



Human Tissue Authority  
Business Plan 2012/13

## Contents

---

Human Tissue Authority remit .....	3
Priorities 2012/13 .....	5
Human resources .....	8
HTA in the wider context .....	9
Collaborative work.....	10
Budget 2012/13 .....	11
Efficiency plans .....	12
Baseline Business Plan 2012/13 – Deliverables .....	14

## Human Tissue Authority remit

---

The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health. We were established under the Human Tissue Act 2004 (HT Act), which covers England, Wales and Northern Ireland, to regulate activities relating to the removal, storage, use and disposal of human tissue. Our overall strategic goal is to maintain and build confidence in these activities by ensuring that they are undertaken safely and ethically, and with proper consent.

The HTA has a number of statutory functions. We inform the public, professionals and the Secretary of State for Health about issues within our remit. We meet this requirement for professionals by providing guidance, including codes of practice; and for the public by providing information to help them make informed decisions.

We license more than 800 organisations that store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We also publish standards that licensed establishments must meet: on consent; governance and quality systems; premises, facilities and equipment; and disposal. We also inspect organisations to check that they maintain good standards and follow appropriate procedures.

As well as licensing under the HT Act, the HTA is the Competent Authority in the UK responsible for ensuring the safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive. We have also been designated as the Competent Authority for the European Union Organ Donation Directive, which is expected to be transposed into UK legislation in August 2012.

The HTA also regulates, through an independent assessment process, the donation of solid organs from living people, ensuring that valid consent has been given and that no reward is sought or offered. We fulfil a similar role for living donation of bone marrow and peripheral blood stem cells from children and adults who lack the capacity to consent. The HTA regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

## Human Tissue Authority remit

---

The HTA also oversees the consent requirements of the HT Act for deceased organ donation.

The Authority – the HTA’s non-executive board – comprises a Chair and Members who are appointed by the Secretary of State for Health. Its primary role is to ensure that the HTA’s statutory responsibilities are met. It achieves this by setting the HTA’s strategic direction and providing both support and challenge to an Executive which is responsible for the discharge of these responsibilities on a day-to-day basis.

This document should be read in conjunction with the Strategic Plan 2012/13 to 2014/15, which sets detail of the HTA’s strategic aims and high level business objectives for the three year beginning April 2012.

## Priorities 2012/13

---

With the interests of both the public and those we regulate at the centre of our work, our overall strategic goal is to maintain and build confidence in the removal, storage and use of human tissue by ensuring that these activities are undertaken safely and ethically, and with proper consent.

Public and professional confidence in the regulation of human tissue is central to our success: building it must shape our day-to-day work, and protecting it is our first priority during the transition to new organisational arrangements resulting from the arm's-length bodies review.

Putting in place the regulatory framework to support the EU Organ Donation Directive is the HTA's most significant change project during 2012/13. The exact shape of this framework will evolve over the business year, for example as a result of stakeholder consultation. Consequently the HTA has had to make a number of assumptions, in particular around costs and fees, which may need to change in-year.

Set out below are the strategic aims, high level objectives and key milestones for 2012/13. This is supported by the Baseline Business Plan 2012/13 – Deliverables (see page 14), which sets out the HTA's key performance indicators and wider performance indicators for this period.

### Aims, objectives and milestones 2012/13

#### Strategic Aim One: To improve the efficiency and effectiveness of our regulatory activity, and our advice and guidance

High level objectives 2012/13:

- a. To fulfil the HTA's statutory remit
- b. To share knowledge and experience gained from regulation and to help licensed establishments better meet HTA quality standards
- c. To improve our processes and practices and collaborate with other bodies to reduce regulatory burden and improve the impact of our work.

During 2012/13 we will:

- Undertake at least 180 site visit inspections
- Ensure that where there are shortfalls against standards these are rectified within agreed timescales
- Implement the regulatory framework to support the Organ Donation Directive by August 2012
- Reach decisions in living organ donation cases within 5 working days for straightforward cases and 10 working days for panel cases

**Strategic Aim Two: To ensure appropriate and effective relationships in our changing operational environment**

High level objectives 2012/13:

- a. To maintain and build confidence amongst professionals and the public in the regulation of the removal, storage and use of human tissue
- b. To work collaboratively during organisational transition to ensure that confidence in regulation is maintained and that human tissue continues to be removed, stored and used safely, ethically and with proper consent
- c. To manage the reputation of the HTA effectively
- d. To engage stakeholders to inform regulatory and organ donation policy and processes

During 2012/13 we will:

- Deliver a programme of engagement activity with the public and patient groups to improve confidence in HTA regulation
- Collaborate with professional stakeholders and partner organisations to improve confidence in our work
- Develop and begin to implement our digital strategy

**Strategic Aim Three: To have a skilled, motivated and dedicated team equipped to do the job in a challenging transitional period**

High level objectives 2012/13:

- a. To further improve the HTA's working environment and culture to retain staff and uphold the HTA's standards and values
- b. To lead, motivate, involve and inform colleagues to deliver excellent work

- c. To attract and retain the right people with the right skills
- d. To improve expertise and support delivery through high quality learning and development

During 2012/13 we will:

- Recruit the right people to fill our essential jobs
- Deliver a high quality learning and development programme
- Engage staff to further improve the HTA as a place to work

**Strategic Aim Four: To ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the tax payer**

High level objectives 2012/13:

- a. To maintain governance arrangements which give appropriate oversight to matters within the HTA's legislative remit
- b. To maintain high quality management skills and practices
- c. To maintain and improve cost-effectiveness and quality by systematically reviewing systems, processes and procedures
- d. To ensure the continued financial viability of the HTA.

During 2012/13 we will:

- Manage HTA finances to ensure that spend does not exceed £4.7m
- Deliver our agreed efficiency plan
- Initiate a project to introduce any necessary organisational changes stemming from the Government's review of arm's-length bodies.

## Human resources

---

### Headcount 2012/13

Full time equivalents (FTEs)

	Q1	Q2	Q3	Q4
Starting count – payroll	44	44	44	44
Starting count – non-payroll	2	2	2	2
Expected transfers in – payroll				
Expected transfers out – payroll				
Changes in non payroll staff				
TOTAL at end quarter	46	46	46	46

There are no expected reductions from natural wastage and redundancy.

### Human resources risks

The HTA manages a number of strategic risks, one of which is related to the inability to carry out our statutory remit. The key factor underpinning this risk is the availability of a suitably qualified and experienced workforce to undertake our frontline regulatory work.

In the 2011/12 business year, the HTA lost around 40 per cent of its Regulation Managers, who carry out inspections and provide expert advice and guidance to our regulated sectors. Analysis from exit interviews has shown that the primary cause of staff departures is the pay structure in place at the HTA and the public sector wide pay freeze, which the HTA started in August 2010. Leavers are reporting that changing jobs is the only way to achieve higher pay.

The HTA has reduced its workforce over the last two years to a level with little or no scope for discretionary activity. From this position, the loss of the skills and experience of any individual member of the HTA team poses a potential risk to the delivery of this business plan.

The HTA has in place a range of contingency options which cover both staff losses and other situations where risks are realised.



## HTA in the wider context

---

### HTA contribution to the Structural Reform Plan

The Department of Health's Structural Reform Plan set out five priority areas for reform:

- A patient-led NHS
- Shift focus and resources towards better healthcare outcomes
- Revolutionise NHS accountability
- Promote better public health
- Reform social care

The HTA contributes directly to three of these.

**A patient-led NHS** – Consent and engagement are central in ensuring patients and the public can make informed decisions, are aware of choices available to them, and have a say in the services they receive. The concept of “no decision about me without me” is a key principle within the Government's reforms. Ensuring that organs, tissues and cells are removed, stored and used with informed consent links all of our regulatory activity.

**Shift focus and resources towards better healthcare outcomes** – We are part of a value chain which ensures the quality and safety of tissues and cells used for patient treatment, so contributing to improved healthcare outcomes. This will also apply in our regulation of the quality and safety of organs for transplant.

In the broader context, increasing our direct contact with the public will increase awareness of the sectors which we regulate and the activities they undertake. This may in turn have beneficial healthcare outcomes, for example, through advances in medical research which can come from consented post mortems.

**Revolutionise NHS accountability** – The structural reform plan commits the Department of Health to the review and reform of arm's-length bodies. Our business plan commits us to working with the Department to deliver the necessary changes resulting from its consultation on the transfer of the HTA's functions.

## Collaborative work

---

Collaboration has always been a key theme for the HTA and we are committed to working in collaboration with partners in the health sector and with the public as a whole. Here we set out examples of our planned future collaboration for 2012/13.

- Participating in a Joint Working Group with the Care Quality Commission and Human Fertilisation and Embryology Authority to share intelligence on establishments and streamline our approach to inspections. We are also working with Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority (Northern Ireland) to achieve similar outcomes.
- Research sector: we will work closely with the new Health Research Authority to provide a single point of access for researchers that retains all the strengths of the current systems, and fully meets the requirements of the legislation.
- Post mortem sector: we will continue to work closely with the Royal College of Pathologists and others via our Histopathology Working Group, to ensure that our regulation is responsive to the needs of the sector whilst maintaining public confidence. In doing so, we will pilot a programme of information sharing and joint inspection activity with Clinical Pathology Accreditation.
- Tissue and cells for patient treatment (human application) sector: working closely with the Medicines and Healthcare products Regulatory Agency to deliver joint inspections of the establishments licensed by both organisations for development of Advanced Therapy Medicinal Products.

## Budget 2012/13

---

The HTA receives funding from two main sources. The majority comes from licence fees, with the balance coming from our sponsors, the Department of Health. We also receive a small amount of further income for undertaking activities on behalf of the devolved administrations.

The licence fee income pays for a wide variety of activity associated with our regulatory remit from evaluating licence applications, making licensing decisions and issuing licences, through to site visit inspections and providing advice and guidance to licensed establishments.

We place great importance on ensuring that our finances are managed efficiently, effectively and in a way which minimises risk.

The high level budget for 2012/13 is shown below.

<b>Income</b>	<b>£000s</b>
Department of Health funding	859
Licence fees	3,723
Other income	100
<b>Total income</b>	<b>4,682</b>
<b>Expenditure</b>	
<i>Operating costs, of which</i>	
Staff costs	2,678
Other operating costs	1,552
<b>Total operating costs</b>	<b>4,230</b>
Capital charges	452
<b>Total revenue expenditure</b>	<b>4,682</b>

## Efficiency plans

An aim of the HTA's strategic plan is to "ensure the HTA is effectively governed and managed efficiently, providing value for money for licensed establishments and the tax payer". High level objectives include:

- To improve our processes and practices and collaborate with other bodies to reduce regulatory burden and improve the impact of our work
- To work collaboratively during organisational transition to ensure that confidence in regulation is maintained and that human tissue continues to be removed, stored and used safely and ethically, and with proper consent
- To maintain and improve cost-effectiveness and quality by systematically reviewing systems, processes and procedures

The HTA has identified and made changes to make efficiency savings of 27% from 2010/11 to 2012/13. Grant-in-aid has reduced by 10% in both 2011/12 and 2012/13. We have reduced licence fees over the same period by making further efficiencies that enable us to manage with 29% less income from licence fees. The HTA envisages making savings of at least 30% from the budget in the baseline year 2010/11 to 2014. Staff numbers would reduce by at least 34% from the agreed staff complement of 67.

### Summary efficiencies to date and planned

£000s				
Year	Staff numbers (FTE)	Costs (staff and other)	Fee income	Grant-in-aid
2010/11	58 (average)	6,393 budget, 5,337 actual	5,234 budget, 4,246 actual	1,059
2011/12	50 at 1/4/11, 48 average expected	5,038 budget, 4,317 forecast	4,028 budget, 4,039 forecast. Unused licence fee will be credited to establishments.	954
2012/13	46	4,682	3,723	859
2013/14	44	4,500	3,627	773

The HTA's detailed efficiency plan summarises the further refinements we plan to deliver our work, whilst maintaining efficiency in the coming years. We expect Grant-in-aid to reduce further (by a total of 33% over three years from the 2010/11 level) and it is important to keep licence fees as low as possible, recognising that licensed establishments live in challenging financial times. At the same time we must continue to be an effective regulator.

The plan states our commitment to working collaboratively with other regulators and the Department of Health, to reduce costs where possible and to realise benefits for those we regulate and to deliver better regulation. The HTA's functions are expected to transfer to another body, or bodies, by 2015, following the Department of Health's consultation.

# Baseline Business Plan 2012/13 – Deliverables

Unique Ref	Strategic aim ref	Corporate business objective	Performance indicators
<b>1. To improve the efficiency and effectiveness of our regulatory activity, and our advice and guidance</b> <b>a. To fulfil the HTA's statutory remit</b> <b>b. To share knowledge and experience gained from regulation and to help licensed establishments better meet HTA quality standards</b> <b>c. To improve our processes and practices and collaborate with other bodies to reduce regulatory burden and improve the impact of our work.</b>			
KPI 1.1	a	To license establishments regulated under the Human Tissue Act, the Quality and safety (tissue and cells) regulations and Quality and safety (organs) regulations	At least 90% of completed applications to vary a licence are processed within 20 working days of receipt (reported quarterly)
PI 1.1	b,c	To review and improve regulatory processes as part of an ongoing programme of quality improvement	100% of regulatory policies and SOPs to be reviewed according to the documented review cycle.
KPI 1.2	a,b	To inspect establishments regulated under the Human Tissue Act, the Quality and safety (tissue and cells) regulations and Quality and safety (organs) regulations	At least 77 inspections of human application establishments to take place during the business year, ensuring EU requirements are met (reported quarterly against profiled inspections).
PI 1.2			At least 180 inspections to take place during the business year across all sectors
PI 1.3			An overall response rate of at least 50% of establishments completing post-inspection surveys (reported quarterly).
KPI 1.3			At least 80% of responding establishments rate the overall inspection process as either 'good' or 'excellent' (reported quarterly)
PI 1.4			At least 80% of responding establishments agree with the post-inspection survey question "Has the inspection process helped improve the way you work?" (reported quarterly)
PI 1.5			At least 90% of draft inspection reports are sent to the DI for a factual accuracy check within 20 working days of the end of the inspection.
KPI 1.4			At least 90% of inspection reports published within 10 weeks of the end of the inspection.
KPI 1.5			At least 90% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed within agreed timescales.
PI 1.6			At least 90% of Corrective and Preventative Action (CAPA) plans are agreed within 20 working days of the finalisation of the inspection report
PI 1.7			At least 90% of Corrective and Preventative Action (CAPA) plans are reported in published inspection reports as completed within 20 working days of completion.
KPI 1.6	a,b,c	To provide advice and guidance to licensed establishments	At least 95% of enquiries are answered within 10 working days of receipt
KPI 1.7	a,b,c	To undertake activity to implement the requirements of the EU Organ Donation Directive	Project Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage.
KPI 1.8	a	To manage the living organ donation approvals process	Complex case requirements adherence by units and IAs - 100% of cases assessed green or amber.
KPI 1.9	a		Proportion of non-panel cases turned around within 5 working days (measured monthly). Target rate 99%.
KPI 1.10	a		Proportion of panel cases turned around within 10 working days (measured monthly). Target rate 99%
PI 1.8	a		Review and recommendations completed within two months of 10 complex cases being assessed.
PI 1.9	a,b,c		To work collaboratively with the Independent Assessors to improve the quality of our work.
PI 1.10	a,b,c		Conference run during Q2 2012/13
PI 1.11	a,b,c		Survey and evaluation completed by the end of Q3 2012/13
PI 1.12	a,b,c	To work collaboratively with the Accredited Assessors to improve the quality of our work.	AAs reaccredited by end 2012/13
PI 1.13	a,b,c	To work collaboratively with the Living Donor Co-ordinators and Transplant Units to improve the quality of our work.	Conference run during Q2 2012/13
KPI 1.11	c	To review Directorate products, processes and policies to ensure they are efficient, effective and within legal remit.	Project Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage of the Living Donation Framework project.
PI 1.14	c		Project Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage of the Code of Practice 2 Update project.
PI 1.15	c		ODD requirements reflected in the living donation system by early August 2012
PI 1.16	c		Project Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage of the Governance Documentation Project.

## Baseline Business Plan 2012/13 – Deliverables (continued)

<b>2. To ensure appropriate and effective relationships in our changing operational environment</b> <b>a. To maintain and build confidence amongst professionals and the public in the regulation of the removal, storage and use of human tissue</b> <b>b. To work collaboratively during organisational transition to ensure that confidence in regulation is maintained and that human tissue continues to be removed, stored and used safely, ethically and with proper consent</b> <b>c. To manage the reputation of the HTA effectively</b> <b>d. To engage stakeholders to inform regulatory and organ donation policy and processes.</b>				
KPI 2.1	a,c	To monitor and evaluate the impact and effectiveness of HTA's communications	Regular evaluation reports produced and analysed by the communications directorate (every two months).	
PI 2.1	a, b, c, d	To work to improve the confidence of the public and patient groups	Programme plan of engagement and collaboration developed for business year 2012/13 by April 2012.	
PI 2.2	a, b, c, d		A signed-off digital strategy and implementation underway by April 2012.	
PI 2.3	a, b, c, d		A signed-off digital strategy and implementation underway by April 2012.	
PI 2.4	a, b, c, d		Non-HTA communications channels used for our communications activity as appropriate (tbc)	
PI 2.5	a, b, c, d		To work to engage with professionals, stakeholders and partner organisations to improve confidence in HTA's work, drive collaboration and influence opinion	Development of engagement plan and approved by SMT by April 2012.
PI 2.6	a, b, c, d		Programme plan of engagement and collaboration developed for business year 2012/13 by April 2012.	
PI 2.7	a, b, c, d		Updated package of tools and guidance to include new language, revised messages and up to date information by summer 2012. Communicated to staff and stakeholders.	
PI 2.8	a, b, c, d		Deliver training session to all staff in updated comms tools and guidance by Summer 2012.	
PI 2.9	a, b, c, d		Provided advice and guidance responses to consultations, and stakeholder correspondence as appropriate.	
PI 2.10	b		To support the HTA in influencing the ALB review and through any subsequent period of change and transition.	HTA's messages communicated effectively to KOL organisations influencing outcomes.
PI 2.11	b	Key messages and briefings around the ALB review and transition are provided, as required by the ALB review timings.		
PI 2.12	a,b	To continue to develop HTA's internal communications	Produce weekly all staff newsletter.	
<b>3. To have a skilled, motivated and dedicated team equipped to do the job in a challenging transitional period</b> <b>a. To further improve the HTA's working environment and culture to retain staff and uphold the HTA's standards and values</b> <b>b. To lead, motivate, involve and inform colleagues to deliver excellent work</b> <b>c. To attract and retain the right people with the right skills</b> <b>d. To improve expertise and support delivery through high quality learning and development</b>				
KPI 3.1	c	To manage HTA recruitment	Target 5% vacancy rate against agreed complement.	
PI 3.1	b	To ensure that HTA has an effective performance management system	100% of performance assessments completed by 18 May 2012 Staff report that the PDP process has improved.	
PI 3.2	a,b	To undertake a Staff Survey	Staff survey completed during quarter 4	
KPI 3.2	a,c	To implement targeted retention initiatives	Target rate of 18% for attrition rate measured monthly on a rolling annual basis.	
PI 3.3	a,b,c,d	To deliver an up to date suite of HR policies	Suite of completed and up to date policies created and available for all staff to access by end May 2012.	
PI 3.4	c	To undertake exit interviews with all departing staff	Leavers information collated and reported to Chief Executive and Senior Management Team on a regular basis for review and action. Action stemming from exit interviews implemented.	
KPI 3.3	d	To deliver an effective learning and development programme	80% of staff attending training courses agree that these have improved job performance and/or career development.	
PI 3.5	a	Provide effective IT systems for HTA	IT systems operational at all times, except for planned outages.	
PI 3.6	a	To provide continuous improvements to IT Systems.	Milestones for each project met	

## Baseline Business Plan 2012/13 – Deliverables (continued)

4. To ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the tax payer			
a. To maintain governance arrangements which give appropriate oversight to matters within the HTA's legislative remit			
b. To maintain high quality management skills and practices			
c. To maintain and improve cost-effectiveness and quality by systematically reviewing systems, processes and procedures			
d. To ensure the continued financial viability of the HTA.			
PI 4.1	a	To gather and act on Serious Adverse Events and Reactions and Serious Untoward Incidents.	At least 50% of establishments report Serious Adverse Events and Reactions within 24 hours of discovery, 80% reporting within 48 hours.
PI 4.2	a		At least 50% of establishments to comply with the requirement to report Serious Untoward Incidents within 5 working days of occurrence.
PI 4.3	a	To manage Authority business professionally and effectively	To ensure that Authority papers for all meetings involving Authority Members are issued a week in advance of meetings. To publish Authority Minutes on the HTA website within 28 days of each Authority meeting.
PI 4.4	a	To lead on corporate policy issues associated with the ALB review and transition to new organisational arrangements.	Responses submitted to any relevant ALB consultations to required deadline
PI 4.5	b	To deliver the HTA strategy and planning function	To publish a strategic plan at the start of the business year. To publish a high level business plan for 2012/13 by end of May 2012.
PI 4.6	b		Operational risk register discussed monthly at BPRG Updated as necessary
PI 4.7	c	To oversee the HTA Quality Management function	To complete a review of the HTA governance arrangements with SMT by end June 2012.
PI 4.8	c		Project Red-Amber-Green (RAG) status remains Amber or Green during project implementation stage of approved projects
PI 4.9	a, c	To ensure appropriate communications business continuity plans and the implementation of an HTA crisis management plan	Crisis management plan is approved and communicated to staff by end of June 2012.
KPI 4.1	a, c	To ensure enquiries are handled in an efficient, effective, consistent and timely manner.	Enquiries project is scoped and implementation is underway. RAG status remains at Green or Amber throughout the project.
KPI 4.2	a	To provide oversight of the ALB review project.	Project Red-Amber-Green (RAG) status remains Green during project implementation stage - report when started
KPI 4.3	c	To deliver the efficiency plans for 2012/13	Staff numbers for 2012/13 do not exceed 46 or spend does not exceed £4.7m
PI 4.10	d	To set appropriate fee levels for 2013/14	Fees to be no more than 2012/13 levels or to generate £3.7m in revenue
PI 4.11	a	To deliver an effective financial management and payments process.	90% of payments made within 5 days of receipt of undisputed invoice.
PI 4.12	a	To ensure effective governance arrangements.	80% of audit recommendations are either Medium or Low in severity.



**Human Tissue Authority**

151 Buckingham Palace Road  
Victoria  
London  
SW1W 9SZ

**Tel** 020 7269 1900

**Fax** 020 7269 1999

**Email** [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)

**Web** [www.hta.gov.uk](http://www.hta.gov.uk)

**Facebook** <http://www.Facebook.com/HumanTissueAuthority>

**Twitter** [http://twitter.com/HTA\\_UK](http://twitter.com/HTA_UK)

Published in April 2012