9 April 2015.

Media activity

5. In Q4 2014/15, we had 31 mentions in the media (all reported in the weekly HTA news digest). This compared with 26 in the previous quarter. We had 193 mentions in the whole of the 2014/15 year.

6. The tables below show the subject of the HTA’s media coverage and the tone of the media coverage in this quarter compared with the previous quarter.
**Media coverage subject type**

<table>
<thead>
<tr>
<th>Media coverage subject type</th>
<th>Q3 14/15</th>
<th>Q4 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate (media about Authority Members or the running of the HTA)</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Organ donation</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Research</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Body Donation/ Anatomy/Public Display</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Post mortem</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Human application</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Legislation/ Regulations</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26</strong></td>
<td><strong>31</strong></td>
</tr>
</tbody>
</table>

**Tone of media coverage**

<table>
<thead>
<tr>
<th>Tone of media coverage</th>
<th>Q3 14/15</th>
<th>Q4 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Neutral</td>
<td>19</td>
<td>25</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26</strong></td>
<td><strong>31</strong></td>
</tr>
</tbody>
</table>

7. Coverage in Q4 was 100% positive or neutral. The compares with 85% in the previous quarter. This is measured against our 2014/15 performance indicator of 90% positive/neutral.

**HTA media stories**

8. In Q4, we issued a number of proactive comments and statements on different parts of the HTA’s work, for example the publication of the HTA’s pregnancy remains guidance and anatomy sector report, our response to the government’s regenerative medicine report and welcoming NHS Blood and Transplant’s 3-for1 living transplant scheme. We also publicised key HTA guidance like contingency planning for mortuaries during busy periods.

9. In this quarter, we worked reactively with a number of journalists from the Daily Mail, The Sun and The Mirror to ensure that our work was described accurately. There was significant interest in living donation, serious incidents in mortuaries and serious events or reactions following Freedom of Information requests. A
Head of Regulation gave an interview about body donation which was carried in the Observer.

Media/journalist enquiries

10. In Q4 2014/15, we had 43 enquiries from journalists, compared to 18 in the previous quarter. Over the year, we have answered 124 media enquiries. Our performance indicator is to answer 100% of media enquiries within the journalist’s deadline. We achieved this.

Social Media

11. The HTA’s Twitter account has 838 followers, up from 767 in the previous quarter; we have 407 Facebook ‘likes’, up from 367, and 244 followers on LinkedIn, up from 189 in the previous quarter.

Stakeholder activity

12. The Chair, the Chief Executive, and/or other members of SMT were involved in several stakeholder meetings and events including:

- Meetings with Arthritis Research, British Heart Foundation, NHS Blood and Transplant, the Coroners Society, the Royal College of Pathologists and Earl Howe.

13. In this quarter, we published our pregnancy remains guidance which was produced in consultation with key stakeholders. This guidance was disseminated to Designated Individuals and other interested stakeholders. We are working with NHS England and the Department of Health to make sure the guidance is given to all hospital Trusts and abortion clinics.

14. We also publicised the HTA’s anatomy report and guidance to transplant teams and Independent Assessor.

Public/patient involvement and engagement

15. During this quarter, the HTA Chair met with the British Heart Foundation and Arthritis Research to talk about areas of joint concern, but specifically patient and public involvement.
Cord blood information campaign

16. Over a three month period at the end of 2014 and beginning of 2015, we ran a survey asking people who had banked cord blood, or who were considering banking cord blood, to respond to a series of questions about their knowledge and understanding of the area. Over 120 people responded.

17. About the people who responded:
- The majority of people responding (55%) were people who were considering banking their cord blood
- Over 20% had banked cord blood
- Just under 20% were considering it as a gift for someone else
- About 5% had given cord blood banking as a gift

18. Where do people bank?
- Of the people who were considering banking cord blood: just under 15% were considering public banking; just under 30% were considering private banking; around 55% were not sure
- Of the people who had banked cord blood, just over 20% had done so in a public bank, and just under 80% did it privately

19. Access to information:
- In only 20% of cases did people feel like they had adequate information about cord blood banking
- Reputation and cost were key considerations for people considering banking

20. Based on the survey results, there is a clear need for further guidance in this area. To address this, the Regulation Team has put together a package of information aimed at the public to better inform them about cord blood banking. We will launch the package of information following the election and further consultation with stakeholders.

21. The All-Party Parliamentary Group on Stem Cell Transplantation published ‘Cord Blood Transplantation: Meeting the Unmet Demand – Progress Review’. The report measures progress since the publication of the group’s original report in 2012. Recommendation 7 of the report is that Antony Nolan, NHS Blood and Transplant and private cord blood banks should work with the HTA to ensure mothers are fully equipped to make an informed decision about cord blood banking.
Enquiries

22. During Q4, we recorded 560 enquiries, compared to 456 in the previous quarter. Over the year we have recorded 2029 enquiries in total. The enquiries included:

- 218 from members of the public, of which 185 were about body donation and 33 were general enquiries. This compares with a total of 197 enquiries from members of the public in the previous quarter, of which 153 were about body donation
- 187 from professionals, compared with 172 in the previous quarter
- 43 from the media, compared with 18 in the previous quarter (as reported in paragraph 10)
- 100 from unknown audiences

23. Of all the enquiries that we received in this quarter, half were received via email and half via phone. Since we launched the new website at the beginning of the quarter, we have received over 150 enquiries via the new web form.

24. The HTA sets itself a KPI of responding to 95% of enquiries in 10 working days. 95% of enquiries were closed in our case management system in Q4, compared to 94% in the previous quarter. Over this quarter, 98% of enquiries were responded to within 20 working days. The cases that fell outside 20 working days tended to involve investigations of establishments.

25. In Q4, 45 body donation packs were issued, compared to 33 in Q3.

26. We received five parliamentary questions in Q4, compared with 15 in the previous quarter.

27. During this period, we had seven Freedom of Information requests, compared to zero in the previous quarter. All were responded to within the 20 day statutory time limit. The requests focused on serious incidents in mortuaries, events and reactions in the human application and organ donation and transplantation sector, IT contracts, expenses, staff leave and third party suppliers.

Digital communications and publications

*Website improvement project, including review of public facing information*

28. During Q4 we launched the HTA’s new website which has received favourable feedback. During February and March 2015, we ran a survey about the new website:

- 81% of responders said that they found the new website ‘better designed and easier to use’. Our KPI was 80%
70% of web users say they ‘could find the information they were looking for’. Our KPI was 60%

**HTA e-newsletter**

29. The HTA launched its redesigned newsletter in January and we have sent out two newsletters in this quarter (January and March). Along with the new design, the new newsletter system allows us to see approximately how many subscribers open the newsletter. The government average is for 24% of subscribers to open newsletters. Against this benchmark the HTA performs well; 33% of Designated Individuals, 60% of those who subscribed via the website, and 27% of previous subscribers opened the newsletter within 48 hours.

**Design and publications**

30. In this quarter, the Communications team designed the new anatomy report and material for the Post Mortem sector workshops. We also produced front covers for the business and strategic plan and the new guidance to transplant teams and Independent Assessors.

**Communications KPI update**

<table>
<thead>
<tr>
<th>KPI</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KPI 2.1 (a) – Project to launch new website platform</strong></td>
<td>Complete</td>
</tr>
<tr>
<td>Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage of approved project.</td>
<td></td>
</tr>
<tr>
<td><strong>KPI 2.1 (b) – Dedicated public-facing section of the website developed by end of Q3, which includes key information on cord blood to support informed consent. Includes information on how to comment on the services regulated by the HTA.</strong></td>
<td>Complete</td>
</tr>
<tr>
<td><strong>KPI 2.2 (a) – 80% of all those responding to a January 2015 survey say that they find the new website ‘better designed and easier to use’</strong></td>
<td>Green (para 28)</td>
</tr>
<tr>
<td><strong>KPI 2.2 (b) – 60% of web users say they ‘could find the information they were looking for’</strong></td>
<td>Green (para 28)</td>
</tr>
<tr>
<td><strong>KPI 2.3 – At least 95% of enquiries are answered within 10 working days of receipt, excluding body donation enquiries</strong></td>
<td>95% (para 24)</td>
</tr>
</tbody>
</table>
Audit and Risk Assurance Committee meeting report - 4 February 2015

Purpose of paper

1. To provide the Authority with the key points arising from the last Audit and Risk Assurance Committee meeting.

Action

2. The Authority is asked to note the content of this paper.

Decision making process to date

3. This paper and the minutes of the meeting have been agreed by Catharine Seddon, Chair of the Audit and Risk Assurance Committee.

Background

4. This is a regular report to the Authority, which is provided three times per year at the Authority meeting following the Audit and Risk Assurance Committee.

Key points from meeting

5. This was the first meeting following the changes to committee and group membership.
6. The annual confidential session between Members and external and internal auditors was held at the start of the Meeting.

7. The Committee was given an overview of changes to the policies and procedures agreed by SMT and approved the HTA Reserves policy and the Treasury Management policy.

8. Internal audit presented their report from the Assurance Mapping Workshop on People activities. The Committee found this very useful and has asked for other key areas to be mapped over time. The Committee also agreed the draft 2015/16 internal audit plan.

9. Alan Clamp and Dawn Pike, HR Manager, presented to the Committee the steps taken by the HTA to ensure a good organisational culture is achieved to manage risks and maximise our performance. There are several means by which staff can give feedback or raise concerns about culture and the Committee discussed the arrangements for whistleblowing. The Executive was asked to consider the need for Freedom to Speak Up champions for staff and the Authority.

10. The area of risk for discussion at the next meeting in June will be the risks to the HTA associated with Designated Individual turnover.

11. Full minutes of the meeting are provided at Annex A.
Annex A – Minutes of Audit and Risk Assurance Committee of 4 February 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>04 February 2015</th>
<th>Author</th>
<th>Seamus Budds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Mary Sumner House, 24 Tufton Street, London SW1P 3RB</td>
<td>Protective Marking</td>
<td>PROTECT</td>
</tr>
</tbody>
</table>

**Present**

<table>
<thead>
<tr>
<th>Members</th>
<th>In attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catharine Seddon (Chair)</td>
<td>Catherine Hepburn (NAO)</td>
</tr>
<tr>
<td>Amanda Gibbon</td>
<td>Jeff Porter (DH)</td>
</tr>
<tr>
<td>Rosie Glazebrook</td>
<td>Anna Wydra (NAO)</td>
</tr>
<tr>
<td>Andy Hall</td>
<td>Lynn Yallop (PwC)</td>
</tr>
<tr>
<td>Bill Horne</td>
<td></td>
</tr>
<tr>
<td>HTA Executive:</td>
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<tr>
<td>Morounke Akingbola (Head of Finance and Governance)</td>
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<tr>
<td>Seamus Budds (Finance Manager)</td>
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<tr>
<td>Alan Clamp (Chief Executive Officer)</td>
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<tr>
<td>Sue Gallone (Director of Resources)</td>
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<tr>
<td>Dawn Pike (HR Manager)</td>
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<tr>
<td>Item</td>
<td>Title</td>
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<tr>
<td>Item 1</td>
<td>Confidential session with auditors</td>
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<tr>
<td>1.</td>
<td>A confidential session between Members and external and internal auditors was held at the start of the Meeting.</td>
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<tr>
<td>Item 2</td>
<td>Welcome and apologies</td>
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<tr>
<td>2.</td>
<td>The Chair confirmed that the new Members of ARAC are Amanda Gibbon, Bill Horne, Rosie Glazebrook and Andy Hall and welcomed them.</td>
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<td>3.</td>
<td>The Chair also welcomed Lynn Yallop from PwC, Catherine Hepburn and Anna Wydra from the National Audit Office (NAO) and Jeff Porter from the Department of Health to the ARAC meeting.</td>
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<td>4.</td>
<td>The Chair thanked in their absence previous members Susan Dilly and Suzanne McCarthy for their significant and valuable contributions during their time on the Committee.</td>
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<td><strong>Action 1</strong> – ARAC minutes to be circulated to Susan and Suzanne.</td>
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<td>Item 3</td>
<td>Declarations of Interest</td>
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<tr>
<td>5.</td>
<td>There were no declarations of interest.</td>
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<tr>
<td>Item 4</td>
<td>Minutes of 06 November 2014</td>
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<tr>
<td>6.</td>
<td>The minutes of the 06 November 2014 meeting were agreed.</td>
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<tr>
<td>Item 5</td>
<td>Matters Arising</td>
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<tr>
<td>9.</td>
<td>Action 4 – Page 5. Assurance mapping work was</td>
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undertaken on 13 January 2015 and the report has been included at agenda item 8.

10. Action 5-7 – Page 6. The ARAC Handbook was updated and the amended Handbook and Terms of Reference have been circulated to Committee members.

11. Action 8 – Page 6. A discussion with Alan Clamp, Chief Executive Officer, and Dawn Pike, HR Manager, on Organisational Culture has been included at agenda item 7. Quality management improvement would be reviewed as a separate topic and discussed at agenda item 8.

<table>
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<tr>
<th>ARAC Chair’s update</th>
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<tr>
<td>12. The Chair reported on a DH conference for Non-executive directors that she had attended, where DH priorities were discussed together with the importance of organisational culture in all Arm’s Length Bodies (ALBs) delivering the Five Year Plan.</td>
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<td>13. The Chair had also responded to an annual survey on how DH internal audit arrangements are meeting the HTA’s needs and invited periodic feedback from Members for input into future similar surveys.</td>
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<tr>
<th>Item 6 Policy review</th>
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<td>14. Sue Gallone presented the Reserves policy drawing the Committee’s attention to the increase of minimum cash reserves to £1.8m to reflect additional cashflow needs.</td>
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<td>15. The Committee sought clarification on the definition of what is seen to be a “suitable period” in paragraph 5. It was agreed to use the wording in paragraph 11 to clarify the meaning.</td>
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<td>16. Subject to that amendment, the policy was agreed.</td>
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<td>17. Morounke Akingbola presented the Treasury Management policy for approval and updated the Committee on the minor changes to other policies that SMT approve.</td>
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<td>18. The Treasury Management policy was agreed and the Committee noted the reviews of other policies. The visibility of appropriate policies to all stakeholders was discussed.</td>
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<tr>
<td>19. It was suggested that, at the next review, policies</td>
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should follow a standard format, starting with principles, to aid clarity.

**Action 2** – SGa to clarify the definition of ‘suitable period’ in paragraph 5 of the Reserves policy.

**Action 3** – SGa to investigate the publishing of HTA policies, where appropriate, on the HTA website.

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<tr>
<th>Item 7</th>
<th>Risk update</th>
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<tr>
<td>20. Sue Gallone presented the latest strategic risk register.</td>
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<td>21. The Committee was informed there had been little change to risk levels and that we plan to adjust the risks in light of the new strategic plan.</td>
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<td>22. The Committee members were asked to assure themselves that risks are being managed appropriately.</td>
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<td>23. The Committee questioned whether the end of several Authority Members’ terms in 2016 had been included in risk 2 – Failure to manage change. Although it was noted that succession planning is included in the existing controls, it was also noted that it does not include specific reference to Authority Members.</td>
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<td>24. Alan Clamp described how culture and behaviour at the HTA are aligned with purpose and how we embed and monitor culture and behaviours, including through feedback and procedures for whistleblowing.</td>
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<td>25. Dawn Pike explained that the HTA engaged staff in reviewing and agreeing values and inviting staff to ‘champion’ a particular value each month.</td>
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<td>26. The Committee heard how the values are promoted to new staff during induction and incorporated into individual objectives where possible. Methods to gauge adherence, including use of the staff survey, were discussed.</td>
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<td>27. Alan Clamp explained the channels of feedback available to all HTA staff for raising concerns including the annual staff survey, a rolling survey (TinyPulse), team meetings, the suggestion box and the staff forum which meets every two months. Responses are given through the internal newsletter and the staff survey action plan.</td>
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| 28. Alan also highlighted the policies that uphold a good
organisational culture: the grievance, bullying and harassment, and whistleblowing policies. Staff wishing to raise concerns can talk to various members of staff, Members of the Authority, the Department of Health, the Whistleblowing helpline, the NAO, or raise concerns through the new Freedom to Speak website (Sir Robert Francis review).

29. It was suggested that SMT may consider adding to the options for each member of staff a designated person outside their own directorate, to whom they could refer concerns.

30. The Committee asked about numbers of grievances and trends. Dawn Pike confirmed it is several years since a grievance was raised.

31. The Committee discussed the Whistleblowing policy and questioned whether Authority Members should have a designated board member, separate from the Chair, with whom they could discuss concerns.

**Action 4 – DP to circulate the results of the last Staff Survey to new Authority Members.**

**Action 5 – SMT to consider assigning additional designated persons for all staff and Authority members to discuss concerns, and to ensure all staff and Authority members are aware of their whistle-blowing options.**

**Action 6 – SGa to provide oral reports of any grievances or disputes under AoB at future ARAC meetings, as well as any incidents of fraud.**

**Action 7 - Any emerging themes on people management, including from exit interviews, and Freedom of Information requests to be reported to future ARAC meetings under AoB.**

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<tr>
<th>Item 8</th>
<th>Internal Audit</th>
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<td>32. Lynn Yallop presented the internal audit progress report for 2014/15 – the plan has been fully delivered using slightly fewer days than were budgeted. The Committee questioned whether there were any plans to do any further work using the unused days. No needs have been identified and a new plan has been developed for 2015/16, but this is flexible if additional needs arise.</td>
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<td>33. Lynn presented the draft 2015/16 internal audit plan.</td>
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The four areas proposed for audit were living organ donation, business continuity, assurance mapping in relation to quality management and document retention.

34. The Committee discussed the number of days allocated to the topics identified. Lynn explained that the audit days are estimated taking into account the risk of the topic and experience, but these may vary when audits are underway and depending on need.

35. The Committee agreed the plan.

36. Lynn presented the Assurance Mapping Workshop report on People activities which was suggested as an addition to the 2014/15 Internal Audit Plan at the previous ARAC meeting.

37. The assurance map demonstrated a good spread of controls with 82% in the first line of defence, 15% and 3% in the second and third lines of defence. The review also identified a positive ratio of preventative (67%) versus detective (33%) controls currently in place. There were two areas where further action was needed to ensure controls were operating effectively.

38. The Committee found the assurance map very useful and revealing. Members felt that assurance mapping will give ARAC confidence to assert that key areas are sufficiently and properly controlled. Whilst ARAC recognised the resource implications for the HTA of detailed assurance mapping, they nonetheless requested that all areas of HTA activity be mapped over time.

Action 8 – SGa and LY to discuss the most valuable areas for assurance mapping that would give ARAC most assurance in the short term and to update ARAC on the timetable for comprehensive mapping.

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<tr>
<th>Item 9</th>
<th>Audit Tracker</th>
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<tr>
<td>39. Seamus Budds presented the audit tracker and the Committee noted progress.</td>
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<td>40. The two remaining recommendations from last year’s IT security audit will be implemented by the end of February 2015.</td>
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| Item 10 | External Audit |
41. Anna Wydra gave oral feedback from the first week of the interim audit. Anna informed the Committee that this year NAO will undertake the interim audit in two separate weeks and the second is scheduled for March 2015.

42. Anna highlighted the areas which NAO focused on during the first week of interim audit: licence fee income, staff costs, high level controls of monthly management accounts and the prior year recommendation on asset valuation.

43. The key findings were that the management accounts were of good quality and NAO is reviewing evidence provided to determine the reliance they can place on these. Two errors were found during work carried out on licence fee income and the implications are being considered. Overall, there were no major concerns.

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<tr>
<th>Item 11</th>
<th>Topics for future risk areas to be addressed</th>
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<tr>
<td>44. The Committee discussed possible areas of risk to be addressed at the June 2015 meeting. It was agreed that Assurance over the risks to the HTA due to turnover of Designated Individuals and DI training will be discussed in June 2015.</td>
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<tr>
<th>Item 12</th>
<th>Any other business</th>
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<tr>
<td>45. Sue Gallone confirmed that there had been no reports of suspected or actual fraud.</td>
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The next meeting is scheduled for 2 June 2015 at the BIS conference centre, 1 Victoria Street: 10.20am for ARAC members; 10.30am for all other attendees and observers.
Feedback Report - October 2014 to March 2015

Purpose of paper

1. To provide a summary of feedback - both positive and negative - and complaints received between October 2014 and March 2015 inclusive, and to describe how any issues raised have been addressed.

Background

2. The first HTA Complaints Report (superseded by this Feedback Report) was provided to the Authority in January 2013. Following that meeting, it was agreed that complaints should continue to be recorded in the HTA complaints log with a six-monthly report being provided to the Authority. Having recently reviewed the HTA complaints process, the Executive decided that the report could be extended to include positive feedback received to give a more rounded view of the HTA’s performance. This is the first such Feedback Report for the Authority. Members’ views on the new format of the report are welcomed.

3. The Senior Management Team (SMT) monitor complaints received on an ongoing basis and also share positive feedback received.

4. This Feedback Report was agreed at the SMT meeting held on 9 April 2015.
**Inspection feedback**

5. The inspection feedback from October 2014 to March 2015 was reviewed in order to capture any comment that may be construed as a complaint. During this period, the HTA inspected 74 establishments of which 23 establishments completed feedback forms, with a total of 33 individual responses received by the HTA.

6. Feedback on the inspections, as in the previous period, was very positive with 85% of respondents rating the inspection process as excellent and 15% of respondents rating the inspection process as good.

7. More than 90% of the responding establishments reported that the inspection process had led to improvements in their work.

8. No negative feedback was received during this period, although some suggestions on how to improve the process were given.

9. All inspection feedback reports were sent to the Heads of Regulation who dealt with any issues raised. The relevant Head of Regulation also decides what, if anything is reported back to the individual or establishments concerned. Similarly, the Heads review whether any of the suggestions made should be implemented more widely.

**Complaints**

*Formal Complaint*

10. One formal complaint was received during this period.

11. An enquiry is deemed to be a complaint if it is an allegation against the HTA about the way we have exercised, or failed to exercise, our functions.

12. When a formal written complaint is received, it is immediately forwarded to the Complaints Officer. The Complaints Officer registers, acknowledges, classifies and assigns the formal complaint for detailed investigation.

13. On 16 October, the HTA received a complaint pertaining to the submission of a Preparation Process Dossier (PPD) by an establishment seeking approval to process, test and store whole umbilical cord blood which was submitted in October 2013. The establishment expressed concern with regards to how the HTA handled and managed their submission. They believed that we had taken too long to reach a decision and had not been coordinated in our approach to requests for information.
14. In response to the complaint, the HTA considered whether we could have dealt with the PPD more quickly and whether we should have requested all information at the beginning of the process. We did not, however, believe this to be the case and, in our reply, explained how we handle PPDs and why it may be necessary to seek additional information once the original request had been complied with. Whilst we did not uphold this part of the complaint, we identified some correspondence which had not been dealt with and we apologised for this.

15. Nothing further has been received from the complainant.

In informal Complaint

16. Two informal complaints were received during this period.

17. When an individual has indicated (in person, on the phone or email) that they are less than happy with the level of service provided by the HTA, this is classified as an informal complaint. In such cases, staff will normally have resolved these issues; however, these types of complaints are recorded on the HTA’s database and logged for future reference to inform actions or improvements. A summary of the complaints is provided below.

Complaint one

18. On 22 December 2014, the HTA received a telephone call from a member of the public initially wanting to speak to a named Head of Regulation. Once aware that the person was unavailable, he became agitated. The caller’s attitude and aggressive tone was unacceptable and the HTA staff member was left with no choice but to terminate the call in a polite but firm manner.

19. The member of public had called previously and spoken to the CEO and Head of Regulation, and was informed at the time that his concerns did not fall within the remit of the HTA. The CEO called the complainant back on 22 December and reiterated this information.

20. The caller has not made contact since.

Complaint two

21. On 23 January 2014, we received a complaint from a member of the public regarding a delay in replying to correspondence over the Christmas period. He felt that the delay was disrespectful based on the nature of the issue he had raised.
22. Following a review of the correspondence, we apologised for the delay. We also reminded colleagues of the impact delays in responding to correspondence can have on those who have recently been bereaved. We remain in correspondence with the complainant about the substantive issues he raised.

Positive feedback

23. This report now includes positive feedback received by HTA staff. Some of the positive feedback received by HTA during this period is summarised below.

Feedback following inspection

24. “Communication was friendly, open and clear. It was a pleasure working with the HTA team”.

25. “Lots of advice received which we found to be excellent and we will take forward to further improve our service”.

26. “With it being our first inspection, I was very pleased to receive their feedback. Comments and advice were extremely useful and I am positive we will use these to improve our service further”.

27. “The auditors were very transparent which was a big help during the audit and their advice was informative and clearly explained”.

28. “The inspection was carried out with a high degree of expertise. The process was managed very well by the HTA team and I felt that they really helped with the improvement of our mortuary service”.

29. “I have been involved in audits by a number of other individuals or organisations and I felt that the HTA audit team were very competent and professional. It was a very useful process for us and it advanced both our compliance and our understanding of our responsibilities under our HTA licence. I can’t really think of any suggestions for improvement. This was one of the best run audits I have been involved with.”

30. The next Feedback report is scheduled for October 2015.

31. Members are asked to note the content of the report.