Strategy

2018 – 2021
Executive Summary
This document sets out the strategy for the Human Tissue Authority (HTA). It describes our strategic approach and direction, key challenges and opportunities, our strategic objectives and how we will deploy our resources on the priority areas identified over the next three years.

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HTA STRATEGY: 2018 – 2021
Introduction from the Chair

I’m delighted to have the opportunity to introduce this new strategy from the Human Tissue Authority, especially one that outlines such bold aspirations.

The HTA’s Strategy 2018 – 2021 establishes the Authority’s overarching approach and objectives for the next three years. It has been developed following a comprehensive review of the extent to which we achieve our overall aim: that of protecting public and professional confidence in the use of human tissue.

This strategy builds on the aims and achievements of the Strategy 2016-2019 and, of course, the lessons learned from over a decade’s experience of regulating organisations that work with human bodies, organs, and other tissue. Above all else, it seeks to mould the HTA into a more sustainable, resilient, and agile regulator; one that is aligned to the needs and demands of the ever changing environment in which we operate. Finally, it responds to the outlook of the wider public, who justifiably expect assurances as to how human tissue is treated and used.

In order to maintain public confidence in the system, and to ensure we remain an effective regulator, we must reflect and react to the speed of change and innovation of science and technology across the areas we regulate.

This is especially critical in the field of life sciences, where Britain is a world leader. The Government’s Industrial Strategy has singled out life sciences for an ambitious programme of investment and innovation and the HTA has a crucial role to play in this. Through its agile and responsive approach we must maintain oversight on the quality and safety of cells and tissue, and act to enable, rather than hinder, safe and ethical innovation.

It is clear from the comprehensive review recently conducted by the HTA that the clarity and certainty created by an effective, right touch regulator plays an essential role in unlocking investment and growth in innovative sectors. Our new Codes of Practice are central to this mission.

The fundamental principle of consent is central to our work, and our guiding principles continue to underpin our regulatory framework. In addition to our statutory role, we are increasingly called upon to provide guidance on areas related to our remit, but not specified under the Human Tissue Act. This is particularly important in areas of emerging technology and cutting-edge research that was not originally envisaged when the HTA was established.

One year on since we launched our new Codes of Practice, we would urge anyone working with materials originating from people, whether their work falls under the remit of HTA legislation or not, to read our Code of Practice A: Guiding Principles and the Fundamental Principle of Consent.

We have a strong track record of working closely with partner organisations, and the positive feedback we have received from our licence-holders is testament to our collaborative approach. As are our dedicated and expert staff, who are the ones that will drive and implement this strategy, ensuring its success. That is why this strategy also emphasises both how we recruit and retain high quality staff to undertake and oversee this crucial work and the need to undertake digital transformation at the HTA so they have the information and resources they need.

I look forward to continuing to build on our previous successes in my first year as Chair.

Nicola Blackwood
Chair of the Human Tissue Authority
About the HTA

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

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

We also have a role in maintaining professional confidence; by assuring that human material being used by professionals has been obtained with the proper consent and is managed with appropriate care.

Our role

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the EU Tissues and Cells Directives (EUTCD);
- We license organisations involved in organ donation and transplantation as required by the EU Organ Donation Directive (EUODD);
- We monitor and inspect or audit organisations to ensure they comply with the requirements of the legislation and our Codes of Practice;
- We use our powers to take regulatory action where we identify non-compliance;
- We assess living organ donations to ensure donors are protected from duress or coercion, and that no reward is offered or given;
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit;
- We monitor developments relating to activities within our remit and advise Government on related issues.

In addition to our statutory role we are increasingly called upon to provide advice on areas related to, but not specified in, our legislation. This is particularly important in areas of emerging technology and cutting-edge research not originally envisaged when the Human Tissue Act was enacted.

Our remit

- Removal, storage and use of human tissue and organs for a number of activities and scheduled purposes as set out in the Human Tissue Act 2004, such as post-mortem examination, anatomical examination, research, transplantation and public display;
- Procurement, testing, preservation, processing, storage, distribution, import and export of tissues and cells for use in patient treatment (human application);
- Donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of organs for transplantation.

Our remit under the Human Tissue Act 2004 extends to England, Wales and Northern Ireland; however, we also carry out some activities in relation to the approval of living organ donations on behalf of the Scottish Government. Our remit as the Competent Authority for the quality and safety of tissues, cells and organs used in transplantation extends to the whole of the UK.

We license approximately 860 premises across the six sectors that we regulate and publish standards and requirements that those working within the regulated fields must meet.

Whilst the HTA has an influential role in superintending compliance and promoting good practice, public confidence in the use of human tissue cannot be safeguarded by the HTA alone. Public confidence is also dependent on the individuals and organisations that undertake activities within the HTA’s remit acting within the standards and requirements of the legislation.
**Guiding principles**

Four guiding principles continue to drive our work and underpin our regulatory framework. They should be followed in dealing with human bodies, tissue and organs:

- **Consent**
  and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.

- **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 communications in matters pertaining to the use of human tissue and bodies.

**Our values**

Our values as an organisation in carrying out our role, expressed in all external interactions:

- **Expertise**
  Being responsive, providing specialist knowledge

- **Excellence**
  focus on achieving exceptional results and inspiring others to do the same

- **Integrity**
  be trustworthy, honest, fair and consistent

- **Respect**
  have empathy and be impartial; value others’ expertise and experience

- **Transparency**
  be open and collaborative, and involve and communicate effectively

**Key activities**

In our previous strategy, we described our key activities as grouped within three themes:

- **Delivery**
  how we achieve our strategic objectives today

- **Development**
  how we will improve in the future

- **Deployment**
  how we effectively use our people and resources

This strategy continues to build on these themes, with a renewed focus on striving to be a more resilient, sustainable and agile organisation in order to meet the challenges ahead. More detail can be found in the Strategic Approach section of this document.
In preparing this strategy, the HTA has undertaken a fundamental evaluation of the extent to which our current strategic approach protects public and professional confidence in the proper use, and quality and safety of, human tissues, cells and organs. We based this evaluation on evidence and analysis from a variety of sources, including the views of those working in establishments we regulate, a new evaluation of public opinion, analysis of the data we hold and the views and opinions of HTA staff and Authority Members.

As a statutory body, our aim remains unchanged. As such, our review focussed on evaluating our future operating environment and whether our resources are optimally aligned to where the risks are greatest.

An assessment of the evidence provides us with great reassurance that both the public and professionals think we are on the right track with our regulatory approach. However, the review identified a number of opportunities and challenges relating to our future operating environment that will require us to adapt as an organisation.

The pace of innovation in cell, tissue and organ based therapies, in life sciences research, and the use of imaging and artificial intelligence in pathology, all have the potential to impact hugely on the way the sectors we regulate work. Many of these developments were unforeseen when the legislation was framed, and we need to be realistic about the limited opportunity for legislative change.

As one of the regulators operating in the field of life sciences, we are clear that effective, right-touch regulation can make a positive contribution to patient outcomes and economic growth. We are determined to play our role in the ambitious plans set out by the Government through the Industrial Strategy, as well as potential changes to organ donation policy and the outcomes of the UK’s exit from the European Union.

We recognise that our staff are our key asset – their skill and dedication lie at the heart of our organisation - and therefore staff recruitment and retention contribute significantly to our strategic risk. As the regulator of six increasingly complex and diverse sectors, and with continued pressure to control our resources, we are acutely aware of the demands this can place on our staff.

This strategy is therefore focussed on the steps we need to take over the next three years in order to operate in a more sustainable way by 2021, building in greater resilience and agility in the face of increasing complexity and uncertainty in our external environment.

**Sustainability**

By sustainable, we mean taking a new approach to recruiting and retaining high quality staff and working in new ways to reduce the growing pressures on the staff we have.

**Resilience**

By resilience, we mean adapting our operating model to retain staff for longer and developing strategic alliances with other organisations to put us in a better position to manage unexpected demands.

**Agility**

By agility, we mean providing a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells, burnishes our reputation as an expert regulator and actively supports the Industrial Strategy for Life Sciences.

Year 1 of this strategy represents a transition between the previous 3 year strategy and the new priorities. Our 2018/19 business plan will therefore reflect the trade-offs between current and emerging business needs.
In order to meet the challenges ahead we require a fresh focus on our:

**People**
Recognising our staff as our key asset, widening the pool of candidates for recruitment and investing in training and development;

**Business Technology**
Ensuring our systems are not reliant on location and making strategic choices about key business systems;

**Information and data**
Meeting our obligations relating to data security and using information and data as a key strategic resource;

**Finance**
Being clear about managing our fee levels based on workload and regulatory effort, including longer term planning to ensure continued financial viability.
Our Strategic Approach

The HTA has never been an organisation to stand still, and is continually looking for ways it can enhance public confidence, better target our regulation and adapt as an organisation.

Our strategic approach is based on right-touch regulation. This means being clear on the risks we are regulating, being proportionate and targeted in regulating those risks, taking into account the role of professional bodies and other regulators, and using the minimum necessary regulatory force to achieve compliance and improvement.

Effective communication is also critical to our strategic approach to ensure that professionals can access advice and guidance from us, and that the public is clear on what they should expect from us and the areas we regulate. How we do this in our daily operation is described in the Delivery section of this strategy.

The HTA has never been an organisation to stand still, and is continually looking for ways it can enhance public confidence, better target our regulation and adapt as an organisation. The Development section of the strategy describes the renewed focus for our development goals during this strategic period to ensure sustainability, resilience and agility in addition to continuing our program of continuous improvement.

Neither Delivery nor Development is possible without resources. The Deployment section of the strategy describes how we lead, manage and develop the HTA’s people, how we raise and use our finances and our plans for accommodation and other key assets.
Our objectives are therefore grouped into three themes. All of these aspects will require a careful balance to make the most of our limited resources and ensure success in delivering our overall aim.

**Delivery**
To deliver the right mix of operational activity to maintain public and professional confidence

**Development**
To make the right investment to continuously improve delivery and deployment

**Deployment**
To make the most effective use of people and resources in pursuit of our goals
Our regulatory approach aims to be right-touch and in line with the principles of better regulation and the Regulators’ Code. This means that we primarily focus our regulation and resources on areas that involve an inherently greater risk to patient safety and public confidence if standards are not maintained.

We employ a range of regulatory tools in order to ensure compliance with the legislative requirements, including licensing, inspection, reporting requirements and the provision of advice and guidance.

**Licensing**

The legislation prescribes certain activities that can only be undertaken by a licensed establishment.

We license establishments across six sectors:

- Post Mortem, Public Display, Research and Anatomy (under the Human Tissue Act 2004)
- Human application – tissues and cells used in patient treatment - (under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which implement the EUTCD)
- Organ Donation and Transplantation (under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, which implement the EUODD)

The establishments we license must adhere to our standards, which align to our core principles.

**Inspections or audits**

We conduct site visits of licensed establishments in order to assess whether our standards are being maintained. We schedule inspections based on a number of factors, including the legislative requirements, and according to the risk of the activities being carried out. We welcome the significant degree of trust that the vast majority of our licensed establishments have in us, as demonstrated by their openness and willingness to improve, which we believe is a key factor in the high level of compliance we see. As a result we only use significant regulatory action when it is appropriate and in the public interest.

We also undertake non-routine inspections, both announced and unannounced, when we have information which indicates that a site visit is required.

**Reporting requirements**

We require incidents and events which pose the highest risk to public confidence and patient safety to be reported to us by licensed establishments. This reporting, along with issues and complaints about licensed establishments that are raised with us by third parties, allows us to take action if required. We also use the insight gained from investigations to share learning with those we regulate.

**Advice and guidance**

We place a great emphasis on providing advice and guidance to both the public and professionals, and recognise the value in supporting establishments to comply, rather than dealing solely with non-compliance. We publish a range of sector specific advice and guidance, as well as answering individual enquiries from establishments and members of the public. We also provide advice and guidance as part of our inspection reports.

**Living donation assessment**

The HTA maintains a system to ensure that donations of organs or tissue for transplantation from living people are given without coercion or reward. The system relies on donor and recipient interviews, undertaken by a group of independent and accredited assessors. They are predominantly volunteers whom we train, accredit and support in order to fulfil our statutory functions, and to whom we offer our thanks and appreciation. Complex cases are reviewed by panels, made up of HTA Authority Members.

**Communication and engagement**

We recognise communication as a key component of effective regulatory delivery. We utilise a range of channels to communicate with professionals, the public and key stakeholders to ensure that there is confidence in HTA regulation and in the services being regulated. We involve these groups to ensure we make decisions that take into account, as far as possible, the operational realities faced by professionals and the concerns of the public. Our formal groups, which report to the Authority include:
as a key tool for achieving benefits for professionals and the public that produces joined up results, reduces our costs or reduces regulatory burdens. The HTA has bilateral agreements with the following:

• The Care Quality Commission;
• The Health Research Authority;
• The Human Fertilisation and Embryology Authority;
• The Medicines and Healthcare products Regulatory Agency; and
• The United Kingdom Accreditation Service.

Working with other organisations
Many of the establishments within our remit are also regulated or accredited by other bodies. We continue to see collaboration as a key tool for achieving benefits for professionals and the public that produces joined up results, reduces our costs or reduces regulatory burdens.

Delivery objectives
Our delivery objectives are:

• Deliver a right touch program of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety;
• Deliver effective regulation of living donation;
• Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;
• 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;
• 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;
• Maintain our strategic relationships with other regulators operating in the health sector.

In the period covered by this strategy, we will:

• Ensure that new applications meet appropriate standards before issuing a licence;
• Use our knowledge of risk in each sector to drive the delivery of the right mix of regulatory tools to support compliance;
• Undertake a risk-based program of site visits which provide assurance that standards are being maintained;
• Publish exception-based reports of inspections in the interests of transparency and to share learning;
• Take a proportionate and risk-based approach to non-compliance, and ensure that where there are shortfalls against standards, these are rectified within agreed timescales;
• Ensure decisions on living organ donation cases meet agreed service standards in a way that provides the necessary protections;
• Engage with, and involve, public and professional stakeholders in our work using a wide variety of channels;
• Use the results of our public evaluation to create awareness of what drives public confidence, what the public are most interested in, and why;
• Seek out opportunities to build new collaborations for the benefit of stakeholders.
Development

To ensure that the HTA’s regulatory approach remains relevant, we actively prepare for the future. We do this through our development activities. As outlined in the Strategic Review section, in this three year period our development goals will focus on building our resilience, agility and overall sustainability as an organisation in addition to maintaining our programme of continuous improvement activity.

Innovation
We see innovation across all the sectors we regulate and actively horizon scan to keep abreast of developments to inform our work, often in collaboration with other organisations. The pace of change requires a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells.

Where emerging issues can be accommodated within the current regulatory framework, we will work to achieve this with agility, proportionality and appropriate assessment of risk. Where they cannot, we will advise relevant Government, professional and public stakeholders, and actively consider the use of soft law tools where this is appropriate.

In the Human Application sector, we will continue to work closely with the Medicines and Healthcare products Regulatory Agency and other regulatory bodies on the Regulatory Advice Service for Regenerative Medicine (RASRM), which we see as a key foundation for the future regulation of novel tissue and cell therapy based products. We will further strengthen our regulation through implementation of the recommendations from our recent review of risk in the Human Application sector.

In living organ donation, we are seeing increasingly complex cases and wider use of the UK living kidney sharing scheme, placing pressure on staff resource. The sustainability of the Independent Assessor framework remains a significant strategic issue, and we have undertaken a project to review options for putting this on a more sustainable footing, with a view to implementation during 2018/19.

Improving compliance
Although in general we see a high level of compliance in our establishments, we have recently seen a number of issues emerge which have had an impact on the number of shortfalls we find. We will use the data and information we hold, and our close links with key stakeholders, to implement a targeted approach aimed at addressing these issues.

Better use of data and information
We already use data and information to inform our risk-based approach to regulation. We recognise that we can improve the quality and make better use of the data and information we hold, in order to ensure we identify trends and prioritise and target our resources effectively across the organisation.

Organisational change
In addition to seeking improvements in our regulatory processes, this strategic period will see us invest significant resources in developing our people, business technology and estates planning. Balancing the use of resources for development and improvement against our core delivery activities will mean a greater emphasis on being clear about our priorities, and promotion of a cohesive, organisation-wide approach to addressing key business concerns.

Further details on how we will shape our future approach are described in the deployment section of this strategy.

Influencing others
We will ensure we reflect our experience of regulating our diverse sectors in submissions and dialogue on the future of regulation, particularly in the context of the Government’s Industrial Strategy and EU Exit. We will be available to offer advice and guidance to colleagues across government and beyond as and when it is needed.
Development objectives

Our development objectives are:

• Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;

• Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;

• 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;

• Develop a blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

In the period covered by this strategy, we will:

• Implement the recommendations from our evaluation of risk across the human application sector and amend our approach as necessary;

• Implement the recommendations from the Independent Assessor Sustainability project;

• Continue to work with establishments to ensure as smooth a transition as possible in implementing the EU Coding and Import Directives and any changes resulting from the UK’s Exit from the EU;

• Continue to develop our approach to engaging with licensed establishments as a key tool in ensuring compliance;

• Develop tools to improve how we prioritise and plan our regulatory activities and manage our resources, including more effective use of information and data;

• Continue to upgrade and develop our core business systems, website, and online portal to better meet our business needs and the needs of our stakeholders;

• Continue to use our unique position to advise Government in matters relating to our remit;

• Plan, develop and implement an organisational transformation programme.
Deployment

People
Our staff are our key asset and are fundamental to successful delivery of our objectives. Our staff survey gives us great reassurance that the HTA is a good place to work, but offers insight into areas we can improve. More fundamentally, in order to achieve our vision to be a more resilient and sustainable organisation by 2021, our People Strategy will require a significant review that will also influence our Estates and Business Technology plans.

We will consider options for widening the pool for recruitment outside London and the South East, as well as ways we can remodel our induction and training to allow staff to become competent more quickly and be less dependent on location.

As a small, expert regulator, it is imperative that we retain the specialist skills of our staff for longer, which is challenging with current financial restraints. We will continue to promote work/life balance and flexible working, with a renewed focus on effective line management, training and development to make the best use of our expert resources.

Business technology
Our business technology has never been more crucial to the success of the organisation and underpins much of what we set out to achieve. Our new strategic vision will require development of IT architecture, which is not dependent on location in preparation for a future office move. We will support our staff with the technology they need to work effectively and efficiently, in the office and remotely. We also recognise the opportunities for technology, digital and data to improve the services we offer, reduce burden and target our resources most effectively.

We take our commitment to information and cyber security very seriously, and will strive to meet our obligations under data protection legislation, the National Data Guardian’s data security standards and relevant UK Government cyber security frameworks.

Estates
Our People Strategy, as outlined above will largely drive our approach to estates. We continue to control our accommodation costs as far as possible by sharing office space; however, our current lease expires in 2021 meaning that we need to evaluate future options.

Expanding our workforce outside London and the South East over this period gives us the opportunity to develop as an organisation that works remotely by design, whilst ensuring that our culture and connectivity are maintained. As well as allowing us to increase the geographic pool from which we recruit, this may also produce rental savings that could be reinvested to address emerging business needs.

Finance
The HTA is funded through licence fees and Grant-in-Aid from the Department of Health and Social Care. For a number of years we have worked hard to keep costs down by finding efficiencies, sharing office space and sharing Director and Head posts with the Human Fertilisation and Embryology Authority (HFEA). Our recent review of the arrangements with HFEA highlighted further opportunities to boost the resilience of both organisations by developing a stronger strategic alliance.

We are aware of the budget constraints faced by many of our licensed establishments and remain committed to living within our means. We will also investigate alternative income streams where these align with core business activity, learning from other Arm’s Length Bodies. As part of our sustainability programme, we aim to signal our budget intentions over the next three years, with a view to providing certainty on fee levels for establishments.
In the period covered by this strategy, we will:

- Act on the feedback provided by our staff surveys to address key issues of concern;
- Remodel our training and induction programme;
- Consider the introduction of a new senior inspector role to improve technical development of staff across the organisation, focussing on training others, quality assurance and providing input to development projects;
- Develop more formal arrangements for greater use of home working to support our recruitment strategy;
- Give greater priority to data management and risk, ensuring that we comply with our requirements under relevant Data Protection legislation;
- Give further consideration to alternative and additional income streams;
- Implement the recommendations of the shared services review with HFCA to improve the resilience of both organisations;
- Improve our video conferencing, online meeting and collaboration capabilities;
- Produce an options appraisal for different models of working as an organisation, which puts our staff at the heart of what we do.

Deployment objectives

Our Deployment objectives are:

- Manage and develop our people in line with the HTA’s People Strategy
- 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
- Plan and prioritise our resources to carefully balance activity across the organisation
The Authority is made up of a Chair and eleven Members:

- Nine are appointed by the Secretary of State for Health and Social Care;
- One is appointed by the Welsh Cabinet Secretary for Health and Social Services; and
- One is appointed by the Minister of Health in Northern Ireland.

The Authority is made up of both lay and professional Members and currently includes an organ donor and a transplant recipient. The professional Members of our board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial, academic and public sector experience.

The Authority’s primary role is to ensure that the HTA’s statutory responsibilities are met and discharged effectively. It achieves this by setting the HTA’s strategic direction and providing both support and challenge to an Executive, which is responsible for the delivery of these responsibilities on a day-to-day basis.

Authority members also fulfil a valuable role in contributing to project work and the HTA’s advisory groups, as well as providing counsel on a range of emerging issues. While the Executive implements this strategy by way of business plans, there are a number of mechanisms in place by which the Authority steers, scrutinises and reviews performance.

The Authority holds five board meetings per year, one of which is in public. These meetings provide the opportunity to assess a range of management information and more detailed reports on progress against elements of the strategy. They also allow the Authority to hold the Executive to account for the HTA’s performance.

Standing items reported to the Authority include:

- Chief Executive’s report – to provide an overall assessment of the HTA’s performance and strategic risks.
- Delivery report – to provide assurance on the delivery of regulatory activities.
- Development report – to provide assurance on the delivery of development activities.
- Deployment report – to provide an update on the deployment of resources.

The board meetings also provide the main means by which the Authority sets the direction on issues of strategic importance that emerge over the course of the year.

The Authority is supported in its work by two standing committees:

- Audit and Risk Assurance Committee; and
- Remuneration Committee.

The Executive also holds quarterly accountability meetings with the Department of Health and Social Care to review progress with delivery of key performance indicators and the management of strategic risks.