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Department
of Health &
Social Care



Framework Agreement Between DHSC and The Human Tissue Authority

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1. Purpose of this Document

1.1 The purpose of this document is to define the critical elements of the relationship between the Department of Health and Social Care ("the Department") and the Human Tissue Authority (HTA). The document is focused on:

- How the Department and the HTA will work in partnership to serve patients, the public, HTA licence fee payers and the taxpayer; and
- How both the HTA and the Department discharge their accountability responsibilities effectively.

Signed by:

Mark Davies

Director of Population Health

DHSC

Allan Marriott-Smith

Chief Executive

HTA

2. HTA's Purpose

2.1 The HTA is an independent regulator created by the Human Tissue Act 2004. Its overall strategic aim is to maintain 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.

2.2 The HTA's statutory duties include:

- Licensing organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- 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 donation 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 our 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 our remit;
- Monitoring developments relating to activities within our remit and advising the Secretary of State, the relevant Northern Ireland department or Welsh Ministers on related issues.

3. Governance

3.1 The HTA is led by a board, “the Authority”, which is made up of a non-executive chair appointed by the Secretary of State for Health and Social Care and 11 non-executive members:

- nine are appointed by the Secretary of State for Health;
- one is appointed by the Welsh Cabinet Secretary for Health and Social Services; and
- one is appointed by the relevant department in Northern Ireland.

The Chief Executive, who is not a member of the board, is appointed by the Authority.

3.2 The Permanent Secretary has appointed a Senior Departmental Sponsor (SDS) who acts as the HTA’s designated, consistent point of contact within the Department. The SDS acts as the link at executive level between the HTA and the senior officials of the Department, and also with ministers. Whilst the SDS role is facilitative and recognises the need for direct engagement between the HTA and other parts of the Department and ministers, it also supports the Permanent Secretary in holding the HTA to account and providing assurance on its performance. The SDS is currently the Director for Population Health. The SDS is supported by a Departmental sponsor team, which is the principal day-to-day liaison between the Department and the HTA.

Process for setting objectives

3.3 In advance of each financial year, the HTA will set itself annual objectives which deliver its statutory remit, and which are aligned to the Department’s strategic objectives for the health and care system.

3.4 The HTA will produce a business plan each year demonstrating how it will meet its legal duties and deliver its objectives. The Department will provide guidance to support this process, which will include target budgets covering administration, programme,

revenue and capital funding. The HTA will reach agreement with the Department on its business plan. To facilitate comment from the Department, including relevant ministers, the business plan will be shared and discussed in advance of its adoption by the Executive. The HTA will be made aware of any concerns the Department may have. Progress on the objectives will be discussed at the annual accountability review.

3.5 The Authority will also produce annually a longer term, three to five year, corporate strategic plan. The Department will be provided with the opportunity to comment on this plan during its development and in advance of its formal adoption by the Authority. There will be no formal requirement for agreeing the strategic plan with the Department before publication.

Discharge of statutory functions

3.6 The HTA will ensure that it has appropriate arrangements in place for the discharge of each of the statutory functions for which it is responsible and is clear about the legislative requirements associated with each of them, specifically any restrictions on the delegation of those functions. It will ensure that it has the necessary capacity and capability to undertake those functions, and will ensure that it has the statutory power to take on a statutory function on behalf of another person or body before it does so. The HTA will also ensure that there is periodic audit of the discharge of its statutory functions so that the delivery of them remains effective, efficient and legally compliant. The HTA should include a review of this in its three-year audit cycle, but ensure that it takes steps to sufficiently assure itself on an annual basis and include details of this within its governance statements.

Cross-government clearance

3.7 In addition to internal governance, cross-government clearance is required for major new policy decisions of the type set out in the Guide to [Cabinet Office and Cabinet Committees](#). Although such cases are likely to be small in number, the Secretary of State will be responsible for obtaining clearance and the HTA will adhere to any conditions

applied through the clearance process. There will also be cases where the Secretary of State must consult Cabinet colleagues before giving the Government's view, even if collective agreement is not required. In such cases, the HTA will supply the Secretary of State with any information he or she needs in a timely fashion.

4. Accountability

Secretary of State

4.1 The Secretary of State is accountable to Parliament for the health system, including the HTA. The Department supports him or her in this role. This involves:

- setting national priorities and monitoring the whole system's performance to ensure it delivers what patients, people who use services and the wider public need and value most;
- setting budgets across the health system, including for the HTA;
- agreeing objectives with the HTA;
- supporting the integrity of the system by ensuring that funding, legislation and accountability arrangements protect the best interests of patients, the public and the taxpayer;
- accounting to Parliament for the HTA's performance and the effectiveness of the health and care system overall.

The Principal Accounting Officer and the HTA's Accounting Officer

4.2 The Department of Health's Permanent Secretary is the Principal Accounting Officer (PAO) and so is accountable in Parliament for the general performance of the health and care system in England, including the HTA. This requires him or her to gain assurance that the HTA is discharging its statutory duties and meeting the objectives set out in the agreed annual business plan. In this way the PAO is able to report to Parliament on the Department's stewardship of the public funds it distributes and for which it holds overall accountability.

4.3 The Department's Permanent Secretary, as the Department's Principal Accounting Officer (PAO), has appointed the HTA's chief executive as its Accounting Officer (AO). The AO may be called to Parliament to account for the performance of the Authority in the discharge of its statutory duties in Parliament. The PAO can also be held to account in Parliament since the PAO's oversight should allow him or her to assess the adequacy of the HTA's stewardship of public funds and discharge of its duties. This assessment includes making judgments about whether the HTA is operating to adequate standards of regularity, propriety, feasibility and value for money (assessed for the Exchequer as a whole).

4.4 The PAO's oversight of the HTA's performance relies upon the provision of information, and processes to enable both parties to review performance. The information provided to the Department by the HTA includes (not an exhaustive list):

- a quarterly assessment of performance against key performance indicators ;
- monthly financial reports
- strategic risk register updated for every quarterly accountability meeting
- annual governance statement

4.5 The processes in place to enable the Department and the HTA to review performance include:

- quarterly accountability review meetings, chaired by the Department, which will include a review of performance and strategic risks ;
- An invitation of attendance of officials from the Department's sponsor team, as observers, at meetings of the Authority and the HTA's Audit and Risk Assurance Committee.

4.6 In accordance with paragraph 16 of Schedule 2 of the 2004 Act, the HTA shall prepare an annual statement of accounts as at 31st March, and send a copy to the Secretary of State and others including the Comptroller and Auditor General.

4.7 The HTA is responsible for the delivery of its objectives and the Department will limit the circumstances in which it will intervene in its activities. The following constraints do, however, apply:

4.7.1 All funds allocated to the HTA must be spent on the statutory functions of the Authority. If any funds are spent outside the statutory functions of the HTA the Department could seek adjustments to the grant in aid for running costs (administration) to compensate.

4.7.2 The Secretary of State may remove the Chair or other member of the Authority on the grounds that they are unable or unfit to carry out his or her duties or have been absent from meetings of the Authority for six consecutive months or longer without the permission of the HTA (Paragraph 9 of Schedule 2 to the Human Tissue Act 2004 as amended).

5. HTA's Board

5.1 The HTA is governed by its board, “the Authority” which meets a minimum of four times a year. The role of the Authority is as described in the [corporate governance code](#) for central government departments and includes 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. It also has a duty to hold its executive management team to account and ensure the organisation is able to account to Parliament and the public for how it has discharged its functions.

5.2 The board is led by a non-executive Chair, who is responsible to the Secretary of State for ensuring that the HTA’s affairs are conducted with probity, and that the HTA’s policies and actions support it in the discharge of its functions and duties efficiently and effectively and meet the Authority’s objectives, including those set out in its business plan. The Director General, Global and Public Health will ensure that there is an annual objective setting and review process in place for the Chair.

5.3 The HTA’s Chair and non-executive members will be appointed by the Secretary of State. The Human Tissue Act 2004 makes provision for a member to be appointed by the National Assembly for Wales and a member to be appointed by the relevant Northern Ireland Department (Schedule 2). Appointments will be transparent, will be made on merit, and are regulated by the Commissioner for Public Appointments.

5.4 Appointment of the Chair and Members of the Authority, as laid out in Schedule 2 of the Human Tissue Act 2004, will be for periods of up to three years. Members may be reappointed, and may serve a maximum of two terms.

5.5 The board appoints a Chief Executive whose responsibilities include:

- Ensuring that the HTA delivers its statutory remit

- Safeguarding the public funds and assets for which the Chief Executive has charge;
- Ensuring propriety, regularity, value for money and feasibility in the handling of those funds;
- The day-to-day operations and management of the HTA;
- Ensuring that the HTA is run on the basis of the standards (in terms of governance, decision-making and financial management) set out in Managing Public Money, including seeking and assuring all relevant financial approvals;
- Together with the Department, accounting to Parliament and the public for the HTA's financial performance and the delivery of its objectives;
- Accounting to the Department's Permanent Secretary, who is Principal Accounting Officer for the whole of the Department of Health's budget, providing a line of sight from the Department to the HTA;
- Reporting on the HTA's performance against its objectives at each of the formal quarterly accountability meetings chaired by the Deputy Director, Population Health Directorate on behalf of the Senior Departmental Sponsor.
- Ensuring effective procedures for handling complaints about the ALB are established and made widely known within the ALB.

5.6 The responsibilities of the board as a whole include supporting the Accounting Officer in ensuring that the HTA exercises proper stewardship of public funds, including compliance with the principles laid out in Managing Public Money; and ensuring that total capital and revenue resource use in a financial year does not exceed the amount specified by the Secretary of State.

5.7 The Authority should ensure that effective arrangements are in place to provide assurance on risk management, governance and internal control. The board must maintain an Audit Committee chaired by a non-executive member with significant experience of financial leadership at board level. Other members need not be main board members but should be able to demonstrate relevant sectorial experience at board level. It is recommended that the committee have at least four members, although this can be fewer if the board feel that is justified. The internal and external auditors must be invited to all meetings and be allowed to see all the papers, unless they concern the appointment of internal auditors.

6. Partnership Working

6.1 The Department and the HTA will work together, and with the Department'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 the Department will follow an 'open book' approach. In the case of issues with an impact on the development or implementation of policy, the Department can expect to be kept informed by the HTA. In the same way, the Department will keep the HTA apprised of developments in policy and Government.

6.2 There are likely to be some issues where the Department or the HTA will expect to be consulted by the other before the Department or the HTA makes a decision or a public statement on a matter. The Department 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, for example through use of dialogue at the Quarterly Accountability meetings.

6.3 The HTA and the Department have also agreed to work to the following shared principles:

- 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 the Department in the discharge of its accountability duties, and the Department 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.

7. Public and Parliamentary Accountability

7.1 The Department and its ALBs 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.

7.2 The Department 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 the Department by, amongst other things, providing information for ministers to enable them to account to Parliament. In its turn, the Department will provide leadership to the system for corporate governance, including setting standards for performance in accountability.

7.3 The HTA will, however, have its own responsibilities in accounting to the public and to Parliament, and its way of handling these responsibilities will be agreed with the Department. In all matters of public and parliamentary accountability the Department and its ALBs will work together considerately, cooperatively and collaboratively, and any information provided by the HTA will be timely, accurate and, where appropriate, consistent with information provided by the Department. To facilitate this, the Department and the HTA have agreed a public and parliamentary accountability protocol 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.

8. Transparency

8.1 The HTA is an open organisation that will carry out its activities transparently. It will demonstrate this by proactively publishing on its website its annual report and key information on areas including pay, 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 annual report will include a governance statement, which is to be reviewed by the Senior Departmental Sponsor. The HTA will hold an annual board meeting open to the public.

8.2 To underpin the principles of good communication, 'no surprises' and transparency, the HTA and the Department will put in place arrangements for managing communications. Further details are provided in Annex C.

8.3 The HTA's board members will 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.

8.4 The HTA will maintain a set of HR policies for all staff which will be consistent 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.

8.5 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 2018
- 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.

8.6 The HTA's Senior Information Risk Owner will ensure that personal information is handled in line with best practice in government and the wider public sector.

8.7 The HTA, like the Department and all its ALBs, should have whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and best practice [guidance](#). It should prohibit the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest.

Sustainability

8.8 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 will be via the Department (including the consolidation of relevant information in the Department's annual resource account), and the Department will ensure that the HTA is aware of the process for this.

9. Audit

9.1 The Comptroller and Auditor General (C&AG) will audit the HTA's annual Report and Accounts. Assuming a satisfactory audit the C&AG will provide an audit certificate and audit report in time for the HTA to lay the Annual Report and Accounts before Parliament in accord with published timetables.

9.2 The Comptroller and Auditor General may also choose to conduct a value-for-money audit of any aspect of the HTA's work: the Authority will cooperate fully with the NAO in pursuing such audits, and give them full access to all relevant files and information.

9.3 The HTA is responsible for establishing and maintaining internal audit arrangements in accordance with the Public Sector Internal Audit Standards. The HTA's internal audit function should report to its Audit and Risk Assurance Committee, and should consider issues relating to the Authority's adherence to its business plan. The Department's Audit and Risk Committee remit includes risk management, corporate governance and assurance arrangements in all its subsidiary bodies and so the HTA's Audit Committee should work closely with the Departmental committee.

10. Delegations and Financial Management

10.1 Details of the HTA's financial arrangements, including funding allocation, in-year reporting, preparation of accounts, and the accounting officer's responsibilities in relation to financial management and the Authority's accounts, are provided in Annex B.

10.2 The HTA's overall revenue and capital resources are set out in its annual budget letter. More details are provided in Annex B.

10.3 The HTA's delegated authorities are issued to it by the Department, including those areas where the Authority must obtain the Department's written approval before proceeding. The HTA will adhere to these delegated authorities.

10.4 The HTA must demonstrate that it is delivering its functions in the most efficient manner, and must provide timely returns to the Department where these are required either by it or by other departments within central government.

10.5 The HTA, as with all public bodies and government departments, must operate within any relevant set of efficiency controls. These controls may affect areas such as information communications technology (ICT), marketing and advertising, consultancy, the public sector estate, recruitment, major projects or strategic supplier management. The Department will ensure that the HTA is kept informed of any efficiency controls in operation.

10.6 A shared or standardised value for money approach will also apply to the use of estate. The HTA will comply with guidance on property and asset management, as set out in Annex A, and the principles set out by the Department's Estate Strategy Optimisation Board.

11. Risk Management

11.1 The HTA will ensure that it deals with the risks that it faces in an appropriate manner, according to best practice in corporate governance, and develop a risk management strategy in accordance with the Treasury guidance [Management of Risk: Principles and Concepts](#). It will adopt and implement policies and practices to safeguard itself against fraud and theft, in line with [HM Treasury guidance](#). It should also take all reasonable steps to appraise the financial standing of any firm or other body with which it intends to enter into a contract or to give grant or grant-in-aid.

11.2 The HTA will develop a reporting process to assure the Authority of financial and operational performance against the business plan at all meetings of the Authority. This will include reports from the Audit and Risk Assurance Committee, as appropriate. This assurance report will include information on risks and how they are being managed in accordance with the Treasury guidance mentioned above. The information prepared will be shared with the Department to enable the Department to assure itself on risk management. The HTA and the Department will agree a process and trigger points for the escalation of risks to the Department's Audit and Risk Committee where those risks will have a potentially significant impact on the HTA, the Department or the wider system that requires a co-ordinated response.

11.3 Risks to the wider system that arise from the HTA's operations, identified by the HTA, the Department or another body will be flagged in the formal quarterly accountability meetings. Such risks may also be flagged by the members of the Authority and escalated to the Department's Audit and Risk Committee for consideration. It is the responsibility of the HTA and its sponsor to keep each other informed of significant risks to, or arising from, the operations of the HTA within the wider system.

11.4 The HTA will have effective and tested business continuity management (BCM) arrangements in place to be able to respond to disruption to business and to recover time-critical functions where necessary. In line with Cabinet Office guidelines, the BCM system should aim to comply with ISO 22301 Societal Security – Business Continuity Management Systems.

12. Human Resources

12.1 The HTA is responsible for recruiting staff, but will comply with any departmental or government-wide recruitment controls. The Department will ensure that the HTA is made aware of any such controls.

12.2 The HTA must obtain the approval of the Secretary of State in respect of policies relating to remuneration, pensions, allowances or gratuities.

12.2.1 In relation to remuneration, the HTA, as with all executive non-departmental public bodies, is subject to the pay remit process, which regulates the pay setting arrangements for its staff (those who are not very senior managers). The pay remit, which is bound by Civil Service Pay Guidance, provides a framework within which the HTA sets:

- The pay envelope for the year (consistent with any limits set by HM Treasury)
- Pay strategies
- Pay reporting.

12.2.2 HM Treasury has delegated the approval of executive non-departmental public bodies' pay remits to parent departments. The HTA is therefore required to submit its pay remit proposals to the Department for approval.

12.2.3 Executive senior managers in the HTA are subject to the Department's pay framework for Executive and senior managers in arm's length bodies, and may be subject to additional governance as specified by the Department. The Department will ensure that the HTA is aware of any such requirements or restrictions.

12.3 In relation to pensions, the organisational pension scheme is the NHS Pension scheme, administered by NHS Pensions and has rules laid down in legislation.

12.4 Like all departments and arm's length bodies, the HTA will be required to follow any requirements for disclosure of pay or pay-related information.

12.5 Subject to its financial delegations, the HTA is required to comply with the Department's and HM Treasury's approval processes in relation to contractual redundancy payments. All novel or contentious payments require the Department's and HM Treasury's approval. Special severance payments are always considered novel or contentious (this includes any proposal to make a payment as a result of judicial mediation).

Equalities

12.6 The public sector equality duty requires the HTA (as a body who exercises public functions) to have due regard, in the exercise of its public functions, 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; and
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The Equality Act 2010 (Specific Duties and Public Authorities) Regulations 2017 impose a number of other duties on specified public authorities. Where they apply, these duties require public authorities 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 (provided the public authority has 150 or more employees) and other persons affected by its policies and practices.
- Every four years, prepare and publish one or more objectives it thinks it should achieve to meet the public sector equality duty.

Although these duties do not formally apply to the HTA, it will evidence its commitment to equalities through the production of an annual report to be considered by the Senior Management Team and shared with staff, as well as regular training for staff.

13. Relations with the Department's other arms length bodies

13.1 The HTA will work in partnership with the Department and its 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, and working to the values set out in the NHS Constitution.

13.2 The Department 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. Relationships with other ALBs is set out in Annex D. Details of the working arrangements with these bodies will be agreed and set out in Memoranda of Understanding and Service Level Agreements.

14. Review

14.1 The Department will agree objectives with the HTA each year which will be published in the annual business plan. The HTA will work with the Department towards preparing, obtaining clearance and publishing its annual business plan as early as possible after the end of the preceding financial year.

14.2 The Department will regularly review the HTA's performance at formal accountability meetings. In addition, the Department will undertake an in-depth review of the HTA as well as its other arm's length bodies on at least a triennial basis.

14.3 The HTA is established by the Human Tissue Act 2004. Any change to its core functions or duties, including mergers, significant restructuring or abolition would therefore require further primary legislation. If this were to happen, the Department would then be responsible for putting in place arrangements to ensure a smooth and orderly transition, with the protection of patients being paramount. In particular, the Department is to ensure that, where necessary, procedures are in place in the ALB so the Department can obtain independent assurance on key transactions, financial commitments, cash flows, HR arrangements and other information needed to handle the transition effectively and to maintain the momentum of any ongoing and/or transferred work.

14.4 This agreement will be reviewed every three years, or sooner upon request of either party.

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