

Human Tissue Authority

Strategy 2024-2027



Foreword

Making sure human tissue, cells and organs are handled with dignity, used with consent and stored safely, is at the heart of our work at the Human Tissue Authority. We will continue to do this in an environment of ongoing change and technical advances. We aim to be an excellent, modern and accountable regulator dealing proportionately with the sectors we oversee today, whilst supporting licensed establishments including frontline NHS services to deliver safe care with dignity and respect.

This new strategy (2024 to 2027) reflects the journey we are on as a flexible and responsive regulator. Maintaining the trust and confidence of the public and professionals across all of our activities is important to us. The strategy focuses on addressing current challenges and adapting to changes, while also exploring new, innovative and smarter ways of working.

Digital and technological innovations are driving growth in life sciences and the broader healthcare system. It is an exciting period of change and as a regulator we aim to assist and promote such growth and play our part in helping service users have the opportunity to access innovative treatment without delay. In the last 12 months, we have witnessed an increasing number of urgent license requests to use tissues and cells in the delivery of acute and often lifesaving treatment to patients.

Over the next 3 years, we are anticipating changes and opportunities for growth in each of the sectors we regulate and overall in life sciences. It is important that any change reflects lessons learned, not least, those arising from the findings of the Independent Inquiry into the issues raised by the David Fuller offending. We believe individuals, living or deceased, must be treated with dignity and respect. The HTA is driving for all facilities that care for the deceased to abide by a duty to respect their dignity.

The HTA is ready to support this exciting period of change through a proportionate and increasingly collaborative approach to regulation. We will continue to ensure those providing services and delivering activities bear the responsibility for meeting and upholding the standards we set. We will work with partners in the wider system including those providing frontline services on the safe use of tissues and cells.

We understand the challenges different parts of the system face and over the last three years we have used our expertise in human tissue to get alongside and address these issues. We have engaged stakeholders and licensees through roundtables and sector-based forums, alongside many front-line interactions. Looking forward, we will continue to focus on building stronger relationships with the sectors we regulate and wider stakeholders. Through more collaboration, we can use our unique position and authoritative voice to facilitate sharing of intelligence and raise standards.

Of course, our people are our greatest asset – their expertise and determination continue to be the driving force to advance our strategic aims. We respect and value their perspective and professionalism and encourage openness and transparency, and autonomy of decision-making. As well as being an effective regulator, we seek to continue being a place where people of whatever background can give of their best, contribute fully within an open, welcoming and transparent environment, and feel a part of something really worthwhile.

Our commitment to the standards which ensure trust and confidence in the use of human tissue and cells remains the same, as do our core principles of dignity and consent. However, we have a greater appetite to test new and alternative approaches to regulation, including analysing the impact and outcomes of our actions.

Based on almost 20 years regulating the use of human tissue, the HTA stands by its core values in delivering its mission – collaboration, openness, respect and excellence. Regulation of any activity cannot be delivered alone. We will collaborate with stakeholders to ensure standards are maintained. By shining a light on good and bad practice we will aim to promote excellence and foster trust and confidence. We will be open in what we find and offer insight based on our expertise and experience. We will respect the skills and expertise of others, while being clear about expectations of good practice.



Lynne Berry CBE
Chair



Dr Colin Sullivan
Chief Executive

About the HTA

The Human Tissue Authority (HTA) is an executive Non-Departmental Public Body sponsored by the Department of Health and Social Care, (DHSC), established under the Human Tissue Act (2004).

We are the independent regulator of organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. We also give approval for organ and bone marrow donations from living people.

Our overall goal is to maintain public trust and confidence in the safe handling of human tissue. Our remit is underpinned by laws, which serve as the basis for the standards and requirements for establishments under our licensing authority. Further details of the standards, sectors and establishments that we regulate can be found on the HTA's website (www.hta.gov.uk).

Overall Goal

With the 20th anniversary of the Human Tissue Act (2004) we have reflected on the past, current and future use of human tissue, how it is regulated and how this could change further. The Act heralded a step change in the regulation of human tissue. One of the founding principles of the HTA and its regulatory approach is the need for proper consent in the removal, use and storage of human tissue, cells and organs. Whilst the use of human tissue, cells and organs have changed the importance of consent remains a core principle in our approach and our goal to provide public trust and confidence.

We set and oversee the required standards through our regulatory approach and licensed establishments must ensure their policies, procedures and practices are compliant. If we find shortfalls in practice, we will be open and transparent in our findings and the steps being taken to achieve compliance. The complexity of activities particularly in the research and human application sectors means we are not regulating in isolation. Collaborating with other regulators and assessment bodies helps ensure that any framework is proportionate, supports the achievement of set standards and does not hinder or stifle innovation or development.

Our strategic ambition for 2027

We are ambitious for the valuable work and impact of the HTA. We have and will continue to embrace the Better Regulation Framework through a proportionate, risk-based approach in the sectors that is focused on achieving the best outcomes. We will provide wider support to these sectors and the NHS to identify performance issues and solutions. We remain steadfast to our vision and mission and committed to delivery because we believe our work brings great value to the public.

Vision

Our vision for the sector is the safe and trusted use of human tissue.

Mission

Our mission is 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.

Our strategy takes account of known **drivers for change**, derived from horizon scanning and collaborative engagement. We understand important changes may occur after the strategy has been finalised, which could affect our priorities. Therefore, it is essential to remain flexible and establish internal processes for the Board and senior management to regularly assess our direction and priorities. Issues that we recognise have an influence and impact include:

- Frameworks aimed to better regulation and greater efficiency and effectiveness.
- Legislative change, for example, the recent changes to section 32 and 33 of the Human Tissue Act (2004)
- Potential changes to the management of the deceased which could impact our codes and standards and the wider sector as a whole.
- Increases in the number of police referrals concerning possible illegality in respect of organ donation.
- The advantages available through greater collaboration between public bodies and the benefit of effective engagement with license holders.
- New scientific and technological advances are creating possibilities that were not there before.
- Technical advances which we can use, primarily in data, digital and intelligence but other areas too, which we can usefully harness to help us do our job better.
- Workforce changes that continue to evolve in a hybrid working environment where many of our front-line staff spend a large proportion of time onsite in licensed establishments.
- The value and impact of regulation activities by stakeholders from the different types of assessment to the provision of advice and guidance.

Taking account of these drivers, it is our **strategic intention** that by 31 March 2027 we will be:

1. **Further recognised across the health and wider systems** as having a valuable role in the regulation and growth of life sciences. We lead the collaboration and holistic working that promotes trust and confidence. Professionals and the public are assured on the safe and trusted use of human tissue and cells.
2. A **more outcome focused and proportionate** regulator with the ability to comment authoritatively on the totality of our insight, quantify our impact and demonstrate our value. We use our expert voice to be open about challenges in sectors and lever improvement and change on areas of concern.
3. Providing greater **consistency and evidence-based** assessment of risk and action taken. Our actions help to anticipate and identify actual and early warning signs of shortfalls in expected practice. We openly bring about change with any remedial action being timely, responsive to risk and impactful. Our commitment is unwavering in the safe use of human tissue.
4. Less reliant on manual processes by **strengthening digital capacity and capability in ways of working** to support a future, sustainable operational excellence.
5. Demonstrating an ongoing commitment to **investing and developing its workforce. Staff have the technical expertise and capability** to deliver open and credible regulation. We demonstrate we are resilient, responsive, efficient and effective, with a strong reputation as an expert regulator with great staff.

Over the next three years our annual business planning process will focus on delivering this ambition with each year's plan taking us on the next step of the journey.

Our four **strategic priorities** for 2024 to 2027 are:

1. **Approach to regulation**

2. **Trust and confidence**

3. **Use of information**

4. **Efficient and effective**

1. Approach to regulation

We are continually looking at how we can develop and adapt our approach to regulation including opportunities to collaborate with stakeholders. We are developing proportionate and bespoke tools for the regulation of human tissues and cells. We are confident in our delivery of regulation, using our expertise and knowledge to seek assurance of compliance with sector-based standards and the HTA's Codes of Practice.

Our ambition:

- We continue to develop, strengthen and deploy the **full scope of our regulatory tools and activities** to ensure standards on the safe use of human tissue are embedded. We drive up standards, actively support innovation and address shortfalls in practice.
- We maintain our **statutory obligations** and are responsive to new and emerging uses and technologies involving human tissue.
- We **target resources, skills and action** to anticipate and respond to risk, strengthen public confidence.
- We are **proactive** in our engagement, understanding and preparedness for new practices and activities.
- We are **authoritative** when providing accurate and expert advice, guidance and insight to a wide range of stakeholders, including the public.

We will measure success through:

- Ensuring our assessments are proportionate, and account for the complexity and inherent risk of each sector and the insight gained from early warning that standards are not being met.
- The range of tools we use to determine compliance with standards. The deployment of different assessment models acting as a proxy to the effective management of risk and the responsiveness of our approach and interventions.
- Provision of advice and guidance to inform and lever improvements and the reassurance that standards are not only met, but they are also maintained by licensed establishments.

2. Trust and confidence

Stakeholders (professional and public) value our role and activities in the safe use of human tissues and cells. As an organisation we aim to maintain, own and be recognised as the expert and authoritative voice on all aspects of the use of human tissue, cells and organs.

Our ambition:

- We are seen as a **trusted and expert voice** in the current and future use of human tissue.
- We use our credibility with stakeholders and public to **shine a light on performance and practices** in the sectors that we regulate.
- Our work is underpinned by principles of **equality, diversity and inclusion**. We encourage the sectors we regulate to respond to the needs of the populations they serve.
- Our leaders are confident and able to **speak openly with authority and credibility** about the system we regulate, our role and impact.
- We continue to be **open and transparent** and collaborate with others in the system to improve the experience of those we regulate.

We will measure success through:

- Being able to quantify and articulate our impact through responsive actions and interventions. The proactive application of our insight drawing on data, intelligence and our expertise.
- Real life examples and case studies that show t changes and improvements driven by HTA action. These will be highlighted through an annual review.
- Working in partnership with stakeholders on issues that resonate with establishments and continue to strengthen our credibility in the regulation of human tissue and associated activities.

3. Use of information

Information and data from a range of sources provides valuable insight into risk and opportunities for improvement. Our aim over the next three years is to strengthen our use of information and intelligence, drawing on the insight it provides. This will help us to be more responsive and targeted in our regulatory activity, in highlighting opportunities to be more efficient and lever changes in performance and practice.

Our ambition:

- We draw on data and information from across the system to provide **insight on the significance of themes** and trends arising from our approach. We play this back to the sectors we regulate to drive whole system improvements.
- We optimise the use of information in our regulatory approach by developing and refining **new and existing evidence-based indicators of risk**.
- We use data and information from a **range of sources to understand our impact** and use this to inform and direct continual improvement in our operations.
- We improve our systems to make it easier to **interrogate and use the information, data and records** we hold to inform our decision making.
- We **strengthen our capacity, capability and confidence** in the use of new and emerging technology.

We will measure success through:

- The publication of data to promote openness and transparency in our activities. The opportunity for collaboration and consideration of additional insight and interpretation of our findings.
- The opportunity to consider and deploy different assessment processes across the breadth of our regulated activities to demonstrate a responsiveness to risk. The proactiveness to early interventions including changes to our standards. The provision of a balanced and objective view on the current and future use of human tissue including cells and organs.
- Investment in technology capacity and capability to enable a more intelligent use of the wealth of information, data, and insight that the HTA holds.

4. Efficient and effective

We are committed to continuing to deliver trust and confidence to the public and professionals in the regulation of human tissues and cells through what we do, when we do it and how we do it. We recognise and value the importance of continual review and learning related to how we work and the impact we have. The HTA does not stand still.

Our ambition:

- As an organisation we are focussed on delivering **effective outcomes** aligned to the ongoing use of human tissues and cells.
- We strive to operate in the most efficient and effective way, maintaining an **evidence based** positive impact on the regulation of human tissues and cells.
- We **invest in our people, systems and processes** to ensure we have the necessary skills to remain responsive to change and support the delivery of a shared vision.
- We will **use information from across the business** to identify opportunities for improvements and target investment and resourcing in all our activities.
- We are committed to ensuring our activities are **impactful**. We understand the current and future practices of the sectors we regulate and identify priority areas of focus through robust planning.
- We have **reduced our carbon use** and waste and support our people to do the same. We understand the need to deliver in a sustainable way and support net zero goals.

We will measure this through:

- The resilience of our operations and delivery against our key performance indicators (KPIs).
- Our assurance framework and internal and external accountability to our Board and our sponsor team at the DHSC.
- A published annual review that will summarise our activity and impact and encourage reflective based learning on our strengths and opportunities for further improvement or focus.

Our Strategic Approach – how we will deliver

Annual Business Planning

Our annual business planning process will provide the vehicle for delivering our three-year strategy. Our business planning process consists of an iterative cycle taking the strategic objectives for the coming year as our starting point. It maps out how we intend to deliver these objectives through effective and efficient core operations and dedicated change activities. We will continue to use active portfolio management to deliver, manage and report on our business plan during the year in question.

As a small regulator with a broad remit spanning six sectors, we optimise resources and opportunities available to us to ensure we remain proportionate and responsive to new and emerging activities and areas of risks in the sectors and activities that we regulate. Based on experience and the inevitable uncertainties, we will rely on our principles and values to help navigate a path that maintains a focus on our overall goal.

Our Guiding Principles

In developing our new Strategy, we used our experience and learning from the past to inform our priorities and importantly how we work together and with stakeholders. As new and emerging practices involving the use of human tissue are identified our guiding principles remain relevant. The principles will continue to drive our work and underpin our regulatory framework. They are:

- **Consent** and the wishes of the donor.
- **Dignity** is paramount in the treatment of human bodies and tissue.
- **Quality** must underpin the management of human bodies and tissue.
- **Honesty and openness** are the foundation of how we approach our work.

Our Values

Our values define how we work and the integrity and behaviours that stakeholders can expect from us when working together. We will make the following values visible and recognised in our delivery:



Collaboration

We work together to achieve a common goal whilst seeking and valuing diverse perspectives. We share ideas and best practices, striving for excellence collectively. Through active listening and teamwork, we promote a culture of collaboration and cooperation.



Openness

We aim to work transparently, with integrity and accountability for our actions and decisions. Embracing change, we take responsibility and remain honest in our interactions, fostering a culture of boldness and candid communication.



Respect

We respect the diversity of people and value their perspectives, professionalism and skills. Fostering trust and promoting autonomy in decision-making. We will challenge unprofessional behaviour while actively listening and being respectful of others' viewpoints.



Excellence

We strive to deliver excellence through expertise, leadership and collaboration. We are committed to personal and professional development, coaching colleagues, and fostering a culture of learning and growth.

We will lean heavily on these values to realise the ambition that we have set and the successful delivery of our goal to maintain public trust and confidence.

Longer term strategic vision

In reviewing and updating our strategic direction we have been struck by the pace of change in life sciences and the challenges that some of the sectors that we regulate are facing relating to workforce, ongoing investment in compliant facilities, changes to legislation and the pressure to maintain standards. We recognise the NHS is one part of the system that has experienced these pressures. The HTA is ready to support improvements in performance through regulatory activity and working in partnership with the wider health system be that through the authorisation of the use and supply of tissue, cells and organs for life saving treatment to proposing a new duty that respects the dignity of the deceased.

In recent years, our focus has been on shining a light on good practice and shortfalls against required standards. As we move forward, we will use our authoritative voice and the insight from our regulation and stakeholder engagement to lever improvements. Our inspections form a small part of how we regulate and over the next three years the adoption of alternative approaches, the greater use of information and what it tells us alongside a more inquisitive approach will help to strengthen our effectiveness. We will continue to build public and professional trust and confidence in what we do.

We will complete a formal, annual review of our strategy and the progress we are making to achieve our ambitions. This review will inform our priority projects and core activities for the next business year and form the basis of our annual business plan. In addition, we will share our progress against our strategy, using case studies of changes, improvements, and accounts of the impact that we are having.

If you would like to be part of our strategy journey sign up via our website (www.hta.gov.uk) for regular updates via our professional newsletter or follow us on X, LinkedIn and Facebook.