Human Tissue Authority
Board Meeting

Date: 14 July 2022

Time: 09.30 - 11.30 Main meeting
11.30 – 12.30 Board and Chief Executive

Venue: Zoom

Meeting Number: 101

Protective Marking: OFFICIAL

Agenda

Meeting Administration

1. Welcome and apologies (LB)

2. Declarations of interest (LB)

Regular Reporting

3. Chairs Report (Oral) (LB)

4. Chief Executive's Report (HTA 20/22) (CS)
   Annex A Framework Agreement (HTA 20a/22)

5. HTA Performance Report (HTA 21/22) (CS)
   Annex A Quarterly Board Data Overview (HTA 21a/22)
   Annex B Summary of Strategic Risk Register (HTA 21b/22)
   Annex C Strategic Risk Register (HTA 21c/22)

6. Update from DHSC Sponsor Team (Oral)

Items for discussion

7. Deemed Consent NI (HTA 22/22) (LD)
   Annex – Draft Code of Practice F Part Two (HTA 22a/22)

8. Development Programme (HTA 23/22) (LD)

9. Horizon Scanning (HTA 24/22) (LD)

10. Risk Appetite (HTA 25/22) (RS)

Committee and Working Groups

11. Audit and Risk Assurance Committee Update (HTA 26/22) (GC)

12. Item 12 is confidential and not included.

Items for information only

13. Minutes of 5 May 2022 (HTA 28/22) (LB)

14. Matters arising from 5 May 2022 (HTA 29/22) (LB)

Any Other Business

15. Any other business (oral)

This version 6 July 2022

Human Tissue Authority Board Meeting

Date: 14 July 2022

Paper reference: HTA 20/22

Agenda item: 4

Author: Dr Colin Sullivan

OFFICIAL

Chief Executive's Report

Purpose of paper

1. To inform the HTA Board of key or current issues from the CEO's perspective.

Action required

2. The HTA Board is asked to note and comment on the issues raised.

Update on Q1

3. During Q1, we have agreed and I have signed the latest 3-year Framework Agreement with our parent Department (DHSC). This sets out the broad governance arrangements within which the HTA and DHSC operate. It is attached at **Annex A** and will be published on Gov.UK and on the HTA's website. We also held the latest quarterly Accountability Meeting with Departmental colleagues on 24 May 2022 in 39 Victoria Street. The next meeting will be in our HQ in Redman Place in September. In the quarter, I also met with colleagues in the Welsh Government.

4. Business Plan – We held an internal review of progress against the business plan at the end of June. We are broadly on track with our delivery of core business activities and work is underway on initiating some of the key projects that we have committed to delivering this business year. Across the business,

heads of functions have been reviewing the KPIs set out in the Business Plan for their respective areas. Work continues to further define and agree our KPIs in the Business Plan as well as reviewing current and pipeline projects in line with our review of Quarter 1 at the end of July.

5. In relation to the Fuller Independent Inquiry, in May, we published on our website (HTA Progress Update on advice to the Secretary of State for Health and Social Care in connection with offending by Fuller in a hospital mortuary | Events | Human Tissue Authority) advice we had provided to the Secretary of State for Health & Social Care in December 2021 about the HTA's role and remit, alongside a brief progress update on what we had been doing since then. This gave some more detail on the steps the HTA had been taking to review the guidance to some of the licensing Standards for the Post-Mortem sector. It also noted that we were engaging with stakeholders involved in mortuary oversight across the wider health sector to coordinate and join up our approach and were preparing to provide input, as required, to Sir Jonathan Michael's Independent Inquiry.

6. Q1 was another busy period for recruitment activity with the appointment of 3 new starters: 1 permanent role, 1 Fixed Term contractor and 1 long term secondee. There have also been ongoing recruitment campaigns for the Deputy Director for Performance & Corporate Governance, a replacement HR Manager, a Project Manager and 3 Regulation Managers.

7. During Q1, meetings with external stakeholders included discussions with Peter Thompson (HFEA CEO), Matt Westmore (HRA CEO), Alan Clamp (Professional Standards Authority CEO) and Martin Jones (Parole Board CEO), in his role as Chair of the Association of Chief Executives.

8. In exploring how best to progress the Review of Inspections, in Q1, I also met with Graham Russell, head of the Office for Product Safety and Standards (OPSS) and Prof Chris Hodges at Oxford University. To progress the Culture Review / OD project, I held discussions with the NHS Leadership Academy and the HSC Leadership Centre.

9. I also convened two meetings of the EDI Diversity Collective Forum meeting for Redman Place which has representation from NICE, HFEA, CQC, HRA, as well as HTA.

10. Separately, I met with the heads of both internal and external audit.

11. In my last CEO Report for the May Board, I highlighted that the HTA was likely to be called to give evidence to the House of Commons Science and Technology Committee Inquiry, “Right to privacy: digital data” in June. This did not transpire as the primary focus of the Committee’s activity has concentrated on other areas.

Current issues

12. As Board members will recall, we have set an ambitious target of completing 210 inspections during the FY 2022/23. This is an increase of 50% on the previous year’s target (140) and is designed to provide greater assurance (by increasing our contact with more establishments annually) facilitated through the application of a wider range of regulatory approaches and taking a more proportionate and risk-based approach. By 15 June, the cut-off date for reporting for this report, we had completed 40 inspections and were on track to accomplish our quarterly target of 56, with inspections not evenly scheduled across a quarter.

13. The Second Permanent Secretary at the Department of Health & Social Care has recently established a forum for DHSC ALB Chief Executives to discuss areas of mutual interest. This should be a further opportunity to collaborate with other health regulators and support one another. Likely areas of focus for this forum will be to look at improved data sharing, opportunities for shared services whether location based or otherwise, and looking at opportunities for refining or streamlining legalisation and to deal with gaps or overlaps. This forum is in addition to the standing National Health CEO’s meeting, led by CQC, which HTA now attends.

14. On 28 June 2022, Cabinet Office published the terms of reference for the UK Covid-19 Inquiry. Since the original announcement of the Inquiry, the HTA has been identifying and collecting information in readiness for any future requests or contribution it may be required to make. At this point, there are no further details of the HTA’s contribution to the inquiry, although we stand ready to assist with any key lines of enquiry.

15. The HTA has been approached by the Isle of Man (IoM) government to explore whether the HTA is able to provide an inspection function for the IoM following the passing of their Human Tissue & Organ Donation Act 2021. HTA can provide support on an advisory basis only which would also include occasional ad hoc technical advice and guidance on a regulatory, inspections and policy basis. This function would not be required until the 2023/24 business year at the earliest and the HTA is working closely with the IoM Public Health Department to explore how best the HTA may support this work and keeping the DHSC Sponsor Team fully informed as these discussions unfold.

16. The HTA has been in discussions with NHSBT, DHSC and colleagues in Devolved Administrations on operationalising the government amendment on Organ Transplant Tourism (a term attributed to illicit travel for transplantation that does not fall within legitimate arrangements). The amendment extends the offences set out in Section 32 (1) of the Human Tissue Act (2004) (and Section 20 of the Human Tissue (Scotland) Act 2006), relating to financial or commercial dealings in human organs for transplantation, as these now have extraterritorial jurisdiction. The amendment took effect on 1 July.

17. The number of cases likely to arise in any year are believed to be low – NHSBT estimate no more than 1-2 per year but we have agreed a process whereby NHSBT will refer any suspicious cases identified by clinicians to us for review. We will pass any case we believe warrants action to the relevant police force via the National Crime Agency. We have also provided updated information on our website. The issue of “consent” and what that means in the different sectors that we regulate continues to be at the heart of so much of what we do, whether it be avoiding coercion and financial incentives or supporting the implementation of deemed consent, as is currently the case in Northern Ireland. This highlights that “consent”, whilst acknowledging there may be evolving societal attitudes over time, will continue to be a key issue for the Board to keep on its radar as part of our horizon scanning.

18. Vision and Mission Statements - After the discussion with the Board in May, these statements were refined further with input from SMT and then looping back to Board members. I have included, below, the final versions of our new Vision and Mission Statements.

> Vision (for the system we regulate): **“The safe and trusted use of human tissue”**
>
> Mission (of the HTA): **"To be an excellent regulator for the use of human tissue with consent and safety, sustaining public and professional confidence, today and in the future."**

19. We have shared these with staff and these “guiding stars” were important to help guide discussions at the latest All-Staff Day held on 30th June in Redman Place.

20. We have also been developing a related Strategic Narrative, which in several paragraphs seeks to expand on our goals, and also, to outline and explain the journey we are embarked upon to reach the ambitions described in these statements.

Recommendation

21. The HTA Board is asked to note and comment on the issues raised.

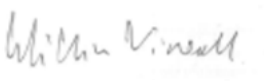
Department of Health & Social Care

HTA
Human Tissue Authority

Framework agreement between the Department of Health and Social Care and the Human Tissue Authority

Published [DD Month Year]

Signed



William Vineall

Date: 9th June 2022

(On behalf of the Department)

Signed

Colin Sullivan

Date: 15 June 2022

(On behalf of the HTA)

Contents

1. Introduction and background 4
Purpose of document 4
Objectives 4
Classification 5
2. Purposes, powers, duties and aims 6
Purposes 6
Powers and duties 6
Aims 6
3. Governance and accountability 8
4. Role of the department 9
The responsible minister 9
Appointments to the board 9
Other ministerial powers and responsibilities 10
The principal accounting officer 10
The role of the senior departmental sponsor 11
The role of the sponsor team 12
Resolution of disputes between the HTA and DHSC 13
Freedom of Information requests 13
Reporting on legal risk and litigation 13
5. The HTA governance structure 15
The chief executive 15
The HTA board 18
The chair's role and responsibilities 21
6. Management and financial responsibilities and controls 24
Delegated authorities 24
Spending authority 24
Banking and managing cash 25
Procurement 25
Risk management 26
Counter fraud and theft 27
Staff 27
7. Business plans, financial reporting and information management 30

Corporate and business plans 30
Budgeting procedures 31
Grant-in-aid and any ring-fenced grants 31
Annual report and accounts 32
Reporting performance to DHSC 32
Information sharing 33

8. Audit 34
External audit 34

9. Reviews and winding up arrangements 36
Review of the HTA's status 36
Arrangements in the event that the HTA is wound up 36

10. Other matters 37
Partnership working 37
Communications between DHSC and the HTA 38
Relations with DHSC's other arm's length bodies 38
Transparency 38
Public and parliamentary accountability 39
Equalities 40
Whistleblowing 41
Sustainability 41

1. Introduction and background

Purpose of document

1.1 This framework agreement has been agreed between the Department of Health and Social Care (DHSC) and the Human Tissue Authority (HTA) in accordance with HM Treasury's handbook Managing Public Money (as updated from time to time) and has been approved by HM Treasury.

1.2 The framework agreement sets out the broad governance framework within which the HTA and DHSC operate. It sets out the HTA's core responsibilities; describes the governance and accountability framework that applies between the roles of DHSC and the HTA; and sets out how the day-to-day relationship works in practice, including in relation to governance and financial matters.

1.3 The document does not convey any legal powers or responsibilities, but all parties agree to operate within its terms.

1.4 References to the HTA include all its subsidiaries and joint ventures that are classified to the public sector and central government for national accounts purposes. If the HTA establishes a subsidiary or joint venture, there shall be a document setting out the arrangements between it and the HTA agreed with DHSC.

1.5 Copies of the document and any subsequent amendments have been placed in the libraries of both Houses of Parliament and made available to members of the public on the HTA's website and on GOV.UK.

1.6 This framework agreement should be reviewed and updated at least every 3 years unless there are exceptional reasons that render this inappropriate that have been agreed with HM Treasury and the principal accounting officer of the sponsor department. The latest date for review and updating of this document is 2025.

Objectives

1.7 DHSC and the HTA share the common objective of maintaining public and professional confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely, ethically and with proper consent. To achieve this the HTA and DHSC will work together in recognition of each other's roles and areas of expertise, providing an effective environment for the HTA to achieve its objectives through the promotion of partnership and trust and ensuring

that the HTA also supports the strategic aims and objectives of DHSC and wider government as a whole.

Classification

1.8 The HTA has been classified as a central government organisation by the Office for National Statistics/HM Treasury Classifications team.

1.9 It has been administratively classified by the Cabinet Office as a non-departmental public body (NDPB).

2. Purposes, powers, duties and aims

Purposes

2.1 The HTA is an independent regulator established under the Human Tissue Act 2004 (the HT Act). Its remit and general functions are set out in sections 14 and 15 of, and schedule 2 to, that Act.

Powers and duties

2.2 The HTA's powers and duties are set out in the HT Act, in particular in part 2.

2.3 The HTA's statutory duties include:

- licensing organisations that remove, store and use human tissue for certain purposes under the HT Act
- licensing organisations involved in preparing tissues and cells for use in patient treatment as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
- licensing organisations involved in organ procurement and transplantation as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)
- superintending compliance with the requirements of the legislation and the HTA's Codes of Practice
- assessment of living organ donations to ensure donors are protected from duress or coercion, and that no reward is offered or given
- providing information, advice and guidance to the public and professionals about the nature and purpose of activities within the HTA's remit
- monitoring developments relating to activities within the HTA's remit and advising the Secretary of State, the relevant Northern Ireland department or Welsh ministers on related issues

Aims

2.4 The HTA's strategic aims are set out in the HTA Strategy 2021-2024. These are:

- further developing our regulatory model and tools to improve outcomes for patients and the public. In particular, the introduction of new regulatory tools and approaches. A number of our licensed establishments will have already experienced some changes such as to licensing and the roll out of Virtual Regulatory Assessments. These will continue alongside our more traditional site visit inspections as these are gradually reintroduced.

- internal innovation to target regulatory interventions better. Greater exploitation of advances in data analytics and technology and the pursuit of data sharing between trusted partners to enhance risk insight and to reduce data collection burdens.

- contributing to a life sciences system-wide approach that will promote the UK as a world leading regulatory environment for innovation in the life sciences. We have an opportunity to use our position within the system and our expertise to become a leading voice in the life sciences landscape.

- collaboration with other regulators. With the move to our new office premises in Stratford, we will be co-locating with a number of partner organisations. This close proximity will allow us to foster even closer strategic relationships with those regulators working across the health and care sector and we are already playing a leading role in the regulators round table, advising ministers on future regulation.

- collaboration with other partner bodies. We plan to improve how we communicate and work with stakeholders so that regulatory considerations are hard-wired into innovation and do not become a barrier or an afterthought. We will also act as a convener amongst system partners to deal with specific challenges of which regulatory issues may form a part.

- saying farewell to a number of well-established board members and welcoming a number of new appointees. We will use this as an opportunity to strengthen our governance arrangements and with their support and encouragement focus more on equality, diversity and inclusion.

3. Governance and accountability

3.1 The HTA shall operate corporate governance arrangements that, so far as practicable and in the light of the other provisions of this framework agreement or as otherwise may be mutually agreed, accord with good corporate governance practice and applicable regulatory requirements and expectations.

3.2 In particular (but without limitation), the HTA should:

- comply with the principles and provisions of the Corporate Governance in Central Government Departments Code of Good Practice (as amended and updated from time to time) to the extent appropriate and in line with their statutory duties or specify and explain any non-compliance in its annual report

- comply with Managing Public Money in so far as it does not contradict the governance arrangements laid out in the legislation pertaining to the HTA.

- in line with Managing Public Money, have regard to the relevant functional standards as appropriate and in particular those concerning finance, commercial and counter fraud

- take into account, the codes of good practice and guidance set out in Annex A of this framework agreement, as they apply to arms' length bodies

3.3 In line with annex 3.1 of Manging Public Money, the HTA shall provide an account of corporate governance in its annual governance statement including the board's assessment of its compliance with the code with explanations of any material departures. To the extent that the HTA does intend to materially depart from the code, the sponsor should be notified in advance and their agreement sought to this approach.

4. Role of the department

The responsible minister

4.1 The Secretary of State for Health and Social Care is accountable to Parliament for all matters concerning the HTA.

4.2 The Secretary of State is responsible for the policy framework within which the HTA operates and has statutory powers in relation to the activities to which the HT Act applies. The Secretary of State also has powers in respect of the HTA which are set out in the HT Act.

4.3 These are:

- power by regulations to add to the activities within the remit of the HTA (section 14(4))
- power to require advice from the HTA on activities within the HTA's remit (section 15(f))
- power through regulations to add to, vary or omit activities for which an HTA licence is required (section 16(5))
- power to approve the HTA code of practice before publication (section 29(1))
- power to appoint the chair and the non-executive members of the HTA, and to determine their terms of appointment and remuneration (schedule 2)
- power to remove or suspend the chair and non-executive members (schedule 2)
- providing the HTA with funding (schedule 2)
- power to direct the HTA, with the approval of the Treasury, as to the form the HTA's accounts must take and power to give a notice specifying the date by which the accounts must be submitted to the Secretary of State, the Welsh Ministers, relevant Northern Ireland Department and the Comptroller and Auditor General (schedule 2)

Appointments to the board

4.4 The chair is appointed by the Secretary of State for Health and Social Care under paragraph 1(a) of schedule 2 to the HT Act. This appointment is subject to the Public Appointments Order in Council and as such must comply with the Governance Code on Public Appointments.

4.5 Non-executive members are appointed by the Secretary of State for Health and Social Care under paragraph 1(b) of schedule 2 to the HT Act. These appointments are subject to the Public Appointments Order in Council and as such must comply with the Governance Code for Public Appointments.

4.6 As set out in paragraph 1 of schedule 2 to the HT Act, of the non-executive members:

- such numbers as Secretary of State sees fit are appointed by the Secretary of State for Health and Social Care
- one is appointed by the Welsh ministers
- one is appointed by the relevant Northern Ireland department

4.7 All such appointments should have regard to the principle that appointments should reflect the diversity of the society in which we live, and appointments should be made taking account of the need to appoint boards which include a balance of skills and backgrounds.

Other ministerial powers and responsibilities

4.8 The Secretary of State is also responsible for:

- the policy framework within which the HTA operates
- setting the performance framework within which the HTA will operate including approving the HTA's Strategy and business plan
- provides guidance and direction to ensure the strategic aims and objectives of the HTA are consistent with those of the department and government
- matters regarding spending approvals, acquisitions, disposals, and joint ventures in line with delegations as set out in the delegation letter

The principal accounting officer

4.9 The principal accounting officer is the permanent secretary of DHSC.

4.10 The principal accounting officer of DHSC designates the chief executive as the HTA’s accounting officer and ensures they are fully aware of their responsibilities. The principal accounting officer issues a letter appointing the accounting officer, setting out their responsibilities and delegated authorities.

4.11 The respective responsibilities of the principal accounting officer and accounting officers are set out in chapter 3 of Managing Public Money.

4.12 The principal accounting officer is accountable to Parliament for the issue of grant-in-aid to the HTA.

4.13 The principal accounting officer is also responsible, usually via the sponsorship team, for advising the Secretary of State on:

- an appropriate framework of objectives and targets for the HTA in the light of the department's wider strategic aims and priorities
- an appropriate budget for the HTA in the light of the sponsor department's overall public expenditure priorities
- how well the HTA is achieving its strategic objectives and whether it is delivering value for money
- the exercise of the ministers' statutory responsibilities concerning the HTA

4.14 The principal accounting officer, via the sponsorship team, is also responsible for ensuring arrangements are in place in order to:

- monitor the HTA's activities and performance
- address significant problems in the HTA, making such interventions as are judged necessary
- periodically, and at such frequency as is proportionate to the level of risk, carry out an assessment of the risks both to DHSC and the HTA's objectives and activities in line with the wider departmental risk assessment process
- inform the HTA of relevant government policy in a timely manner
- bring ministerial or departmental concerns about the activities of the HTA to the full HTA board and, as appropriate, to the departmental board requiring explanations and assurances that appropriate action has been taken

The role of the senior departmental sponsor

4.15 A director is appointed as the senior departmental sponsor who acts as the HTA's designated, consistent point of contact within DHSC and manages their overall relationship with DHSC. The senior departmental sponsor acts as the link at executive level between the HTA and senior officials of DHSC, and with ministers.

4.16 Whilst the senior departmental sponsor role is facilitative and recognises the need for direct engagement between the HTA and other parts of DHSC and ministers, it also supports the Secretary of State and Permanent Secretary in holding the HTA to account. The senior departmental sponsor is also responsible for agreeing the objectives for, and reviewing the contribution of, the chair of the HTA.

The role of the sponsor team

4.17 The HTA sponsor team in DHSC supports the senior departmental sponsor and is the primary contact for the HTA. The responsible senior civil servant for this relationship is the director of the directorate that the sponsor team is a part of. They are the main source of advice to the Secretary of State on the discharge of their responsibilities in respect of the HTA. They also support the principal accounting office on their responsibilities toward the HTA.

4.18 The sponsor team will liaise regularly with counterparts in the HTA to support effective corporate relationships and co-ordinate assurance and accountability functions.

4.19 Officials of the sponsor team will liaise regularly with HTA officials to review performance against plans, achievement against targets and expenditure against its departmental expenditure limit and annual managed expenditure allocations. The HTA and the sponsor team will hold quarterly accountability meetings. The sponsor team will also take the opportunity to explain wider policy developments that might have an impact on the HTA.

4.20 Information will be provided to DHSC by the HTA including (not an exhaustive list):

- quarterly business scorecards that show performance against agreed key performance indicators and monthly budgetary performance returns to finance
- monthly updated strategic risk register
- annual governance statement

4.21 The process in place to enable DHSC and the HTA to review performance include:

- quarterly accountability meetings between HTA and the sponsor team
- attendance of officials from DHSC, as observers, of the full authority and HTA Audit and Risk Assurance Committee
- the HTA will also prepare an annual report of the 12 months ending on 31st March, setting out the its activities, how it has discharged its statutory duties, and what

progress it has made towards its objectives. The report will also set out activities the HTA proposes to undertake in the succeeding 12-month period

Resolution of disputes between the HTA and DHSC

4.22 Any disputes between DHSC and the HTA will be resolved in as timely a manner as possible. DHSC and the HTA will seek to resolve any disputes through an informal process in the first instance. If this is not possible, then a formal process, overseen by the senior departmental sponsor, will be used to resolve the issue. Failing this, the senior departmental sponsor will ask the relevant policy director general to oversee the dispute. They may then choose to ask the Permanent Secretary to nominate a non-executive member of DHSC's board to review the dispute, mediate with both sides and reach an outcome, in consultation with the Secretary of State.

Freedom of Information requests

4.23 Where a request for information is received by either party under the Freedom of Information Act 2000, or the Data Protection Act 1998 or Data Protection Act 2018, the party receiving the request will consult with the other party prior to any disclosure of information that may affect the other party's responsibilities.

Reporting on legal risk and litigation

4.24 The HTA shall provide a quarterly update to the sponsor on the existence of any active litigation and any threatened or reasonably anticipated litigation. The parties acknowledge the importance of ensuring that legal risks are communicated appropriately to the sponsor in a timely manner.

4.25 In respect of each substantial piece of litigation involving the HTA, the parties will agree a litigation protocol which will include specific provisions to ensure appropriate and timely reporting on the status of the litigation and the protection of legally privileged information transmitted to the sponsor to facilitate this. Until such time as a protocol is agreed, the parties will ensure that:

- material developments in the litigation are communicated to the sponsor in an appropriate and timely manner
- legally privileged documents and information are clearly marked as such
- individual employees handling the legally privileged documents are familiar with principles to which they must adhere to protect legal privilege

- circulation of privileged information within government occurs only as necessary

5. The HTA governance structure

The chief executive

Appointment

5.1 The chief executive of the HTA is appointed by the board of the HTA at the discretion of the chair and with the approval of the Secretary of State for Health and Social Care.

Responsibilities of the HTA's chief executive as accounting officer

5.2 The chief executive as accounting officer is personally responsible for safeguarding the public funds for which they have charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of the HTA. In addition, they should ensure that the HTA as a whole is run on the basis of the standards, in terms of governance, decision-making and financial management, that are set out in box 3.1 of Managing Public Money. These responsibilities include the below and those that are set in the accounting officer appointment letter issued by the principal accounting officer of the sponsor department.

Responsibilities for accounting to Parliament and the public

5.3 Responsibilities to Parliament and the public include:

- signing the accounts and ensuring that proper records are kept relating to the accounts and that the accounts are properly prepared and presented in accordance with any directions issued by the Secretary of State

- preparing and signing a governance statement covering corporate governance, risk management and oversight of any local responsibilities, for inclusion in the annual report and accounts

- ensuring that effective procedures for handling complaints about the HTA, in accordance with Parliamentary and Health Service Ombudsman's Principles of Good Complaint Handling, are established and made widely known within the HTA and published on the HTA's website

- acting in accordance with the terms of Managing Public Money and other instructions and guidance issued from time to time by DHSC, HM Treasury and the Cabinet Office

- ensuring that as part of the above compliance they are familiar with and act in accordance with:
    - any governing legislation
    - this framework agreement
    - any delegation letter issued to body
    - any elements of any settlement letter issued to the sponsor department that is relevant to the operation of the HTA
    - any separate settlement letter that is issued to the HTA from the sponsor department
- ensuring they have appropriate internal mechanisms for the monitoring, governance and external reporting regarding compliance any conditions arising from the above documents
- giving evidence, normally with the principal accounting officer, when summoned before the public accounts committee on the HTA’s stewardship of public funds

Responsibilities to DHSC

5.4 Responsibilities to DHSC include:

- establishing, in agreement with DHSC, the HTA's corporate and business plans in the light of DHSC's wider strategic aims and agreed priorities
- informing DHSC of progress in helping to achieve DHSC's policy objectives and in demonstrating how resources are being used to achieve those objectives
- ensuring that:
    - timely forecasts and monitoring information on performance and finance are provided to DHSC
    - DHSC is notified promptly if over or under spends are likely and that corrective action is taken
    - any significant problems - whether financial or otherwise and whether detected by internal audit or by other means - are notified to DHSC in a timely fashion

Responsibilities to the board

5.5 The chief executive is responsible for:

- advising the board on the discharge of their responsibilities as set out in this document, in the founding legislation and in any other relevant instructions and guidance that may be issued from time to time
- advising the board on the HTA's performance compared with its aims and objectives
- ensuring that financial considerations are taken fully into account by the board at all stages in reaching and executing its decisions, and that financial appraisal techniques are followed

Managing conflicts

5.6 The chief executive should follow the advice and direction of the board, except in very exceptional circumstances with a clear cut and transparent rationale for not doing so.

5.7 If the board, or its chair, is contemplating a course of action involving a transaction which the chief executive considers would infringe the requirements of propriety or regularity or does not represent prudent or economical administration, efficiency or effectiveness, is of questionable feasibility or is unethical, the chief executive, in their role as accounting officer, should reject that course of action and ensure that the board have full opportunity to discuss the rationale for that rejection.

5.8 Such conflicts should be brought to the attention of the principal accounting officer and the responsible minister as soon as possible.

5.9 Furthermore, and if agreed with the responsible minister, the accounting officer must write a letter of justification to the chair of the board setting out the rationale for not following the advice and recommendation of the board and copy that letter to the Treasury Officer of Accounts.

5.10 If the responsible minister agrees with the proposed course of action of the board, it may be appropriate for the minister to direct the accounting officer in the manner as set out in Managing Public Money paragraph 3.6.6 onwards.

The HTA board

Composition of the board

5.11 The HTA will have a board in line with good standards of corporate governance and as set out in in its establishing statute and in guidance as set out in Annex A. The role of the board shall be to direct the HTA, and to deliver the objectives, in accordance with the purposes as set out above, their statutory, regulatory, common law duties and their responsibilities under this framework agreement. Detailed responsibilities of the board shall be set out in the board terms of reference. Remuneration of the board will be disclosed in line with the guidance in the government Financial Reporting Manual (FReM).

5.12 The board will consist of a non-executive chairperson and such number of other non-executive members, appointed by the Secretary of State, as the Secretary of State thinks fit that have a balance of skills and experience appropriate to directing the HTA's business. Not less than half of the members are persons who do not have, and have not had, a professional interest in any of the kinds of activity within the remit of the HTA. The chair and chief executive decide the balance of skills across the HTA's board, which may include members who have experience of legal and regulatory expertise, leading digital transformation, professional experience in any of the sectors regulated by the HTA and experience of organ donation and transplantation either from a patient or practitioner perspective. The board will consist of a number of independent non-executive members, as determined in the relevant legislation and appointed by the Secretary of State, who, through the Chief Executive and Accounting Officer, ensure that the executive is supported and constructively challenged in its role.

5.13 The senior executives, known as the HTA Senior Management Team, including the Finance Director (suitably qualified as set out in Annex 4.1 of MPM) and the Chief Executive, as Accounting Officer, will attend the regular, published meetings of the HTA Board.

Board committees

5.14 The board may set up such committees as necessary for it to fulfil its functions. As is detailed below at a minimum this should include an Audit and Risk Assurance Committee chaired by an independent and appropriately qualified non-executive member of the board.

5.15 While the board may make use of committees to assist its consideration of appointments, succession, audit, risk and remuneration, it retains responsibility for, and endorses, final decisions in all of these areas. The chair should ensure that

sufficient time is allowed at board meetings for committees to report on the nature and content of discussion, on recommendations, and on actions to be taken.

5.16 Where there is disagreement between the relevant committee and the board, adequate time should be made available for discussion of the issue with a view to resolving the disagreement. Where any such disagreement cannot be resolved, the committee concerned should have the right to report the issue to the sponsor team, principal accounting officer and responsible minister. They may also seek to ensure the disagreement or concern is reflected as part of the report on its activities in the annual report.

5.17 The chair should ensure board committees are properly structured with appropriate terms of reference. The terms of each committee should set out its responsibilities and the authority delegated to it by the board. The chair should ensure that committee membership is periodically refreshed and that individual independent non-executive directors are not over-burdened when deciding the chairs and membership of committees.

Duties of the board

5.18 The board is specifically responsible for:

- establishing and taking forward the strategic aims and objectives of the HTA consistent with its overall strategic direction and within the policy and resources framework determined by the Secretary of State
- providing effective leadership of the HTA within a framework of prudent and effective controls which enables risk to be assessed and managed
- ensuring the financial and human resources are in place for the HTA to meet its objectives
- reviewing management performance
- ensuring that the board receives and reviews regular financial and management information concerning the management of the HTA
- ensuring that it is kept informed of any changes which are likely to impact on the strategic direction of the HTA or on the attainability of its targets, and determining the steps needed to deal with such changes and where appropriate bringing such matters to the attention of the responsible minister and principal accounting officer via the executive team, sponsorship team or directly

- ensuring that any statutory or administrative requirements for the use of public funds are complied with; that the board operates within the limits of its statutory authority and any delegated authority agreed with the sponsor department, and in accordance with any other conditions relating to the use of public funds

- ensuring that, in reaching decisions, the board takes into account guidance issued by the sponsor department

- ensuring that as part of the above compliance they are familiar with:

    - this framework agreement

    - any delegation letter issued to the body

    - any elements of any settlement letter issued to the sponsor department that is relevant to the operation of the HTA

    - that they have appropriate internal mechanisms for the monitoring, governance and external reporting regarding any conditions arising from the above documents and ensure that the chief executive and the HTA as a whole act in accordance with their obligations under the above documents

- demonstrating high standards of corporate governance at all times, including by using the independent audit committee to help the board to address key financial and other risks

- appointing a chief executive and, in consultation with the department, set performance objectives and remuneration terms linked to these objectives for the chief executive which give due weight to the proper management and use of public resources

- determining all such other things which the board considers ancillary or conducive to the attainment or fulfilment by the HTA of its objectives

5.19 The board should ensure that effective arrangements are in place to provide assurance on risk management, governance and internal control.

5.20 The board should make a strategic choice about the style and shape of risk management and should lead the assessment and management of opportunity and risk. The board should ensure that effective arrangements are in place to provide assurance over the design and operation of risk management, governance and internal control in line with the Management of Risk – Principles and Concepts (The Orange Book). The board must set up an Audit and Risk Assurance Committee, chaired by an independent and appropriately qualified non-executive member, to provide independent advice and ensure that the department's Audit

and Risk Assurance Committee are provided with routine assurances with escalation of any significant limitations or concerns. The board is expected to assure itself of the adequacy and effectiveness of the risk management framework and the operation of internal control.

The chair's role and responsibilities

5.21 The chair is responsible for leading the board in the delivery of its responsibilities. Such responsibility should be exercised in the light of their duties and responsibilities as set out in their contract of employment/appointment letter, the priorities in the chair's letter issued to them by the sponsor team, the statutory authority governing the HTA, this document and the documents and guidance referred to within this document.

5.22 Communications between the HTA's board and the responsible minister should normally be through the chair.

5.23 The chair is bound by the Code of Conduct for Board Members of Public Bodies, which covers conduct in the role and includes the Nolan Principles of Public Life.

5.24 In addition, the chair is responsible for:

- ensuring, including by monitoring and engaging with appropriate governance arrangements, that the HTA’s affairs are conducted with probity
- ensuring that policies and actions support the responsible minister’s and where relevant other ministers’ wider strategic policies and where appropriate, these policies and actions should be clearly communicated and disseminated throughout the HTA

5.25 The chair has the following leadership responsibilities:

- formulating the board’s strategy
- ensuring that the board, in reaching decisions, takes proper account of guidance provided by the responsible minister or DHSC
- promoting the efficient and effective use of staff and other resources
- delivering high standards of regularity and propriety
- representing the views of the board to the general public

5.26 The chair also has an obligation to ensure that:

- the work of the board and its members are reviewed and are working effectively including ongoing assessment of the performance of individual board members with a formal annual evaluation and more in-depth assessments of the performance of individual board members when being considered for re-appointment

- in conducting assessments that the view of relevant stakeholders including employees and the sponsor team are sought and considered

- the board has a balance of skills appropriate to directing the HTA's business, and that all directors including the chair and chief executive continually update their skills, knowledge and familiarity with the HTA to fulfil their role both on the board and committees. This will include, but not be limited to, skills and training in relation to financial management and reporting requirements, risk management and the requirements of board membership within the public sector

- board members are fully briefed on terms of appointment, duties, rights and responsibilities

- they, together with the other board members, receive appropriate training on financial management and reporting requirements and on any differences that may exist between private and public sector practice

- the responsible minister is advised of the HTA's needs when board vacancies arise

- there is a board operating framework in place setting out the role and responsibilities of the board, consistent with the Government Code of Good Practice for Corporate Governance

- there is a code of practice for board members in place, consistent with the Cabinet Office Code of conduct for board members of public bodies

Individual board members' responsibilities

5.27 Individual board members shall:

- comply at all times with the Code of conduct for board members of public bodies, which covers conduct in the role and includes the Nolan Principles of Public Life as well as rules relating to the use of public funds and to conflicts of interest

- demonstrate adherence to the 12 Principles of Governance for all Public Body Non-Executive Directors as appropriate

- not misuse information gained in the course of their public service for personal gain or for political profit, nor seek to use the opportunity of public service to promote their private interests or those of connected persons or organisations

- comply with the board's rules on the acceptance of gifts and hospitality, and of business appointments

- act in good faith and in the best interests of the HTA

- ensure they are familiar with any applicable guidance on the role of Public Sector non-executive directors and boards that may be issued from time to time by the Cabinet Office, HM Treasury or wider government

6. Management and financial responsibilities and controls

Delegated authorities

6.1 The HTA's delegated authorities are set out in the set out in DHSC's Schedule of Delegations and delegation letter. This delegation letter may be updated and superseded by later versions which may be issued by DHSC in agreement with HM Treasury.

6.2 In line with Managing Public Money Annex 2.2 these delegations will be reviewed on an annual basis. Delegation letters will be updated from time to time by DHSC, in agreement with the HM Treasury spending team.

6.3 The HTA shall obtain DHSC's and where appropriate HM Treasury's prior written approval before:

- entering into any undertaking to incur any expenditure that falls outside the delegations or which is not provided for in the HTA's annual budget as approved by DHSC
- incurring expenditure for any purpose that is or might be considered novel or contentious, or which has or could have significant future cost implications
- making any significant change in the scale of operation or funding of any initiative or particular scheme previously approved by DHSC
- making any change of policy or practice which has wider financial implications that might prove repercussive or which might significantly affect the future level of resources required
- carrying out policies that go against the principles, rules, guidance and advice in Managing Public Money

Spending authority

6.4 Once the budget has been approved by DHSC, the HTA has authority to incur expenditure approved in the budget without further reference to DHSC, on the following conditions:

- the HTA shall comply with the delegations set out in the delegation letter. These delegations shall not be altered without the prior agreement of the sponsor department and as agreed by HM Treasury and Cabinet Office as appropriate

- the HTA shall comply with Managing Public Money regarding novel, contentious or repercussive proposals

- inclusion of any planned and approved expenditure in the budget shall not remove the need to seek formal departmental approval where any proposed expenditure is outside the delegated limits or is for new schemes not previously agreed

- the HTA shall provide the sponsor department with such information about its operations, performance, individual projects or other expenditure as the sponsor department may reasonably require

Banking and managing cash

6.5 The HTA shall maximise the use of publicly procured banking services (accounts with central government commercial banks managed centrally by government banking).

6.6 The HTA shall only hold money outside government banking service accounts where a good business case can made for doing so and HM Treasury consent is required for each account to be established. Only commercial banks which are members of relevant UK clearing bodies may be considered for this purpose.

6.7 Commercial accounts, where approved, shall be operated in line with the principles as set out in Managing Public Money.

6.8 The accounting officer is responsible for ensuring that the HTA has a banking policy as set out in Managing Public Money and ensuring that the policy is complied with.

Procurement

6.9 The HTA shall ensure that its procurement policies are aligned with and comply with any relevant UK or other international procurement rules and in particular the Public Contracts Regulations 2015.

6.10 The HTA shall establish its procurement policies and document these in a Procurement Policy and Procedures Manual.

6.11 In procurement cases where the HTA is likely to exceed its delegated authority limit, procurement strategy approval for the specific planned purchase must be sought from DHSC's sponsor team.

6.12 Goods, services, and works should be acquired by competition. Proposals to let single-tender or restricted contracts shall be limited and exceptional, and a quarterly report explaining those exceptions should be sent to DHSC.

6.13 Procurement by the HTA of works, equipment, goods, and services shall be based on, a full option appraisal and value for money, i.e. the optimum combination and whole life costs and quality (fitness for purpose).

6.14 The HTA shall:

- engage fully with DHSC and government-wide procurement initiatives that seek to achieve value for money from collaborative projects
- comply with all relevant Procurement Policy Notes issued by Cabinet Office
- co-operate fully with initiatives to improve the availability of procurement data to facilitate the achievement of value for money.
- ensure their commercial capability is developed in line with government Commercial Function people standards

6.15 The HTA shall comply with the Commercial and Grants standards. These standards apply to the planning, delivery, and management of government commercial activity, including management of grants in all departments and arm's length bodies, regardless of commercial approach used and form part of a suite of functional standards that set expectations for management within government.

Risk management

6.16 The HTA shall ensure that the risks that it faces are dealt with in an appropriate manner, in accordance with relevant aspects of best practice in corporate governance, and develop a risk management strategy, in accordance with HM Treasury guidance Management of Risk – Principles and Concepts (The Orange Book).

6.17 The HTA shall promptly notify DHSC of any operational and financial risks arising from their activities which may have a potentially significant impact on them, DHSC, another health and care body or the wider system. These will be discussed in meetings they have with the senior departmental sponsor and the sponsor

team. Such risks shall also be notified by the HTA's risk function or board to DHSC's risk team and may be escalated to DHSC's Audit and Risk Committee for consideration. The chair of the HTA's Audit and Risk Assurance Committee shall also escalate any risk concerns to the department's risk team and may be asked to attend DHSC's Audit and Risk Committee to explain risks. It is the responsibility of the HTA and the sponsor team to keep each other informed of significant risks to, or arising from, the operations of the HTA within the wider system.

Counter fraud and theft

6.18 The HTA shall adopt and implement policies and practices to safeguard itself against fraud and theft.

6.19 The HTA shall act in line with guidance as issued by the Counter Fraud Function and in compliance with the procedures and considerations as set in in Managing Public Money Annex 4.9 and the Counter Fraud Functional Standard. The HTA shall also take all reasonable steps to appraise the financial standing of any firm or other body with which it intends to enter a contract or to provide grant or grant-in-aid.

6.20 The HTA shall keep records of and prepare and forward to DHSC an annual report on fraud and theft suffered by the HTA and notify DHSC of any unusual or major incidents as soon as possible. The HTA shall also report identified loss from fraud, bribery, corruption and error, alongside associated recoveries and prevented losses, to the counter fraud centre of expertise in line with the agreed government definitions as set out in Counter Fraud Functional Standard.

Staff

Broad responsibilities of staff

6.21 Within the arrangements approved by the Secretary of State for Health and Social Care and the Treasury the HTA will have responsibility for the recruitment, retention and motivation of its staff. The broad responsibilities toward its staff are to ensure that:

- the rules for recruitment and management of staff create an inclusive culture in which diversity is fully valued, appointment and advancement is based on merit; there is no discrimination against employees with protected characteristics under the Equality Act 2010

- the level and structure of its staffing, including grading and staff numbers, are appropriate to its functions and the requirements of economy, efficiency and effectiveness
- the performance of its staff at all levels is satisfactorily appraised and the HTA performance measurement systems are reviewed from time to time
- its staff are encouraged to acquire the appropriate professional, management and other expertise necessary to achieve the HTA's objectives
- proper consultation with staff takes place on key issues affecting them
- adequate grievance and disciplinary procedures are in place
- whistle-blowing procedures consistent with the Public Interest Disclosure Act are in place
- a code of conduct for staff is in place based on the Cabinet Office's Model Code for Staff of Executive Non-departmental Public Bodies.

Staff costs

6.22 Subject to its delegated authorities, the HTA shall ensure that the creation of any additional posts does not incur forward commitments that will exceed its ability to pay for them.

Pay and conditions of service

6.23 The HTA's staff are subject to levels of remuneration and terms and conditions of service (including pensions) within the general pay structure approved by the sponsor department and the Treasury. The HTA has no delegated power to amend these terms and conditions.

6.24 If civil service terms and conditions of service apply to the rates of pay and non-pay allowances paid to the staff and to any other party entitled to payment in respect of travel expenses or other allowances, payment shall be made in accordance with the Civil Service Management Code and the annual Civil Service Pay Remit Guidance, except where prior approval has been given by the department to vary such rates.

6.25 Staff terms and conditions should be set out in an employee handbook, which should be provided to DHSC together with subsequent amendments.

6.26 The HTA shall abide by public sector pay controls, including the relevant approvals process dependent on the organisations classification as detailed in the Senior Pay Guidance and the public sector pay and terms guidance.

6.27 The HTA shall operate a performance-related pay scheme that shall form part of the annual aggregate pay budget approved by the department where relevant with due regard to the senior pay guidance.

6.28 The travel expenses of board members shall be tied to the rates allowed to senior staff of the HTA. Reasonable actual costs shall be reimbursed.

Pensions, redundancy and compensation

6.29 Compensation scheme rules and pension scheme rules shall reflect legislative and HM Treasury guidance requirements regarding exit payments.

6.30 HTA staff shall normally be eligible for a pension provided by the NHS Pension Scheme. Staff may opt out of the occupational pension scheme provided by the HTA, but that employers' contribution to any personal pension arrangement, including stakeholder pension shall normally be limited to the national insurance rebate level.

6.31 Any proposal by the HTA to move from the existing pension arrangements, or to pay any redundancy or compensation for loss of office, requires the prior approval of the department. Proposals on severance must comply with the rules in chapter 4 of Managing Public Money.

6.32 HTA shall seek approval from DHSC's Remuneration Committee for recruiting to executive and senior managers posts or paying above the relevant ceilings in the executive and senior managers' pay framework. All applications will need approval from the HTA sponsor team before being considered by the Committee.

7. Business plans, financial reporting and information management

Corporate and business plans

7.1 The HTA shall submit annually to the sponsor department a draft of the corporate plan covering three years ahead. The draft should be submitted in line with the agreed annual timetable established by DHSC. The HTA shall agree with DHSC issues to be addressed in the plan and the timetable for its preparation. The plan shall reflect the HTA's statutory and/or other duties and, within those duties, the priorities set from time to time by the responsible minister (including decisions taken on policy and resources in the light of wider public expenditure decisions). The plan shall demonstrate how the HTA contributes to the achievement of DHSC's medium-term plan and priorities and aligned performance metrics and milestones.

7.2 The first year of the corporate plan, amplified as necessary, shall form the business plan. The business plan shall be updated to include key targets and milestones for the year immediately ahead and shall be linked to budgeting information so that resources allocated to achieve specific objectives can readily be identified by DHSC. Subject to any commercial considerations, the corporate and business plans should be published by the HTA on its website and separately be made available to staff.

7.3 The following key matters should be included in the plans:

- key objectives and associated key performance targets for the forward years, and the strategy for achieving those objectives
- key non-financial performance targets
- a review of performance in the preceding financial year, together with comparable outturns for the previous 3 years, and an estimate of performance in the current year
- alternative scenarios and an assessment of the risk factors that may significantly affect the execution of the plan but that cannot be accurately forecast
- other matters as agreed between DHSC and the HTA

Budgeting procedures

7.4 Each year, in the light of decisions by DHSC on the updated draft business plan, DHSC will send to the HTA by an agreed date:

- a formal statement of the annual budgetary provision allocated by DHSC in the light of competing priorities across DHSC and of any forecast income approved by DHSC
- a statement of any planned change in policies affecting the HTA

7.5 The approved annual business plan will take account both of approved funding provision and any forecast receipts, and will include a budget of estimated payments and receipts together with a profile of expected expenditure and of draw-down of any departmental funding and/or other income over the year. These elements form part of the approved business plan for the year in question.

Grant-in-aid and any ring-fenced grants

7.6 Any grant-in-aid provided by DHSC for the year in question will be voted in DHSC's supply estimate and be subject to Parliamentary control.

7.7 The grant-in-aid will normally be paid in monthly instalments on the basis of written applications showing evidence of need. The HTA will comply with the general principle, that there is no payment in advance of need. Cash balances accumulated during the course of the year from grant-in-aid or other Exchequer funds shall be kept to a minimum level consistent with the efficient operation of the HTA. Grant-in-aid not drawn down by the end of the financial year shall lapse. Subject to approval by Parliament of the relevant estimates provision, where grant-in-aid is delayed to avoid excess cash balances at the year-end, DHSC will make available in the next financial year any such grant-in-aid that is required to meet any liabilities at the year end, such as creditors.

7.8 In the event that DHSC provides the HTA separate grants for specific (ring-fenced) purposes, it would issue the grant as and when the HTA needed it on the basis of a written request. The HTA would provide evidence that the grant was used for the purposes authorised by DHSC. The HTA shall not have uncommitted grant funds in hand, nor carry grant funds over to another financial year.

Annual report and accounts

7.9 The HTA board must publish an annual report of its activities together with its audited accounts after the end of each financial year. The HTA shall provide its finalised (audited) accounts in line with the agreed annual timetable established by DHSC in order for the accounts to be consolidated within DHSC's accounts. A draft of the report should be submitted to DHSC two weeks before the proposed publication date. The accounts should be prepared in accordance with the relevant statutes and specific accounts direction issued by DHSC as well with HM Treasury's Financial Reporting Manual.

7.10 The annual report and accounts shall:

- cover any corporate, subsidiary or joint ventures under its control
- comply with the Financial Reporting Manual and in particular have regard to the illustrative statements for a non-departmental public body
- outline main activities and performance during the previous financial year and set out in summary form forward plans

7.11 Information on performance against key financial targets is included within the annual report and subject to the auditor's consistency opinion. The report and accounts shall be laid in Parliament and made available on the HTA's website, in accordance with the guidance in the Financial Reporting Manual.

Reporting performance to DHSC

7.12 The HTA shall operate management, information and accounting systems that enable it to review in a timely and effective manner its financial and non-financial performance against the budgets and targets set out in the corporate and business plans.

7.13 The HTA shall inform DHSC of any changes that make achievement of objectives more or less difficult. It shall report financial and non-financial performance, including performance in helping to deliver ministers' policies, and the achievement of key objectives regularly through Quarterly Accountability meetings with DHSC.

7.14 The HTA's performance shall be formally reviewed by DHSC four times a year.

7.15 The responsible minister shall meet the chair and chief executive once a year.

Information sharing

7.16 DHSC has the right of access to all HTA records and personnel for any purpose including, for example, sponsorship audits and operational investigations.

7.17 The HTA shall provide DHSC with such information about its operations, performance, individual projects or other expenditure as DHSC may reasonably require.

7.18 DHSC and HM Treasury may request the sharing of data held by the HTA in such a manner as set out in central guidance except insofar as it is prohibited by law. This may include requiring the appointment of a senior official to be responsible for the data sharing relationship.

7.19 As a minimum, the HTA shall provide DHSC with information monthly that will enable DHSC satisfactorily to monitor:

- the HTA's cash management
- its draw-down of grant-in-aid
- forecast outturn by resource headings
- other data required for the Online System for Central Accounting and Reporting (OSCAR)
- data as required in respect of its compliance with any Cabinet Office Controls pipelines or required in order to meet any condition as set out in any settlement letter

8. Audit

8.1 The HTA shall:

- ensure that DHSC's internal audit team have complete access to all relevant records
- ensure that any arrangements for internal audit are in accordance with the Public Sector Internal Audit Standards as adopted by HM Treasury
- set up an audit committee of its board in accordance with the Code of Good Practice for Corporate Governance and the Audit and Risk Assurance Committee Handbook
- forward the audit strategy, periodic audit plans and annual audit report, including the HTA Head of Internal Audit opinion on risk management, control and governance as soon as possible to DHSC
- keep records of, and prepare and forward to DHSC an annual report on, fraud and theft suffered by the HTA and notify DHSC of any unusual or major incidents as soon as possible
- share with DHSC information identified during the audit process and the Annual Audit Opinion Report (together with any other outputs) at the end of the audit, in particular on issues impacting on DHSC's responsibilities in relation to financial systems within the HTA

External audit

8.2 The Comptroller and Auditor General (C&AG) audits the HTA’s annual accounts, and lays them before parliament, together with their report.

8.3 In the event that the HTA has set up and controls subsidiary companies, the HTA shall, in the light of the provisions in the Companies Act 2006, ensure that the Comptroller and Auditor General has the option to be appointed auditor of those company subsidiaries that it controls and/or whose accounts are consolidated within its own accounts. The HTA shall discuss with DHSC the procedures for appointing the Comptroller and Auditor General as auditor of the companies.

8.4 The Comptroller and Auditor General:

- shall consult DHSC and the HTA on whom – the National Audit Office or a commercial auditor – shall undertake the audit(s) on their behalf, though the final decision rests with the Comptroller and Auditor General

- has a statutory right of access to relevant documents, including by virtue of section 25(8) of the Government Resources and Accounts Act 2000, held by another party in receipt of payments or grants from the HTA

- shall share with the sponsor department information identified during the audit process and the audit report (together with any other outputs) at the end of the audit, in particular on issues impacting on DHSC's responsibilities in relation to financial systems within the HTA

- shall consider requests from departments and other relevant bodies to provide regulatory compliance reports and other similar reports at the commencement of the audit. Consistent with the Comptroller and Auditor General's independent status, the provision of such reports is entirely at the Comptroller and Auditor General's discretion

8.5 The Comptroller and Auditor General may carry out examinations into the economy, efficiency and effectiveness with which the HTA has used its resources in discharging its functions. For the purpose of these examinations the Comptroller and Auditor General has statutory access to documents as provided for under section 8 of the National Audit Act 1983. In addition, the HTA shall provide, in conditions to grants and contracts, for the Comptroller and Auditor General to exercise such access to documents held by grant recipients and contractors and sub-contractors as may be required for these examinations; and shall use its best endeavours to secure access for the Comptroller and Auditor General to any other documents required by the Comptroller and Auditor General which are held by other bodies.

9. Reviews and winding up arrangements

Review of the HTA's status

9.1 The HTA will be reviewed as part of the wider Public Bodies Reviews programme, at a time determined by the DHSC's ministers and their principal accounting officer.

Arrangements in the event that the HTA is wound up

9.2 DHSC shall put in place arrangements to ensure the orderly winding up of the HTA. In particular, it should ensure that the assets and liabilities of the HTA are passed to any successor organisation and accounted for properly. (In the event that there is no successor organisation, the assets and liabilities should revert to the sponsor department.) To this end, DHSC shall:

- have regard to Cabinet Office guidance on winding up arm's length bodies
- ensure that procedures are in place in the HTA to gain independent assurance on key transactions, financial commitments, cash flows and other information needed to handle the wind-up effectively and to maintain the momentum of work inherited by any residuary body; specify the basis for the valuation and accounting treatment of the HTA’s assets and liabilities
- ensure that arrangements are in place to prepare closing accounts and pass to the Comptroller and Auditor General for external audit, and that, for non-Crown bodies, funds are in place to pay for such audits. It shall be for the Comptroller and Auditor General to lay the final accounts in Parliament, together with their report on the accounts
- arrange for the most appropriate person to sign the closing accounts. In the event that another arm's length body takes on the role, responsibilities, assets and liabilities, the succeeding arm's length body accounting officer should sign the closing accounts. In the event that DHSC inherits the role, responsibilities, assets and liabilities, DHSC’s principle accounting officer should sign

9.3 The HTA shall provide DHSC with full details of all agreements where the HTA or its successors have a right to share in the financial gains of developers. It should also pass to DHSC details of any other forms of claw-back due to the HTA.

10. Other matters

Partnership working

10.1 To support the development of their relationship, DHSC and the HTA have agreed to a set of shared principles:

- working together with each other, and with DHSC's other arm's length bodies, for patients, people who use services and the public, demonstrating our commitment to the values of the NHS as set out in its constitution

- respect for the importance of autonomy throughout the system, and the freedom of individual organisations to exercise their functions in the way they consider most appropriate

- recognition that the Secretary of State is ultimately accountable to Parliament and the public for the system overall. The HTA will support DHSC in the discharge of its accountability duties, and DHSC will support the HTA in the same way

- working together openly and positively. This will include working constructively and collaboratively with other organisations within and beyond the health and social care system

10.2 DHSC and the HTA will work together, and with DHSC's other arm's length bodies, in the interests of patients, people who use services and the public to maximise the health and wellbeing gain for the population, working to the values set out in the NHS Constitution. To support this, the HTA and DHSC will follow an ‘open book’ approach. In the case of issues with an impact on the development or implementation of policy, DHSC can expect to be kept informed by the HTA. In the same way, DHSC will seek to keep the HTA apprised of developments in policy and government. There are likely to be some issues where DHSC or the HTA will expect to be consulted by the other before DHSC or the HTA makes either a decision or a public statement on a matter. DHSC and the HTA will make clear which issues fall into this category in good time. The sponsor team will be responsible for ensuring that this works effectively.

10.3 To support the Secretary of State and the principal accounting officer in their accountability functions, the HTA must provide the Secretary of State with such information relating to the exercise of its functions as he or she may request. It is therefore expected that DHSC will, when required, have full access to the HTA’s files and information. If necessary, the senior departmental sponsor’s team will be responsible for prioritising these requests for information.

Communications between DHSC and the HTA

10.4 This section sets out the basic principles guiding co-operation and collaborative working between DHSC and the HTA, across all aspects of communication and marketing activities, to deliver impactful and cost-effective communications in the context of our shared accountability to parliament and the public.

10.5 The principles include regular collaboration and information sharing between DHSC and the HTA to ensure communications are aligned and to amplify their impact. All organisations commit to undertaking this collaboration and information sharing in a timely manner, of content being shared with the public, media or other stakeholders. To ensure that, as a system, we are communicating with the public, workforce and our stakeholders in a coordinated manner so as to not confuse or undermine another part of the system.

10.6 To achieve this, DHSC and HTA communications team will have regular check-in points, including for the heads of communication and media and marketing teams, to agree communication plans. In particular, the HTA and DHSC will give each other sufficient advance notice of public facing communications to allow for necessary clearances with the relevant teams as set out in the Communications and Marketing Guidance annex of the ALB Schedule of Delegations.

Relations with DHSC's other arm's length bodies

10.7 DHSC and its arm's length bodies have complementary but distinct roles within the system to ensure that service users receive high quality services which deliver value for public money. Details of the working arrangements with other arm's length bodies and key bodies will, where appropriate, be agreed and set out in a partnership agreement.

Transparency

10.8 The HTA is an open organisation that carries out its activities transparently. It demonstrates this by proactively publishing on its website key information on areas including pay, diversity of the workforce, performance, the way it manages public money and the public benefits achieved through its activities, and by supporting those who wish to use the data by publishing the information within guidelines set by the Cabinet Office. The HTA holds open board meetings in line with the Public Bodies (Admission to Meetings) Act 1960. The HTA will publish an annual report. The annual report will include a governance statement, which is to be reviewed by the senior departmental sponsor.

10.9 To underpin the principles of good communication, ‘no surprises’ and transparency, the HTA and DHSC have put in place arrangements for managing communications.

10.10 The HTA’s non-executive board members operate within the general principles of the corporate governance guidelines set out by HM Treasury. They will also comply with the Cabinet Office's Code of Conduct for Board Members of Public Bodies and with the HTA’s rules on disclosure of financial interests, including those of board members.

10.11 The HTA has developed a code of conduct for all staff which will comply with the principles in the Cabinet Office's model code for staff of executive non-departmental public bodies, which includes rules on conflicts of interest, political activity and restrictions on lobbying.

10.12 The HTA will take all necessary measures to ensure that:

- patient, personal and/or sensitive information within its care and control is well managed and protected through all stages of its use, including through compliance with the Data Protection Act

- it provides public assurance in respect of its information governance practice by completing and publishing an annual information governance assessment using an agreed assessment mechanism

- it meets its legal obligations for records management, accountability and public information by compliance with relevant standards, including government and NHS codes of practice on confidentiality, security and records management

10.13 The HTA’s Senior Information Risk Owner and Caldicott Guardian will work together to ensure that both patient and other personal information are handled in line with best practice in government and the wider public sector.

Public and parliamentary accountability

10.14 DHSC and its arm's length bodies share responsibility for accounting to the public and to Parliament for policies, decisions and activities across the health and care sector. Accountability to Parliament will often be demonstrated through parliamentary questions, MPs' letters and appearances before parliamentary committees. Accountability to the public may be through the publication of information on the HTA's website, as well as through responses to letters from the public and responses to requests under the Freedom of Information Act.

10.15 DHSC and its ministers remain responsible to Parliament for the system overall, so will often have to take the lead in demonstrating this accountability. Where this is the case, the HTA will support DHSC by, amongst other things, providing information for ministers to enable them to account to Parliament. In its turn, DHSC provides leadership to the system for corporate governance, including setting standards for performance in accountability.

10.16 The HTA, however, has its own responsibilities in accounting to the public and to Parliament, and its way of handling these responsibilities has been agreed with DHSC. In all matters of public and parliamentary accountability, DHSC and its arm's length bodies will work together considerately, cooperatively and collaboratively, and any information provided by the HTA is to be timely, accurate and, where appropriate, consistent with information provided by DHSC. To facilitate this, DHSC and the HTA have agreed a public and parliamentary accountability protocol (Annex B) that sets out how they will work together to secure the confidence of the public and Parliament, and to maintain the service levels that MPs and the public have come to expect. This will be reviewed, as a minimum, on a tri-annual basis, alongside this framework agreement.

Equalities

10.17 The public sector equality duty requires the HTA (as a public body) when exercising its function to have due regard to the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it

10.18 The specific duties require the HTA, as a public body, to:

- annually publish information to demonstrate compliance with the Public Sector Equality Duty. This information must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees and other persons affected by its policies and procedures
- prepare and publish one or more objectives it thinks it should achieve to meet the Public Sector Equality Duty. This was required by 6 April 2013 and is required every four years thereafter.

Whistleblowing

10.19 The HTA, as with DHSC and all its arm's lengths bodies, has whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and best practice guidance. The Act prohibits the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest.

Sustainability

10.20 As a major public sector body, the HTA has a key role to play in driving forward the government’s commitment to sustainability in the economy, society and the environment. As a minimum, the HTA should comply with the Greening Government Commitments that apply to all government departments, executive agencies and non-departmental public bodies, set out in the action plan for driving sustainable operations and procurement across government. Reporting is via DHSC (including the consolidation of relevant information in DHSC's annual resource account) and DHSC will ensure the HTA is aware of the process for this.

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Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 21/22

Agenda item: 5

Author: CEO and Senior Management Team

OFFICIAL

HTA Performance Report

Purpose of paper

1. To inform the Board of the HTA's performance in Q1 against our objectives and operational delivery targets.

Decision making to date

2. The SMT agreed this paper on 23 June for submission to the HTA Board.

Action required

3. The HTA Board is asked to note and comment on the performance recorded and the context provided.

Operational Delivery

(a) Regulation

4. The data summary for Regulation Directorate is at Annex A (HTA 21a/22). As we noted in the previous Performance Report, the HTA is now using Key Performance Indicators (KPIs) and exception-based reporting as the basis for reporting to the Board.

5. Given the need to finalise Board papers before the end of June for the July meeting, a cut-off date of 15 June was used. An oral update will be provided at the Board meeting if there are any significant changes over the last 2 weeks of Q1 of which the Board should be made aware.

6. In the Annex, KPIs that were met in Q1 are colour-coded green and marked as 'on track'. KPIs that were not met have been colour-coded amber or red. Amber KPIs reflect those that were almost met or those for which the volume of activity was considered to be a contributing factor. No further action is planned for amber KPIs at this stage.

7. KPIs with a 100% completion target have been colour-coded red if there has been any deviation from this target in the quarter. In Q1, the HTA received one Freedom of Information request that required greater than 20 working days for us to respond. The delay was attributable to several factors, including the volume of information requested, the need to redact personal data and remove duplications from the final response, and the fact that we had to seek legal advice prior to responding.

8. A second KPI has been marked as red in this quarter. 24 out of 35 (69%) corrective and preventative actions were implemented within agreed timescales to address major shortfalls identified on inspection. As this figure differs notably from the target of 90%, further work will be undertaken to determine the root cause and to identify any corrective measures that may be needed.

9. The Board will be aware that the HTA has set a target of 210 inspections for 2022/23. This is significantly higher than the 2021/22 target of 140 and is intended to comprise a mixture of on-site, virtual and hybrid (combination on-site and virtual) inspections. This raised target (50% up from last year) should enable the HTA to increase our reach across our regulated sectors through adopting alternative models, such as more thematic inspections.

10. The inspection plan for the year incorporates some variability by and within quarters. Inspections were on track during Q1 for the reporting period, with 41 inspections carried out by 15 June and the target of 56 expected to be accomplished by the end of June, given the uneven scheduling referred to above.

(Our quarterly plan is for inspections as follows: Q1 – 56, Q2 – 49, Q3 – 52, Q4 – 53.)

11. We continue to be on track to meet site visit obligations in the Human Application sector by the end of October. Previously, we thought it would not be until December 2022 that we would reach this point.

12. Going forward, we intend to include additional data in the performance data Annex under the heading 'Progress' that will enable the Board to review trends for each KPI. The best way of doing this for each KPI is currently being finalised.

13. During Q1, a cumulative critical shortfall was found at an establishment in the Post-Mortem sector. This related to the premises and particular concerns around the management of risks to the dignity of the deceased during movement across the hospital site. Whilst that inspection report is not yet finalised, immediate regulatory action was taken to issue notice of Directions requiring the establishment to take urgent action to address these concerns, through its own internal risk management processes.

14. Incidents across the different sectors we regulate remain stable.

15. In April, the Head of Regulation for the ODT sector gave two external presentations covering issues such as the regulatory challenges in the sector.

16. In May, a training session was held for 4 Board Members on the consideration and assessment of living uterine donations. As these cases are considered novel, they would require decisions by the Board.

(b) Finance

Table 1 Financial position for May 2022/23

£k	Year to Date				Outturn			
	Actuals	Budget	Variance		Forecast	Budget	Variance	
	£	£	£	%	£	£	£	%
Income	(1,709)	(1,628)	(81)	5%	(5,462)	(5,381)	(81)	2%
Expenditure	737	833	(95)	-11%	529	5,381	(95)	-2%
Net (surplus)/deficit	**(972)**	**(795)**	**(176)**	**22%**	**(176)**	**0**	**(176)**	**59317%**

17. Table 1 provides a summary of year-to-date income and expenditure to the end of May 2022 (period 2). The large net surplus results in phasing of income, with over a third of income invoiced in April and therefore reported. Further detail of our expenditure is contained at Annex 1 to this paper

Income

18. Licence fee income is currently £81,000 above budget, the April invoice run for the Human Application sector annual licence fees totalled £1,675,000 against a budget of £1,593,000. All other sectors will be invoiced in September 2022 with the drawdown of Grant in Aid from DHSC taking place quarterly from July 2022.

Expenditure

19. Several vacant posts in the process of recruitment have resulted in a £53,000 unspent in staff costs for the first two months of the year. A further £42,000 underspend against budget arises from non-staff costs and is mainly due to budget phasing.

20. Certain non-staff cost budgets are phased equally across the financial year as the expenditure can be unpredictable, for example legal and other professional costs and conference attendance.

Outturn

21. The current projected underspend is £176,000. This arises from significant variances to the budget in three main areas; income generated from the Human Application licence fees of £81,000; staff costs variance of £53,000; and other costs of £42,000.

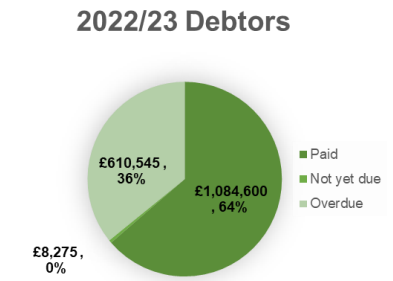
22. The additional income and the underspend in staff costs total £134,000 and represent funds that can be reallocated to costs not already committed. The £42,000 underspend in non-staff costs should not be reallocated yet as the variances most likely arise as a timing issue between actual costs and the budget,

23. Including the unallocated £200,000 contingency, the total funds available for redirection are £334,000 currently. A more in-depth review and re-forecast is taking place at the end of Q1 and will include further allocation of these available of funds to projects currently in business case stage.

Other key performance indicators

Debtors

24. Outstanding debt from licensing activities is provided below.

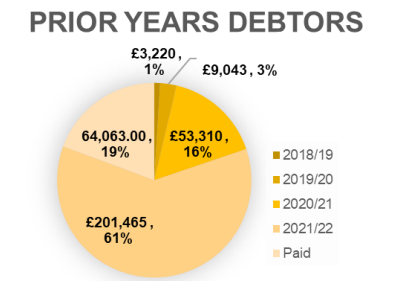


Total value £1,703,420 (162 invoices)

Total paid £1,084,600 (100 invoices)

Total not yet due £8,275 (3 invoices)

Total overdue £610,545 (59 invoices)



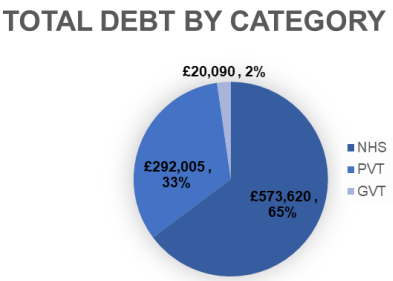
Total value £267,038 (51 invoices)

2018/19 £3,220 (4 invoices)

2019/20 £9,043 (8 invoices)

2020/21 £53,310 (10 invoices)

2021/22 £201,435 (29 invoices)



Outstanding £885,715 (113 invoices)

Total Government - £20,090 (4 invoices)

Total NHS £573,620 (62 invoices)

Total Private £292,005 (47 invoices)

25. Figure 1 shows the 2022/23 only position, the April invoice run for the Human Application (HA) sector generated £1.7m income, £81k above the figure budgeted. As of 31 May 2022, 64% of invoices had been paid. Usual debt management procedures will now be followed in respect of the remaining 36%.

26. Figure 2 provides a breakdown of the outstanding debt prior to this financial year. Payments totalling £64,063 (11 invoices) have been received in respect to invoices since March 2022, this is a result of targeted debt recovery from the HA sector.

27. Of the remaining 51 invoices outstanding 39 (76%) relate to the PM, Research and ODT sectors. These are currently the focus for targeted recovery action prior to the upcoming September invoice run for these sectors.

28. Figure 3 illustrates the total outstanding debt (all years) by sector, as can be seen clearly over two thirds of this debt is within NHS organisations. For comparison the table below sets out the total debt from license fees outstanding at the end of each of the last 5 financial years.

£k	2017/18	2018/19	2019/20	2020/21	2021/22
Outstanding Fees	5	250	424	188	309

29. The position does fluctuate annually and is thought to be somewhat dependent on available cash balances at NHS organisations during the year end process. When considered against the data contained within Figure 2, although significant balances can be carried into future years, overall debt recovery levels are high, albeit over a prolonged period.

30. As part of our strengthening of the financial management team we will be recruiting additional support during Q2 / Q3 of this financial year to accelerate the recovery of historic debt and to actively pursue this year's licence fees to reduce the outstanding debt position at year end.

Financial risks and mitigations

31. Financial risk remains low, with the focus of the Executive on debt recovery and ensuring that plans are agreed and funded by the end of the Q1 to ensure underspends are minimised this financial year.

(c) Governance

32. The Risk Summary document is at **Annex B** (HTA 21b/22) and the Strategic Risk Register is at **Annex C** (HTA 21c/22) to this paper.

33. The risk register was fully reviewed at the commencement of the business year to reflect the business plan and organisation priorities and emerging issues. To provide further clarity, individual risks relating to HR and IT issues were created from the previous combined risk 4.

34. The risks were discussed in some detail at the June Audit, Risk and Assurance Committee meeting and an additional paper has been tabled to this meeting to discuss risk tolerance and appetite in relation to the changed register.

(d) People Issues

Diversity and Inclusion

35. The CEO has conducted the first meetings of a new Equality, Diversity and Inclusion (EDI) network (Diversity Collective) forum engaging with those regulators we are collocated with at Redman Place. The purpose of this group is to encourage and enable us all to take advantage of scale and to share and adopt best practice across the network. There will also be an opportunity to share colleague support groups. This will enable the HTA to provide broader support mechanisms across the protected characteristics.

COVID-19 response

36. We have now moved out of COVID response activity and from 1 June 2022, all colleagues are expected to work to their contractual agreements and the office is available for colleagues to freely utilise.

37. Following DHSC guidance, COVID related sickness absence is being managed in line with our Sickness Policy, this includes any instances of ‘Long COVID’.

Sickness absence

38. There have been 21 days of sickness related absence in Q1 with the majority reported as cold/flu. These are distributed across 12 colleagues throughout this period. Sickness absence during Q1 was higher than the reported sickness absence in Q1 2020/21 at 15 days, it is significantly higher than Q1 2019/20 with 7 days reported sickness related absence.

Recruitment and Retention

39. During Q1, 6 members of staff resigned, as follows:

    1. HR Manager leaving at the end of June
    2. Head of HR leaving at the end of July.
    3. Regulation Manger leaving beginning of August.
    4. Communications Officer left beginning of July
    5. Communications Manager will leave end of July
    6. Policy Manager will leave end of August

40. Through Q1, SMT have approved a programme of recruitment for 6 roles.

    - Head of HR in interview process
    - Three Regulation Manger posts offers accepted- candidates start in July and August.
    - Interim HR manager will start mid-July.
    - Deputy Director Performance and Governance will start at the beginning of July

41. Additionally, during Q1 there were 3 new starters joining the HTA.

    1 permanent Communications & Engagement Manger,
    1 Fixed Term contractor Project Manager
    1 long term secondee as Head of Communications and Engagement.

Engagement Survey

42. Considerable analysis has been conducted into the results of the bi-annual Engagement survey. The response rate was very positive at 81%. Most

colleagues 89% feel connected to the purpose of the HTA and the role they do (97%), with the freedom to carry out their objectives (92%). Additionally, 89% feel supported by their Line Manager. However, coaching and development, feeling valued and recognised and receiving regular thanks and praise all scored between 60% – 70%. Communication, Change Management and Leadership all scored very low, with responses to these questions between 24% - 37%.

43. The results have been reviewed by SMT and Heads of Function. All colleagues were encouraged to engage in further departmental discussions and a wider discussion was held via a facilitated workshop on 30 June at the All-Staff event. The discussions on that day are really the start of our OD/Culture Review. In progressing this work, we are being assisted by the Health & Social Care (HSC) Leadership Centre.

Training

44. The Q1 quarterly mandatory training programme which included Data Protection and Information Security with a deadline of 21 June, was completed by 91% of colleagues by the deadline.

45. During Q1, 1 colleague requested HTA support under the Career Investment Scheme and this was approved by SMT.

Wellbeing

46. Through Q1, our monthly themes have focused on understanding neurodiversity and embracing diversity of thinking. At the end of June, we held a listening event where staff were encouraged to talk openly about challenges, they face in living with neurodiverse conditions such as dyslexia and autism.

47. The Social Committee has been struggling to maintain momentum with other initiatives and new committee members now being sought to re-energise this staff engagement forum. Through Q1, 3 Friday Superbowl events, hosted by a different colleague each time and with questions from the audience to the colleague in the spotlight, were held. These have been engaging and have enjoyed good attendance levels.

(e) Digital, Data and Technology

Communication and Engagement

48. Through Q1 we have appointed a Head of Communication & Engagement and a Communication & Stakeholder Engagement Manager. We have also been developing an implementation approach for the Communication Strategy. We have reviewed and updated media and stakeholder contacts and put in place a regular news roundup for HTA staff and the board.

49. Social media activity and engagement has increased, seeing a modest uplift in engagement and followers. The team are going to focus in on Twitter and LinkedIn as the primary social media channels for HTA.

50. The Comms team have reviewed the stakeholder engagement activity and are developing an engagement approach for Q3 onwards. Two existing members of the communication team are leaving the HTA in July.

51. During Q1 we received a total of 5 FOI requests - 1 is still pending clarification and 1 was received on Tuesday 28th June.

Function	Clarifications sought	Deadline met
Regulation (PM)	Yes	No
IT	No	Yes
IT	Yes	Still pending
HR	Yes	Yes
Regs	Just received on 28th June	

Recommendation

52. The HTA Board is asked to note and comment on the performance recorded and the context provided.

Annex 1 – Detailed Expenditure table

£k	Year to Date				OUTTURN			
	Actuals	Budget	Variance		Forecast	Budget	Variance	
	£	£	£	%	£	£	£	%
EXPENDITURE SUMMARY								
Staff Costs	579	632	(53)	-8%	3,829	3,882	(53)	-1%
Non-Staff Costs	158	201	(42)	-21%	1,472	1,514	(42)	-3%
Gross Costs	**737**	**833**	**(95)**	**-11%**	**5,301**	**5,396**	**(95)**	**-2%**
Non-Staff Costs								
Travel & Subsistence	15	23	(8)	-35%	136	144	(8)	-5%
Training & Recruitment	7	25	(18)	-72%	121	139	(18)	-13%
Conference & Project Costs	2	12	(10)	-83%	117	127	(10)	-8%
Post, Stationery & Printing	0	1	(1)	-100%	16	17	(1)	-5%
Other Costs	7	6	1	23%	38	37	1	4%
I.T. & Telecommunications	53	59	(6)	-10%	364	370	(6)	-2%
Legal & Professional	21	13	9	66%	88	79	9	11%
Consultancy	14	0	14	0%	39	25	14	57%
Accommodation	33	45	(12)	-26%	258	270	(12)	-4%
Non-Cash Costs	0	5	(5)	-100%	225	230	(5)	-2%
Capital Charges	6	13	(7)	-57%	71	78	(7)	-9%
Total Non-Staff Costs	**158**	**201**	**(42)**	**-21%**	**1,472**	**1,514**	**(42)**	**-3%**
Organisational Development Costs				0%				0%
Contingency				0%	200	200	0	0%
Total Revenue Expenditure	**158**	**201**	**(42)**	**-21%**	**1,672**	**1,714**	**(42)**	**-2%**

HTA 21a/22

Board Performance Report
Q1 2022/23

HTA
Human Tissue Authority

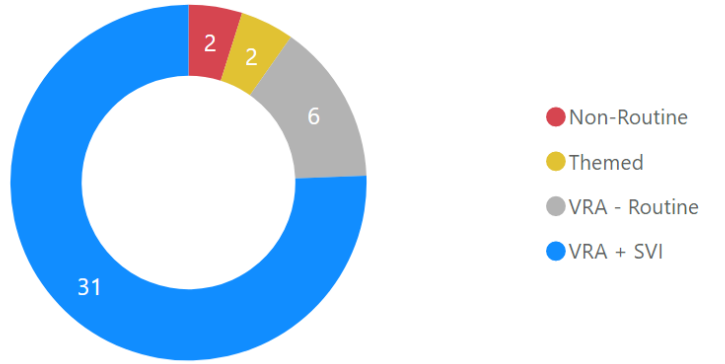
Inspections

41
Q1* 2022/23

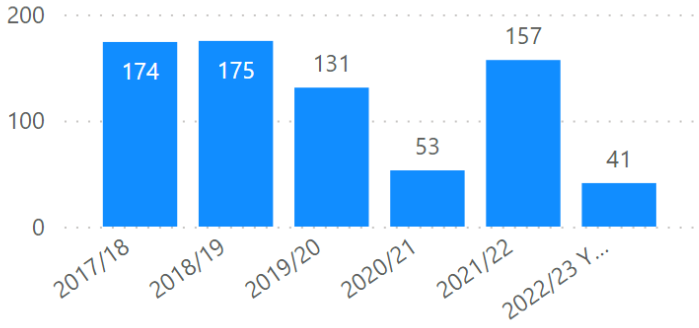
210
2022/23 Target

Inspections 2022/23

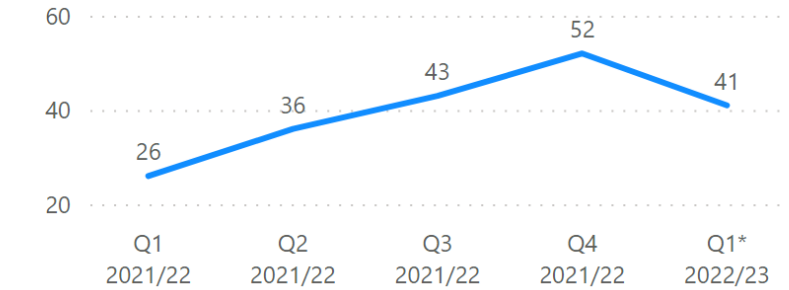
Inspection Type Q1* 2022/23



Inspections by Year



Inspections by Quarter

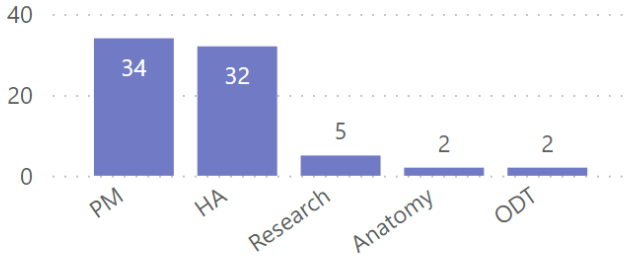


CAPAs

Open CAPA Plans

75

Open CAPA Plans by Sector



Age	CAPA Plans
0-6 Months	62
6-12 Months	9
+24 Months	4
Total	**75**

Licensing

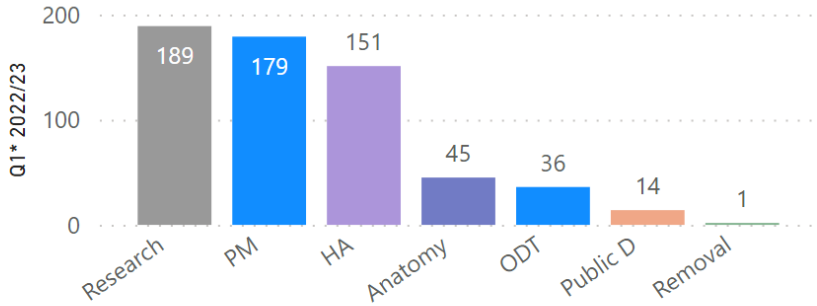
Main Licences

615
+3

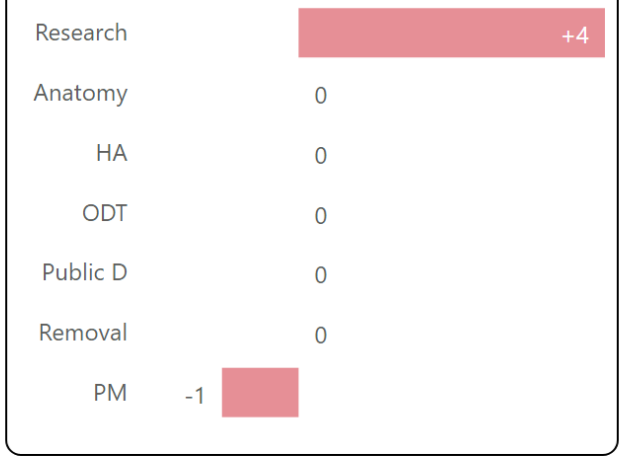
Satellites

333
+3

Main Licence by Sector



Changes in Sector compared to previous quarter (Main Licence Only)



***ALL Q1 2022/23 data from 1/04/22 - 15/06/22**

Business Plan KPIs

11	2	4	5	0	0
Metrics	Off track	Amber	On track	Not started	Completed

Name	Status	Value	Volume	Progress	Due date
210 Inspections covering all sectors	On track	41/210			31 Mar 2023
Atleast 90% of draft inspection reports are sent to DI for a factual accuracy check within 20 working days of the substantive completion of the inspection	On track	91 %	30/33		31 Mar 2023
At least 90% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed within agreed timescales	Off track	69 %	24/35		31 Mar 2023
At least 95% of enquiries are answered within ten working days of receipt	Amber	94 %	320/340		31 Mar 2023
All FOIs d/w in line with HTA procedures and meet statutory timetable	Off track	67 %	2/3		31 Mar 2023
At least 90% of licence variation requests are processed within 20 working days of receipt	On track	90 %	55/61		31 Mar 2023
At least 90% of completed applications are processed within 90 working days of receipt	Amber	75 %	6/8		31 Mar 2023
100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days	On track	100 %	143/143		31 Mar 2023
100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days	On track	100 %	29/29		31 Mar 2023
At least 90% of inspection/audit reports are published on the HTA website within 10 weeks of the substantive completion of the inspection/audit	Amber	88 %	36/41		31 Mar 2023
A decision is reached on at least 90% of Preparation Process Dossiers within 20 working days of receipt of the completed dossier or any additional information requested by the HTA	Amber	80 %	8/10		31 Mar 2023

Latest review date – 19/05/22

Strategic risk register 2022/23
Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Risk owner	Status	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	**8 – Medium**	Director of Regulation	Below tolerance	⇔⇔⇩⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**9 - Medium**	Director of Regulation	Above tolerance	⇔⇔⇩⇔
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	**8 - Medium**	Director of Regulation	Below tolerance	⇔⇔⇔⇩
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	**9 - Medium**	Director of Data, Technology and Development	At tolerance	⇧
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	**6 - Medium**	Director of Resources	Above tolerance	⇔⇔⇔⇔
R6: Failure to achieve the benefits of organisational transformation	Development (a-d) objectives	**9 - Medium**	Director of Data, Technology and Development	At tolerance	⇔⇔⇔⇔
R7: Failure to optimise the safe use of existing and available digital data and technology	Delivery (a-e), Development (a-d) Deployment (a, c and d)	**12 - High**	Director of Data, Technology and Development	Above tolerance	⇧

* Strategic objectives 2021-2024:
** This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g.⇧⇔⇩⇔).

R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15 - High	**2**	**4**	**8 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
At tolerance. We have a good regulatory framework, with moderate assurance on a recent internal audit on the Effectiveness of the Inspection Process in Quarter 4 2021/22 (final report issued 11 April 2022) and previously substantial assurance on an internal audit on key regulatory processes in Quarter 4 2018/19 (final report issued 16 April 2019). The HTA has set a target of 210 establishment assessments for 2022/23 (a combination of onsite and virtual regulatory assessments) and remains on track to meet this target. This level of assessment is a significant increase on previous years and even if not explicitly met will lead to wider reach than in previous years. The re-introduction of KPIs for timeliness of report completion and publication will provide visibility at SMT and board level of our performance in providing our findings to establishments and stakeholders in a timely manner. We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued. We continue to actively manage a small number of more unusual regulatory matters with establishments. SMT believes this risk continues to be below tolerance in June 2022.

R2: There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20	**3**	**3**	**9 - Medium**
Tolerance threshold:					**6 - Medium**

Commentary
This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control. The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in several different circumstances over the past two years. These have included managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. During the 2022/23 business year we will undertake a business continuity or critical incident test event to ensure our plans and response is effective. We also found these arrangements useful and effective in preparing for and managing our response to the public revelation of sexual offending in a mortuary through the trial of Fuller and subsequent actions from Quarter 3 of 2021/22 onwards. Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial. we now believe that the likelihood of this risk materialising has reduced but given continuing uncertainties, we believe it is still above the tolerance level and has remained unchanged from the last review.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 - High	**2**	**4**	**8 – Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance. We have no indications of any current specific factors that would contribute to this risk. The HTA continues to communicate our remit and advise where appropriate. The HTA is in ongoing dialogue with DHSC (Department of Health and Social Care) and wider stakeholders regarding Sir Jonathan Michael's Independent Inquiry into offending by Fuller and is currently preparing to submit further evidence to the Inquiry. The HTA is ensuring that clear media lines are prepared and shared with the public and the media when necessary. The HTA has an established Horizon Scanning process and is building its Policy function. The HTA is working with colleagues in the Northern Ireland Executive and NHSBT (NHS Blood and Transplant) to ensure there is effective implementation of the recent passing of the deemed consent for organ and tissue donation in Northern Ireland through changes to the Code of Practice F, Part 2. Whilst the recent amendment to s32 Human Tissue Act 2004 by the Health and Social Care Act 2022, to introduce an offence for 'organ tourism', is not expected to have any direct operational impact, the HTA continue to engage and support implementation of this change with NHSBT. All these matters are being actively managed. SMT consider this risk to have reduced in likelihood, but the impact to be more damaging should it occur; this results in the risk moving to below the agreed tolerance level.

R4: Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	3	12 - High	**3**	**3**	**9 – Medium**
Tolerance threshold:					**9 - Medium**

Commentary
Above tolerance. A significant amount of work was undertaken in 2021/22 to mitigate the risks associated with workforce. Actions included a partial organisational redesign, recruitment of fixed term contracts to a number of significant and standalone roles ensuring the short-term skill and competencies need was addressed and the identification of additional skills required to support agreed activity going forward. The HTA has reframed this risk for 2022/23 to reflect wider workforce issues that need to be considered beyond numbers of staff and vacancies. As we reflect on the past year and look forward the HTA requires a range and changing set of skills, capabilities and capacity to fulfil its functions and objectives. The diversity of our workforce and the adoption of new ways of working will be essential to ensure our approach to regulation remains responsive, proportionate and supportive to the sectors we regulate and the wider functions we deliver. The SMT's first full consideration of this re-stated risk is to amend the likelihood scoring to 3 and reduce the likely impact of this risk. As we progress work on our EDI strategy and consideration of joint or shared HR services we would expect this risk to reduce towards a 2-2 scoring.

R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – High	**3**	**2**	**6- Medium**
Tolerance threshold:					**3 - Low**

Commentary

Above tolerance.

Budgets for 2022/23 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £80k) and depreciation and amortisation costs (Ring Fenced RDEL).

The Department have provided additional GIA funding for support in assisting the FII, for 2022/23 only we have been delegated and addition £195k. Invoicing for licence fees in the HA sector were issued in April 2022, this has increased our overall debtors' figure, but aged debt continues to fall. Following the material underspend that emerged at the end of 2021/22 SMT have agreed to introduce a target of an underspend below 3% for 2022/23 and this will be monitored monthly.

There are no emerging financial pressures, SMT will be reviewing the financial position monthly with formal quarterly reviews with each Directors feeding on to the portfolio management process to ensure more timely decisions to invest emerging underspends in areas identified in our activity pipeline. We expect to revisit the scoring of this risk following the Q1 finance review and portfolio meeting.

Activity is planned later in this business year to review the current assumptions in our fees model and ensure they reflects any changes in our approach regulation activity or focus.

SMT have agreed that this risk is unchanged.

R6: Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	3	9 – Medium	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance. The Development Programme was adversely impacted in 2021/22 by the availability and commitment of resources (people and financial). Despite an agile approach and incremental developments the deliverables at year end were not as had been intended. A review has been undertaken in Q1 2022/23 with the aim of reframing the approach to development, change and transformation. This review has included a restating of the case for change, the identification of internal and external drivers and the alignment with the strategic direction of the HTA. A revised programme will be presented to SMT for agreement and reporting to the Board in July. The risk is at tolerance as plans for delivery are implemented. SMT discussed the planned activity and felt that progress in the first half of the year on the Review of Inspections and the work to refresh the HTA's values and culture would provide some demonstrable evidence that could reduce this risk. The work to establish pooled / shared services for HR and IT should help to provide a stronger foundation for realising opportunities for modernisation and transformation.

R7: Failure to optimise the safe use of existing and available digital data and technology

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**4**	**3**	**12 - High**
Tolerance threshold:					**9 - Medium**

Commentary
Over the last 2 years the HTA has been progressing with the planned development of its digital data and technology (systems and architecture) as part of the Development Programme. The planned development had been incremental based on available resources and aimed to future proof business needs. The planned developments also sought to mitigate areas of potential and actual risk that have been the result of limited financial investment and build resilience into systems through compatible design. The failure to maintain investments into the development systems, architecture and supporting resources is a current risk which if left will increase. Work is underway to explore alternative models for service and resource provision and the capabilities to support the development of HTA IT systems as required. Milestones for delivery will be identified through the work to restate the development programme activity for IT and SMT acknowledged that any transition would lead to increased risk in this area As a result of this assessment SMT agreed to increase the residual impact of this risk to 3 – resulting in a High risk score of 12, which is above agreed tolerance. Work to establish pooled / shared services for IT should help to provide a stronger more assure platform on which to optimise the safe use of data and technology

Reviews and revisions

(23/02/22) SMT review March 2022

Risks 1,2 and 4 were discussed in detail. SMT agreed that the impact score of risk 1 should be reduced as the tools in place continue to work; risk 2 likelihood score was also adjusted down; and risk 4 likelihood has been reduced from 3 to 2 reducing overall rating to 8 as key posts have been recruited to.

(19/05/22) SMT review April/May 2022

The SMT reviewed the current register in light of the finalised business plan and agreed the following:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-framed to reflect the fact that it is broader than just the Development programme.

(09/06/22) SMT review June 2022

Following the full review of risks for the new business year SMT reviewed the risk register following a detailed discussion at the HTA ARAC meeting:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-frame to reflect the fact that it is broader than just the Development programme.

Strategic Aims

Delivery: Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.
(a) Deliver effective regulation of living donation.
(b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
(c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
(d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development: • Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.
(a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
(b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
(c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

Deployment: Manage and develop our people in line with the HTA's People Strategy
(a) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
• Provide a suitable working environment and effective business technology, with due regard for data protection and information security
• Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HTA's strategy or purpose.

Whether it is possible for the HTA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in risk order.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Rare	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Very low	2=Low	3=Medium	4=High	5=Very High

	Risk Scoring Matrix				
IMPACT	5. Very High	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1.Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
	Likelihood					
Risk score = Impact x Likelihood		1.Rare (≤3%)	2.Unlikely (3%-10%)	3.Possible (10%-50%)	4.Likely (50%-90%)	5.Almost certain (≥90%)

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HTA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change unless the organisation's role or environment changes dramatically.

Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

Assessing inherent risk

Inherent risk is usually defined as ‘the exposure arising from a specific risk before any action has been taken to manage it.’ This can be taken to mean ‘if no controls at all are in place.’ However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

‘the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.’

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

NEW - HTA Strategic Risk Register 2022-23

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
1	***There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.*** *Risk Owner:* ***Nicky Harrison***	***Causes*** • *Failure to identify regulatory non-compliance* • *Regulation is not transparent, accountable, proportionate, consistent and targeted* • *Regulation is not sufficiently agile to respond to changes in sectors* • *Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)).* • *Inadequate adherence to agreed policies and procedures in particular in relation to decision making* • *Poor quality or out of date policies and procedures* • *Failure to identify new and emerging issues within HTA remit* • *Failure to properly account for Better Regulation* • *Insufficient funding in regulated sectors* ***Effects*** • *Loss of public confidence* • *Compromises to patient safety* • *Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance* • *Reputational damage*	**5**	**3**	*Ongoing*	**Regulatory model**	**4**	**2**		**10**	1	2	3			
						Regulatory model comprising a mixture of proactive and targeted regulatory assessments (e.g. through inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc). Process for consideration of police referral maintained and used. Annual collection of activity data in HA sector; periodic collection of information from other sectors.			Remote assessment methodologies are embedded into business, alongside a decision-making framework to inform appropriate decisions about type and composition of inspections. A formal review of inspections is on the business plan for 22/23. An ambitious target of 210 risk-based inspections has been implemented to give greater coverage across our sectors as we emerge from pandemic restrictions.		X			Preventative	.	Remote assessment methodologies incorporated into BAU in all sectors, as evidenced in Business Plan and inspection schedule. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - report agreed late May 2021; Moderate assurance; considered by ARAC; all actions now complete (per ARAC Quarter 3 2021). Internal audit on Effectiveness of the Inspection Process (finalised April 2022). Moderate assurance, with actions ongoing and monitored by ARAC. Police referral made Q1 20/21 has been investigated by the police, supporting Witness Statements provided by the HTA, decision pending with CPS.
						Regulatory decision-making framework			Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.		X			Preventative	Details of Regulatory Decision Meetings recorded in CRM included in business monitoring/reporting. Case Review Meetings summarised in CRM.	Satisfactory Internal Audit Report (strong assurance) November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision-Making SOP updated February 2020 and currently being reviewed/revised. Evidence of regulatory decision making framework being used in practice e.g. Case Review Meetings recorded in CRM, numbers of RDMs reported monthly
						Well established processes support our core regulatory business.			Completion of further management actions identified by Internal Audit of effectiveness of the inspection process - by Quarter 3 2021. (Reviewed by ARAC.) (Principally ensuring other regulatory processes and documentation (SOPs) were updated to take account of VRAs.)				X	Detective	Internal audit conducted on Key Regulatory Processes late 2018/19, receiving substantial assurance and noting good areas of best practice. Internal audit on the Inspection Process during Covid-19 conducted late 2020/21 - see R4. Moderate assurance and management actions complete, as noted by ARAC Quarter 3 2021. Internal audit on Effectiveness of the Inspection Process (finalised April 2022). Moderate assurance, with actions ongoing and monitored by ARAC.	Internal Audit 2021: low priority actions all complete by Autumn 2021. Internal audit 2022: low and medium priority actions to be completed within the 22/23 business year.
						Quality management systems										
						HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model			The HTA's Corporate Service Manager coordinates activities to ensure policies are reviewed and updated.		X			Preventative/Monitoring	Management oversight, through business monitoring and reporting.	Limitations in QMS remain. QMS and performance reporting includes evidence of degree to which the documents are current.
						Training and development of professional competence					X			Preventative	Annual PDPs, which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs.	Evidence of corporate training programme, including quarterly mandatory training. Mix of in-person and virtual Regulation-led Training sessions to be scheduled following confirmation of All-HTA meeting dates. 'Lunch and Learn' programme.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas			As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps.		X	X		Preventative/Monitoring	SMT assessment of skills requirements and gaps as vacancies occur. Recruitment policy.	Staffing levels and risks reported quarterly to the Board. Recruitment policy reviewed by SMT May 2021.
									Regulatory model							
									Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.		X			Preventative		
									Other							
									Strengthening horizon scanning arrangements		X			Preventative		

NEW - HTA Strategic Risk Register 2022-23

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2	***There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.*** ***This might be an incident:*** • ***relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)*** • ***caused by deficiency in the HTA's regulation or operation*** • ***where we need to regulate, such as with emergency mortuaries*** *Risk owner:* ***Nicky Harrison***	***Cause*** • *Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)* • *Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)* • *Failure to work effectively with partners/other organisations* • ***Breach of data security*** • ***IT failure or attack incident affecting access to HTA office*** • *External factors such as terrorist incident, large scale infrastructure failure or pandemic* ***Effect*** • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	***5***	***4***	*Ongoing*	Critical Incident Response Plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	***3***	***3***		***6***	X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Version 21 of CIRP published May 2022. CIRP deployed in March 2020 to manage coronavirus pandemic. CIRP used as framework for managing 'Operation Sandpiper' critical incident.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 X	2	3	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant or, if role is vacant, cover arrangements put in place.	CIRP reviewed and updated to version 21 in May 2022.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media. Experience of engaging and managing a contract with Crisis comms consultants to support the HTA on a specific critical incident.		X			Preventative	Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant. Media enquiries successfully managed during critical incident phase of Fuller work.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy			Engagement with other potential investigatory authorities, such as NHS Counter Fraud Authority		X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes. Police referral policy approved by the Board February 2022.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.		X			Preventative Reports to Board of key decisions in Chief Executive's Report to the Board.		Number of Regulatory Decision Meetings detailed in monthly management performance pack, for review by SMT. Regulatory Decision Making SOP currently under review (to be finalised July 2022)
						IT security controls and information risk management					X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020. Cyber Security has been a standing agenda item in the form of a dashboard report at each ARAC meeting.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 2020. Need for formal IT Disaster Recovery Plan and regular exercise regime		X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic from March 2020. CIRP deployed for a short period in May / June 2021 to deal with confidential matter. CIRP used as basis for Fuller response planning in Autumn 2021.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic and more recently in the HTA's response to Sandpiper, managed as a critical incident.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test. SMT note CIRP framework used in managing the HTA's planning for and response to the critical incident arising from the police investigation, 'Operation Sandpiper'.	Noted in ARAC Audit Tracker.
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.			Awareness raised of PM sector reporting requirement (HTARIs) at external training events e.g. AAPT training Quarterly meeting with NHSBT to review ODT SAEARs cases over 90 days and any complex cases. **Publication of quarterly incident numbers in the professional e-newsletter may remind establishments to report.**		X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process. **Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM).** Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.	Findings at inspections. Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector **- latest meeting was June 2022** **Most recent SARE report submitted summer 2021**. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. **Publication of incident numbers in the regular (bimonthly) Professional Newsletter.**

NEW - HTA Strategic Risk Register 2022-23

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3	**There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.** *Risk Owner:* ***Nicky Harrison***	***Cause*** ***External factors*** • *No scheduled review of Human Tissue Act 2004 and associated regulations, or Quality and Safety Regulations (other than for EU Exit)* • *Rapid advancements in the life sciences* • *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in currency exchange rates* • *Deemed consent for Organ donation in England* ***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 and treatments carried out in a single surgical procedure* • *Police holdings* • *Products of conception and fetal remains* • *Data generated from human tissue* • *Funeral directors* • *Forensic research facilities* • *Cryonics* • *Body stores / Taphonomy* • *Imported material* • *Clinical waste* • *DNA* • *Other* • *Inadequate stakeholder management* ***Effect*** • *Diminished professional confidence in the adequacy of the legislation* • *Reduced public confidence in regulation of matters relating to human tissue* • *Reputational damage*	*4*	*3*	*Ongoing*	Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DHSC and manage messages	***3***	***3***		**9**	*1*	*2* *X*	*3*	*Monitoring*	*Ongoing log*	*Log in place and shared with Board in outline at the Strategic planning session in 2021.* *HS process under active review and*
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			*Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement.* *Updated C&E Strategy planned for Q4.*		*X*			*Preventative/ Detective*	*Stakeholder Group meeting minutes* *Authority minutes (including Public Authority Meeting)* *TAG and HWG meetings* *Evidence of engagement with other relevant stakeholder forums, not necessarily organised by HTA.*	*Last Stakeholder and Fees Group meeting in October 2019; Histopathology Working Group February 2020;* *Transplant Advisory Group October 2019.* *Public Authority MeetingMay 2022* *Professional newsletters issued regularly - last one May 2022* *Sector-specific engagement e.g. with the post-mortem sector through multi-agency forums (Death Investigation Group, Excess Deaths Working Group).*
						Active management of issues raised by the media – including the development of the HTA position on issues			*Lines currently under review and update*		*X*			*Preventative/ Detective*	*Quarterly reports to Board on communication (including media) activities*	*Last report to May Board meeting (2022).*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence						*X*		*Monitoring*	*Quarterly Accountability meetings with DH superseded during the pandemic by DHSC attendance at Board meetings for assurance plus DHSC sponsor team's engagement with HTA.*	*Quarterly Accountability meetings restarted - last one, May 2022* *Monthly DHSC/HTA meetings - last one, May 2022*
						Action where we believe it will support public confidence			*COVID-19 guidance* *Reactive media lines* *Publication of statements and advice e.g. to Secretary of State*		*X*			*Preventative*	*Guidance updated in response to the coronavirus outbreak and published on the website, including sector-specific guidance also published.* *Advice to Secretary of State published on website in Q1 (Inquiry into mortuary offences)*	*Updates to the Board and DHSC at Board meeting May 2022.*
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge			*Demonstrate ongoing engagement of Devolved Assembly in Wales and N Ireland. Effective engagement and collaboration demonstrated through the revision of Code D.*		*X*			*Preventative*	*Duty and its uses understood by SMT and Chair*	*Advice and guidance continues to be provided in relation to section 32 amendment (commercial dealings).* *Engagement with DHSC over Fuller issues - advice submitted to Secretary of State 15 December 2021 (published on website in Q1) Also engagement with Welsh Government officials on this matter.* *Ongoing engagement with NI Executive over NI Deemed Consent -HTA has update its Code of Practice (F) in recognition of this.*
						No further changes to HTA's Standards since significant changes launched April 2017.			Work planned in 2022/23 to review and update codes of practice. Focus will be on factual updates.		*X*			*Preventative*	*Updated draft guidance produced for revised Code D.* *Updated draft of Codes of Practice D to enhance consent expectations for imported bodies and body parts for public display.*	*Draft revised Code of Practice D (Public Display) to align consent expectations for imported bodies and body parts with those for material originating in England, Wales and Northern Ireland received Parliamentary approval in July 2021.*
						Training and development relating to professional conduct and behaviours while engaging with stakeholders					*X*			*Preventative/Detec*	Annual PDPs, which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs. Staff engagement with - and promotion of - values (HR-led)	Evidence of corporate training programme, including quarterly mandatory training. Mix of in-person and virtual Regulation-led Training sessions to be scheduled following confirmation of All-HTA meeting dates. 'Lunch and Learn' programme.
						Stakeholder evaluation surveys undertaken in Q4 2019/20 and Q4 of 2021/22, reported to Board in May 2022 and used to inform further developments.			Work in Q1 to identify and pilot new approaches to stakeholder engagement		*X*			*Preventative*	*Evidence from surveys used as an evidence and information source to inform and drive improvements*	*Evidence from stakeholder survey presented to the Board in May 2022.*

NEW - HTA Strategic Risk Register 2022-23

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
4	***Failure to adequately deliver a diverse, capable workforce the HTA requires or needs to fulfill its functions and objectives*** *Risk Owner:* ***Louise Dineley - moving to Richard Sydee August 2022***	• ***Cause*** *Lack of knowledge about individuals' expertise* • *Poor job and organisational design resulting in skills being under used* • *Poor line management practices* • *Poor project management practices* • *Poor leadership from SMT and Head* • *Loss of productivity as a result of the effects of changes to ways of working* • *Lack of ring-fenced resource for 'no-deal' EU Exit* ***Effect*** • *Poor deployment of staff leading to inefficient working* • *Disaffected staff* • *Increased turnover leading to loss of staff* • *Inadequate balance between serving Delivery and Development objectives*	*3*	*4*		***People capability***	*4*	*2*	*All major projects have project management rigour further enhanced through benefits realisation and plans to assess ROI at year end.*	**9**	***1***	***2***	***3***			
						People Strategy for the period 2019 to 2021 is in effect			Recruitment to identified vacancies and skills gaps ongoing. Succession planning and future skills needs to be developed further as part of a workforce model. Work planned for Q2 & 3.		***X***	***X***		*Preventative/ Monitoring*	*Board approval of the Strategy*	*Board approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2021*
						Full suite of people policies and procedures (including performance management)			*Review of processes and procedures required to ensure these are appropriately supporting and enabling adherence to the relevant policies. Development of new policies relating to e.g. Due Diligence and Contracting of Suppliers to be undertaken to ensure alignment with DHSC and UKGOV requirements (Q2). Overarching guidance document to assist Line Managers / Heads of Function in understanding corporate policies / relevance to their teams to be developed (for Q2).*		***X***			*Preventative/ Monitoring*	*Full suite of policies in place and available on Wave*	*https://intranet.hta.gov.uk/pages/policies_forms*
						External assessment of utilisation of capabilities			*Further work may be identified as part of the Cultural Review in Q2 Q 3*				***X***	*Monitoring/ Detective*	*Internal audit 'Utilisation of capability' provided moderate assurance*	*ARAC received the audit report and monitors progress against recommendations - most recently June 2021.*
						Adherence to the HTA Workforce Capability Development Framework					***X***			*Preventative*	*SMT approved the Framework in September 2020 - as a response to internal audit recommendations*	*ARAC to receive update on the Framework at its meeting in October 2020*
						Investment in the development of the HTA leadership team			*Further work may be identified as part of the Cultural Review in Q2 Q 3*		***X***			*Preventative*	*External consultants engaged to assess team and individual development needs and design appropriate interventions*	*The current programme of work was completed in June 2021.*
						Handover process is formalised via a checklist to ensure corporate knowledge is retained			*Ensure the process identified and published is adhered to. Ensure that documentation is saved in the appropriate EDRMS folder for wider access as needed.*		***X***			*Preventative/ Monitoring*	*Handover checklist is in place and in operation.*	*Evidence provided to internal audit June 2021.*
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills. Work to adopt a portfolio management approach to support more effective resource deployment and identification of skills required.		***X***	***X***		*Preventative/ Monitoring*	*Director and Head of HR assessing capability needs as part of future operating model* *HTA Workforce Capability Development Framework sets out how capability needs will be met* *Head of HR has implemented a register of skills within the HTA*	*SMT will be agreeing its approach to filling specific immediate capability needs in October* *Development Programme is picking up medium to long term capability needs.*
									Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focusing on short and long term impacted deliverables.			***X***		*Preventative/ Monitoring*	*SMT terms of reference and SMT minutes*	*SMT ToRs revised and approved.* *HMT ToRs in development* *HTAMG ToRs to be revised subsequently*

NEW - HTA Strategic Risk Register 2022-23

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY I	INHERENT RISK PRIORITY L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY I	RESIDUAL RISK PRIORITY L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
5	*There is a risk that the HTA has insufficient or ineffective management of its financial resources* *Risk Owner:* *Richard Sydee*	***Cause*** • *Fee payers unable to pay licence fees -* • *The number of licenced establishments changes, leading to reduced fee income* • *Management fail to set licence fees at a level that recover sufficient income to meet resource requirements* • *Failure to estimate resource required to meet our regulatory activity* • *Poor budget and/or cash-flow management* • *Unexpected increases in regulatory responsibilities* • *Unforeseeable price increases / reductions in GIA* • *Fraudulent activity detected too late* ***Effect*** • *Payments to suppliers and/or staff delayed* • *Compensatory reductions in staff and other expenditure budgets* • *Increased licence fees* • *Requests for further public funding* • *Draw on reserves* • *Failure to adhere to Cabinet Office Functional Standards* ***Leading to:*** • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and non payment of fees*	*5*	*4*	Ongoing	Budget management framework to control and review spend and take early action	**2**	**3**		3	**X**	**X**		All	Budgetary control policy reviewed and agreed by SMT	Revised version reviewed by SMT in November 2020. AUD 16b/21. Next review November 2022.
						Financial projections, cash flow forecasting and monitoring					**X**			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in May 2022
						Licence fee modelling								Preventative	Annual update to fees model	Fees agreed by the Board at rhe November 2021 meeting
						Rigorous debt recovery procedure					**X**			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstanding debt is being reduced. Older debt are being collected. Although we maintain a tight grip on our position, the overall environment is more uncertain than normal. Additional resource is being sourced for this area.
						Reserves policy and levels reserves					**X**			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2021
						Delegation letters set out responsibilities					**X**	**X**		Preventative	Delegation letters issued annually	Issued in April 2022
						Fees model provides cost/income information for planning					**X**			Preventative	Annual review of fees model, reported to SMT and Authority	Went to the Board November 2021, a review of the current data underoinning the fees model will be undertaken in Q2-3 of 2022/23 financial year
						Annual external audit							**X**	Detective	NAO report annually	Unqualified Accounts produced June 2021 - 2022 awaiting final sign off by C&AG
									Monitoring of income and expenditure (RS) **Ongoing**				**X**	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Lreviewed monthly
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**		**X**	**X**		Detective	Quarterly Finance Directors and Accountability meetings	Monhtly DHSC Finance Director meeting provides overisight of future changes/issues. Quarterly meetings with DHSC finance covers specific HTA issues.
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards		**X**	**X**		Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions made quarterly last submission April 2021 (Q4 2020/21). Counter-fraud activities now part of BAU.

NEW - HTA Strategic Risk Register 2022-23

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6	***Failure to identify opportunities and achieve the benefits of continual change and improvements to support the modernisation of the HTA*** ***(Development objectives a-d)*** ***Risk owner*** **Louise Dineley**	***Causes*** • *Uncertainty of funding* • *Programme and project benefits poorly defined and understood* • *Inadequate programme and project governance arrangements* • *Poorly specified programme and projects* • *Insufficient programme, project and change management skills* • *Inadequate leadership of change* • *Inability to access the necessary skills required at a affordable cost* • *Lack of staff buy-in to change* • *Management and Head stretch of delivering transformation alongside business as usual and other development activity* • *Insufficient agility in (re)deploying people to change projects* • *Poorly specified procurement and inadequate contract management* • *Realisation of single points of failure for DDAT and People Strategy* ***Effects*** • *Wasted public money* • *Failure to achieve the central strategic intent of the Authority* • *Distracts senior management from operations at a time when demands have increased* • *Reputational damage* • *Unaffordable cost over run* • *Staff demotivation* • *Data remains under-utilised* • *Technology inadequate to meet future needs (cost, functionality)* • *Limited ability to achieve improvements in efficiency and effectiveness* • *Pace of change is inadequate and impacts negatively on other work*	**3**	**3**		SMT experience of organisational change, programme and project management.	3	3	*Change Manager appointed in August 2020. Ongoing organisational preparedness remains a key workstream in the 21/22 plan.*	**9**	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development will act as Programme Director.
						HTA approach to the management of change projects *(underpinned by project management methodologies)*					X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively
						A number of trained project managers among HTA staff			*Project Management skills further strengthened by introduction of a toolkit and induction session by PM*		X			Preventative		
						Experience of procurement and contract management					X			Preventative		
						Existing mechanisms for engaging staff			*Plans developing for strengthening internal communications function*		X			Preventative		
						Well established corporate governance arrangements and financial controls						X		Monitoring	*Internal audit of key controls*	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			*Further alignment of projects on the business plan to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*		X			Preventative	*Progamme plan in place*	Update reported to July Board meeting
						Project management rigour including benefits to be realised.			Embed Benefits Realisation Management methodology within programme		X			Preventative		
						Monthly reporting to SRO in place			Introduce a Programme Management function		X			Preventative		*Ongoing focus in 21/22 to embed PMO skills and build wider capability across the business*
									Board approval to proceed at key Gateway decision points			X		Monitoring		
									Training plan to encompass project and change management and HTA approach		X			Preventative		*Change management training activity is now in progress following the appointment of the HTA Change Manager. Mandatory all staff sessions were undertaken in quarter 3. Further osu planned in Q4*
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver the DDAT Strategy		X			Preventative		*Plan in place, work ongoing in 2020/21.*
									SROs identified for Programme and individual projects		X			Preventative		*High level plan in place for 2021/22*
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events		X			Preventative		*Reset and relaunch event planned in Q4 providing focus to developments over the next 15 months. Review of stakeholder engagement also extends to inviting a wider contribution to future development plans.*
						Scope of projects aims to deliver benefits including on a phased and incremental design			Establish an external stakeholder communications and engagement plan		X			Preventative		*Work progressed in Q4 20/21*
									Recruitment of new Board Member(s) with digital and organisational change experience			X		Monitoring		
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace							X	Monitoring/ Detective		
						Identified success measures and benefits to be realised for the Development Programme and individual projects							X	Preventative		

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7	**Failure to optimise the safe use of existing and available digital data and technology** *Risk Owner:* ***Louise Dineley***	• ***Cause*** • *Data holdings poorly managed and under-exploited* • *Inadequate business technology or training in the technology available* • *Lack of ring-fenced resource for 'no-deal' EU Exit* ***Effect*** • *Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed* • *Poor use of technology resulting in inefficient ways of working* • *Inadequate balance between serving Delivery and Development objectives*	3	4		**Data capability**	4	2		9						
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)			Ongoing development of the electronic management of all information and records. Phase 1 complete. Phase 2 in planning.		X		X	Preventative/ Monitoring	Upgrades to CRM, are priortised and carefully developed and managed into live environment. Internal audit of personal data security.	Major CRM upgrade completed successfully. Ongoing review of security and version patches part of routine activity.
						No common understanding of the breadth of data that we hold within systems or how it is actively managed			Creation and publication of a single common data model on intranet. Business System Owner roles, with IT collaboration to identify and work towards a Roadmap of changes needed as part of the Business Planning round					Preventative	Internal audit of data and technology practices	
						Appropriate procedures to manage personal data including GDPR compliance.					X		X	Preventative/ Monitoring	Internal audit of data and technology practices	Part of ongoing Cyber and data security and SIRO reporting. Now absorbed in BAU Information Governance and Cyber Security work
						Business technology capability										
						Staff training in key business systems and mandatory training on policies and required controls.			System development needed to enable devolution of responsibility to line managers for verifying and ensuring that all their staff are up to date on their mandatory training. Supportive guidance document to assist Line Managers / Heads of Function in understanding corporate policies / relevance to their teams and risks (to HTA) of non-adherence to training to be developed .		X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New remote induction programme was launched in Summer 2020.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date			Quarterly Reporting to ARAC on Cyber Security and system security in place.		X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Cyber Security update and Annual SIRO report reviewed and agreed at SMT and ARAC June 2022
									Business technology							
									Identify refresher training plus any targeted software specific training needs via the regular PDP process.		X			Preventative	Evidence of targeted training in last quarter to support the roll out and adoption of EDRMS. Further strengthening of core training requirements included in updated induction programme.	
						System performance analytics available and reported monthly			Use of data analytics to inform and drive changes in practice.						Analytics provide assurance on system performance and support targeted intervention with members of staff as necessary.	

Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 22/22

Agenda item: 7

Author: Dr Julie Edgeworth, Audrey Jessiman, Jess Porter

OFFICIAL

Deemed Consent Northern Ireland

Purpose of paper

1. To provide an update to the Board on the outcome of the public consultation on the proposed changes to Code of Practice F, Part two ("The Code"), which took place between 6 May and 24 June.

2. To seek approval from the Board to the revised Code F Deemed Consent prior to it being submitted to the Department of Health & Social Care (DHSC) for it to be laid before Parliament and delivered to the offices of the NI Assembly in September.

Decision making to date

3. The SMT agreed this paper on 23 June 2022 for submission to the Board.

4. At the February Board meeting, Members agreed revisions could be made to the Code to reflect the changes to legislation in NI arising from the passage of the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022.

5. In March, the revised Code, with proposed changes, was shared with Members by correspondence. At the May Board meeting, Members noted the timetable for the consultation on the revised Code.

Action required

6. Members are invited to review this paper outlining the proposed additional amendments to the Code and are asked to approve draft Version 2 of the Code (attached).

Background

Legislative update

7. The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 was passed by the Northern Ireland Assembly in February 2022 and received Royal Assent on 30 March 2022. The Act, when it comes into force in Spring 2023, will amend the definition of 'appropriate consent' as set out in the Human Tissue Act 2004 for NI and introduce a deemed consent system for deceased organ and tissue donation in NI.

8. To date, deemed consent has not applied in NI and this is reflected in the current version of the Code.

Public and key stakeholder consultation

9. A public consultation was held between 6 May and 24 June inviting feedback on the revisions to the Code. Direct communications to stakeholders across the UK, alongside a rolling series of social media alerts, have been used to encourage engagement in the consultation and to provide those with an interest the opportunity to respond.

10. Throughout the consultation and revision process, the HTA has worked closely with colleagues within the Department of Health (DoH) NI, to ensure they have full oversight of the proposed changes. HTA's Head of Regulation (ODT) is also a member of the project board with oversight for the implementation of the new legislation in Northern Ireland.

11. Roundtable consultation events were held with key NI stakeholders and across the UK, including, members of the Clinical Advisory Group (CAG) and other key groups in NI, colleagues in Wales and DHSC providing an opportunity to discuss the proposed changes to the Code.

12. Due to the movement of organs for transplantation between NI and the Republic of Ireland (ROI), the HTA has engaged with the Health Products Regulatory Authority in ROI.

13. The HTA held information sessions for Members during June to enable detailed discussions on the revisions prior to finalisation.

Feedback from consultation

14. Feedback received during roundtable consultation events has been very positive, stating the draft Code is very clear and helpful. Stakeholders found scenario examples helpful: requests were made for additional examples to address NI specific challenges regarding cross-border working and residency. Additional scenario examples, shaped with input from key operational stakeholders in NI, have therefore been included in the revised draft of the Code.

15. Some feedback raised during the consultation has highlighted a requirement for broader changes to the Code. These are not being taken forward at this time, as to do so, would require a separate and more detailed consultation process and could have consequential implications for other Codes. All issues flagged, however, have been noted: these will be considered as part of a future review of the full suite of Codes of Practice. This has been made clear during the roundtable discussions and will be emphasised in follow-up communications on the outcome of the consultation process.

16. During the consultation, it was noted that the proposed revisions to Code F as a result of the legislative change in NI will create a minor factual inaccuracy in Code of Practice A. This, and other factual inaccuracies in the Codes identified to date, will be addressed as part of a wider Codes review later this business year, prior to Code F coming into force in Spring 2023.

17. To ensure transparency, following closure of the public consultation, a summary of the responses to the survey and feedback received as part of the roundtable and wider engagement events with stakeholders will be published on the HTA website and the link circulated via direct communication to stakeholders.

Proposed changes

18. **Annex A** provides a summary of the additional amendments made to the draft Code following the public consultation and stakeholder engagement events.

19. Legal advice has been sought by the HTA on the updated changes and revisions to the revised Code: this includes specialist legal advice from NI. The DHSC has also sought legal advice as part of this review. The revised Code of Practice Code F presented reflects these reviews.

Next steps

20. Subject to Board approval, the HTA will request DHSC to lay the revised draft Code before Parliament, as required by the Human Tissue Act (2004), in September 2022.

21. The HTA must publish the revised draft Code on its website at the point it is laid before Parliament for the negative procedure. To avoid causing confusion to stakeholders, the draft Code will be published on a separate page to the existing Codes of Practice, clearly indicating it has been laid before Parliament for the negative procedure and this Code is in draft format and not in force.

22. A direct communication with links to the draft Code will be sent to all those who have participated in the consultation process, advising them the draft Code has been laid before parliament for the negative procedure.

23. NHSBT needs approximately 6 months to train the Specialist Nurses for Organ Donation (SNODs) on the revised Code prior to implementation of the law. To support this, a direct communication to NHS Blood & Transplant colleagues will be sent informing them the draft Code is available, caveated that the Code is subject to objection by Parliament. DHSC has agreed, in writing, that the draft Code can be shared with NHSBT for this training purpose, even if, given parliamentary recess periods in September and October for Conference season, the 40-day lay period has not concluded.

24. Colleagues in the DoH in NI have indicated secondary legislation will be laid following summer recess to bring the new legislation into force in Spring 2023. The HTA will continue to liaise with DoH NI colleagues to co-ordinate issuing of Directions to bring the revised Code into force.

25. A direct communication, with a link to the finalised Code, will be shared with all stakeholders at the point the new Code comes into force. This revised Code will replace the existing Code on the main Codes of Practice pages of the HTA website.

Recommendation

26. The Board is asked to approve the revised Code F (Deemed Consent). It will then be submitted to the Department of Health & Social Care (DHSC) for it to be laid before Parliament and delivered to the offices of the NI Assembly in September.

Annex A

Below are the proposed further amendments to the Code. The revisions made to the current wording of the Code are shown in red, underlined text.

Main body of text

The changes that have been made are to add clarity and ensure accurate references to other legislation in NI.

Current Wording	Pre-consultation proposed wording	Post-consultation wording (reflecting feedback)
32. ***Ordinarily resident*** refers to people living in England on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration but deemed consent will not apply unless someone has been ordinarily resident in England for at least 12 months immediately before their death.	32. ***Ordinarily resident*** refers to people living in England or Northern Ireland on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration. For deemed consent to apply in England, the potential donor must have been ordinarily resident in England for at least 12 calendar months immediately prior to their death. For deemed consent to apply in Northern Ireland, the potential donor must have been ordinarily resident in Northern Ireland for at least 12 calendar months immediately prior to their death.	32. ***Ordinarily resident*** refers to people living in England or Northern Ireland on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration. For deemed consent to apply to a person who dies in either England or Northern Ireland, the potential donor must have been ordinarily resident in that jurisdiction for at least 12 calendar months immediately prior to their death. The definition or ordinarily resident is the same in England and Northern Ireland.
58. Controlled DCD describes organ retrieval which takes place after the planned withdrawal of life-sustaining	58. Controlled DCD describes organ retrieval which takes place after the planned withdrawal of life-sustaining treatment at	58. Controlled DCD describes organ retrieval which takes place after the planned withdrawal of life-sustaining treatment at

treatment at the end of a critical illness. In those circumstances a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005) by the treating medical team in consultation with those close to the patient.	the end of a critical illness. In those circumstances a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005) by the treating medical team in consultation with those close to the patient.	the end of a critical illness. In those circumstances a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005 for England and the Mental Capacity Act (NI) 2016 for Northern Ireland) by the treating medical team in consultation with those close to the patient.
90. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. Commitments made in Parliament during the passage of the Deemed Consent Act that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14).	90. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. Commitments made in [the Westminster] Parliament during the passage of the Deemed Consent Act that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14).	90. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. Commitments made in Parliament during the passage in England of the Organ Donation (Deemed Consent) Act 2019 that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14). Whilst this commitment was specifically made in relation to England, the HTAs view is that this should also apply in Northern Ireland.

91. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. Commitments made in Parliament during the passage of the Deemed Consent Act that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14).	92. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. During the passage of the legislation which led to the Organ Donation (Deemed Consent) Act 2019 in England, a commitment made in Parliament that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14). Whilst this commitment was specifically made in relation to England, the HTAs view is that this should also apply in Northern Ireland.	92. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed. ~~Commitments made in Parliament~~. During the passage ~~in England~~ of the legislation which led to the Organ Donation (Deemed Consent) Act 2019 in England, a commitment made in Parliament that donation would not proceed in these circumstances, led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14). Whilst this commitment was specifically made in relation to England, the HTA's view is that this should also apply in Northern Ireland.
177. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.	177. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.	177. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental

		Capacity Act (NI) 2016, rather than the HT Act 2004.
203. The Deemed Consent Act allows the storage and use of organs and tissue in Northern Ireland, which are removed in England. No such provision is needed in Wales or Scotland as this is covered by current legislation. 204. This will mean that organs and tissue removed when consent in England has been deemed can be lawfully transplanted into patients in Wales, Northern Ireland and Scotland (providing all other statutory and regulatory requirements have been met). 205. This also means that organs and tissue removed in England for the purpose of transplantation when consent has been deemed can be stored, used, processed 76 and distributed lawfully across the whole of the UK and Europe	201. Organs and tissue removed when consent has been deemed can be lawfully transplanted into patients in England, Wales, Northern Ireland and Scotland providing all other statutory and regulatory requirements have been met. 202. This also means that organs and tissue removed for the purpose of transplantation when consent has been deemed can be stored, used, processed and distributed lawfully across the whole of the UK and Europe.	201. Organs and tissue removed when consent has been deemed can be lawfully stored, used, processed, distributed and transplanted into patients across the UK providing all other statutory and regulatory requirements have been met. Organs and tissue can, on occasion, be offered to a recipient in other countries where there is no suitable recipient in the UK.

	204. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.	204. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.

New and revised examples

Feedback from the consultation expressed a desire for additional and amended examples to be included in the Code to provide further clarity on when deemed consent is applicable. To address these comments, the following revised and additional examples were drafted with input from key operational stakeholders in NI.

Example – Northern Ireland

An adult dies in hospital in Northern Ireland on 20 August. Their death is diagnosed and confirmed using neurological criteria. The SN establishes by speaking to the family that the potential donor moved to Northern Ireland on 1 August of the previous year. Deemed consent does apply, as the potential donor had lived in Northern Ireland for at least 12 calendar months prior to their death.

The location used in the following example has been amended from Dublin to Paris, based on feedback that using a location across the Border from NI could lead to confusion.

Example - England
A potential donor worked in London and lived there four nights a week, spending the other three nights at their family home in Paris. The potential donor dies in England. The SN should ask questions of the family to establish where the potential donor would have considered themselves ordinarily resident. It will then be for the SN to weigh up the information to establish whether the potential donor was ordinarily resident in England. If the SN establishes that the potential donor considered Paris to be their home and London to be their place of work only, consent could not be deemed.

An additional example added to the same section of the Code to address specific issues that may arise in NI.

Example – ordinarily resident in England and Northern Ireland
The SN establishes by speaking to the family of a potential donor that they split their time equally between Manchester and Omagh and would have considered themselves ordinarily resident in both cities. Deemed consent can apply as the donor was ordinarily resident in both England and Northern Ireland.

Additional example added to address specific issue of cross-border working and residency.

Example – living and working across borders
A potential donor lived in Dublin. They worked in Belfast at the weekends, commuting every Friday morning from Dublin and staying in Belfast until Sunday evening. The potential donor dies whilst at work in Belfast. The SN should establish with the family where the potential donor would have considered themselves ordinarily resident. If the SN establishes that the potential donor considered Dublin to be their home, consent could not be deemed

Glossary changes

	Current wording	Pre-consultation wording	Post-consultation wording
Deemed consent	Deemed consent means that all individuals over 18 in England will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision to not donate their organs and/or tissue, i.e. they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent. Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in England for at least 12 months immediately before their death.	Deemed consent means that all individuals over 18 in England or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue, i.e. they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent. Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident for at least 12 months immediately before their death.	Deemed consent means that all individuals over 18 in England or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue, i.e. they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent. Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.

Excepted adult	An adult who had not been ordinarily resident in England for a period of at least 12 months immediately before their death; or who lacked the capacity to understand the notion of deemed consent for a significant period before their death.	An adult who (i) died either in England or in Northern Ireland and had not been ordinarily resident in the country of their death for a period of at least 12 months immediately before dying; or (ii) who lacked the capacity to understand the notion of deemed consent for a significant period before their death.	An adult who (i) died either in England or in Northern Ireland and had not been ordinarily resident in that jurisdiction for a period of at least 12 calendar months immediately before dying; or (ii) who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

Definition of transplantation in glossary reverted to previous definition as defined in the other Codes of Practice to maintain consistency. This revision will be considered as part of a wider review of the suite of HTA Codes.

Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.	A process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient. This is not limited to cases where the process of transfer requires a donated organ to be physically implanted into the recipient's body.	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.

Code F: Donation of solid organs and tissue for transplantation

Part two – Deceased organ and tissue donation

Contents

Introduction to the Human Tissue Authority Codes of Practice 3
Introduction to Code F – Part Two 5
Scope of this Code of Practice 5
Interpretation and general guidance 7
Research 8
Offences under the HT Act 9
Conditions on consent for organ and tissue transplantation 9
End of Life Care 10
Structure and navigation 11
Organ donation after death 11
Donation after Brainstem Death (DBD) 12
Donation after Circulatory Death (DCD) 12
Tissue donation after death 12
Consent 13
Overview 13
Recording a decision about organ and tissue donation 14
Role of the family 15
Consent which is expressly given 19
Establishing whether a potential donor made a decision in life – adults 19
The NHS Organ Donor Register as a source of consent 19
Nominated representative 22
The role of qualifying relationships in expressed consent situations 24
Establishing whether or not deemed consent applies 25
Consent for organ and tissue donation – children 25
Circumstances in which consent can be deemed 26

Circumstances in which consent cannot be deemed 27
Residency 28
Ordinarily resident 29
Students 32
Prisoners 32
Other groups 32
Mental capacity 33
Significant period 34
Information that would lead a reasonable person to conclude that the potential donor would not have consented 35
Other considerations 36
Novel transplants 36
Use of organs and tissue across borders 37
Interventions prior to death 37
Preservation for transplantation after death 38
Coroners 39
Licensing under the HT Act 39
HLA tissue typing 39
Licensing requirements - Research 39
Status and use of the Codes of Practice 40
Other advice and guidance 41
Annex A 42
Legislative background and context 42
Scotland 43
Glossary 47

Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:

    a) post-mortem examination;
    b) anatomical examination;
    c) public display of tissue from the deceased; and
    d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

2. The HTA also assesses applications for organ donation, bone marrow donation, and peripheral blood stem cell (PBSC) donations from living people.

3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.

4. This document is part of a suite of Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under 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.

5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it 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.

6. HTA Code A: Guiding principles and the fundamental principle of consent contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:

    a) consent;
    b) dignity;
    c) quality; and
    d) honesty and openness.

7. With regard to organ and tissue donation, this means donated organs and tissue must be used in accordance with the consent in place. Donors and their families must be given the opportunity to access the information they need to be able to

make a decision. Those discussing consent should do so with sensitivity and an appreciation of the particular circumstances in each case. It also means that the donor must always be respected and that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.

8. Code of Practice F is published as two main sections:

    a) Code of Practice F (Part One) Living organ donation; and
    b) Code of Practice F (Part Two) Deceased organ and tissue donation

    Code of Practice F (Part Two) provides guidance to Specialist Nurses for Organ Donation (SNODs), Specialist Nurses for Tissue Donation (SNTD), Specialist Requesters (SR), and others who seek consent for deceased organ and tissue donation. See also paragraphs 25-26 for more information on the role of Specialist Nurses (SN).

9. In combination, Code of Practice A and this Code (Code of Practice F) aim to support organ and tissue donation and transplantation, where appropriate consent is in place. This Code of Practice provides anyone undertaking activities relevant to this sector with a reference source, which gives practical advice on the steps necessary to comply with the relevant legislation and HTA policy.

Introduction to Code F – Part Two

10. Organ and tissue transplantation from deceased donors have the potential to greatly enhance or save the life of a person receiving a transplant. Donation has the scope to save thousands of lives.

11. While the HTA does not promote organ and tissue donation, it does play a central role in ensuring public confidence in the safe and ethical use of human organs and tissue with proper consent. Trust and confidence in the organ and tissue donation system as a whole requires widespread acceptance of its legitimacy. This means it is reliant not only on the lawful fulfilment of the donor's decision, but on the sensitive support of those close to the donor who are involved as part of end-of-life care. This in turn requires practitioners to be sympathetic to the needs of individuals in every case where donation after death is a possibility.

12. A core principle underpinning this Code is that, in reaching a decision about organ and tissue donation as part of end-of-life care, medical practitioners should make every effort to establish the decision of the potential donor during his or her lifetime and support the fulfilment of this decision.

13. Each set of circumstances surrounding a donation is unique and it is impossible to be prescriptive about precisely what should happen in every case. It is the role of the practitioner to balance the information available to them and reach a judgement about whether it is right for a donation to proceed. Sometimes clinical staff will reach the judgement that although there is a legal basis to proceed with the donation, the human considerations involved mean that it should not go ahead. While the presence of appropriate consent permits organ and tissue donation to take place, it does not mandate that it must.

14. The guidance in this Code of Practice reflects the HTA's position that where the risks to public confidence might outweigh the benefits of donation proceeding, donation should not proceed even though the law permits it.

15. The HTA has a statutory role in superintending compliance with this Code of Practice.

Scope of this Code of Practice

16. In deceased donation, the removal, storage and use of organs and tissue, (including Vascularised Composite Allografts) for transplantation is governed by the HT Act. Before organs and tissue can be removed, stored or used for transplantation, appropriate consent must be obtained. This Code of Practice advises practitioners on meeting the necessary consent provisions for this activity to be undertaken lawfully.

17. The sections relating to consent which is expressly given, and the examples, apply to both England and Northern Ireland unless otherwise stated. Any reference made to "deemed consent" throughout this Code of Practice applies to either the Organ Donation (Deemed Consent) Act 2019 in England or the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022, or both (as applicable).

18. England and Northern Ireland have separate deemed consent legislation. Both modify the appropriate consent provisions in the HT Act for organ and tissue donation and transplantation after death such that consent can be deemed in certain circumstances.

19. In England and Northern Ireland, all individuals over 18 are considered potential organ and tissue donors after death, unless they make a decision that they do not want to be a donor, they have nominated a representative to make a decision on their behalf after death or they are an excepted adult.

20. Deemed consent only applies to certain organs and tissue: the list of organs and tissue excluded from deemed consent in England is set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020. The list of organs and tissue excluded from deemed consent in Northern Ireland is set out in the XXXXXXXX.

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21. In Wales, the Human Transplantation (Wales) Act 2013 introduced deemed consent for deceased organ and tissue donation in 2015. Practitioners in Wales should continue to follow the Code of Practice on the Human Transplantation (Wales) Act 2013.

22. In Scotland, the Human Tissue (Authorisation) (Scotland) Act 2019 introduced deemed authorisation for deceased organ and tissue donation in 2021.

23. In addition to the consent requirements above, establishments licensed by the HTA may also be subject to the licensing requirements of both the HT Act and The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (Statutory Instrument (SI) 2012 No. 1501) (the Q & S (Organs) Regulations). This Code of Practice does not include detailed information on the Q & S (Organs) Regulations. Further information can be found in Annex A and the HTA publication 'The Quality and Safety of Organs Intended for Transplantation – a documentary framework'. In addition, establishments may be subject to the licensing requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (Q & S Regulations). Licensed establishments are required to meet the standards which are detailed in the HTA's 'Guide to Quality and Safety Assurance for Human Tissues and Cells

for Patient Treatment' Further information on the licensing requirements under the HT Act can be found in paragraphs 217-222.

Interpretation and general guidance

24. This section explains terms that appear throughout the Code of Practice in relation to organ donation.

25. This Code provides guidance to Specialist Nurses involved in organ donation (SNOD), Specialist Nurses involved in tissue donation (SNTD), Specialist Requesters (SR) or other clinical staff who seek consent for deceased organ and tissue donation. The acronym ***SN*** for ***Specialist Nurse*** is used in this document but refers to a SNOD/SNTD/SR or others seeking consent. The individual leading the family approach for organ donation must be suitably trained and qualified, with sufficient knowledge and skills to sensitively answer any questions and have the time to support the family. The HTA is of the opinion that the SN is the most suitable person to lead the family approach, working in collaboration with the treating medical team.

26. When a SN is required to make a difficult decision, or encounters an unusual situation, they should draw on the necessary decision-making support. SNs should discuss the situation with colleagues and, if necessary, contact a member of their senior management team to make the final decision. This ensures consistency of approach and high-quality decision making.

27. In England and Northern Ireland, there is a particular legal role for individuals who stood in a ***qualifying relationship*** (see paragraph 136) to a potential donor. This Code makes clear the role of those in a qualifying relationship.

28. In practice, there may be other people involved in the end-of-life care of an individual, beyond those who stood in qualifying relationship, who may be able to provide background knowledge about them and assist in establishing their decision with regard to organ and tissue donation. This Code uses the term ***family*** to denote this wider group. Family encompasses those in a qualifying relationship to the deceased person immediately before death and may also include other family members, close friends and those who may have been familiar with the faith and beliefs of the potential donor. This Code outlines the role of the family in the donation process and distinguishes this from the legal role of individuals standing in a qualifying relationship to the potential donor.

29. This Code makes reference to ***information that would lead a reasonable person to conclude that the potential donor would not have consented to organ and tissue donation.*** This reflects the language of the HT Act (as

amended) which requires that information used for this purpose can only be provided by a person who stood in a qualifying relationship to the potential donor immediately prior to death. We consider that the term information should be interpreted widely to include any insight into the decision of an individual with regard to organ and tissue donation. This information may be in writing, but could equally be oral information, for example a report or recollection of a prior conversation held with the potential donor.

30. ***Permitted material*** refers to organs and tissue for which deemed consent could be used as a lawful basis for removal for transplantation provided the donor is not a child or an excepted adult. Material that is excluded from deemed consent is set out in The Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and the XXXXXX in Northern Ireland. Material which is not permitted must have expressed consent for donation.

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31. Where ***expressed consent*** is used, this refers to a decision to consent to organ and tissue donation that was expressed by an individual in life. This is not a legal definition but is used to distinguish this form of consent with deemed consent.

32. ***Ordinarily resident*** refers to people living in England or Northern Ireland on a lawful, voluntary and properly settled basis. Ordinary residence can be of long or short duration. For deemed consent to apply to a person who dies in either England or Northern Ireland, the potential donor must have been ordinarily resident in that jurisdiction for at least 12 calendar months immediately prior to their death. The definition or ordinarily resident is the same in England and Northern Ireland.

33. Where ***capacity*** is referred to in the Deemed Consent Act, this is interpreted to mean capacity under the Mental Capacity Act (MCA) 2005. Where capacity is referred to in The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022, this is understood to mean capacity under The Mental Capacity Act (NI) 2016.

34. ***Significant period*** refers to a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed due to the lack of capacity of the donor before death. As guidance, this period of time should be considered to be 12 months at the point of death.

Research

35. Use of organs and tissue for non-transplantation purposes, such as research, is outside the scope of deemed consent. Consent for research cannot be deemed.

36. Material removed when consent has been deemed for the purpose of transplantation, which cannot be used for this purpose, can be used for research if expressed consent for this purpose is obtained in accordance with the requirements of the HT Act.

Offences under the HT Act

37. The HT Act establishes a number of offences, for which the maximum penalty is imprisonment and/or a fine. In relation to organ and tissue donation, the offences are as set out below.

38. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.

39. Section 8 of the HT Act makes it an offence to store or use donated material for anything other than a qualifying purpose.

40. Section 32 of the HT Act makes it an offence to engage in commercial dealings in human material for transplantation.

41. Section 34 creates an offence of failing to comply with the Regulations made under this section, and failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations. This offence is subject to a fine only.

Conditions on consent for organ and tissue transplantation

42. The HT Act recognises that individuals have the autonomous right to give or refuse consent to all or any of their organs or tissue being used for transplantation after their death.

43. Consent may be limited in a variety of ways. The HT Act does not prevent an individual from placing limits on their consent via the imposition of conditions, for

example, to participate in particular research studies or to donate specific organs and tissue and not others.

44. However, no organ should be transplanted under a form of consent which seeks to impose restrictions on the class of recipient of the organ, including any restriction based on a protected characteristic or based on language. This includes the recipient's age, disability, gender, marriage or civil partnership, pregnancy or maternity, race (which includes colour, nationality and ethnicity), religion or belief (which includes philosophical belief), sex or sexual orientation, or political opinion. This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010 and in Northern Ireland section 75 of the Northern Ireland Act 1998.

45. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK. As a matter of policy, NHSBT does not accept organs from deceased donors where any restriction is attached. However, requested allocation of a deceased donor organ to a specific recipient can be considered if this is carried out in line with NHSBT policy, as set out in "Introduction to Patient Selection and Organ Allocation Policies Appendix 1" (Requested Allocation of a Deceased Donor Organ).

46. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could not or would not be fulfilled, as valid consent would not be in place. Only the person who has attached the condition to the consent can put the condition aside.

Example

An individual decides to donate their organs after death, but only wants to do so on the condition that they are received by someone of the same ethnic origin. While there is nothing to prevent the individual expressing this as a condition, their organs could not be retrieved or transplanted while this condition remains in place.

End of Life Care

47. This Code should be read alongside the most recent applicable professional guidance regarding end-of-life care and organ and tissue donation.

48. The HTA's remit is to provide guidance on what constitutes lawful consent to organ and tissue donation after death has been diagnosed either using

neurological criteria or circulatory criteria. Diagnosis of death is a matter for clinicians providing end of life care.

49. For a patient undergoing end of life care, the medical team, in discussion with the family, may decide to withdraw life-sustaining treatment. This would usually be expected to result in death diagnosed using circulatory criteria with the possibility of Donation after Circulatory Death (DCD) (see paragraphs 58-60). Where the patient lacks capacity and has not made a prior advance decision to refuse treatment, any decisions about the timing of withdrawal of life-sustaining treatment or the institution of new therapies or treatments to enable organ donation to proceed must be taken in the patient's best interests. The patient's known decision with regard to organ and tissue donation, whether recorded or as expressed to the family, is one factor to include in the assessment of the patient's best interests. Any discussion with the family should be approached and conducted sensitively.

50. It is appropriate that other national professional bodies and healthcare agencies, who have responsibility for, or are involved in organ and tissue donation, issue guidance consistent with the law, ethics and best clinical practice. These organisations should be aware of, and incorporate where appropriate, the recommendations in this Code.

Structure and navigation

51. The first section of the Code of Practice F provides an overview of deceased organ and tissue donation (see paragraphs 54-63).

52. The Code of Practice has further sections on consent, including the role of the family in the consent process and the need to take into account the donor's faith and beliefs (see paragraphs 80-103). The Code then provides advice on consent that is expressly given (see paragraphs 104-119) and deemed consent in England and Northern Ireland (see paragraphs 151-196).

53. A glossary with terms specific to this Code of Practice is available at the end of the document. All of the Codes of Practice can be viewed, downloaded and printed from the HTA's website.

Overview of deceased organ and tissue donation

Organ donation after death

54. There are two types of organ donation after death which are undertaken in the UK: donation that takes place after a death which is diagnosed and confirmed using neurological criteria, (commonly known as 'Donation after Brainstem Death') or donation which takes place after a death which is diagnosed and confirmed using circulatory criteria (commonly known as 'Donation after Circulatory Death').

55. Consent to both types of organ donation may, in the appropriate circumstances, be deemed in England and Northern Ireland.

56. Further guidance on the diagnosis and confirmation of death can be found in the Academy of Medical Royal Colleges (AoMRC) Code of Practice for the Diagnosis and Confirmation of Death 2008.

Donation after Brainstem Death (DBD)

57. Donation after Brainstem Death is donation that takes place following tests to diagnose and confirm death using neurological criteria. Increasingly this is referred to as diagnosis and confirmation of death by neurological criteria. The majority of patients will have suffered a spontaneous and devastating bleed in the brain. Others may have suffered head trauma, for example in a car accident, or a hypoxic (lack of oxygen) event, for example following cardiac arrest. The patient's organ support, including mechanical ventilation, is maintained while consent is established or sought and (where applicable) arrangements are put in place for organ donation.

Donation after Circulatory Death (DCD)

58. Donation after Circulatory Death may be either controlled or uncontrolled.

59. Controlled DCD describes organ retrieval which takes place after the planned withdrawal of life-sustaining treatment at the end of a critical illness. In those circumstances a decision is taken that continued treatment is no longer in the patient's best interests (in line with the Mental Capacity Act 2005 for England and the Mental Capacity Act (NI) 2016 for Northern Ireland by the treating medical team in consultation with those close to the patient.

60. Uncontrolled DCD occurs following a sudden, irreversible cardiac arrest. Currently there are no uncontrolled DCD programmes in the UK, although it is practised internationally, particularly in France and Spain. Tissue donation after such an unexpected death could still be possible.

Tissue donation after death

61. Tissue donation is a possibility after death for both organ donors and those who are not suitable to donate organs.

62. Consent for tissue donation will be sought by a trained SN who is responsible for identifying the last known decision of the donor.

63. Deemed consent legislation applies only to certain tissues. Exceptions are set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and the XXXX in Northern Ireland.

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Consent

Overview

64. In all cases of donation, the decision of the potential donor either to consent, or not to consent to donation of organs or tissue for transplantation is paramount. If a person made a decision to donate or not to donate organs and tissue when they were alive, their consent cannot be deemed.

65. The Organ Donor Register (ODR) operates throughout the UK to allow individuals to record their decision either to donate or not to donate organs and/or tissue after their death, or to nominate a representative to make a decision on their behalf.

66. Individuals may nominate one or more representatives to make a decision on their behalf about donation of their organs and tissue after they have died. There are specific requirements (see paragraphs 79-85 of Code of Practice A) under the HT Act in relation to nominated representative/s.

67. In England and Northern Ireland, the implementation of deemed consent legislation amended the HT Act so that where an adult has neither: a) made a decision to donate or not to donate organs or tissue before their death; nor b) appointed a nominated representative to make a decision on their behalf after their death, consent for donation of permitted organs and tissue will be considered to be in place ("deemed consent").

68. This will be the case unless the potential donor is a child, an excepted adult, or information is provided by a person in a qualifying relationship that would lead a reasonable person to conclude that the potential donor would not have consented. If such information is provided, then consent cannot be deemed and the donation must not proceed.

69. Under deemed consent in England and Northern Ireland:

70. A child is a person under the age of 18.

71. An excepted adult is:

    a) An adult who died either in England or in Northern Ireland and had not been ordinarily resident in the country of their death for a period of at least 12 months immediately before dying; or
    b) An adult who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

72. Deemed consent only applies to certain organs or tissue, referred to as permitted material for the purposes of transplantation. Further information on this is given in paragraphs 197-200.

73. Where the potential donor is an excepted adult, consent cannot be deemed. Donation can only proceed where consent has been expressly given, either by the potential donor before their death, or by a nominated representative or a person in a qualifying relationship.

74. Where the potential donor is a child, consent cannot be deemed and donation can only proceed where consent has been expressly given either by the potential donor before their death, or by a person with parental responsibility. If there is nobody with parental responsibility, consent can be given by a person in a qualifying relationship. A child cannot appoint a nominated representative (see paragraph 147).

75. Where consent is deemed, there are particular considerations about activities before death, which are outlined in the Preservation for Transplantation section in paragraphs 205-214.

76. The existence of appropriate consent permits an activity to proceed, but does not mandate that it must.

Recording a decision about organ and tissue donation

77. Neither the HT Act nor the deemed consent legislation in England or Northern Ireland mandate how a person must record their decision about organ and tissue donation.

78. This means that it is for the individual to decide how they wish to do this. Options include registering their decision to donate or not to donate on the ODR, telling a friend or family member, or recording it in writing. Further information is provided in paragraph 29 and 108-119.

79. The ODR is checked in every potential case of organ and tissue donation and the information stored is communicated to the family.

Role of the family

80. The family play a crucial role in the donation process. The nature of the role with respect to consent will depend on a number of factors including whether consent has been expressed by the potential donor, whether the circumstances are such that consent may be deemed, or whether a person in a qualifying relationship will be asked to make the decision. The role of the family should be to help establish the decision of the individual with regard to donation.

81. Sensitive communication and engagement with the family by the SN and medical team play an essential part in supporting the family throughout the donation process.

82. There are many factors that need to be considered in deciding whether donation can proceed, based on the circumstances of each case. Each stage of organ donation, from intensive care admission to organ retrieval, is comprehensively set out in NHSBT's guide 'The Journey through Intensive Care and the Gift of Organ Donation' that may provide useful information for families.

83. If the potential donor has expressed consent, the SN should discuss this decision with the family. The family will be asked to provide additional and detailed medical and social history about the potential donor. This is not part of the consent process, but a necessary part of clinical practice so that decisions can be made about the suitability of organ and/or tissue donation in light of all of the relevant information. This information should not be sought from the family until consent to donation has been established.

84. If the potential donor has expressed consent, but no family is available to provide medical and social history, consent would still be in place and donation could still proceed. However, this requires a clinical judgement and risk assessment by the medical team in order to protect any recipients of organs or tissue. The medical team should also take account of any conditions placed on consent by the donor and assess whether these can be fulfilled before reaching the final decision about whether or not to proceed.

85. If there is an expressed decision on the ODR that the person did not want to be a donor, this should be communicated to the family by the SN or medical team. Donation must not proceed unless the family has information that the person had expressed consent to donation which superseded the individual's earlier decision.

86. If there is no expressed decision and the potential donor was an adult who nominated a representative, any decision on consent must be made by that nominated representative (see paragraphs 120-133). The role of the family in circumstances where the nominated representative gives consent is equivalent to that where the donor themselves had expressed consent.

87. If the nominated representative cannot be reached or is unable to make a decision, consent may be deemed (see paragraph 92 and 154). In such circumstances, the role of the family is the same as that in other circumstances where consent may be deemed (see paragraph 88).

88. If there is no expressed decision by the potential donor, they have not nominated a representative/s and they are not a child or an excepted adult, then consent may be deemed. The SN should explain this to the family and have a sensitive discussion to best support their needs and to facilitate donation. In these circumstances, deemed consent legislation allows for someone in a qualifying relationship to provide information that would lead a reasonable person to conclude that the person did not want to be a donor. If such information is provided, then donation must not proceed (see paragraphs 187-196).

89. If the family of the potential donor object to the donation where appropriate consent (whether expressed or deemed) is in place, the SN should discuss the matter sensitively with them to understand and, if appropriate, attempt to overcome their concerns.

90. Although the family cannot revoke legally valid consent, their views will always be taken into account throughout the donation process and will have a strong influence on whether or not donation proceeds. The presence of valid consent is sufficient for donation to be lawful but does not mandate that it must proceed.

91. Family members may have differing views about donation when appropriate consent is in place. The SN, in discussion with the medical team, should provide the family with the appropriate time and information they need to come to an agreement. Further guidance on specific situations is given in paragraphs 117 and 196 .

92. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, donation should not proceed.

Commitments made in Parliament during the passage in England of the Organ Donation (Deemed Consent) Act 2019 that donation would not proceed in these circumstances led the HTA to conclude that the risks to public confidence of proceeding in these circumstances would outweigh the benefits (see paragraphs 13 and 14). Whilst this commitment was specifically made in relation to England, the HTAs view is that this should also apply in Northern Ireland.

Taking account of the potential donor's faith and/or beliefs

93. Discussions with the family should aim to establish the potential donor's decision with regard to organ and tissue donation. Taking account of the potential donor's faith and/or beliefs, be they cultural, spiritual, religious or non-religious is an important part of person-centred care. Such beliefs should be considered sensitively and as a decisive factor in determining the views of the potential donor regarding consent for donation. As such, these discussions should seek to involve individuals who are familiar with the faith and/or beliefs of the potential donor.

94. The maintenance of trust in the organ donation and transplantation system requires the sensitive consideration of matters of faith and/or belief. SNs should be given the necessary training and support to help them identify and meet the widest possible range of needs. Training should include an awareness and understanding of different cultural and religious and non-religious beliefs, and how these may influence donation decisions. Training should also include the identification of sources of assistance that may be offered to, or requested by, families in order that they are informed and supported.

95. Since December 2018, when registering a decision to consent to organ and tissue donation on the ODR, individuals have been able to record whether their faith and/or beliefs are important to them in relation to organ donation. The text on the ODR reads, “I would like NHS staff to speak to my family and anyone else appropriate about how Organ Donation can go ahead in line with my faith or beliefs”.

96. Where an individual has indicated that this statement applies to them, the SN must explain this to the potential donor’s family and discuss the potential donor’s faith and/or beliefs with respect to organ and tissue donation. The SN should answer any questions and seek further guidance and support from faith leaders if required.

97. Certain faiths may have specific faith and/or belief statements that form the basis on which potential donors have come to a decision about whether to donate their

organs and tissue. SNs should be aware of these statements and ensure that families are aware of them as they will determine the basis on which donation can be made.

98. Some faith and/or belief communities may also have specific arrangements in place to support families and SNs with appropriate, real-time advice that will facilitate the donation process in line with an individual's decision including, in some cases, dedicated telephone helplines. Where an individual has made clear that they wish for donation to go ahead in accordance with their beliefs and practices, the family should be made aware that this support is available and SNs should ensure available services are utilised where this is indicated.

99. Where an individual has indicated that the statement in paragraph 95 does not apply to them, this should be explained to the family. SNs should still explore the potential donor's faith and/or beliefs and those of the family, while recognising that these are unlikely to have been a defining factor in the individual's donation decision.

100. For ODR registrations prior to December 2018, the SN should explore whether faith and/or beliefs were important to the potential donor through conversations with the family.

101. The views of the potential donor and their family should be discussed sensitively and openly. Without making assumptions, discussions should establish whether the potential donor held particular faith, belief or cultural views that could influence how and whether donation could proceed. The faith and/or beliefs of the donor, and how they respond to aspects of that faith and/or belief, may be different to that of the family and should be considered in order to reach the decision that is right for the donor.

102. Where an individual has registered as a potential donor, but their family disagrees that donation is consistent with the potential donor's faith and/or belief, the SN should explore any issues raised by the family and support them to address any concerns. Where indicated, SNs can facilitate consultation with religious and non-religious leaders to provide counsel or clarification on donation. For example, the family may wish to ensure appropriate end of life rituals are followed or that any religious obligations are observed should donation take place.

103. Hospitals may also have faith-trained co-ordinators, a chaplaincy service representing different faiths, or accredited non-religious pastoral carers, which can help support families.

Example

A potential donor registered a decision to consent to donate all organs and tissue on the ODR. They have also recorded that their faith or beliefs are important to them in relation to organ and tissue donation on the ODR. The SN should explain this to the potential donor's family and discuss the potential donor's faith, beliefs and values. The SN should support the family and answer any questions they may have. The SN may also seek further guidance and support on behalf of the family from faith or belief representatives if required.

Consent which is expressly given

Establishing whether a potential donor made a decision in life – adults

104. The HT Act establishes the principle that the decision to consent to the use of organs and tissue for transplantation after death rests first and foremost with the potential donor. As such, the potential donor's valid consent where this is recorded, or last known decision as expressed to the family, should form an integral part of end-of-life care planning.

105. The HT Act makes clear that where an adult with capacity made a decision to consent to organ and tissue donation after their death, such consent is sufficient for donation to be lawful but does not mandate that it must proceed.

106. Where an adult with capacity made a decision not to consent to organ and tissue donation after their death, donation must not proceed as consent is not in place.

107. In every case where organ and tissue donation is a possibility, the SN should determine whether the potential donor has made a decision with regard to organ and tissue donation. The SN should seek to establish the most recent decision of the potential donor in conversation with their family, i.e. the decision in force immediately before their death.

The NHS Organ Donor Register as a source of consent

108. The ODR operates throughout the UK to allow individuals to record their decision about organ and tissue donation or nominate a representative. The ODR allows people to record whether they want to donate all, some, or no organs and tissue.

109. The ODR allows the following decisions to be recorded:

a. I consent to donate all my organs and tissue after death;
b. I consent to donate some (specified) organs and tissue after death; or
c. I do not consent to donate my organs and tissue after death.

110. NHSBT provides the form 'Appointing a representative to make organ donation decisions on your behalf' to allow potential donors to appoint a nominated representative.

111. As long as a potential donor registered their decision voluntarily, had the information they needed to make the decision to register and had mental competence or capacity when they registered, then the decision recorded on the ODR constitutes valid and appropriate consent at the time of registration. For children this is a test of competence, for adults it is capacity (see paragraph 146.

112. A legally valid decision from the potential donor is sufficient to allow organs and tissue to be retrieved for transplantation where they have decided to donate. Similarly, in circumstances where they have decided not to donate, donation cannot proceed. There is no legal right for anyone in a qualifying relationship to revoke a legally valid decision to give or withhold consent.

113. If the recorded decision was not to consent to organ and/or tissue donation, then this can be communicated to the family. If the family believe that this was not the most recent decision of the potential donor, the SN should obtain information from the family about the potential donor's more recent decision to consent to organ donation.

114. If it is clear to the SN that the potential donor had changed their mind, having previously recorded a decision not to consent on the ODR, then donation could proceed.

Example

A potential donor has registered their decision not to consent to organ and tissue donation on the ODR. The SN or clinician will inform the family that a decision not to consent to organ and tissue donation exists and that it will be honoured. The family believe that there is a more recent decision to donate. The SN or clinician should obtain information from the family of the potential donor's more recent decision to consent to organ and tissue donation.

115. If the family believe that a potential donor who was registered on the ODR had revoked their decision to consent to organ and tissue donation, the SN should obtain information from the family about the potential donor's more recent decision to refuse consent to donation (see paragraphs 89-90 and 187-196).

Example

A potential donor registered a decision to consent to donate all organs and tissue on the ODR. The potential donor's mother says that her son subsequently changed his mind about donation prior to his death. The SN will have a sensitive discussion with the potential donor's mother to understand the context of the information that is presented, by exploring with her the son's decision to change his mind. The discussion will focus on what the potential donor decided, as his last known decision will have primacy.

116. In making a decision about whether there is valid consent to proceed with donation, the SN must make a judgement about the reliability of the information provided. It may be helpful to consider the following:

a) Is the information in writing, signed and dated by the potential donor and witnessed? If this is the case, then this is likely to be an expressed decision by the potential donor (it is important to note that revocation of a decision to consent, or a decision not to consent, does not need to be in writing, but that a written revocation would be considered more reliable).
b) Is the information given orally? If so, can it be confirmed by more than one person?
c) Is the information presented as reflecting the views of the potential donor, or the views of the family? If the latter is the case, then this is likely to constitute an objection rather than information about the potential donor's decision.

117. Where valid consent has been given by the potential donor, but the family object to organ and tissue donation proceeding, then they should be sensitively supported to respect the potential donor's consent in order to ensure his or her decision is fulfilled. The family's objection does not nullify valid consent from the potential donor.

Example

A potential donor registered a decision on the ODR to consent to their organs and tissue being donated for transplantation. However, the family do not want tissue donation to proceed. The SN will explore the family's concerns and answer any questions they may have. The discussion will focus on what the potential donor had decided. As the potential donor's consent is valid and their views have primacy, donation could be lawful but this does not mandate that it must proceed.

118. As set out in paragraph 76, the existence of appropriate consent permits donation to proceed, but does not mandate that it must. The final decision about whether to proceed rests with the SN and the medical practitioners caring for the patient, in conversation with the family.

119. Those close to the patient will be involved in making best interests' decisions for the patient who lacks capacity when DCD is a possibility. As described in paragraph 47, consent via the ODR is one factor to take into account when assessing whether interventions to facilitate organ and tissue donation are in the potential donor's best interests.

Nominated representative

120. If the potential donor's decision is not known and they were an adult who had nominated a person to make a decision regarding organ and tissue donation after their death, then a decision on consent must be given by that nominated representative (see paragraphs 130-131).

121. A child under the age of 18 cannot appoint or act as a nominated representative under the HT Act.

122. The name and contact details of the nominated representative/s may have been recorded via NHSBT's form Appointing a representative to make organ donation decisions on your behalf (see paragraph 110). If there is a recorded nominated representative/s, the SN should contact them and ask them to make a decision on behalf of the potential donor.

123. If the details of the nominated representative are readily available, the SN does not need to carry out the checks at paragraphs 126-129.

124. It may be the case that a potential donor nominated a representative/s but did not use the form or tell their family about them. It is recognised that it is not practical for the SN to make extensive checks to establish whether a potential donor nominated a representative/s. If, having asked the family, the SN is not made aware of a nominated representative/s at this stage, it is reasonable to proceed as if no representative had been appointed.

125. If the SN has been informed orally that there is a nominated representative/s, the checks at paragraphs 126-129 below should be undertaken to ensure the nominated representative/s have authority under the HT Act.

126. If the nomination was made orally, the SN should check that the appointment was witnessed by at least two people present at the same time. This can be confirmed either by asking the two witnesses, or by producing a document signed by the two witnesses confirming that they witnessed the nomination.

127. If the nomination was made in writing, the SN should be assured that one of the statements at a) to c) below is true:

a) The document making the nomination was signed by the potential donor in the presence of a witness who confirmed the signature; or
b) It was signed by another person at the direction of, and in the presence of, the potential donor, and in the presence of a witness who confirmed the signature; or
c) It was contained in the will of the potential donor, and that will was made lawfully.

128. If more than one person has been nominated, only one of them needs to give consent unless the terms of the appointment specify that they must act jointly.

129. If the appointment requires that multiple representatives must act jointly, this means that all representatives must agree in order for consent to be given. In these circumstances, if one representative cannot be contacted then the other representative(s) cannot give consent and consent may be deemed (see further at paragraph 131 below).

130. There will be no consent if a nominated representative is not available to give consent under the appointment. In such cases, the nomination may be disregarded. This includes situations where it is not reasonably practical to

communicate with the nominated representative within the time available or if they are not available.

131. If, despite all reasonable efforts, the nominated representative cannot be contacted in time to make a decision, or is unable to make a decision, then consent may be deemed if the potential donor is not an excepted adult (see paragraph 71).

132. In a situation where consent could be deemed but there is no family to speak with to establish the individual's last known decision, the HTA advises that donation should not proceed (see paragraph 92).

133. In all other circumstances, consent may be given by a person in a 'qualifying relationship' (see paragraph 136).

The role of qualifying relationships in expressed consent situations

134. When deemed consent does not apply, appropriate consent may be given by someone who was in a qualifying relationship with the potential donor immediately before their death.

135. Further information on qualifying relationships can be found in paragraphs 32-39 of Code of Practice A.

136. The HT Act includes at section 27(4) a list of qualifying relationships that are ranked:

d. Spouse, civil partner, or partner;
e. Parent or child;
f. Brother or sister;
g. Grandparent or grandchild;
h. Child of a brother or sister (niece or nephew);
i. Stepfather or stepmother;
j. Half-brother or half-sister; or
k. Friend of long standing.

137. A person is another person's partner if the two of them lived as partners in an enduring family relationship. A partner can be of a different sex or be of the same sex.

138. A friend of long standing is not defined in the legislation. It does not necessarily require a specified time period attached to the friendship. Whether someone is a friend of long standing will depend on all the facts and

circumstances and should be considered on a case-by-case basis. The SN may ask questions and/or request information as necessary to establish what degree of friendship existed and whether the relationship could reasonably be considered to be a friendship of long standing.

139. Where there is disagreement between people in different positions on the ranked list, it is recommended that the SN seeks to provide those people with the time and information they need to come to an agreement.

140. If it is not possible to reach an agreement, the hierarchy of consent applies and a decision on consent should be obtained from the person whose relationship to the potential donor is accorded the highest ranking on the list (see paragraph 136). The decision whether or not to proceed lies with the SN, with the necessary decision-making support from senior management, in conversation with the family.

141. In a situation in which the list is ranked and agreement cannot be reached between people of the same rank, it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SN will need to carefully consider the emotional impact of any decision on the wider family.

Establishing whether or not deemed consent applies

142. If the potential donor has neither made a decision in relation to organ and tissue donation nor appointed a nominated representative/s, then a decision must be made as to whether or not deemed consent may apply.

143. In England and Northern Ireland, deemed consent does not apply to:

l. children under 18
m. excepted adults
n. material which is not permitted material (see paragraphs 197-200).

144. If deemed consent does not apply, move to section on ‘The role of qualifying relationships in expressed consent’.

145. If deemed consent does apply, move to section on ‘Deemed consent’.

Consent for organ and tissue donation – children

146. The position for a child, who was competent to reach a decision before they died and consented to organ and tissue donation taking place after their death, is legally no different from that of an adult. The child's consent is sufficient to make the removal, storage or use of their organs and tissue for transplantation lawful.

147. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that in this instance the appropriate consent for organ and tissue donation will be that of a person with parental responsibility for the child immediately before they died. The consent of only one person with parental responsibility is necessary. Where no person had parental responsibility for the child immediately before they died, appropriate consent will be that of someone in a qualifying relationship to them. See also paragraph 141.

148. Consent for organ and tissue donation from a child under 18 cannot be deemed.

149. A child cannot nominate a representative to make a decision regarding organ and/or tissue donation.

150. Further information on consent by and on behalf of a child can be found in paragraphs 87-94 of Code of Practice A.

Deemed consent

Circumstances in which consent can be deemed

151. In cases where the decision of a potential donor regarding consent for organ and tissue donation cannot be established either from the ODR or from family, or where a nominated representative has not been appointed or is unable to act, then consent can be deemed, unless the potential donor is an excepted adult (see paragraph 71 on excepted adults).

152. There may be occasions where a potential donor has neither recorded a decision nor appointed a representative and, despite the efforts of the SN, there is no family in existence or available for the SN to speak with. The HTA advises that, in these circumstances, donation should not proceed (see paragraph 92).

153. When SNs are required to make a difficult decision, or encounter an unusual situation, there are decision-making processes in place to support them. SNs are always able to discuss the situation with colleagues and if necessary contact a member of the senior management team to make a final decision. This ensures consistency of approach and high-quality decision making.

154. If a person appointed a nominated representative to make a decision, the decision of the nominated representative should be acted upon. If the nominated representative cannot be contacted in time to make a decision, or is unable to make a decision, then consent can be deemed subject to the exceptions set out below. The SN should make every reasonable effort to contact the nominated representative and the family should be given the opportunity to provide further information (see paragraph 92 and paragraphs 187-196).

Example

A potential donor has lived and died in England. The potential donor:
has not recorded a decision about organ and tissue donation on the ODR or expressed a decision in writing or verbally to family; is not an excepted adult, and there is no information that would lead a reasonable person to believe they did not want to be a donor.

The potential donor's consent could be deemed and donation could lawfully proceed.

The same would apply if the donor had lived and died in Northern Ireland.

Circumstances in which consent cannot be deemed

155. Consent cannot be deemed if:

o. the donor is an excepted adult or a child
p. a person in a qualifying relationship provides information that would lead a reasonable person to conclude that the potential donor would not have consented
q. the transplantation activity involves relevant material which is excluded from deemed consent, see paragraph 30.

156. If a potential donor made a decision in regard to organ and tissue donation when they were alive, they have given expressed consent and their consent cannot be deemed.

157. In circumstances where consent cannot be deemed, consent should be sought from a person in a qualifying relationship (see paragraph 136).

158. For excepted adults (see paragraph 71), consent cannot be deemed and consent should, in these circumstances, be sought from a person in a qualifying relationship (see paragraph 136).

159. Independent Mental Capacity Advocates (IMCA) act as safeguards for people who lack capacity, where it is not possible for them to be represented by family or friends, and can sometimes be involved in decision making on their behalf. An IMCA may be involved in decisions up to the point of death, but not beyond it. IMCAs can only act for individuals aged 16 and over. IMCAs are not lawfully entitled to give or refuse consent for organ and tissue donation on behalf of a potential donor, as they are not in the list of qualifying relationships.

160. If the potential donor had an IMCA appointed and in place prior to death this is likely to indicate that they were an excepted person who lacked the capacity to understand the notion of deemed consent for a significant period before their death. This will be a relevant consideration for the SN when determining whether consent can be deemed.

Residency

161. For deemed consent to apply in England, the potential donor must have been ordinarily resident in England for at least 12 calendar months immediately prior to their death. For deemed consent to apply in Northern Ireland, the potential donor must have been ordinarily resident in Northern Ireland for at least 12 months immediately prior to their death. For the purposes of deemed consent, the time of death is taken to be the date on which death is confirmed by one of the processes laid out in the AoMRC Code of Practice for the Diagnosis and Confirmation of Death 2008.

162. For the purposes of the HT Act: (i) “in England” means within an English local authority area. Information on the local authorities can be found on the local government structure and elections webpage; and (ii) “in Northern Ireland” means within one of Northern Ireland's local council areas. Information on local councils in Northern Ireland can be found on the NI direct government services webpage.

163. In most cases a SN will be able to establish where the potential donor lived, and whether they were ordinarily resident (see paragraphs 167-174) at an address or several addresses, either from medical records or through discussions with family.

164. If there is reasonable cause for doubt, the SN should check whether the potential donor’s address was in England or Northern Ireland (as applicable). If it

is not possible to access the relevant records for a period of time, which could mean the opportunity for donation is missed, and it cannot safely be assumed where the potential donor was ordinarily resident, then consent should not be deemed.

Example – England

An adult dies in hospital in England on 15 January. Their death is diagnosed and confirmed using neurological criteria. The SN establishes by speaking to the family that the potential donor moved to England on 17 January of the previous year. Deemed consent does not apply, as the potential donor had not lived in England for at least 12 calendar months prior to their death. Consent may be given by a nominated representative or someone who was in a qualifying relationship with the deceased person immediately before their death.

Example – Northern Ireland

An adult dies in hospital in Northern Ireland on 20 August. Their death is diagnosed and confirmed using neurological criteria. The SN establishes by speaking to the family that the potential donor moved to Northern Ireland on 1 August of the previous year. Deemed consent does apply, as the potential donor had lived in Northern Ireland for at least 12 calendar months prior to their death.

165. The 12-month period test does not involve counting the number of days. Rather, it is necessary to establish that a potential donor had been ordinarily resident for at least twelve calendar months. See paragraph 161.

166. In some cases, it may not be possible to establish the exact date. When this is the case and there is no clear information available, consent should not be deemed.

Ordinarily resident

167. A potential donor will be “ordinarily resident” when that residence is lawful, adopted voluntarily, and for settled purposes as part of the regular order of their life for the time being. Ordinary residence can be of long or short duration, but deemed consent will not apply unless someone has been ordinarily resident for at least 12 months immediately before dying. The criteria which must be established are:

a) The residence is lawful.

British and Irish citizens have a right to live in England and Northern Ireland so will always be in either country lawfully. Some Commonwealth citizens also have an automatic right to live in England and Northern Ireland. For people who do not have an automatic right, they will need permission to be in England or Northern Ireland (as the case may be) to be lawfully resident, for example, immigration permission.

Subject to guidance on duration above, an asylum seeker awaiting determination of their claim for asylum is likely to be considered lawfully resident in England and Northern Ireland. A failed asylum seeker cannot be considered lawfully resident, and therefore cannot be ordinarily resident.

People who are unlawfully in England or Northern Ireland, and who do not have permission to enter or remain cannot be ordinarily resident.

b) The residence was adopted voluntarily.

It will be rare for a person not to be in England or Northern Ireland voluntarily. For example, the fact that the potential donor chose to come to England or Northern Ireland at the request of an employer, rather than seek another job, is unlikely to make their presence in England or Northern Ireland involuntary. Prisoners are considered at paragraph 173.

c) The potential donor was resident for settled purposes.

There must be an identifiable purpose for their residence within England or Northern Ireland with a sufficient degree of continuity to properly be described as settled. Business, education, employment and family can all provide a settled purpose, but this list is not exhaustive. There may be one purpose or several, and it may be for a limited period. Students are considered at paragraphs 170-172.

d) The potential donor's residency in England or Northern Ireland supported the regular order of their life for the time being.

There is no requirement for any person to be living in England or Northern Ireland permanently or indefinitely. The potential donor may have had temporary absences from England or Northern Ireland and still be considered ordinarily resident. It is also possible to be ordinarily resident in more than one country.

168. These qualities must be assessed on a case-by-case basis weighing up the relevant information. Whether the requirements have been satisfied will primarily be a question of fact. In many cases, the SN will be able to establish easily whether the potential donor's residence was characterised by the requirements above. When ordinary residence is initially unclear, it is recommended that there is a sensitive discussion with family to gain more information about where the potential donor would have considered themselves ordinarily resident.

169. When a SN has reasonable cause to doubt that the potential donor was ordinarily resident, then consent should not be deemed.

Example - England

A potential donor worked in London and lived there four nights a week, spending the other three nights at their family home in Paris. The potential donor dies in England. The SN should ask questions of the family to establish where the potential donor would have considered themselves ordinarily resident. It will then be for the SN to weigh up the information to establish whether the potential donor was ordinarily resident in England. If the SN establishes that the potential donor considered Paris to be their home and London to be their place of work only, consent could not be deemed.

Example – ordinarily resident in England and Northern Ireland

The SN establishes by speaking to the family of a potential donor that they split their time equally between Manchester and Omagh and would have considered themselves ordinarily resident in both cities. Deemed consent can apply as the donor considered themselves ordinarily resident in both England and Northern Ireland.

Example – Northern Ireland

Two friends who are ordinarily resident in Wales go on a holiday to Northern Ireland. During the holiday, one of the friends dies in hospital. Deemed consent does not apply as the person was not ordinarily resident in Northern Ireland. Consent may be given by a nominated representative or someone who was in a qualifying relationship with the person immediately before their death.

The same would apply if the two friends had gone on holiday to England and one of the friends had died in England.

Example – Ireland, living and working across borders

A potential donor lived in Dublin. They worked in Belfast at the weekends, commuting every Friday morning from Dublin and staying in Belfast until Sunday evening. The potential donor dies whilst at work in Belfast. The SN should establish with the family where the potential donor would have considered themselves ordinarily resident. If the SN establishes that the potential donor considered Dublin to be their home, consent could not be deemed.

Students

170. Education can have the quality of a settled purpose and a student may be regarded as ordinarily resident in the place in which they are studying or the place they consider their home.

171. Students could be considered ordinarily resident in England or Northern Ireland (as the case may be) as soon as they begin studying, but their consent could only be deemed if they are 18 years old and after at least 12 months of being ordinarily resident immediately before dying.

172. It will be for the SN to discuss this with the potential donor's family to determine whether the student's residence had the necessary qualities described above before deciding whether deemed consent applies. The SN will want to gain an understanding of where the student would have considered themselves ordinarily resident.

Prisoners

173. A person who is in prison cannot be considered to be residing voluntarily, and cannot be considered ordinarily resident during their time in prison. This includes prisoners who normally live in England or Northern Ireland and who are in prison in either of these countries. People in prison cannot have their consent to organ and tissue donation deemed.

Other groups

174. There are other groups of people, for example those detained under mental health legislation, where it may be more difficult to establish whether they reside voluntarily. There are also those who live in England or Northern Ireland lawfully

but not for a settled purpose and/or as part of the regular order of their lives. For example, diplomats, armed forces personnel or other posted workers who spend a portion of their time in England or Northern Ireland, but who do not regard it as their home. It will be for the SN to ask questions of family to establish whether the person was ordinarily resident on a case-by-case basis.

175. Spouses or family members of armed forces personnel are generally considered ordinarily resident if they choose to join them.

Mental capacity

176. Deemed consent does not apply to people who, for a significant period before their death (see paragraphs 183-186), lacked the capacity to understand that consent to donation can be deemed.

177. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.

178. If a potential donor lacked capacity to understand that consent can be deemed for a significant period before their death, then the person is an excepted adult, and their consent cannot be deemed. Therefore, consent should be sought from a nominated representative or a person in a qualifying relationship (see paragraph 136).

179. If, at the point at which a potential donor lost capacity, deemed consent did not apply to them, for example, they were a child or did not live in England or Northern Ireland, then their consent cannot be deemed.

180. In some cases, it will be evident that a potential donor lacked capacity for a significant period before their death as they may, for example, have been suffering from a persistent disorder of consciousness (coma, vegetative or minimally conscious state).

181. In other cases, to establish whether a potential donor lacked capacity for a significant period before their death, the SN should take the following steps:

a) Check the medical records of the potential donor to establish whether there was any history of conditions or illness, which may have affected the potential donor's capacity to understand that consent could be deemed. It is important to note that a record of an episode, or episodes, of such an illness would not necessarily mean that a potential donor lacked capacity to understand that consent could be deemed. However, it should prompt further investigation by the SN.

b) If there is no indication in the medical records of a condition or illness, which may have impacted the potential donor's capacity to understand that consent could be deemed, or any assessment of the potential donor's capacity to understand this, the SN should document this on the consent form and/or medical records.

c) If there is an indication in the medical records of a condition or illness that may have affected the potential donor's capacity to understand that consent could be deemed, the SN should undertake further investigations of the condition or illness. The issue of mental capacity should be raised by the SN when speaking to the family to ascertain if the potential donor had the capacity to understand that consent to organ and tissue donation could be deemed.

d) Where there is information about a condition that may have affected the potential donor's capacity to understand that consent could be deemed, in most cases it will be the family who are able to provide the SN with the most accurate information as to whether the potential donor had the capacity to understand that consent to organ and tissue donation could be deemed. The SN should ask the family whether they believe the potential donor had the capacity to understand that their consent could be deemed. This may be a detailed discussion, and if at the end of this the SN is not satisfied that the potential donor had the capacity to understand that consent could be deemed, then consent should not be deemed.

182. If the potential donor had been in hospital for some time it may be appropriate to speak to a member of the team caring for them about their capacity.

Significant period

183. The potential donor will be an excepted adult only if they lacked capacity to understand that consent could be deemed for a significant period prior to their death.

184. The HT Act says that a 'significant period' means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed. The significant period test is, therefore, based on what a reasonable person would consider to be a sufficiently long period, given the circumstances of each case and the facts presented.

185. In practice, as guidance a 'significant period' should mean that the potential donor did not have capacity to understand that consent could be deemed for a period of twelve months immediately before their death. The twelve-month period is provided as guidance for England and Northern Ireland in order to provide regulatory certainty to SNs and other practitioners and is consistent with how deemed consent works in Wales.

186. The lack of capacity to understand that consent can be deemed for a significant period only negates deemed consent. If the potential donor had made an expressed decision to consent, or not to consent, while they had capacity to make that decision then that decision remains valid regardless of a subsequent loss of capacity.

Information that would lead a reasonable person to conclude that the potential donor would not have consented

187. If a potential donor is not a child or an excepted adult, and they had neither made a decision in life nor appointed a nominated representative/s who had given consent under that appointment, then their consent to organ and tissue donation may be deemed.

188. When this is the case, the SN should have a discussion with the family and give them the opportunity to provide information that would lead a reasonable person to conclude that the potential donor would not have consented. This information can only be provided by a person in a qualifying relationship.

189. SNs must take all reasonable steps in the circumstances of the individual case to discover whether any person in a qualifying relationship is available to provide such information. When there is no family found or available, donation should not proceed (see paragraph 92).

190. Any person in a qualifying relationship can provide information to show that the potential donor would not have consented. The hierarchy of qualifying relationships does not apply for the purposes of providing such information. This means that, in practice, it is the quality of the information that should be considered by the SN, and not the relationship to the potential donor of the person presenting it.

191. When there is written information from the potential donor, and this is signed by a witness, this would form the expressed decision of the potential donor and so consent cannot be deemed.

192. When there is written information from the potential donor that has not been witnessed, it will be for the SN to decide whether this is information that would satisfy a reasonable person.

193. Where there is other oral information, it will be for the SN to decide whether this is information that would satisfy a reasonable person.

194. The reasonable person test involves the person making the assessment (in this case the SN and medical team), deciding how much reliance to place on the information presented.

195. In order to assess the reliability of the information presented, the following questions may help the SN:

a) Is the information presented as reflecting the views of the potential donor, or the views of the family? The test requires that information presented must be the potential donor's view.

b) Is the information oral? If so, is it confirmed by more than one person?

c) How recent is the information? The SN should establish when the record was made, or when the conversation took place, and note this in the potential donor's medical record or other appropriate document.

d) How well does the person providing the information know the potential donor? It is not always the case that a person knows someone well simply because they are related.

196. Information that the potential donor was not aware that deemed consent affected them is not sufficient, on its own, to lead a reasonable person to conclude that the potential donor would not have consented to organ and tissue donation.

Other considerations

Novel transplants

197. Deemed consent only applies to certain organs and tissue: the list of organs and tissue excluded from deemed consent in England is set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 which are subject to Parliamentary approval. The list of organs and tissue excluded from deemed consent in Northern Ireland is set out in the XXXXXX.

Commented [DJE4]: Title to be added once confirmed.

198. The Department of Health and Social Care in England and the Department of Health in Northern Ireland respectively consulted on the list of organs and tissue where expressed consent will still be required for the purpose of transplantation in each country.

199. The list of those organs and tissue is published on the HTA's website, and this will be updated when changes are made to the list.

200. For the organs and tissue on this list, expressed consent must be given for the removal, storage or use for the purpose of transplantation to be lawful.

Use of organs and tissue across borders

201. Organs and tissue removed when consent has been deemed can be lawfully stored, used, processed, distributed and transplanted into patients across the UK providing all other statutory and regulatory requirements have been met. Organs and tissues can, on occasion, be offered to a recipient in other countries where there is no suitable recipient in the UK.

Interventions prior to death

202. The HT Act 2004 does not address the matter of steps which may be taken prior to the death of a potential donor who may become a donor after death is diagnosed and confirmed using circulatory criteria.

203. Where the potential donor does not have capacity, interventions before death are governed in England by the Mental Capacity Act 2005, and in Northern Ireland by applicable mental health law including the Mental Health (Northern Ireland) Order 1986 and the Mental Capacity Act (NI) 2016, rather than the HT Act 2004.

204. The taking and storage of blood samples from a potential donor is necessary to ensure that the organ and tissue can be used for transplantation. Blood samples should only be taken in cases where expressed consent for donation has been given (by the potential donor, their nominated representative or someone in a qualifying relationship) or consent has been deemed (which could only occur following discussion with the family).

Preservation for transplantation after death

205. Section 43 of the HT Act allows for minimum steps to be taken to preserve parts of a potential donor's body when it is, or may be, suitable for transplantation, but consent or the absence of consent has not yet been established.

206. These provisions relate only to the preservation of a potential donor's body after their death. Information on interventions prior to death is provided in paragraphs 203-204.

207. In order for preservation to be lawful, the body of the potential donor must be lying in a hospital, nursing home or other institution in England or Northern Ireland.

208. The steps which can be taken to preserve the organs within the body for transplantation must be minimal and it is a requirement that the least invasive procedure is used.

209. Whether a procedure meets this test will depend on the facts of the case, including how invasive it is, when consent might be obtained, and how the family would perceive it.

210. In all cases, steps should therefore be taken as soon as possible to establish the decision on donation, or where this is unknown, whether consent can be deemed. Where possible, appropriate consent for donation should be established before the preservation process begins, or alternatively consent for the preservation process prior to donation.

211. The taking and storage of blood samples from a deceased person is necessary to ensure the preserved organ and tissue can be used for transplantation. Blood samples should only be taken in cases where expressed consent for donation has been given (by the deceased, their nominated representative or someone in a qualifying relationship) or consent has been deemed (which could only occur following discussion with the family).

212. If it is established, either (a) that consent has not been expressly given, and that consent cannot be deemed, or (b) a decision has been made not to donate, then the steps taken to preserve organs for the purpose of transplantation should cease or be withdrawn promptly.

213. An area of development in retrieval surgery is organ recovery. During the dying process organ injury can occur. Organ recovery seeks to maintain and improve viability leading to high quality organ transplants, as well as using organs that previously would not have been considered transplantable. Organ recovery procedures use machine perfusion of the organs, which takes place either in the donor after death (in situ) or on the organ following retrieval from the donor in specialist machines (ex situ).

214. These organ preservation techniques cannot be considered to be minimum steps and must only be used only where appropriate consent to donation is in place (see paragraph 205).

Coroners

215. Where the person's death is violent or unnatural, or is sudden and the cause is unknown, the matter of organ and tissue donation must be referred to the coroner. In such cases agreement (or a lack of objection) of the coroner should be sought before any transplantation activities can be undertaken, or steps can be taken to preserve the organs within the body of the person.

Licensing under the HT Act

HLA tissue typing

216. If samples of relevant material from a deceased donor, such as blood, lymph nodes or spleen, are being stored for tissue typing to determine the suitability of an organ for a recipient, this is storage for the purpose of transplantation and excepted from licensing under the Human Tissue (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 if the material is stored for less than 48 hours. If those samples of relevant material are subsequently stored as part of the diagnostic archive of the recipient, a licence is not required. However, if such samples are subsequently stored for research within the scope of the HT Act, they must be stored on HTA-licensed premises, subject to any applicable licensing exemptions. Further guidance can be found in the HTA's Code of Practice E on Research.

Licensing requirements - Research

217. A licence is required under the HT Act for the removal of relevant material from a deceased person for the scheduled purpose of research 'in connection with disorders, or the functioning, of the human body'. The removal must take place on premises specified in the licence.

218. The storage of relevant material for the purpose of research also requires a licence, unless it is for a specific research project, which is approved by a recognised research ethics committee.

219. If relevant material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the storage of this material must be on premises specified in the licence unless the research has ethical approval as indicated above.

220. Relevant material removed for the purpose of transplantation can be used for research with the valid consent of the donor, a nominated representative or a person in a qualifying relationship to the donor (see paragraphs 30-39 of Code of Practice A).

221. In cases where it is unknown whether donated tissue or organs will be used for transplantation or research, valid consent should be obtained at the outset for both transplantation and research. For further guidance on valid consent, refer to Code of Practice A.

222. Further guidance on both consent and licensing requirements for research can be found in Code of Practice E on Research. This guidance is applicable to cases involving research using tissue and organs from a deceased donor; Code of Practice E provides guidance on research using tissue from the living.

Status and use of the Codes of Practice

223. Throughout the Codes, the word '**must**' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA's licensing Standards. We use the word '**should**' when providing advice on how to meet these requirements.

224. 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 when considering whether there are grounds to take regulatory action.

Other advice and guidance

225. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.

226. The HTA's Codes of Practice and other HTA 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 relevant legislation.

Annex A

Legislative background and context

227. The Human Tissue Authority (HTA) is the regulator for human organs, tissue and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.

228. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes[1] in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

229. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:

a) the person died before the HT Act came into force on 1 September 2006; and
b) at least 100 years have elapsed since the date of the person's death.

230. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.

231. The HTA is the UK regulator for tissue and cells (other than reproductive cells). Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q & S Regulations) (as amended) , the HTA licenses and inspects establishments that undertake the procurement, testing, processing, storage, distribution, import and export of tissue and cells for human application.

232. With the exception of Code of Practice A: Guiding principles and the fundamental principle of consent, and Code of Practice F, the Codes of Practice do not provide guidance on complying with the requirements of the Q & S Regulations. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

233. The HTA is the UK regulator for the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (the Q&S (Organs)

[1] Defined by the HT Act and explained in further detail in the glossary.

Regulations). With the exception of Code of Practice A: Guiding principles and the fundamental principle of consent, and Code of Practice F, the Codes of Practice do not provide guidance on complying with the requirements of the Q & S (Organs) Regulations. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

234. A deemed consent system for organ and tissue donation after death is operational in England, Northern Ireland and Wales. This does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales.

235. The deemed consent legislation in England and Northern Ireland respectively relate to donation of those organs and tissue which constitute "permitted material" from the deceased, and as such does not have an impact on the HTA's regulation of living organ donation. Exceptions to the definition of "permitted material" are set out in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and XXXXX.

Commented [DJE5]: Reference to NI document to be added when available.

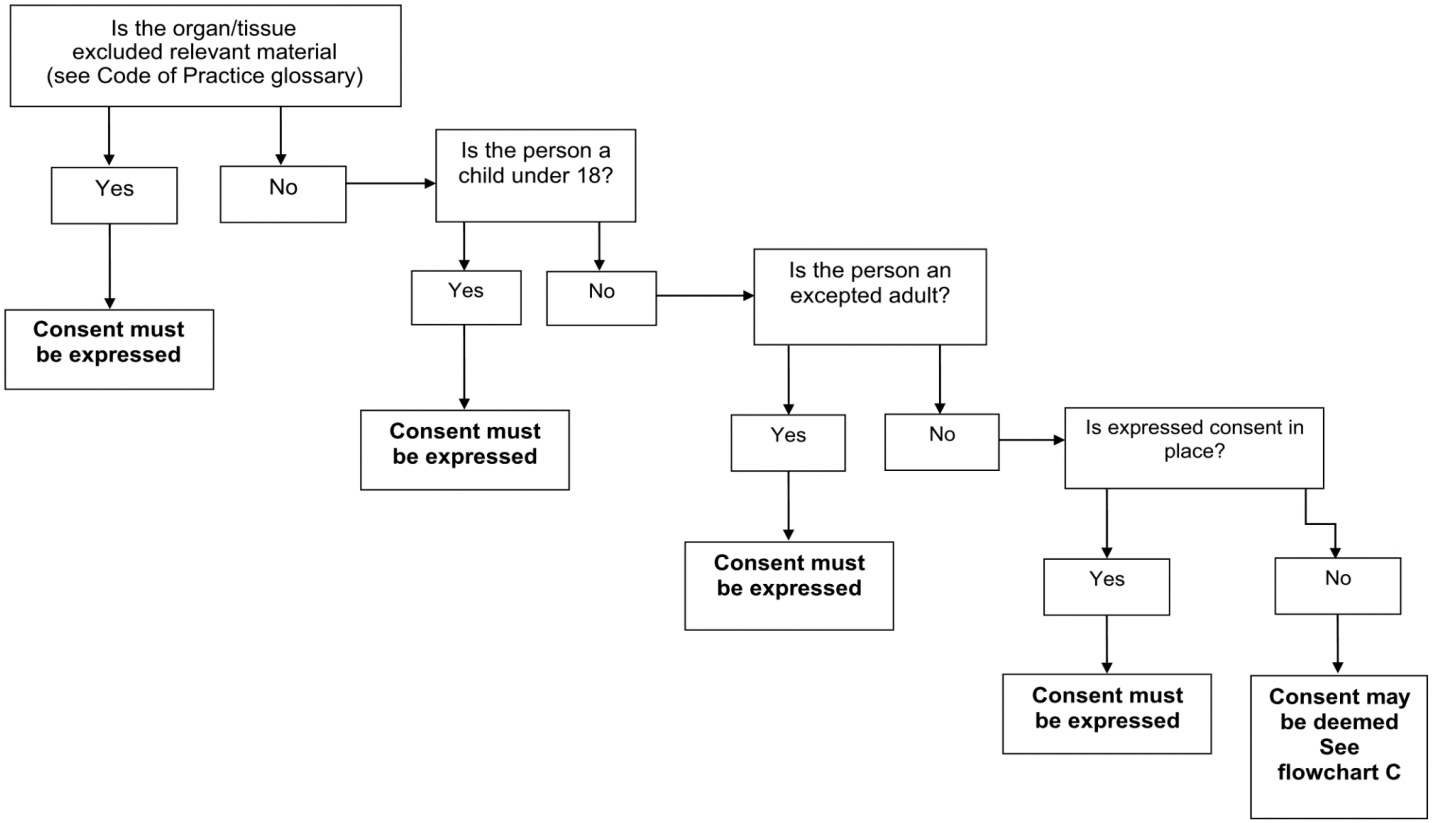
Scotland

236. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.

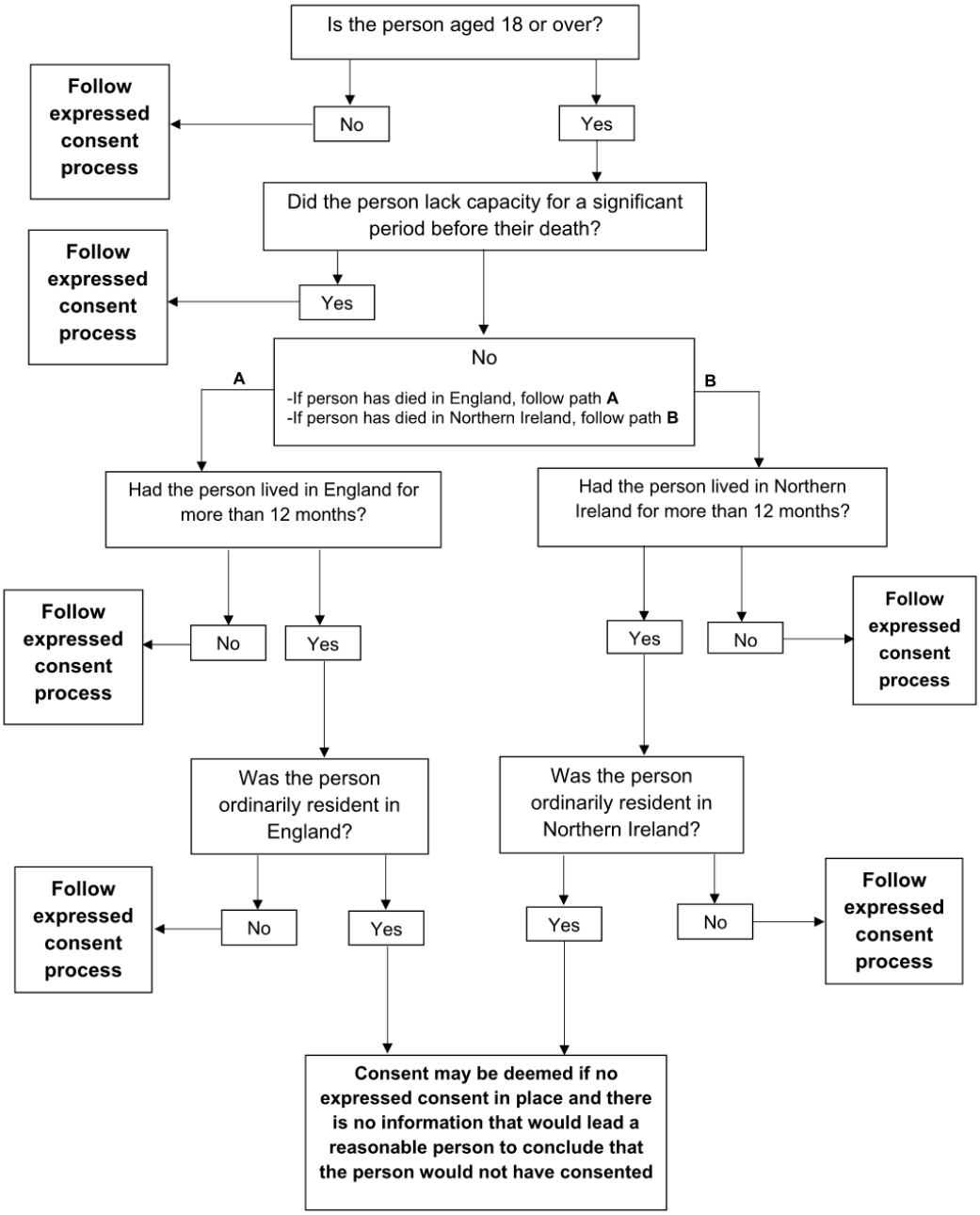
237. The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act) and The Human Tissue (Authorisation) (Scotland) Act 2019 apply in Scotland.

238. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this Code does not apply in Scotland.

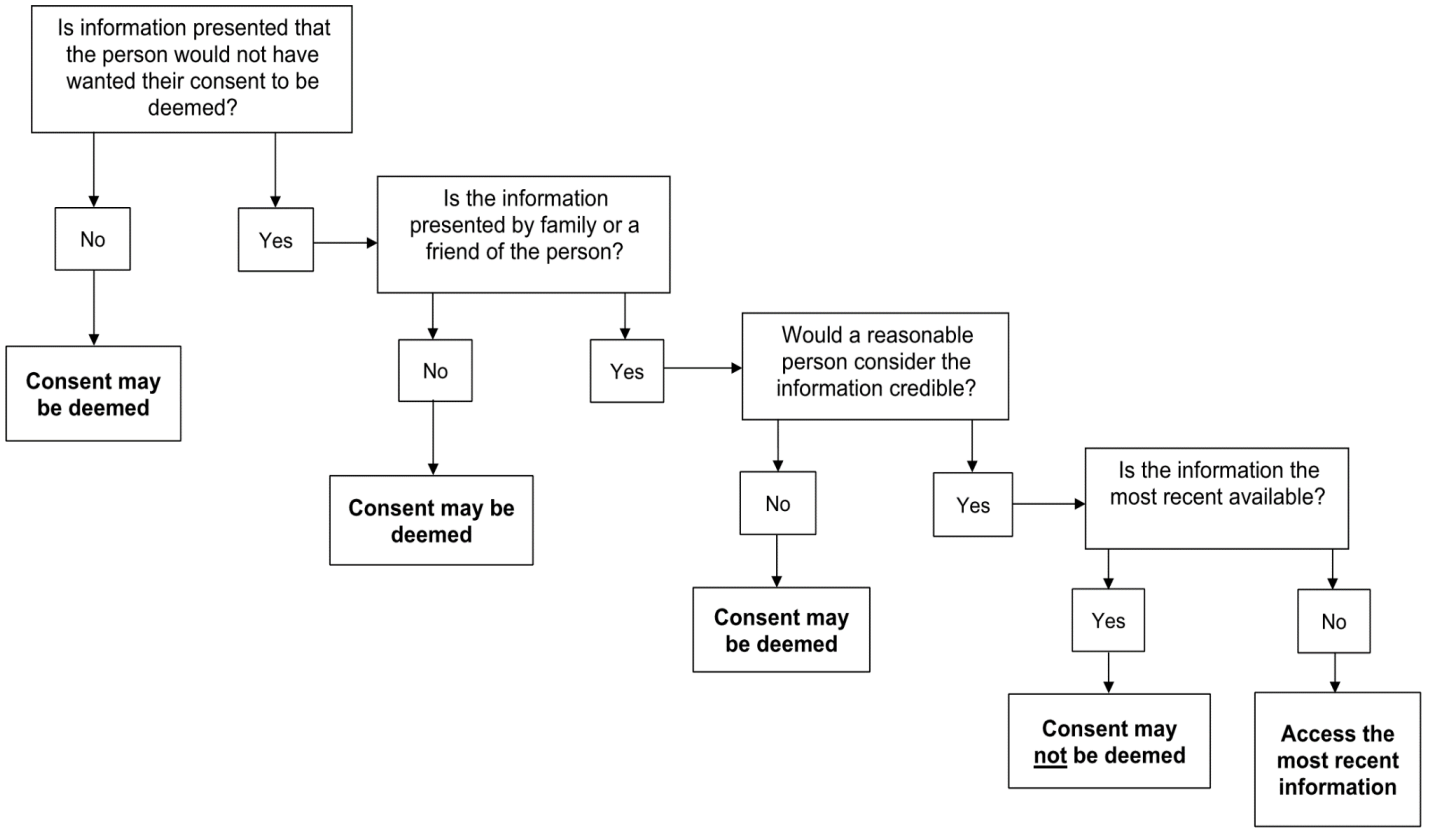
Flowchart A - Overview of deemed and expressed consent



Flowchart B – Can deemed consent apply to the person?



Flowchart C – Is there information that would lead a reasonable person to conclude that the person would not have consented?



Glossary

Term	HTA definition
Anatomical examination	Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.
Appropriate consent	Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative, deemed consent or (in the absence of any of these) that of a person in a qualifying relationship to them immediately before they died.[1]
Best interests	An assessment of a person's best interests takes into account not only the risks and benefits of a proposed intervention, but also its wider emotional, psychological and social aspects.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Deemed consent	Deemed consent means that all individuals over 18 in England or Northern Ireland will be considered to have agreed to become an organ and tissue donor after their death, unless they made a decision not to donate their organs and/or tissue, i.e. they have opted out; they have nominated a representative to make a decision on their behalf after death about whether to donate; or are excluded from deemed consent. Deemed consent does not apply to people who lack mental capacity for a significant period before their death, children under 18 and people not ordinarily resident in the jurisdiction in which they have died for at least 12 months immediately before their death.
Diagnosis	The identification of the nature of an illness or other problem.
Directed donation	A form of donation where a person, usually a living person, donates an organ or part organ to a specific, identified recipient with whom they have a genetic or pre-existing emotional relationship.
DNA	DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics. Find out more information about the HTA's role with regards to DNA on the HTA's website.

Term	HTA definition
Donated material	For the purposes of the HT Act, the term 'donated material' refers to the body of a deceased person, or relevant material which has come from a human body, which is being stored or used for scheduled purposes with appropriate consent.
Donation (organ and tissue)	The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.
Donation after Brainstem Death (DBD)	A form of organ donation in circumstances where a patient, whose death has been diagnosed and confirmed using neurological criteria, continues to be ventilated. This keeps the heart beating and blood circulating after death, until after donation takes place.
Donation after circulatory death (DCD)	A form of organ donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs after death is diagnosed and confirmed using cardio-respiratory criteria. This is described as controlled when treatment has been actively withdrawn within a hospital setting or uncontrolled where a patient has experienced an unexpected cardiac arrest from which they cannot be resuscitated.
Excepted adult	An adult who (i) died either in England or in Northern Ireland and had not been ordinarily resident in that jurisdiction for a period of at least 12 calendar months immediately before dying; or (ii) who lacked the capacity to understand the notion of deemed consent for a significant period before their death.
Expressed consent	Expressed consent is consent to donation given by the potential donor, their nominated representative, or their family.
Family	Throughout the Code, the term family should be taken to mean people involved in the end-of-life care of an individual, who may be able to provide information about them and their decision with regard to organ and tissue donation. Family encompasses those in a qualifying relationship to the deceased person immediately before death and may also include other family members, close friends and those who may have been familiar with the faith and beliefs of the potential donor.

Term	HTA definition
Human application	In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.
Licensed premises	Where the licensed activity takes place.
Licensing	A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.
Minimum steps	The HT Act allows for the minimum steps necessary to be taken to preserve organs in a state which allows successful donation, using the least invasive procedure such as cold perfusion and intraperitoneal cooling.
Nominated representative	A person appointed by an individual to represent them after their death for the purposes of activities under the HT Act for which consent is required. A nominated representative may be entitled to consent to, or refuse to consent to, the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.
Novel transplants	Transplants that are new and are usually at a research or practical evaluation stage, or have gone through research and service evaluation stages, but are still rare and unusual. An example of a novel transplant would be face transplantation.
Organ	Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.

Term	HTA definition
NHS Organ Donor Register (ODR)	A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ and tissue donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs or tissues after their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs and tissues.
Parental responsibility	A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is set out in the Children Act 1989.
Perfusion	A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death.
Post-mortem examination	Also called an autopsy, a post mortem is an examination of the body after death. Post mortems are performed if the cause of death is not known or if there are any unusual circumstances. Information obtained from a post mortem often helps bereaved families understand what happened to their loved one as well as helping doctors learn about how diseases can affect the body.
Potential donor	Every human source, whether living or deceased, of tissue, cells, organs or part organs.
Practitioner	A person working with relevant material in an establishment licensed by the HTA.
Procurement	The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.
Qualifying relationship	The relationship to the deceased of a person/s who can give consent for the removal, storage and use of organs and tissue from the deceased person's body for scheduled purposes in certain circumstances, or provide information that would lead a reasonable person to conclude that a potential donor would not have consented in circumstances where consent could be deemed. Those that are in a qualifying relationship are: a spouse or partner; a parent or child; a brother or sister; a grandparent or grandchild; a niece or nephew; a stepfather or stepmother; a half-brother or half-sister; a friend of longstanding.
Reasonable person	A reasonable person is one who exercises an ordinary degree of care, skill, and judgement in particular circumstances.

Term	HTA definition
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website.
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.
Scheduled purpose	Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also relate to activities for scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only. • Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation. • Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, and quality assurance.

Term	HTA definition
Specialist Nurse (Specialist Nurse for Organ Donation (SNOD)/Specialist Requester (SR)/Specialist Nurse in Tissue Donation (SNTD))	A senior nurse who is the focal point of contact for organ and tissue donation within the Hospital / Trust. The role encompasses different aspects which all come together in the identification and referral of potential organ and tissue donors. It is recognised as best practice to have a SNOD/SR/SNTD involved in the donation conversation. The SNOD/SR/SNTD is the expert in both donation conversation and the legislation and are represented as 'SN' throughout this document.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplantation	An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.
Valid consent	Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code of Practice A: Guiding principles and the fundamental principle of consent.
Vascularised Composite Allograft transplant	The transplantation of parts of the human body that contains multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue, that is recovered from the human donor as an anatomical or structural unit and requires its own blood supply and without altering its relevant characteristics. This may include novel transplants such as face, hand and limb and uterus.

Human Tissue Authority Board meeting

Date: 14 July 2022

Paper reference: HTA 23/22

Agenda item: 8

Author: Louise Dineley

OFFICIAL

Development Programme

Purpose of paper

1. The purpose of this paper is to:
    a. Provide an update on the review of the Development Programme.
    b. Outline the confirmed development work to be progressed in phase 1 (2022/23) and subsequent phases.

Decision making to date

2. The SMT agreed this paper on 23 June 2022 for submission to the HTA Board.

Action required

3. The Board is asked to note the review of the former Development Programme and the reframed work and endorse the revised scope of works.

4. It is recommended that a Programme Initiation Document, the operational document for delivery, is shared with the Board following agreement by SMT in Q2.

Background / Introduction

5. In Autumn 2020, the HTA embarked on a programme of development and change, informed by several different drivers including:
    a. Lessons learned exercise of the HTA's response to wave 1 of the Covid Pandemic
    b. The data and technology deficits that are inherent in HTA activities and its then model of regulation
    c. Effective participation by the HTA in external initiatives and changing priorities such as innovation and growth in life sciences; data driven regulation and digital transformation.

6. The systems, processes, and service models at the HTA have largely evolved over time and, whilst these systems may be functional, they are a constraining factor to our future development and change requirements. To achieve the scale of change and additional functionality required for responsive regulation and innovation in the life sciences sector, we need to establish a stronger foundation for the HTA to build upon. Embarking on key development activity carries risks and we need to be assured of access to uninterrupted capacity and capability in IT skills and knowledge before any major change is started. As has happened in the recent past, the HTA's pace of change could be adversely impacted by not having unbroken availability to suitably skilled and experienced resources.

7. In reviewing and reframing our development needs and a future programme of work, we have considered the problems that need addressing. This is important in establishing a case for change and in outlining a vision of a future state with intended benefits. This approach also considers risk and conveys a summary of the risk of not progressing identified actions.

2022/23 Programme Proposals

8. Our review has reframed the HTA's approach to reflect a more corporately owned and embedded change and transformation agenda, consistent with and as a part of an overall change management portfolio approach that is managed collectively by SMT. This approach aims to align projects within and outside of the Development Programme to a shared strategic direction of travel with outputs being used to inform future phases of development and opportunities for investment through the HTA's business planning and portfolio management

process. These relate back to our strategic ambitions as outlined in our new vision and mission.

9. The Development programme to date was defined by 6 projects which were highlighted to the Board in May 2022. Our review has indicated that there is still a need for these projects, although the phasing of this work needs to be adjusted reflecting priorities, dependencies, and resource capacity. We therefore propose that the initial focus of this work will be targeted in the IT area, which is essential paving work to future progress. This refocused programme, will create phases of development and change and a pipeline of prospective projects.

10. Establishing a strong foundation for change is critical. The identification and planning for the projects in phase 1 reflect this. To date, a key constraint to progressing developments has been resources, which has been most evident in IT where internal resources have had to absorb development activities and the expectation of skills and expertise normally reserved to dedicated specialist roles as Developers and System Designers.

Phase 1 – 2022/23: Digital & Data Development Programme

11. Phase 1 is an enabling phase and will be focused on a smaller number of projects. The two projects identified have been prioritised to, firstly, establish the capacity and capability within the IT service model and, secondly, to maintain a level of momentum to the work progressed to date through operational use and small-scale improvements.

12. The two projects identified for 2022/23 are:

    (A) Progress a shared service model for core IT service provision and the development of the HTA's digital capabilities (data and technology).

13. This project aims to provide a stronger foundation than is currently possible for future development of the HTA's systems and facilitate access to the required specialist skills and resources, which as a small organisation we have found it difficult to attract or financially sustain on a permanent basis. The delivery of this project is estimated to run for the duration of 2022/23 with changes to delivery model given a target date effective from 1 April 2023. This may be ambitious but

major development is impacted until we have a more robust and resourced foundation in place.

The initial scoping of the project was explored using a problem definition statement to define the problem we are trying to address and the likely outcome. The statement is included below.

"The HTA's digital and technological capabilities no longer fully meet current or future business needs. Systems are old with limited functionality that restricts the automated use of new and existing data across regulatory activities. The HTA needs to use new digital capabilities to ensure our staff and establishments have efficient and effective access to information and the insight it provides."

Our vision and intended benefits from a strengthened service model are:

- We want to use new data and technology to make it quicker and easier for us to provide robust regulation
- Our use of technology will help make it simpler and easier to share data and services, making us more resilient and efficient and freeing up staff time to focus on what is important.
- Our people are at the heart of what we do, so we want to make sure that we have the skills and capabilities to develop and use the systems and provide operational resilience to our activities.

The limited resource capacity in IT is not only a constraint to development activity, it also impacts on day-to-day operational activity, for example, the amount of time required to complete our annual DSPT (Data Security & Protection Toolkit) return prior a submission to NHS Digital. This return does not distinguish between the size or activities of an organisation. The submission focussed on evidencing the robustness of our IT operational capabilities, and whilst work has been progressed in-year to improve the picture from last year, further work is required that extends beyond existing resources. By potentially partnering with a larger organisation, we buy-into proven more mature services and assurance mechanisms and provide a better basis for assuring IT services whilst in parallel developing systems for future needs.

Further benefits aligned to efficiencies may also be possible, but these are of lesser significance given the scale of the operation and are unlikely to be realised in years 1 & 2. A high-level delivery plan has been prepared and the scoping of

the HTA's requirements post 1 April 2023 has been drafted. Currently, HTA staff are having exploratory conversations with potential future partners to identify interest and capability. Subsequent stages of option evaluation, procurement, due diligence, service level agreement development, award, and any necessary transfer of services have been included in the delivery plan.

The Board should note that the transition and adoption of an IT shared service model does carry several risks, including financial risk. Based on the work to date, it is anticipated that the future cost of a shared service model will be higher than the total current IT service model costs (including maintenance contracts and allocated resource). This higher cost is reflective of the enhanced specification and additional services being sought, but which are considered necessary. As part of the options taken forward for consideration, affordability will need to be a factor but, in that regard, it is likely that a "do nothing" option of remaining with the current model would also necessitate cost increases aligned to adequate resourcing.

At this early stage of the shared service model, we need to be mindful of the more immediate risk to the maintenance of existing systems and a safe and secure service to the HTA in the intervening period. Maintenance of existing systems is critical as a mitigation to future risk and the options that may present as part of a future shared service model.

(B) Operational development of HTA data capabilities building on version 1 of the Regulatory Insight Model and Index (RIMI).

Previous proposals and planned work have recognised that we do not have the in-house skills nor experience to focus internal resource capacity on exploiting the data we have for useful insight. The importance of continuing to develop and strengthen capability in our use of data remains a priority. However, the scope of work in Phase 1 would focus on opportunities for iterative and small-scale improvements to existing data and systems.

Version 1 of the RIMI will be launched and operationalised to help guide a more focussed use of regulatory resources. Data collected from establishments will be refined along with their data collection mechanisms using scheduled compliance updates, to minimise their ongoing burden and using existing resources. This focus on existing systems eliminates dependencies on other projects and enables

the piloting of further improvements, such as the use of additional data sets and automation of existing manual analysis to support the consistent and regular identification of risk.

Future phases

14. The components of future phases will be informed by the work to date, outputs from Phase 1 and supplemented by the recommendations and outcomes of wider activity and projects across HTA, such as the Review of Inspections and developing the HTA's Culture (the OD/Culture Review).

15. Dependent on the availability of skilled resources, such projects might include:

    (C) A future system architecture to support the HTA manage, develop, and optimise the use of full organisational knowledge to create actionable insight; and (D) Development of an HTA Target Operating Model.

16. In addition to these identified projects, we will be looking to determine other areas that may justify support once scoped, if they rank more highly that those currently under consideration for future phases. Our established Horizon Scanning and Stakeholder Engagement capabilities will continue to inform such further opportunities.

17. This redesign and focus of the previous programme of work to focus at this stage on Technology and Data, is not without risk, which include:

    - Failure to continue to develop wider data management and analytical capabilities in-year will limit the strengthened insight that the HTA has been seeking from its data in identifying risk, sharing data, and providing an authoritative voice to the sectors and future innovation.

    - The absence of a Target Operating Model (TOM) in the short-term maintains the distinctive nature of functions rather than provides a collective overview and establishment of a regulatory profile of a license and an establishment. The review of inspections will be partial mitigation as an interim measure in helping the development of greater proportionality although it could maintain the focus of the HTA's regulatory model on inspection in the meantime.

- The absence of any further development of the HTA's IT systems and infrastructure (new or completion of existing) in 2022/23 means the gap between where we are and where we need to be will continue to increase - although the move to a shared service, with potentially more mature systems and larger robust teams is considered an essential cost for future proofing.

- The adoption of a Shared Service Model that delivers the greater level of IT support and resilience we need, may be unaffordable. The future specification of a Shared Service Model aims to deliver a wider set of services and access to skills and resources. It is anticipated that the initial cost will be higher than current contracts and allocated resource. Although future benefits of resilience, efficiencies and economies of scale may be realised, these will not be immediately available.

18. Our approach to development in 2022/23 will be incremental, starting with the essential paving activities outlined for Phase 1. As noted above, this approach is not without risk, but that risk is considered lower in the longer term than trying to achieve all that is available and potentially required without a larger strategic IT partner providing a strong foundation for change.

Recommendation

19. The Board is asked to note the review of the former Development Programme and the reframed work and endorse the revised scope of works.

20. It is recommended that a Programme Initiation Document, the operational document for delivery, is shared with the Board following agreement by SMT in Q2.

Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 24/22

Agenda item: 9

Author: Louise Dineley**,** Audrey Jessiman,

OFFICIAL

Horizon Scanning

Purpose of paper

1. This paper is a discussion paper for the Board. It seeks to outline a process for engaging the Board in horizon scanning and the issues which emerge from that work. The process will cover the identification of potential issues including an indicative programme of exploring and informing future positions on emerging items.

Decision making to date

2. The SMT discussed on 23 June 2022 and agreed a paper on Horizon Scanning be submitted to the HTA Board.

Action required

3. The Board is invited to:
   a. Discuss the proposed process for engagement on horizon scanning and agree next steps.
   b. Identify any existing or emerging issues for consideration.

Background

4. In April 2021, the HTA restructured and rolled out a revised horizon scanning process across the organisation. This has included guidance for staff, an updated horizon scanning log and a dedicated page on the staff intranet, WAVE, being developed. A Horizon Scanning Group (HSG) has been formed, with an identified individual from each business area responsible for collating and adding items to the Log and attending monthly HSG meetings.

5. The HSG review emerging themes and issues which are then shared with the Heads of Management meeting. The Heads consider items and make recommendations on those issues for onward transmission to the SMT for further review.

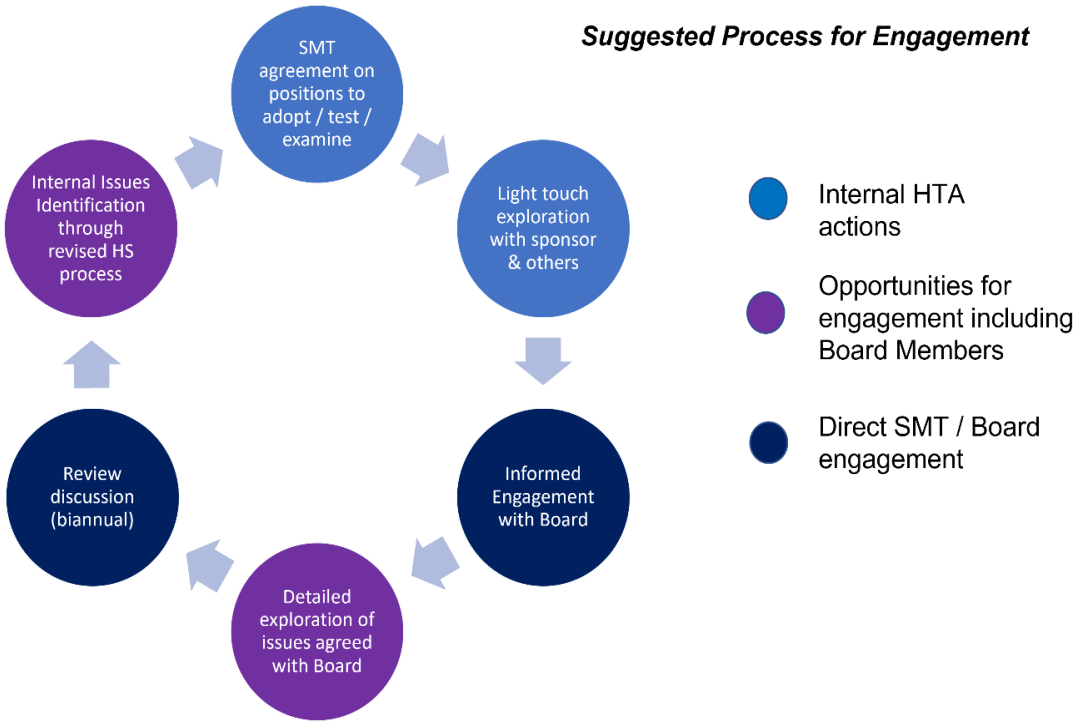
6. To date, this process has helped to raise the level of engagement and contribution from across the business to enable the HTA to be more responsive to changes in the operating landscape of Life Sciences and Regulation. Examples of this are evident in the Anatomy and Research sectors with changes to body donation activity during the pandemic and the heightened pace of research. The lens through which identified issues are viewed has to date been a mix of some more immediate, operationally focused elements, such as issues with existing Codes or guidance materials, as well as some longer-term more strategic issues for consideration such as regulatory gaps or how HTA should respond to emerging sector developments.

7. As part of the HTA's approach to horizon scanning further revisions and strengthening of the process are needed, to enable a more strategic consideration of the strengths, weaknesses, opportunities, and threats to the sectors we regulate and to the organisation. How horizon scanning currently informs SMT consideration of longer-term strategic direction setting, and organisational vision will develop alongside the new portfolio management process as one source of intelligence informing operational and strategic priorities. It is felt that engagement of the Board will assist with the medium to longer term strategic view and issues to be explored with strategic partners, DHSC and other key stakeholders. Board members bring unique perspectives based on the diversity of their experience and backgrounds that may challenge previous positions and perceptions of risks and opportunities for the HTA, both in terms of technical areas within the sectors regulated and wider organisational issues.

Proposed Process

8. The proposed approach to engagement we wish to explore with the Board is based on a continual cycle. This cyclical approach could be aligned with annual Board activities such as business and strategic planning activities and formally reviewed in-year at set intervals.

9. The approach is based on six stages as outlined below, with opportunities for both direct and informal Board engagement at four of these.



Identification of emerging themes – there are several ways in which we will be seeking the Board's engagement and contribution to the identification of emerging issues. As part of a strengthened internal scanning process, there will be opportunities for Board members – as a collective or individuals – to provide inputs. For example:

- Creation of a dedicated email address so Members can send direct inputs, suggestions, and thoughts at any time, on areas to be included in horizon scanning.
- Direct requests to individual Members based on their areas of interest, study, research, expertise and experience for their inputs and views on emerging areas identified by the internal team.

- Discussion and challenge to the executive through papers presented to the Board.

In all cases, these views will be fed into the initial strategic assessment by SMT of all emerging issues, with SMT deciding which elements to adopt, to test or explore further. An initial light-touch exploration of those issues with DHSC where appropriate (e.g., on policy/regulatory issues), or with other key stakeholders, will support the development of analytical papers for further SMT consideration, with an overarching paper prepared for discussion with the Board. That paper will facilitate discussion and challenge of the executive and identify potential areas that the Board may wish to explore further.

It is important to note that while a strengthened and updated horizon scanning process will be better able to inform consideration of higher-level or longer-term issues, it may never capture all such issues. Unexpected or extremely rare events often referred to as “black swans” may not be identified or considered. Whilst such events and circumstances cannot be fully eliminated, a cycle of continual review will help to mitigate significant issues, including threats and opportunities, being missed.

HTA positions to adopt and / or test – at a strategic level the SMT will, in first instance, review those elements emerging from horizon scanning to agree, given resourcing and business planning objectives, those issues to be identified and explored further. It is anticipated that this work will initially be at a light-touch level aimed at providing sufficient information to support wider discussions on strategic direction, the review and updating of strategic objectives and to assess potential risks including resourcing and legislative constraints. The output from these initial positions will be reviewed by SMT to assess which need to be brought to the Board’s attention for further discussion, prior to a wider assessment and discussion (e.g., with working groups or at roundtables). Essentially, this is an initial assessment to inform whether further resources should be put into addressing or pursuing an issue, or whether it is retained on a watching brief until more information becomes available or understanding on a topic evolves. The evolution of the HTA’s thinking will also draw from other sources such as the Accountability Review, future opportunities for collaboration between ALBs and engagement with Department for Health & Social Care (DHSC) and devolved administration officials and ministers.

***Formal Engagement with the Board**:* suggested twice per annum, during the development sessions of SMT/Board meetings, emerging strategic issues will be discussed with the Board. Those inputs and discussions will be shaped by the initial exploratory discussions HTA holds internally, with DHSC as sponsor (e.g., to gauge appetite for activity in new or emerging areas) and will seek Board discussion and approval for advancing activities. This will also provide an opportunity for assessing how such activities align with existing strategic priorities (are they supportive, additional to, or enabling existing priorities), and to consider the impacts of these for the HTA's longer term objectives, vision, and mission. This formal engagement supplements reporting to the Board on horizon scanning.

***Detailed Exploration of Issues**:* – the identification and agreement of issues for further, more detailed exploration is a first step although more detailed examination will be required in most instances, to clarify the relevance, impact, and significance to the HTA. This critical "exploration" which will include Board members, may take several different forms, for example:

- Dedicated Board workshops (e.g., the impact of regulatory reform),
- Use of roundtable forums involving Board members with special interests (e.g., regulation and external stakeholders (e.g., novel treatments and / or procedures using tissues and cells), and
- The use of established working groups or the creation of new working groups, for issues either new to regulation or of a complex nature (e.g., regulation of DNA).

In the last year we have used roundtables to explore the next steps on issues identified through horizon scanning with external partners and there are plans to commence a scheduled programme of roundtables by the beginning of Q3 on emerging issues. A high-level indicative programme of issues to be explored is outlined below:

- Shared strategic priorities for the HTA and health teams in the Devolved Administrations and DHSC over the next 3 years
- Activities and sectors new to regulation and potential alternative models of regulation
- Overview of the changes and challenges to individual sectors for example the future of transplantation; the pace of research

Review Discussion with Board – the delivery of the HTA's operational and strategic role needs to be kept regularly reviewed to ensure we maintain the required level of responsiveness and relevance to the sectors regulated and across regulation. It is proposed that are two points of formal review each year. The first session would form part of the annual review of the strategy and provide an opportunity to consider existing and additional issues arising from horizon scanning, ensuring that business plans for the coming year are appropriately reflecting priorities that the Board has agreed need to be addressed, or ensuring that appropriate resources are available to monitor, track or prepare for longer-term priorities. The second session is proposed mid-year in line with other corporate cycles. This review would provide an opportunity to align with business planning, annual reporting, and any commissions for future Board meetings.

10. It is proposed that this approach is piloted for a full cycle with a first workshop in Autumn 2022.

Emerging issues for the Board's engagement

11. There are currently several topics being considered at an executive level as issues presenting over the next 12 – 24 months. In broad terms, they are fall under sectors and activities on the periphery or new to regulation and the alternative models of regulation (if required) to be explored. For example:
    - Regulation of DNA
    - Xenotransplantation
    - Regulation of aesthetic treatments and products
    - Cryogenics preservation
    - Uterine transplantation

12. Looking to the future, the following themes have been identified from horizon scanning over a medium to longer term. As high-level themes, these potentially represent some significant, complex issues which will benefit from a further study and exploration to assist the HTA to understand their importance:
    - Future model of regulation and expectations of the public, professionals, and other stakeholders
    - Impact of regulatory reform
    - The need for new or amended primary legislation
    - Life Sciences – changes in the sectors we regulate (e.g., growth, innovation etc).

Next Steps

13. We aim to use Q2 to:
    - Refine this process in readiness for a pilot in Autumn 2022.
    - Develop a working programme of engagement up to 31 March 2023 providing visibility to Board members on areas of engagement and expressions of interest.

Recommendations

14. The Board is invited to:
    a. Discuss the proposed process for engagement on horizon scanning and agree next steps.
    b. Identify any existing or emerging issues for consideration.

Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 25/22

Agenda item: 10

Author: Richard Sydee

OFFICIAL

Risk Appetite

Purpose of paper

1. This paper outlines recommendations from the Audit, Risk and Assurance Committee (ARAC) meeting held on 9 June 2022 for the Board to review and agree risk appetite and tolerance levels within the HTA's Risk Management policy.

Decision making to date

2. The Audit and Risk Committee met on 9 June and having noted the risk appetite and tolerance statement contained within the risk management policy recommended that these be presented to the Board for review.

3. The SMT agreed this paper on 23 June 2022 for submission to the HTA Board.

Action required

4. The Board is asked to note the redefined strategic risks for the 2022/23 business year and consider any changes it may wish to make to the current risk appetite statements at Annex A.

Background

5. The strategic risks are reviewed annually by the Executive to ensure they align to the strategic objectives and deliverables agreed within the annual business plan. The executive team reviewed the risk register for the 2022/23 business year and made a number of changes:

    - Most risk titles have been redrafted to better reflect the strategic impact the risk poses.
    - Risk 4 from the 2021/22 register has been revised and now focuses only on workforce and capability issues – with the IT risks now contained separately at Risk 7.
    - Risk 6 has been refocussed to consider the wider organisation transformation aims we have in relation to IT, Inspection process and ambitions to reshape other corporate functions

6. ARAC reviewed the revised strategic risk register at its meeting of 9 June 2022 and, noting the change to the nature and number of strategic risks, recommended that the Board review its Risk Appetite statements as contained within the Risk Management & Strategy Policy

7. Annex A reflects the minor changes to the risk appetite statements, to include new and redefined strategic risks. The Board are asked to consider whether these statements accurately reflect the agreed position for risk appetite. Any changes require Board approval, and it is good practice to review risk appetite annually, or an alternatively agreed frequency to ensure they reflect the Boards position of any changes to the HTA's operating landscape.

8. The Board may also wish to consider the stated risk tolerance levels contained with the Strategic Risk register for each risk, and whether they agree with the assessed score in light of any changes proposed to the risk appetite statements.

Recommendation

9. The Board is asked to note the redefined strategic risks for the 2022/23 business year and consider any changes it may wish to make to the current risk appetite statements at Annex A.

Annex A – Extract from the HTA Risk Management Strategy & Policy

Risk Appetite Statement

- Risk appetite is the amount of risk an organisation is willing to accept in pursuit of its strategic goals.

- Following our review of the existing approach to risk we propose that the risk appetite statement considers separately five key areas of risk to which the HTA is exposed and provides an outline of the HTA's appetite for managing these types of risks. The HTA does not have a single risk appetite, but rather appetites across the range of its activities. We recognise that in pursuit of our strategic priorities and outcomes we may choose to accept different degrees of risk in different areas of the business.

- Where we choose to accept an increased level of risk, we will do so, subject always to ensuring that the potential benefits and threats are fully understood before actions are authorised, that there is sufficient capacity, and that sensible and proportionate measures to mitigate risks are established.

- The Executive will manage strategic risks in a manner that is consistent with this statement. The strategic plan and the business plans within the HTA should also be consistent with this statement.

- Below are the risk appetite descriptions established for each key activity identified.

Business Area Risk Appetite Levels

Regulation

Risk 1 – There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.
Risk 2 – There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

- The HTA has **NO** appetite for any activity that disregards the need to obtain consent and any incidents that lead to serious public harm or breach of Data Protection Act.

- There is **LOW** appetite for risks that may result in the HTA providing misleading advice, especially when this advice could lead to an adverse impact on patient safety.

Corporate Governance

- There is a **LOW** appetite for activity that may result in non-compliance with legislation, statutory obligations, and government policies. The HTA has a **ZERO** tolerance for deliberate non-compliance with legal, statutory and policy requirements, except in exceptional circumstances.

Reputational

Risk 3 – There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

- Although the HTA will not tolerate (**ZERO**) any action that could cause reputational damage it will explore innovative ways of regulating in line with better regulation principles and will have a clear view on its regulatory risk and areas of oversight.

Capabilities

Risk 4 - Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives
Risk 6 - Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

- The HTA has a **MODERATE** appetite for change to ensure it has the right resources, capabilities, and organisational structure to optimise performance in the future whilst delivering value for money.

Information security and management

Risk 7 - Failure to optimise the safe use of existing and available digital data and technology

- The HTA has a **LOW** appetite for risk that could lead to information or data security breaches and a **LOW** appetite for system failures that could disrupt normal business. We have **NO** appetite for activities that may increase our exposure to threats on our assets arising from external malicious threats.

- The HTA has **LOW** appetite for activities that may compromise processes governing the use of information, its management and publication. The HTA has **ZERO** tolerance for the deliberate misuse of its information.

Risk 5 – There is a risk that the HTA has insufficient or ineffective management of its financial resources

- The HTA has a **LOW** risk appetite in relation to management of its finance. It will not tolerate annual expenditure in excess of income or any form of spend that contravenes HMT guidance. In addition, The HTA has **ZERO** appetite for any incidence of fraud and fraudulent behaviour.

Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 26/22

Agenda item: 11

Author: Richard Sydee

OFFICIAL

Audit and Risk Assurance Committee update

Purpose of paper

1. This paper provides an overview of the business of the Audit, Risk and Assurance Committee (ARAC) meeting held on 9 June 2022.

Action required

2. The Board is asked to note the content of this report.

Background

3. The Committee discussed the following items as material elements of the meeting.

Internal Audit

4. The Committee noted four reports since their last meeting that concluded the 2021/22 internal audit plan, these included three moderate assurance reports for Equality, Diversity & Inclusion; Financial Management (Budgeting) and

Effectiveness of the inspection process. The fourth, an advisory review of HTA's Business Planning and Performance Monitoring processes was not an audit but provided helpful recommendations for the revised process currently being implemented within the organisation.

5. The Committee then received the internal audit opinion for 2021/22 from the Head of Internal Audit, which concluded that an overall rating of moderate assurance could be provided. This was in keeping with previous years and was noted by the Committee.

Annual Report and Accounts 2021/22

6. The Director of Resources presented the Annual Report and Accounts for the 2021/22 financial year to the Committee. The committee noted and discussed material movements in the accounts from the previous financial year and the new disclosures for this reporting year.

7. The Committee then received the draft External Audit completion report from Dean Gibbs of KPMG on behalf of the National Audit Office. The committee noted that there were no material errors found or audit adjustments recommended and that the opinion was for the accounts to be unqualified.

8. Subject to the conclusion of the audit process with no further material findings, the Committee endorsed the recommendation that the Annual Report and Accounts be signed by the Accounting Officer.

Strategic Risk Register

9. The revised Strategic Risk Register (SRR) was considered by the Committee, this had been updated to reflect the 2022/23 Business Plan and included updates to several risk areas and the Executive's decision to create separate risks for people & capability and for technology, which had previously been a combined risk. The Committee also noted revisions to the HTA's approach to Risk Management.

10. The Committee agreed revisions to the policy, and recommended that the Board consider the stated risk appetite and tolerance levels contained within the policy for each of the 7 strategic risks at the next Board meeting

Other items

11. The Committee received an update on Cyber Security from Louise Dineley, Director of Data, Technology & Development, and noted the annual report from the Senior Information Risk Owner.

12. The Committee noted that the HTA was in the process of finalising it's annual Data Security Protection Toolkit submission to NHS Digital, which was due on 30 June 2022. Background information for all Board members on DSPT with an update since the ARAC meeting is provided at Appendix A.

13. The Committee also reviewed revisions to the HTA's Critical Incident Response Plan and Business Continuity Disaster Recovery Plan, a paper capturing the responses from the ARAC review of its effectiveness, and a report on Equality, Diversity & Inclusion within the HTA.

Recommendation

14. The Board is asked to note the content of this report.

Appendix A

Data Security Protection Toolkit (DSPT)

Background

NHS Digital (NHS D) requires all public bodies who work with NHS patient data to complete the DSPT, each body must undertake a self-assessment against a set of prescribed assertions – statements describing requirements, standards of training. security or documentation that NHS D expect each body to have in place. Although this has been extant since 2016, the HTA were only required to take this assessment for the first time in 2021. The DSPT is applied across very different organisations from large NHS Foundation Trusts through to ALBs like us, although there are some differences in terms of applicable standards, it is still very much a one size fits all approach to data security.

Our discussion with other ALBs highlights that successful submission favours large, well-resourced teams, and even with external support it has taken these organisations several years to compile a full evidence base to support meeting all the standards and assertions.

Following the HTA self-assessment against the DSPT, internal audit (IA) undertook a mandatory review of supporting evidence against a pre-defined number of the assertions (review by an independent body of supporting evidence being a mandatory requirement of the DSPT). This audit found gaps in the level of evidence required to support the HTA's assessment of "met" against several assertions. This resulted in an audit finding of Limited, and several recommendations to enhance the HTA's approach to this year's annual exercise.

DSPT is a useful governance process and one that SMT is working towards meeting. However, given our organisational size and resources there are some assertions we are unlikely to able to meet and others where the evidence requirement is difficult to meet, without significant investment. It is also important to note that this assessment does not automatically give assurance on the HTA's overall provision on data and IT security – as it does not represent an active test of our systems and approach, rather it establishes whether our underlying governance and documentation sets out in detail our approach.

2022 DSPT Audit

The HTA has moved forward in its approach to the DSPT assessment for 2022, with a more structured approach, and with an earlier commencement date and more time being devoted to this year's submission

That said, progress has been hampered given the loss of key IT colleagues between November and May, which has limited the available resource to progress this return, not least, when faced with other competing priorities for these IT staff to progress.

We have made a self-assessment, and the HTA continues to believe it meets the majority of the DSPT assertions relating to its approach to IT and Information security and governance but a notable amount of work is still required.

We have been able to improve the evidence base for some assertions, building on the audit feedback on those that were tested in 2021. However, the assertions to be tested in 2022 are different – and the NHS D guidance we were working to has, in discussion with our internal auditors, highlighted some areas where we now feel our evidence will not support the "met" standard.

To provide further clarity, the DSPT guidance to organisations provides some advice on the evidence required to support an assessment of "met" against an assertion. NHS D have recently provided a far more granular and detailed list of evidence sources to auditors, a list that our internal auditor has agreed would have been useful for us to have seen prior earlier – a recommendation they we will be feeding back to NHS D at the end of the process for this year.

Considering the more detailed evidence requirements from NHS D, we revised our self-assessment opinion on whether we were able to evidence having "met" some of the assertions.

Next Steps

GIAA commenced their assessment w/b 27th June. A final report will be agreed with them in the coming weeks and the 2022 submission made.

We acknowledge the difficulty of getting all the strands to "met". Longer-term strategic changes to the delivery of IT for HTA become pertinent here as a means of helping us do this.

Remuneration Committee Update - Confidential

Minutes of the One-hundredth meeting of the Human Tissue Authority Board

Date: **5 May 2022**

Time: **10.00-12.30**

Venue: 2 Redman Place, London

Protective Marking: OFFICIAL

Attendees:

Board Members
Professor Gary Crowe, Acting Chair
Professor Deborah Bowman
Tom Chakraborti
Helen Dodds
Ellen Donovan
Dr Charmaine Griffiths
Andy Greenfield

Apologies
Lynne Berry, HTA Chair
Dave Lewis

Observers
Maria Nyberg, Deputy Director Health Ethics, DHSC
Jacky Cooper, Team Leader Human Tissue Policy and Ethics of Consent

HTA attendees
Dr Colin Sullivan, Chief Executive
Louise Dineley, Director of Data, Technology and Development
Nicolette Harrison, Director of Regulation, HTA
Richard Sydee, Director of Resources
TJ O'Conner, Executive Assistant
Alison Margrave, Board Support (minutes)
Audrey Jessiman, Head of Policy and Development (items 6 and 7)
Paul Clements, Chief Technology and Information Officer (item 7)
Ranjan Sen, Project Manager (item 7)

Item 1 – Welcome and apologies

1. The Acting Chair welcomed Board Members, HTA Staff, observers from the Department of Health and Social Care and members of the public to the one-hundredth meeting of the HTA's Board.

2. Lynne Berry, Chair of HTA, sent apologies due to illness.

Item 2 – Declarations of interest

3. The Acting Chair asked Members if there were any new declarations of interest; none was declared.

Item 3 – Chair's Report

4. The Acting Chair provided an oral update on the following items on behalf of the Chair:
    - Recruitment progress for Board members and induction meetings for the newly appointed Board Members.
    - One to one priority setting meetings with Board Members.
    - Board effectiveness review work with the Chief Executive
    - Meetings with DHSC and NHSBT

Item 4 – Chief Executive's Report (HTA 12/22 and HTA 12a/22)

5. Dr Colin Sullivan introduced the report and highlighted that the Business Plan had been completed in March and sent to the Department for approval. He spoke about the reintroduction of KPIs and how these will be used to measure and support the work of HTA.

6. He spoke to the increased number of inspections HTA expects to complete in the year and the proposed review of the inspection process. The support work for the Fuller Independent Inquiry and the advice given to the Secretary of State was highlighted. He spoke to the accountability meetings with DHSC, the proposed framework agreement with DHSC and the Public Bodies Review Programme.

7. In response to questions, the Chief Executive provided more information about the review of inspections and confirmed that HTA will be giving an oral response to the House of Commons Science and Technology Committee Inquiry, "Right to privacy: digital data".

8. In response to a question the Chief Executive provided further information about HTA's recruitment strategy and how interim positions are used to ensure continuity of work.

9. The Board noted the report.

Item 5 – HTA Performance Report (HTA 13/22, HTA 13a/22, HTA 13b/22 and HTA 13c/22)

10. Dr Colin Sullivan introduced the report and provided several highlights to Board Members. He explained the new format of the data annex which provides historical data so trends can be seen more easily. In response to a question, he stated that the KPIs are being developed and are still considered work in progress.

11. In response to questions, both the Chief Executive and Director of Resources gave further information regarding debt recovery processes, budget allocation for maximum value for money and risk register tolerance levels and monitoring. The Director of Resources provided information to the Board on the progress of the year-end audit.

12. The Chief Executive provided further information about how HTA supports staff wellbeing and mental health both formally and informally and gave examples of some of these activities.

13. In response to a question, the Director of Regulation provided further information about outstanding Corrective and Preventative Action (CAPA) plans and how HTA works with establishments to monitor and review these. The Board were informed that specific updates and lessons learnt experiences were shared in HTA's professional newsletter.

14. The Board noted the report.

Item 6 – Communication and Engagement Strategy (HTA 14/22, HTA 14a/22 and HTA 14b/22)

15. Audrey Jessiman, Head of Policy and Development, introduced the report and provided further detail about the Strategy and annexes presented to the Board. She explained how the external company had conducted their research and the main findings of this which then helped to shape and develop the proposed communication and engagement strategy. She explained the 4 key principles

set out within the strategy and how these support HTA's overarching strategic approach.

16. In response to questions the Director of Data, Technology and Development provided further information about resources and staffing and stated that the approach contained in the strategy is a step-change towards being more proactive and all staff will have a responsibility.

17. The Board discussed the 4 key principles of the proposed strategy and the importance of trust and confidence in the work of HTA.

Action 1

18. The Board approved the Communications and Engagement Strategy and the underpinning indicative actions outlined for FY22/23 in the associated Action Plan.

Item 7 – Development Programme Annual Report (HTA 15/22)

19. The Director of Data, Technology and Development introduced the report and stated that the year had not gone as planned due to other pressures and resources being allocated to other priorities. This meant that some aspects of the programme were not fully achieved, as reflected in the report before the Board.

20. Ranjan Sen, Project Manager, spoke to some of the success from the Development Programme which have been embedded in HTA's business as usual work such as horizon scanning and the electronic filing system. There are several key learning points which can be used to align future work and governance to ensure that HTA becomes a data driven organisation.

21. The Board thanked the HTA staff for the frankness of the report and discussed a number of aspects including the possibility of shared facilities with other organisations and the opportunities this would present; the reframing of priorities for the programme and the wellbeing of staff involved in the programme.

Action 2

22. The Board noted the Annual Report and agreed the recommendation to pause current activities to enable a review of the current focus and structure of the

Development Programme, noting that a further report will be brought to the July Board Meeting.

Item 8 – Remuneration Committee Terms of Reference (HTA 16/22)

23. Dr Colin Sullivan introduced the report and explained the enhanced role which is being proposed for this Committee. He stated that he had worked with DHSC to ensure that the proposed Terms of Reference align with those of their Remuneration Committee.

24. The Board welcomed the wider holistic responsibility on people issues which will sit with this Committee and asked that the Committee's name reflect this added responsibility.

Action 3

25. The Board agreed the revised Terms of Reference for the Remuneration & People Committee and agreed that these Terms of Reference should be included in the standing orders.

Item 9 – Minutes of 10 February 2022 (HTA 17/22)

26. The Board noted the proposed amended minutes of the meeting of 10 February 2022 and agreed these.

Item 10 – Matters arising from 10 February 2022 (HTA 18/22)

27. The Board noted the progress which had been made against the actions from the previous meeting.

28. In response to a question, the Chief Executive stated that a report on Horizon Scanning would be brought to the July Board meeting.

Item 11 – Deemed Consent NI (HTA 19/22)

29. The Board noted the information report on Deemed Consent in Northern Ireland.

Item 12 – Questions from observers

30. The Chair informed the meeting that a number of pre-submitted questions from observers had been received by the deadline. The topics raised focused on the following issues:

Information about the work of HTA. The Chief Executive informed the meeting that the website www.hta.gov.uk is the primary source of current information about the HTA. He remarked that there are public guides available to our Codes of Practice which explain the role of HTA and these can be found on the HTA's website.

Interaction between the work of Coroner's Office and the Human Tissue Act, any plans for training and standardisation of forms. The Director of Regulation informed the meeting that the Coronial Service is a separate service that works under Coroners' Regulations, not the Human Tissue Act. HTA is happy to provide advice and training to any professionals and organisations who wish to understand more about the Human Tissue Act. The HTA appreciates that practices vary amongst establishments and between Coroners' Services. She noted that the HTA provides advice and guidance to licensed establishments with a view to encouraging effective communication between the establishment and the local Coroner's service

Samples being taken for DNA analysis at Funeral Directors premises which are not currently licensed by the HTA. The Director of Regulation informed the meeting that HTA has been liaising with representatives in the Funeral sector to understand the most effective ways to raise awareness of the legal and regulatory frameworks that may be relevant to their members' activities. She remarked that if anyone has specific information about concerns that samples may have been taken from the deceased on unlicensed premises, these can be reported to the HTA directly through the relevant links to "enquiries" on HTA's website.

Possibility of a small purse or wallet card that combines the individual's wishes about organ and body donation. The Director of Regulation informed the meeting that separate body donor and organ donor cards already exist and HTA is not aware of any plans for these cards to be combined. It was noted that organ and body donation are quite distinct and separate services. Organ donation is managed by NHS Blood and Transplant (NHSBT) an

donation is managed by local Anatomy Schools. HTA has no direct role in either organ or body donation but instead is responsible for ensuring that any such donations occur with appropriate consent and meet our regulatory requirements and expectations

Whether HTA works in specific areas of clinical research. The Director of Regulation informed the meeting that HTA's role in relation to research is set out in Code E, the Research Code of Practice, which is available on the HTA website. The HTA licenses organisations for storage for research in England, Wales and Northern Ireland. HTA's licensing role in research is limited to licensing premises - such as tissue and brain banks - storing tissue from the living and deceased. HTA ensures that this tissue is removed and stored in an appropriate and well managed way, it does not license the 'use' of tissue for research or approve individual research projects or clinical trials nor does it have a role in the ethical approval of research. HTA does, however, work in partnership with other organisations - including research regulators - to ensure that the regulatory environment is easy for researchers to navigate and understand. Depending on the area of clinical research, researchers may need to at least be aware of other regulators, such as the Health Research Authority, the Medicines and Healthcare products Regulatory Agency and/or the Human Fertilisation and Embryology Authority.

Body Donation and how to find information about this. The Director of Regulation informed the meeting that information on body donation is available on the HTA's website, including an online body donation information pack that gives information about how to contact local anatomy schools to volunteer to donate your body and the consent requirements for body donation. She noted that the HTA has no direct role in body donation but is instead responsible for ensuring that body donation occurs with appropriate consent and meets HTA's regulatory requirements and expectations

31. The Acting Chair thanked the observers who provided these questions and acknowledged the richness and variety of questions being asked.

Item 13 – Any other business

32. There being no further items the Acting Chair officially closed the 100th meeting of the HTA Board and thanked all who prepared and attended the meeting.

Date of Next Meeting

14 July 2022 – virtual meeting

Meeting actions

Action 1
The Board approved the Communications and Engagement Strategy and the underpinning indicative actions outlined for FY22/23 in the associated Action Plan.

Action 2
The Board noted the Annual Report and agreed the recommendation to pause current activities to enable a review of the current focus and structure of the Development Programme, noting that a further report will be brought to the July Board Meeting.

Action 3
The Board agreed the revised Terms of Reference for the Remuneration & People Committee and agreed that these Terms of Reference should be included in the standing orders.

Human Tissue Authority
Board meeting

Date: 14 July 2022

Paper reference: HTA 29/22

Agenda item: 14

Author: Alison Margrave, Board Support

OFFICIAL

Matters Arising from previous HTA Board meetings

Date Added	Action	Target date	Revised date	Status
Feb 22	The Board agreed that HTA should proceed with the proposed review of the Code of Practice F.	July 22		See agenda item 7
July 22	The Board approved the Communications and Engagement Strategy and the underpinning indicative actions outlined for FY22/23 in the associated Action Plan	July 22		Completed
July 22	The Board noted the Annual Report and agreed the recommendation to pause current activities to enable a review of the current focus and structure of the Development Programme, noting that a further report will be brought to the July Board Meeting.	July 22		See agenda item 8
July 22	The Board agreed the revised Terms of Reference for the Remuneration & People Committee and agreed that these Terms of Reference should be included in the standing orders.	July 22		Completed