

The birth of a regulator



Human Tissue Authority Annual Report and Accounts 2005/06

Human Tissue Authority

Annual Report and Accounts 2005/06

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Introduction by the Chair and Chief Executive

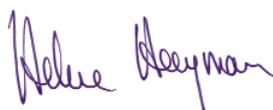
We hope this first Annual Report and Accounts for the Human Tissue Authority captures the sense of collective purpose and energy that has taken us from establishment to regulator in just one year.

The past 12 months have been a demanding, rewarding and successful time for our staff as they have set about the task of establishing a new regulatory authority. We are aware of the tremendous efforts that have been made by the entire team and would like to record our appreciation and thanks to them for their commitment and energy. We would also like to thank the Authority members who have shown such willingness to roll up their sleeves to help the Executive implement the work programme. Finally, we would like to thank all our colleagues outside the HTA who have helped and supported us during the year, especially the many HTA stakeholders who gave up so much of their time to help us develop our policies and the regulatory framework. Thanks are due to colleagues in the Department of Health, Human Fertilisation and Embryology Authority and Government Actuary's Department.

The focus of the HTA is firmly on the future. Our goal is not only to promote best practice across the sectors we regulate, but also to be an exemplar in how modern regulation should be executed: we are committed to implementing the recommendations in the reports published by Philip Hampton and the Better Regulation Task Force; and we will continue to work in partnership with our stakeholders to develop our regulatory requirements and policies.

The work that lies ahead will no doubt be as challenging, interesting and fulfilling as that in 2005/06 – perhaps even more so as we continue to establish our regulatory systems and policies whilst at the same time we prepare to transfer our work to the new Regulatory Authority for Tissue and Embryos, that the Government is committed to establishing.

The accounts for the HTA have been audited by the Comptroller and Auditor General and show a total expenditure for the year of £1.2m. All our funding in 2005/06 came from grant-in-aid from the Department of Health. When set against what has been achieved, we take the view that this represents real value for money and demonstrates appropriate propriety and discipline in the expenditure of public funds. We hope others will agree that the Authority has made a successful start to its regulatory life.



Baroness Hayman
Chair



Adrian McNeil
Chief Executive

About the Human Tissue Authority

The role of the Human Tissue Authority (HTA) is to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of 'Scheduled Purposes' – such as research, transplantation, and education and training – set out in the Human Tissue Act 2004 (HT Act).

The HT Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA will perform certain tasks on behalf of the Scottish Executive.

The HTA is also the Competent Authority in the UK, under the European Union Tissue and Cells Directive, for regulating the donation, procurement, processing and storage of human tissue (apart from gametes and embryos).

As the regulator under the HT Act, we are responsible for licensing a number of activities and carrying out inspections to ensure licence conditions are being met. These licensable activities are

- The carrying out of an anatomical examination
- The storage of human bodies for anatomical examination and related research
- The carrying out of post mortem examinations, including removal and storage of human tissue
- The storage and use of human bodies or parts for public display
- The storage of human tissue for other Scheduled Purposes, such as research.

We are also responsible for approving transplantation of organs and bone marrow from living donors.

Further information about our work is available on our website www.hta.gov.uk

Consent: our guiding principle

“The Human Tissue Act presents a fundamental change in that a patient can state their wishes about what happens to their body after death, and can also nominate a representative to make decisions on their behalf.” **Ruth Musson, Pathology Specialist Nurse at Queen's Medical Centre in Nottingham and HTA member.**

The fundamental principle underpinning the work of the HTA is the right of the individual to consent to any part of their body being used for a Scheduled Purpose. Or, where consent has not been in place at death, that there are recognised systems and frameworks which ensure that appropriate consent will be obtained before any such procedures are carried out. Therefore, consent must be obtained if body parts, organs and tissue from the living or the deceased are to be used in a lawful way. This includes the use of DNA.



As a regulator, the HTA sees its role as embedding best practice when obtaining consent to ensure that professional and public confidence is enhanced in matters relating to the use of human organs and tissue – a confidence based on the assurance that obtaining consent involves not just a procedure but a true, open and honest dialogue. We believe this to be one of the most effective ways of supporting not only the patient or their family and friends, but also the important work that is carried out by dedicated professionals to improve healthcare.

The HTA as a regulator: our values and objectives

“Our aim is to provide an environment that will increase the confidence of the public and professionals alike. We hope that we can help foster an environment of trust in which patients are able to have confidence that their wishes will be respected, and that scientific and medical research can flourish on that basis.” **Baroness Hayman, Chair of the HTA.**

If scientific and medical developments are to flourish, it is essential that they are underpinned by a robust and proportionate regulatory system. We aim to create and foster an environment in which patients and families have confidence that their wishes are respected, and where professionals support, understand and work within a clear regulatory framework.



Our intention is to be a modern regulator, building confidence across our stakeholder groups through the promotion of best practice. To achieve these goals we have set ourselves the objectives to:

- Establish an environment in which human tissue is removed, stored, used and disposed of according to the wishes of the individual.
- Create a regulatory system that is known, understood and accepted by those affected by it.
- Support and regulate systems that ensure the removal, retention, use and disposal of human tissue and organs is legal, ethical and respectful.
- Work in partnership with other regulators to streamline inspection and documentation and avoid duplication.
- Involve the professionals who work in the establishments to be regulated, as well as the public, when developing and enhancing the regulatory system.
- Provide a supportive environment in which all in the field, whether licensed or seeking to be licensed, are encouraged to strive for the highest standards of practice, and in which adverse events are reported and lessons learnt.
- Encourage consultation and dialogue, and provide advice and guidance.
- Implement the system in a way that keeps cost proportionate to risk.
- Work with the Human Fertilisation and Embryology Authority (HFEA) to ensure that Government proposals to create the Regulatory Authority for Tissue and Embryos (RATE) are carried out as efficiently and effectively as possible.



Policy development: an inclusive dialogue

“The Authority has set out from the start to operate in an open and consultative way. It is important we ensure that our Codes of Practice and regulatory arrangements are appropriate as they will lay down the guidelines and requirements for removing, storing and using human tissue and organs. That is why we have engaged the representatives from healthcare, science, patient groups and the public from the outset.” **Adrian McNeil, Chief Executive of the HTA.**

Collaboration is one of our founding principles. We are committed to developing policy and a regulatory framework for the removal, storage, use and disposal of human tissue by working with the relevant communities that have an interest in these matters. We believe that open and honest dialogue between us and our stakeholders will help create a regulatory system that is as relevant and supportive as it can be of

the many and varied interests of those who remove, store and use human tissue. The first fruits of this collaboration and dialogue – our first six Codes of Practice and licensing standards for all the sectors we regulate – have now been produced.

How we communicate and develop policy is an evolving process, and will remain so. During our start-up year much of our work has been in identifying stakeholders, building new networks and discovering the wealth of good practice and experience that is already thriving across all the sectors we regulate. The evidence of our commitment to this method of working is shown in our use of working groups and workshops in 2005/06 (see page 20).

Review of 2005/06

April – June

April

1 April sees the birth of the HTA.

The Department of Health assists the newly appointed Chair, Baroness Hayman, to decide the organisation and infrastructure of the Authority. All the other Authority members are appointed from 1 April by the Secretary of State for Health. By law, the Chair and at least 50% of the Authority must be lay members (people who have no past or present professional interest in the work of the HTA). There is also representation from the Welsh Assembly Government and the Northern Ireland Department of Health, Social Services and Public Safety. The members of the Authority are listed on page 24.

The Department of Health continues to manage the Human Tissue Working Group, a cross section of HTA stakeholders, that is putting the final touches to a draft framework for the first five statutory Codes of Practice to hand over to the HTA to consider.

May

We appoint our first member of staff when Jo Bennett starts work as the Committee Secretary and the Authority meets for the first time. They agree the governance arrangements including Standing Orders and Codes of Conduct for members.

The process and timetable for consulting on the first five draft Codes of Practice is agreed. This will take place over a 12-week period from July to October and will be conducted online and through workshops across England, Wales and Northern Ireland. It is clear from the outset that the Authority intends to be open, transparent and inclusive.

With the help of colleagues from the Office of Government Commerce, a list of suitable accommodation for the new organisation is drawn up and visits and discussions on the viability of each begin. We soon find ideal offices on the ground floor of the offices of the Government Actuary's Department (GAD) at Finlaison House in the City. Negotiations begin in earnest to agree our terms of occupancy and the earliest possible date we can move in.

In the meantime, interviews are held to find the new Chief Executive and Adrian McNeil is appointed.

June

The Chief Executive sets about appointing his Senior Management Team. The recruitment is successful and all four Director posts – Communications, Policy, Regulation and Resources – are filled. The draft Codes of Practice are agreed by the Authority for consultation. Preparations for consultation on the Codes gather pace as the process must begin in early July.



The terms of our tenancy of Finlaison House are agreed and a moving in date of 4 July is set. We need to move very fast to build the whole physical and IT infrastructure from scratch.

July – September

July

The move to Furnival Street starts: Colin Pavelin, Director of Resources, is the first to establish himself in the new premises, but he is soon joined by Adrian McNeil, Jo Bennett, Gina Page, Personal Assistant to the Chair and Chief Executive, and Peter Lemmey, Director of Policy. This brings the team up to a total of five.

The first HTA website is launched on 11 July and the consultation on the draft Codes of Practice starts the following day. To mark the launch, an event is held at the Royal United Services Institute in Whitehall, London. The event is attended by many stakeholders and a keynote speech is given by Rosie Winterton MP, Minister for Health. The five draft Codes published for consultation are: Consent; Donation of organs, tissue and cells for transplantation; Post mortem examination; Anatomical examination and removal, storage, use and disposal of human tissue and organs.

August

The team continues to grow at the HTA. Dr Sandy Mather takes up post as Director of Regulation and Dr Shaun Griffin as Director of Communications. The Senior Management Team holds an away day to identify their values, objectives and workstreams for the coming year. The first of our shared service contracts are agreed, which sees the HFEA providing human resource services and GAD providing financial and IT services to the HTA.

Even though this is traditionally the quiet month, work at the HTA continues apace. The initial meeting of the first of the policy working groups, the Transplantation Working Group, is held on 10 August. Preparations are made for other time-limited working groups to be established.

September

The consultation on the Codes of Practice steps up a gear as workshops are held in London, Belfast, Sheffield and Builth Wells, Powys. The workshops prove to be very well received and immensely informative.

We hold the first two meetings of the Regulation working group. We also hold the first of our workshops to develop licensing standards for establishments storing tissue for human application.

The next stage of staff recruitment starts at the beginning of the month and nine posts are advertised at Manager and Officer level. The vacancies are advertised in the national press and the main recruitment network of the civil service and the NHS. The response to the advertisement is astounding with nearly 500 applications for the nine posts.

The Authority holds its first annual away-day. The strategic objectives and vision for the HTA are agreed and an outline work plan for the coming 12 months takes shape over two days of workshops and debate.



October – December

October

The consultation on the Codes of Practice closes on 4 October. 117 responses are received from a wide range of interested parties via our online consultation, including individuals and lay and professional representative bodies; and more than 100 people have attended the four workshops. Analysis of the comments now begins. The analysis is done by five response analysis groups consisting of two Authority members and either the Chief Executive or the Director of Policy.

The HTA continues to develop other areas of its remit. As part of the work on regulation of transplantations, nominations are called for to create a network of Independent Assessors (IAs) who will work at a local level to ensure that all transplantations are conducted in line with the HTA's guidance: they will assess all living donor organ transplants and recommend approval by the HTA. Following completion of the training, the IAs will be accredited by the HTA to act both as our representative and as an advocate for the donor. Over 100 people working in the transplantation field are nominated for training to become IAs.

Ministers require the HTA to become one of the Competent Authorities under the European Union Tissue and Cells Directive (EUTCD). This means we will have to start licensing establishments storing tissue for human application from 7 April.

As a further move towards becoming an independent regulator, all aspects of HTA finance are transferred from the Department of Health to direct control of the HTA.

November

More new staff arrive: Mark Chiswell, Licensing Manager, Hazel Uppington, Regulation Officer, Stephen Cobb, Administration Assistant and Mandip Kaur, Policy Officer. An induction day is held involving all the staff who have already started, as well as those that are about to.

The Authority agrees the regulatory aims and objectives that should apply across its remit. Policy development work, especially revision of the Codes of Practice and dealing with the growing numbers of enquiries, continues at a rapid pace. The first meeting takes place of the working group dealing with the importing and exporting of human bodies, body parts and tissue.

We hold the first of three workshops to help us develop the standards and licensing requirements for establishments storing tissue for human application. We decide to incorporate the standards into a self-assessment compliance report to form the basis of licence applications. These workshops include a cross-section of the representatives from the sector and prove invaluable in helping us develop relevant and proportionate requirements. The workshops are well received and much appreciated by the stakeholders as an opportunity to contribute to the development of licensing standards.

December

Priya Goyal, Policy Manager and Stuart Giblin, Communications Officer, arrive. The Executive makes the strategic decision to conduct as much as possible of its business electronically, for the sake of efficiency and economy, and prepares for online licensing applications and assessments. The licensing process for establishments storing tissue for human application starts to take shape – in discussion with the Department of Health – and is to be used as the model for September. We do this in close collaboration with the Department of Health who are preparing the necessary secondary legislation.

Final draft Codes of Practice are agreed by the HTA and passed to Ministers for their approval. The Authority also begins to consider in earnest the options for licensing and inspection.

Our first Business Plan is shared with the Authority and the Department of Health, along with our three-year Strategic Plan. Work is already underway to develop the training programme for accrediting IAs.

January – March

January

Mark Gilbert joins as Business Programme Manager, Daisy Thomas completes the communications team as Communications Manager and Imogen Swann starts as Inspections Manager. Sinead Glasgow is appointed as the legal adviser to the HTA. Sinead is a shared member of staff between us and the HFEA, her employers.

Enquiries start to flood in to the HTA mailbox and to individual members of staff and we develop a standard operating procedure for replying to this correspondence.

We run a workshop on our licensing standards at a conference organised the British Association of Tissue Banking.



Preparation for licensing under the EUTCD intensifies: the Executive discuss and agree with the Department of Health their proposals for licensing from 7 April and work together to ensure that the legislative framework reflects these requirements. The Authority endorses the proposals for implementing licensing under the EUTCD from 7 April. Meanwhile, we start a pilot to test the online application process for licences to store tissue for human application. Volunteers for the pilot include representatives from England, Wales, Scotland and Northern Ireland, as well as a mix of public and private tissue establishments. This is a vital “dry run” to help us fine-tune the application system.

We hold the first of two workshops on storage for research, attended by researchers, and representatives from the Central Office for Research Ethics Committees and tissue banks. Evaluation shows how positively the sector views the events.

February

Two more members of staff join us – Kristi Collins (a secondee from the National Patient Safety Agency) takes up the post of Regulatory Project Manager and Carly Tutty is the new Personal Assistant to the Chief Executive. This brings the HTA staff total to 18.

The first of six training days for IAs is held on 3 February.

The Authority agrees the fee structure for licensing establishments storing tissue for human application. The maximum fee is set at £4,500 and reduces to £250 for satellite centres. The HTA decides that it should charge lower fees to those establishments that are currently accredited by, or who have recently been inspected by, the Medicines and Healthcare products Regulatory Agency.

We work closely with the Department of Health to decide how best the Human Tissue Act can be commenced to allow us to fulfil our responsibilities as Competent Authority under the EUTCD.

Preparation for licensing other sectors that fall under the HTA's remit from 1 September begin in earnest and we hold a pathology workshop.

A contractor is engaged to develop the database which will enable us to evaluate licence applications and record decisions and conditions imposed on licences electronically.

The communication strategy is agreed by the Authority. It reflects our principles of being an open and inclusive regulator. The strategy aims to raise awareness about the work of the Authority and promote its activities. We also develop a Freedom of Information Publication Scheme as part of our policy on openness and transparency.

The working group on public display of bodies and body parts meets for the first time to begin the development of a Code of Practice on this issue within the HTA's remit. The workshop we hold for licensing of anatomy is viewed as "highly informative"; and the workshop on pathology clears a lot of issues and provides a firmer basis for licensing this sector.

March

We prepare to process the first applications for licences under the EUTCD: we recruit and train four Licensing Evaluation Officers on two-month contracts; and we set up Licensing Evaluation Panels from the Executive to decide the issue of licences.

Around 100 applications are received from potential Designated Individuals and Licence Holders (who will supervise compliance with the licensing arrangements at establishments) to attend training workshops. We publish our guidance for Designated Individuals and Licence Holders on the website to help them to understand the Human Tissue Act.

We hold a joint workshop with the Central Office for Research Ethics Committees and finalise the standards for licensing. We have now tested out the standards with representatives from all sectors and are ready to publish them on our website in April.

Our sixth Code of Practice on the Donation of allogenic bone marrow and peripheral blood stem cells is circulated for consultation.

Work is also well underway for our launch event on 25 April, which will be held at the British Medical Association. The event will allow us to inform our stakeholders about how we will operate as a regulator, the standards by which we will be licensing, and about our Codes of Practice. A media

briefing is planned for the same day at the Science Media Centre, to help raise awareness of what the HT Act means for professionals and the public.

Following a tendering exercise, an agency is appointed to work with us to redevelop the HTA website. The new site will have greater functionality, allowing online licence application from all sectors in time for 1 September.



Working groups and workshops

Import and export working group

The group was established to draft a Code of Practice. The group members were selected to ensure coverage of the sectors involved in the import and export of human bodies, body parts and tissue.

Group members:

- Kate Robson-Brown, HTA member (co-Chair)
- Peter Lemmey, Director of Policy (co-Chair)
- El-Nasir Lalani, HTA member
- Christiane Abouzeid, Regulatory Affairs Manager, BioIndustry Association
- Mike Adams, Senior Research Fellow, Department of Anatomy, University of Bristol
- Bob Coleman, Chief Scientific Officer, Pharmagene Laboratories Ltd
- Mark Lowdell, Director of Laboratory of Cellular Therapy, Royal Free Hospital
- Stella Mason, Keeper of the College Collections, The Royal College of Surgeons England
- Bernard Moxham, Professor of Anatomy, Cardiff School of Biosciences
- David Shute, Director of Information, Technology and Support Services, UK Transplant
- Frank Varey, Senior Policy Advisor, HM Revenues and Customs

Public display working group

The group was established to draft a Code of Practice. The group members were chosen to ensure coverage of the museum, university and collections sectors involved in the public display of human tissue.

Group members:

- Kate Robson-Brown, HTA member (co-Chair)
- Peter Lemmey, Director of Policy (co-Chair)
- Jane Jeffs, HTA member
- Tara Camm, Principal Solicitor, The Wellcome Trust
- Tim Easthope, Senior Officer – Artist Development, Arts Council
- Stella Mason, Keeper of the College Collections, The Royal College of Surgeons England
- Paul O'Higgins, Foundation Professor of Anatomy, Hull York Medical School
- Lisa O'Sullivan, Senior Medical Curator, Science Museum
- Jerry Weber, Senior Advisor – Quality Standards, Museums, Libraries and Archives Council

Regulation working group

The aim of the working group is to provide strategic advice to the Authority on the HTA's regulatory functions as set out in the HT Act and the EUTCD, and also to manage on behalf of the Authority the work programme for licensing. The members of the group were chosen from the Authority.

Group members:

- James Ironside, HTA member (Chair)
- Ceri Davies, HTA member
- Jane Jeffs, HTA member
- Suzi Leather, HTA member
- Keith Rigg, HTA member
- Helen Shaw, HTA member
- Adrian McNeil, Chief Executive
- Sandy Mather, Director of Regulation

Storage of tissue for human application working group

The aim of the working group is to establish and pilot our methodology to allow us to license establishments storing tissue for human application. This methodology will then be used to produce a framework for licensing the other sectors from 1 September 2006.

The members of the group vary but they have been selected to ensure representation from those establishments that stored tissue for human application both in the commercial and public sectors, as well as representation from the devolved assemblies and the Department of Health.

Workshops were held in September and November 2005 in preparation for implementation of the EUTCD in April 2006. Participants included: HTA members, Bristol Eye Hospital, National Blood Service, Oswestry Tissue Bank, Medicines and Healthcare products Regulatory Agency, Human Fertilisation and Embryology Authority, Department of Health and the Health Quality Service.

Transplantation working group

The aim of the group is to implement the HTA's responsibilities for transplantation of human tissue under the HT Act, its regulations and Codes of Practice. This involves planning and implementing the transition from the Unrelated Live Transplant Regulatory Authority (ULTRA) to the new HTA

approval arrangements, which will come into force on 1 September 2006.

Group members:

- Adrian McNeil, Chief Executive (Chair)
- Keith Rigg, HTA member
- Kesh Baboolal, Consultant Nephrologist, Renal Unit, University Hospital of Wales
- Lisa Burnapp, Nurse Consultant, Guy's and St Thomas' Hospital
- Derwood Pamphilon, Consultant Haematologist, National Blood Service
- Fiona Wellington, Donor Transplant Coordinator Regional Manager, UK Transplant
- Shaun Griffin, Director of Communications
- Peter Lemmey, Director of Policy

Anatomy workshop

An Anatomy workshop was held in February to develop a draft compliance report to be used by the anatomy sector when applying for licences. Participants included: HTA members, Northern Ireland Department of Health, Social Services and Public Safety, Welsh Assembly Government, London and South East Committee of Licensed Teachers of Anatomy, British Association of Clinical Anatomists, and Cardiff School of Biosciences.

Pathology workshop

A pathology workshop was held in February to produce the standards by which the HTA would licence the carrying out of post mortems. Participants at the workshop were selected to ensure representation from those involved in post mortems, including pathologists and mortuary technicians. Participants included: HTA members, Northern Ireland Department of Health, Social Services and Public Safety, Welsh Assembly Government, professional body representation included the Royal College of Pathologists, the Institute of Biomedical Scientists, the British Neuropathological Society and the British Paediatric Pathology Association.

Research workshop

A joint workshop with the Central Office for Research Ethics Committees (COREC), discussing the licensing and ethical review of centres storing tissue for human research was held in March 2006. The aim of the workshop was to gather information

about the sectors we regulate and to gain their input into the licensing process. Participants included: HTA members, onCore UK, Glasgow Biobank, Kings College London, Queen Mary's School of Medicine and Dentistry London, National Translational Cancer Research Network, Bristol Registry of Childhood Cancer, Cancer Research UK, University of Newcastle, Central Office for Research Ethics Committees, NHS Research and Development Forum, UK Biobank, UK Parkinson's Disease Society Tissue Bank, Welsh Assembly Government, Asterand, University College London, Department of Health, University of Manchester, Welsh Cancer Bank, UK Human Tissue Bank, National Patient Safety Agency, Medical Research Council, Astra Zeneca, University of Cambridge, Barts and The London Medical School, University of Leeds, Bioindustry Association.

Chief Executive report

The HTA was established on 1 April 2005 under the Human Tissue Act 2004 (HT Act), which extends to England, Wales and Northern Ireland. The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health.

Remit

The HTA has two principal statutory functions. The first is to inform the public and the Secretary of State for Health about issues within our statutory remit. We fulfil this remit by issuing Codes of Practice including:

- Consent
- Donation of solid organs, tissue and cells for transplantation
- Post mortem examination
- Anatomical examination
- Removal, storage and disposal of human organs and tissue
- Donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation
- Public display
- Import and export of human bodies, body parts and tissue

The second of our principal statutory remits is to license and inspect the:

- storage of human bodies for anatomical examination;
- carrying out of post mortem examinations;
- removal of tissue from the body of a deceased person for Scheduled Purposes except transplantation;
- storage and use of human bodies or parts for public display; and
- storage of human tissue for other Scheduled Purposes, for example research.

The HTA is also the competent authority under the EU Tissue and Cells Directive for regulating the establishments storing tissue for human application.

Principles and values

The HTA will adopt the following core values in achieving our strategic aims and objectives:

- Behaving with integrity
- Being open and transparent
- Engaging stakeholders
- Working collaboratively (with other regulators)
- Being responsive.

In striving to be a model, modern regulator the HTA will apply the principles found in the reports by Hampton and the Better Regulation Task Force. These state that a regulatory system should be:

- proportionate;
- accountable;
- consistent;
- transparent; and
- targeted.

Resources

As an Executive non-Departmental Public Body, the HTA receives a proportion of its income through grant-in-aid from the Department of Health. For the financial year covered by these accounts, grant-in-aid was the HTA's sole source of income. However, in the future the majority of our funding will be found through fees charged for licensing and regulation services. Our total annual expenditure will be in the region of £3 million. About two thirds of this will be met by fees. The HTA is not a profit-making organisation.

All HTA staff are employed through the HFEA on fixed term contracts. The staff are then seconded to the HTA for the same period as their contract. Staff are also given the opportunity to second from their original employer if this arrangement is acceptable. In 2005/6 four staff took this option.

We are committed to remaining a small operative hub with a staff size to match. Not only is this our preferred organisational structure, but it also sits well with the aims of the Government's review of Arm's Length Bodies. To maintain a small core staff and achieve a level of service that is of high-quality and meets the needs of staff, business and clients, we buy in many of our back-office services. These include:

- Human Resources – provided by the HFEA on a service level agreement that covers all our HR requirements.
- Legal advice and services – once again provided through a service level agreement that provides HTA with the services of a senior and junior legal adviser, both of whom are employed directly by the HFEA.
- Financial services – GAD supply all financial services to the HTA, including internal audit.
- Facilities management – supplied through an agreement with our landlord, GAD, which provides all IT maintenance and back-up services, as well as building, security and cleaning services.

As the work of the HTA progresses, all future services we may require will be, in the first instance, considered for contracting out.

Governance

The Management Board has met monthly (with the exception of August). It focuses on the overall strategic management of the Authority and takes decisions on all the key high level issues affecting the HTA. Day-to-day operational issues are delegated to individual members of the Executive, in accordance with their job descriptions, via the office of the Chief Executive.

Audit Committee

The Audit Committee is chaired by Sharmila Nebhrajani, a non-executive member of the HTA, who is a member of the Institute of Chartered Accountants of England and Wales. Other non-executive members are Michael Banner, Shirley Harrison, David Sharpe, James Underwood and Michaela Willis. The Chief Executive, Director of Resources, Internal and External Auditors, Department of Health Business Change Manager and the HTA's Business Programme Manager are invited to attend. The Committee's terms of reference underline the support this body provides to the Accounting Officer throughout the year, in particular in providing evidence to justify signing the Statement of Internal Control. The Committee meets at least four times a year but only met once during 2005/06 due to its start-up status.

Register of interests

The HTA maintains a register of interests which details company directorships and other significant interests held by Authority members which may conflict with their HTA responsibilities. Persons wishing to view the register should apply in writing to the Director of Resources.

Disabled persons

As the HTA is committed to providing equal opportunities for all staff, disability is not a bar to recruitment or advancement. The HTA observes good practice in the areas of employment particularly relevant to staff with disabilities and provides all necessary facilities.

Information for staff and communications policy

The HTA keeps all members of staff informed of changes in and affecting the Authority. We operate a system of monthly staff meetings, chaired in rotation by each of the staff members. We also produce regular emails, office notices and updates of other general information are also used.

Training and development

The HTA recognises that people are the most important resource to manage. The Authority operates both Personal Development and Continual Professional Development Plan systems to encourage staff to consider and evaluate the professional and personal development they need.

Payment of suppliers

The HTA adheres to the Better Payment Practice Code. The policy is that all bills should be paid in accordance with credit terms, or where no such terms exist, within 30 days of the receipt of goods or services, or upon the presentation of a valid invoice, whichever is the later. The calculation of payment performance for 2005/06 has been based on continuous monitoring of payments since October 2005 after outsourcing finance activities to the GAD. On this basis, we can report that 85.0% of payments met the policy criteria. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

Auditor

The Comptroller and Auditor General is the external auditor for HTA's accounts. The auditor's remuneration in 2005/06 was set at £12,500. No fees were incurred for non-audit work.

To the extent of my knowledge, as Accounting Officer for the HTA, I am confident that:

- a) There is no relevant audit information of which the HTA's auditors are unaware and;
- b) I've taken all steps that I ought to have taken to make myself aware of any relevant audit information and to establish that the HTA's auditors are aware of this information.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date 30 June 2006

The Authority

The Authority consists of 17 members who have been appointed by the Secretary of State for Health. They come from a variety of medical, scientific, legal, administrative and political backgrounds.

The Rt Hon Baroness Hayman, Chair (lay member)

Helene Hayman has worked in the voluntary sector and the National Health Service in a variety of roles for over thirty years. She entered the House of Lords in 1996 and was a member of the Government from 1997 to 2001, serving at the Department of Environment, Transport and the Regions; Department of Health; and as Minister of State at the Ministry of Agriculture, Fisheries and Food.

Professor Michael Banner (lay member)

Michael Banner is Director of the ESRC Genomics Forum, and Professor of Public Policy in the Life Sciences in the School of Clinical and Molecular Medicine, Edinburgh University. Amongst previous Committee experience, he chaired a Committee of Enquiry for MAFF from 1993–1995, the CJD Incidents Panel at the Department of Health, and the Home Office's Animal Procedures Committee from 1998–2006.

Dr D Ceri Davies (professional member)

Ceri Davies has been a Licensed Teacher of Anatomy for more than twenty years and is a member of the Council of the Anatomical Society of Great Britain and Ireland. Ceri is currently Reader in Neuroscience at St George's University of London.

Shirley Harrison (lay member)

Shirley Harrison is a magistrate and chairs the South Yorkshire Probation Board. She acts as a patient representative in the field of cancer research, with particular interests in translational research and genetics. Her professional career has been in marketing and public relations as a practitioner, an academic and an author. She is managing director of Harrison Research & Consultancy Limited.

Professor James Ironside, Deputy Chair (professional member)

James Ironside is Professor of Clinical Neuropathology in the University of Edinburgh,

and an Honorary Consultant Neuropathologist in the Lothian Health University Hospital and Tayside Health University Hospital, Scotland. He has been using human tissues in diagnosis, education and research for 30 years, and was formerly Deputy Chair of the Spongiform Encephalopathy Advisory Committee.

Jane Jeffs (lay member)

Jane Jeffs is a lay member who has had personal experience of bereavement and the debate around post mortem examinations and organ retention and disposal. She was Chief Officer of a Community Health Council before her retirement and in that role carried out research into public opinion regarding post mortems. She was a member of the Welsh Organ Retention Advisory Group and is the member of the Authority appointed by the Welsh Assembly Government.

Professor El-Nasir Lalani (professional member)

El-Nasir Lalani is the Robert Leith Professor of Pathology and Academic Head, Department of Pathology in the Division of Cancer Studies at the University of Birmingham. He is also an Honorary Consultant Histopathologist at the University Hospital Birmingham NHS Foundation Trust.

Dame Suzi Leather (lay member)

Suzi Leather has chaired the Human Fertilisation and Embryology Authority since 2002 and is the inaugural chair of the School Food Trust. Her particular interests and experience include regulation and public health. Dame Suzi was founder Deputy Chair of the Food Standards Agency and has chaired an NHS Trust, as well as being founder Chair of the UK's first combined Health Living Centre and UK Online centre. Dame Suzi's academic background is in political science.

Ruth Musson (professional member)

Ruth Musson started her career in public service administration, before qualifying as a Registered General Nurse, later gaining experience in a number of fields, including medicine, terminal care and research. She now leads a small team of nurses and a midwife who work with families, clinical teams, coroners and researchers addressing all issues relating to consent, retention and return of tissues from post mortem examinations.

Sharmila Nebhrajani (lay member)

Sharmila Nebhrajani is BBC New Media and Technology's Chief Operating Officer where she is responsible for the operational management, financial and business strategy, editorial compliance, business development and commissioning relationships with the independent production sector across bbc.co.uk and the BBC's interactive television services. She is also Deputy Chair of the Human Fertilisation and Embryology Authority and a member of the Olympic Lottery Distributor.

Dr Andrew Reid (professional member)

Andrew Scott Reid was appointed in November 2002 as the full-time coroner for the jurisdiction of the Inner Northern District of Greater London, consisting of the London boroughs of Camden, Hackney, Islington and Tower Hamlets. Dr Reid deals with Inquests at Poplar and St Pancras Coroner's Courts.

Keith Rigg (professional member)

Keith Rigg is Consultant Surgeon, Director of Transplantation and Clinical Director for General Surgery at Nottingham University Hospitals NHS Trust. He is currently a council member of the British Transplantation Society and Chair of the Transplant Training Advisory Committee; and a medical member of the Unrelated Live Transplant Regulatory Authority (ULTRA).

Dr Kate Robson-Brown (lay member)

Kate Robson-Brown is Senior Lecturer in Biological Anthropology and Graduate Dean of Arts at the University of Bristol. She is Director of the University archaeological skeletal collections and the Bristol Osteoarchaeological Research Group. Her research interests include human evolutionary anatomy and forensic anthropology.

Dr David Sharpe (lay member)

David Sharpe is a Barrister practising law primarily in Belfast but also in London, where he is a member of Chambers at 12 King's Bench Walk. He has experience of acting for both patients and doctors (and other healthcare professionals) in medical litigation and inquests. David is the member of the Authority appointed by the Northern Ireland Department of Health, Social Services and Public Safety.

Helen Shaw (lay member)

Since 1994 Helen Shaw has been Co-Director of INQUEST, an organisation with a national reputation for excellence and a proven track record in providing advice and support about the inquest system to bereaved families and their lawyers. She was a member of the Retained Organs Commission from 2001–2004. Helen is also Vice-Chair of the National Bereavement Partnership.

Professor Sir James Underwood

(professional member)

James Underwood is Professor of Pathology at the University of Sheffield and Consultant Histopathologist to the Sheffield Teaching Hospitals NHS Foundation Trust. He is currently Dean of Sheffield University's Faculty of Medicine. Sir James was an observer on the Retained Organs Commission and President of the Royal College of Pathologists from 2002–2005.

Michaela Willis (lay member)

Michaela Willis is the Chief Executive of the National Bereavement Partnership, a registered charity offering a unique service by providing information, advice and support to people who have experienced bereavement, and to professionals working with bereaved people, particularly where a post mortem is requested or required.

Attendance at Authority meetings

The first meeting of the Authority was held on 17 May 2005. This means a total of 10 meetings were held throughout 2005/06; member attendance is listed below. The business of attending Authority meetings represents only a fraction of the work carried out by Authority members. All members, especially in this start-up year, have been involved in working with the Executive to deliver the HTA's work. This has included chairing and participating in working groups and workshops, representing the HTA in the media and at conferences, and providing valuable advice and guidance to the Executive throughout the policy development process. Please see the list of working groups and workshops for further information on member time commitments.

Name	Authority meetings attended
Helene Hayman	10
Michael Banner	07
Ceri Davies	09
Shirley Harrison	09
James Ironside	09
Jane Jeffs	08
El-Nasir Lalani	08
Suzi Leather	06
Ruth Musson	09
Sharmila Nebhrajani	09
Andrew Reid	07
Keith Rigg	09
Kate Robson-Brown	07
David Sharpe	05
Helen Shaw	09
James Underwood	08
Michaela Willis	06

Attendance at Audit Committee meetings

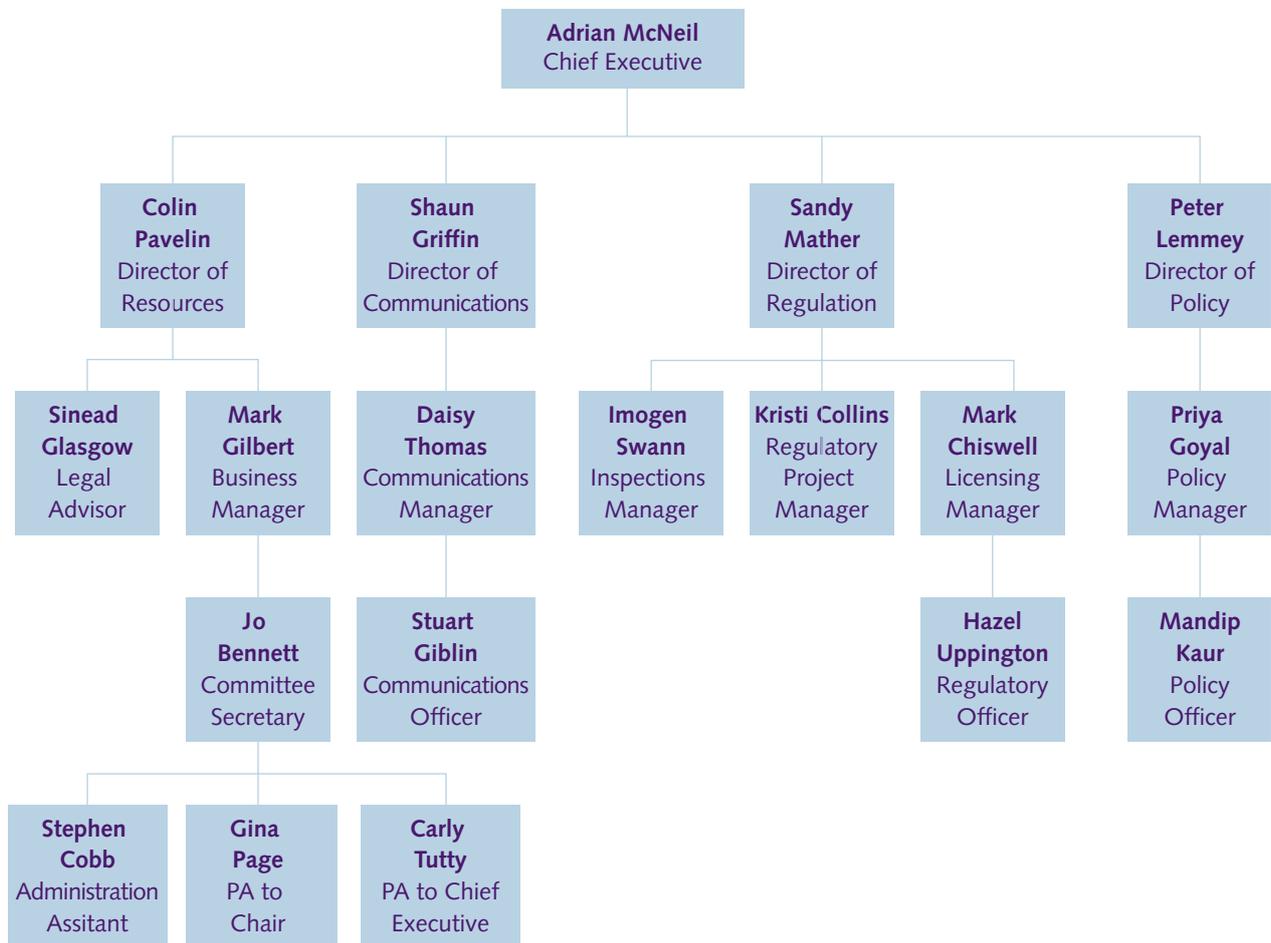
The first meeting of the Audit Committee was held on 17 January 2006. As it was a start-up year, there was only one meeting held in 2005/06. The Committee will meet at least once per quarter year in the future.

Name	Audit Committee meetings attended
Sharmila Nebhrajani	01
Michael Banner	01
Shirley Harrison	01
David Sharpe	00
James Underwood	01
Michaela Willis	01

The Executive

The day-to-day running of the organisation and our licensing and inspection operations are managed by a small core team, which is split into four directorates and led by a Chief Executive. The majority of our corporate support functions, such as finance and human resources, have been outsourced.

(At 31 March 2006.)



Management commentary

Financial position

In its first year of operation the HTA has been preparing to undertake its role as the organisation regulating removal, retention, use and storage of human tissue in England, Wales and Northern Ireland. The expenditure this year has been focussed on setting up business systems to enable the HTA to operate as a fee-earning regulatory body from 2006/07.

There have been clear risks associated with our position as an Authority in start-up mode during the financial year 2005/06. Our major risk for the year 2005/06 was securing enough funding from the Department of Health to ensure that all necessary frameworks were in place for the HTA to commence its work as a regulator in April 2006. For the coming year our most evident risk is not generating enough income to meet the shortfall between our grant-in-aid funding from Department of Health and our full operational costs for the year. We will also be faced with the prospect of closure as our functions are transferred to RATE, currently intended for establishment in 2008. Risk from the establishment of RATE will be based around the remit, location and corporate structure which will lead to pressure on resources of all kinds. To manage such risks to the delivery of the HTA remit, the Authority operates a risk register which is reviewed regularly, both at senior management level and by the Authority members via the Audit Committee, and agreed actions planned and implemented accordingly.

Total expenditure was over £1.2 million. Salaries expenditure represent 44% of total expenditure, whilst expenditure relating to office premises such as rent, utilities and facilities management constitutes 22%. Other costs have been kept to a minimum through efficiency measures and by outsourcing certain services such as finance, IT support and payroll.

The proportion of staff costs is expected to rise as most staff were recruited during the last four to six months of the year. Whilst most expenditure this year has been contributable to start-up costs, next year will see a growth in programme expenditure as policy and regulation is completed.

The summary table below includes data taken from our accounting schedules and notes contained in these annual accounts:

Table 1 – Income and expenditure for the year ended 31 March 2006

	2005/06 £'000
Income	
Amounts already accounted for by Dept of Health	92
Grant drawn down	1,132
Total income	1,224
Expenditure	
Staff costs	540
General administrative costs	661
Total expenditure	1,201
Operating surplus	23

Equal opportunities and diversity

The HTA is fully committed to providing equal opportunity for all staff, regardless of colour, nationality, ethnic origin, religion, gender, sexual orientation, age, marital status or trade union affiliation.

Key Performance Indicators 2005/06

Each year, we will agree a business plan with the Department of Health (DH) that includes performance targets covering delivery of our statutory remit and public accountability. Working towards the establishment of RATE will be a target in each of our annual plans. The HTA agreed with the DH the following Key Performance Indicators (KPIs) for the year 2005/06.

Ministerial performance targets

- (1) Have in place a minimal licensing scheme to regulate those establishments covered by the EUTCD by 1 April 2006.
- (2) Statutory Codes of Practice laid before Parliament and any necessary standards and inspection protocols drafted by April 2006.
- (3) Develop financial and administration systems in accordance with better regulation and governance procedures.
- (4) Develop arrangements with the HFEA, including the provision of back office functions and systems that can be easily integrated on the establishment of RATE.

Corporate performance targets

- (5) Maintain robust, in-year, financial management to ensure that operating costs are kept within budget and requests for grant in aid do not exceed allocations.
- (6) Staff numbers to be monitored closely in-year. All steps should be taken to avoid any expansion in permanent staffing (not on fixed term contracts); unless a business case can be made for the increase.

Progress against our KPIs were monitored throughout the year through weekly Senior Management Team meetings, business programme management and regular business meetings with colleagues at the Department of Health. All targets were met except KPI 2 (laying Codes in Parliament). The delivery date for this KPI was renegotiated during the year with DH to take account of changes in the DH timetable for the implementation of legislation. The new KPI on laying the Codes before Parliament will be picked up in 2006/07, taking into account the second phase of HTA regulation, which is due in September 2006.

2005/06 Accounts

The Annual Accounts have been prepared and issued by the Human Tissue Authority (HTA), under directions given by the Secretary of State with the approval of the Treasury in accordance with Schedule 2 (S16) of the Human Tissue Act 2004. The Accounts demonstrate the resources that have been used by the HTA in delivering HTA's objectives. These Annual Accounts have been prepared in accordance with the guidance set out in the Government Financial Reporting Manual (FRoM) for 2005/06.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date 30 June 2006

Remuneration report

Salary and pension entitlements of Authority members

Members of the Authority are remunerated at a level per annum which is agreed with the Secretary of State for Health. This remuneration does not include any pension entitlements. Any increase or change to the remuneration is notified to the HTA by its sponsor department, the Department of Health.

Remuneration policy

All staff employed at the HTA are seconded through other government bodies. Because of this arrangement, the HTA does not have its own remuneration policy as all staff are governed by the remuneration policies pertaining to their particular home Department, Agency or Non-Departmental Public Body. This includes all annual reporting procedures and setting of pay increases that may be awarded in any particular year.

Service contracts

All positions in the HTA are filled through fair and open competition. All service contracts in the HTA are issued until 30 June 2008 when the transfer of work to the proposed new authority, RATE, will be commenced. In the event of a resignation, a three month notice period is generally required and vacancies will be filled through the provisions laid down in the HTA's service level agreement for Human Resource services with the HFEA.

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the Authority members and senior management. These details are shown in accordance with the Government Financial Reporting Manual (FRM).

Authority members remuneration

All members of the Authority are appointed by the Secretary of State for Health via the Offices of the Commissioner for Public Appointments through a process of open competition. They are paid an annual remuneration that does not include any provision for pension payments. Increases to this remuneration are agreed in accordance with guidance from HM Treasury. In the financial year 2005/06 these payments were as follows:

Chair (x1)	£25–30,000
Member (x16)	£0–5,000

Senior manager remuneration

Under the Human Tissue Act 2004, the HTA has the right to appoint such staff as it considers appropriate and can determine their terms and conditions. All senior management vacancies were filled through fair and open competition. A starting salary setting formula is applied in the HTA at all levels. This is: earning less than the payband minimum, 10% or minimum salary, whichever is the higher; already within the pay range offered, 10% or the maximum of the pay range offered, whichever is the lower; already above the pay range offered, a special business case needs to be made before any offer of employment is made.

Post	Start date	Salary per annum
Chief Executive	1 July 2005	£75–80,000
Director of Communications	15 August 2005	£50–55,000
Director of Policy	18 July 2005	£65–70,000
Director of Regulation	15 August 2005	£55–60,000
Director of Resources	1 July 2005	£40–45,000

Remuneration report (senior staff salaries)

Name of Officer	Total salary including performance pay (ii)	Real increase in pension at age 60 (iii)	Real increase in pension at age 60 (iv)	Pension at 31/03/06 (v)	Lump sum at 31/03/06 (v)	CETV at 31/03/06 (vi)	CETV at 31/03/06 (vii)	Employee contributions and transfers-in (ix)	Real increase in CETV as funded by employer (x)
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Adrian McNeil Chief Executive Officer	55–60	2,5–5	12,5– 15	35– 37,5	105– 107,5	585– 587,5	802,5– 805	0–2,5	100– 102,5
Shaun Griffin Director of Communications	30–35	0–2,5	0	0–2,5	0	0	5-7,5	0–2,5	5–7,5
Peter Lemmey Director of Policy	45–50	0–2,5	0–2,5	30– 32,5	92,5– 95	587,5– 590	702,5– 705	0–2,5	12,5– 15
Sandy Mather Director of Regulation	35–40	0–2,5	0	15– 17,5	0	127,5– 130	190– 192,5	0–2,5	20– 22,5
Colin Pavelin Director of Resources	30–35	0–2,5	2,5–5	7,5– 10	22,5– 25	77,5 80	122,5– 125	0–2,5 0–2,5	20– 22,5

Salary

'Salary' includes gross salary; performance pay or bonuses; overtime; reserved rights to London weighting or London allowances; recruitment and retention allowances; private office allowances and any other allowance to the extent that it is subject to UK taxation.

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the Inland Revenue as a taxable emolument. No payments of this kind were reported in the accounting period.

Cash equivalent transfer value

Columns (vii) and (viii) of the above table show the staff member's cash equivalent transfer value accrued at the beginning and end of the reporting period. Column (x) reflects the increase in cash equivalent transfer value effectively funded by the employer. It takes account of the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

A cash equivalent transfer value is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A cash equivalent transfer value is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or

arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The cash equivalent transfer value figures, and from 2003/04 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Principal Civil Service Pension Scheme arrangements and for which the Civil Superannuation Vote has received a transfer payment commensurate to the additional pension liabilities being assumed. They also include any additional pension benefit accrued to the member as a result of their purchasing additional years of pension service in the scheme at their own cost.

Cash equivalent transfer values are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries, as advised by the actuary to the Principal Civil Service Pension Scheme.

The real increase in the value of the CETV

This takes account of the increase in accrued pension due to inflation and contributions paid by the officer, and is calculated using common market valuation factors for the start and end of the period.

Civil Service pensions

Pension benefits are provided through the Civil Service pension arrangements. The PSCPS is an unfunded multi-employer defined benefit scheme but HTA is unable to define its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 2003 by the Scheme Actuary, Hewitt Bacon Woodrow. Details can be found in the resource accounts of the Cabinet Office at www.civilservice-pensions.gov.uk

From 1 October 2002, civil servants may be in one of three statutory based "final salary" defined benefit schemes (classic, premium, and classic plus). New entrants after 1 October 2002 must join premium.

Classic scheme

Benefits accrue at the rate of 1/80th of pensionable salary for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. Members pay contributions of 1.5 per cent of pensionable earnings. On death, pensions are payable to the surviving spouse at a rate of half the member's pension. On death in service, the scheme pays a lump sum benefit of twice pensionable pay and also provides a service enhancement on computing the spouse's pension. The enhancement depends on length of service and cannot exceed 10 years. Medical retirement is possible in the event of serious ill health. In this case, pensions are brought into payment immediately without actuarial reduction and with service enhanced as for widow(er) pensions.

Premium

Benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum, but members may commute some of their pension to provide a lump sum up to a maximum of 3/80ths of final pensionable earnings for each year of service or 2.25 times pension if greater (the commutation rate is £12 of lump sum for each £1 of pension given up). For the purposes of pension disclosure the tables assume maximum commutation. Members pay contributions of 3.5 per cent of pensionable earnings. On death, pensions are payable to the surviving spouse or eligible partner at a rate of 3/8ths the member's pension (before any commutation). On death in service, the scheme pays a lump sum benefit of three times pensionable earnings and also provides a service enhancement on computing the spouse's pension. The enhancement depends on length of service and cannot exceed 10 years. Medical retirement is possible in the event of serious ill health. In this case, pensions are brought into payment immediately without actuarial reduction. Where the members' ill health is such that it permanently prevents them undertaking any gainful employment, service is enhanced to what they would have accrued at age 60.

Classic plus scheme

This is essentially a variation of premium, but with benefits in respect of service before 1 October 2002 calculated broadly as per classic.

Pensions payable under classic, premium, and classic plus are increased in line with the Retail Prices Index.

The schemes are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under classic, premium, and classic plus are increased annually in line with changes in the Retail Prices Index. New entrants after 1 October 2002 may choose between membership of premium or joining a good quality 'money purchase' stakeholder arrangement with a significant employer contribution (partnership pension account).

Employee contributions are set at the rate of 1.5% of pensionable earnings for classic and 3.5% for premium and classic plus. Benefits in classic accrue at the rate of 1/80th of pensionable salary for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum (but members may give up (commute) some of their pension to provide a lump sum). Classic plus is essentially a variation of premium, but with benefits in respect of service before 1 October 2002 calculated broadly as per classic.

The partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date 30 June 2006

Statement of the Authority's and Chief Executive's responsibilities

Under the Human Tissue Act 2004, the Human Tissue Authority (HTA) is required to prepare annual accounts for each financial year, in conformity with a Secretary of State direction, detailing the resources acquired, held or disposed of during the year and the use of resources by the HTA during the year. The Annual Accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the HTA, the net resource outturn, resources applied to objectives, recognised gains and losses and cash flows for the financial year.

The Department of Health has appointed the Chief Executive as Accounting Officer of the Authority with responsibility for preparing the HTA's accounts and for transmitting them to the Comptroller and Auditor General.

In preparing the accounts the Accounting Officer is required to comply with the Government Financial Reporting Manual prepared by Treasury, and in particular to:

- a) observe the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- b) make judgements and estimates on a reasonable basis;
- c) state whether applicable accounting standards, as set out in the Government Financial Reporting Manual, have been followed, and disclose and explain any material departures in the accounts;
- d) prepare the accounts on a going concern basis.

The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which an Accounting Officer is answerable, for keeping proper records and safeguarding the Authority's assets, are set out in the Accounting Officers' Memorandum, issued by the Department of Health, and published in Government Accounting.

Statement on Internal Control

Scope of responsibility

1. As Accounting Officer, I have responsibility for maintaining a sound system of Internal Control that supports the achievement of the Human Tissue Authority's policies, aims and objectives, whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Government Accounting.
2. The Assurance and accountability frameworks are still being finalised but existing agreements with the Department of Health require:
 - a) Department of Health approval of the HTA's Strategic and Business Plans including a full risk assessment;
 - b) HTA to submit monthly budget profile and headcount reports and quarterly performance reports to the Department of Health;
 - c) Quarterly Accountability reviews to be held between the HTA's Senior Management Team, the senior department sponsor and the Arm's Length Body Business Change Manager;
 - d) Annual accountability review meetings with the public Health Minister.
3. Department of Health officials attend Authority meetings, Audit Committee meetings and other HTA committees or working groups at the invitation of HTA officials, as observers. Officials from the National Audit Office (NAO) also attend Audit Committee meetings as observers.
4. The HTA has maintained close links with the Department of Health throughout its initial start-up period and has held regular meetings with representatives from the departmental sponsoring group.

The purpose of the system of Internal Control

5. The system of Internal Control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of Internal Control is based on an ongoing process designed to identify and prioritise the risks to the achievement of departmental policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of Internal Control has been introduced in the HTA as the year has progressed to 31 March 2006 and subsequently up to the date of approval of the Annual Report and Accounts, and accords with Treasury guidance. The system of internal control will continue to develop as the HTA introduces new procedures to meet objectives.
6. The 2005/06 financial year was divided into two halves. From 1 April to 1 October, the HTA budget was managed and monitored through the Department of Health's VISTA accounting system by Department of Health staff. This split system made controlling and monitoring our budget difficult. As of 1 October, HTA took control of all its finance systems, but remained financed through a cash only system drawing down funds from its grant-in-aid allocation when required. However, throughout this period, the Authority and its Senior Management Team monitored HTA budgets through a monthly reporting system and a basic system of internal controls was in place. Management of risk was also carried out at this level and in the same way. Both these systems are being further developed as the HTA beds down as an established public body, building on advice from our Internal Auditor and our financial services providers, the GAD, to accommodate the changing nature of our business as we move towards becoming a fully fledged regulator.

Capacity to handle risk

7. The HTA understands the importance of risk management and internal control. All members of the Authority and the Executive have responsibilities for risk management.
8. The Authority is ultimately responsible for overseeing management of the HTA's strategic risks. I am responsible for providing leadership for management of risk within the organisation and all members of the Senior Management Team are responsible for managing the strategic or operational risks that may impact the delivery of policies and objectives in their areas of work.
9. In order to strengthen its internal controls and provide assurance, the HTA commissions an Internal Audit service through the GAD and is also subject to external audit by the office of the Comptroller and Auditor General.

The risk and control framework

10. The HTA was established on 1 April 2005 and therefore spent much of the year putting the necessary systems and processes in place to enable it to function as a regulator from April 2006. These include the Audit Committee and a developing risk register which was managed monthly by the Senior Management Team. Where appropriate, risk was also indirectly assessed by the Authority as its monthly meetings. The Regulation directorate has also maintained a risk register for activities related to licensing and inspection and this is regularly reviewed.
11. The HTA recognises the need to ensure that its risk management and Internal Control arrangements are fit for purpose and applied throughout the organisation as it develops its functions and works towards achieving its objectives. It also recognises the role of the Audit Committee as vital in ensuring that all elements of our risk and internal controls framework are scrutinised and reviewed on a regular basis. The Audit Committee is charged by the Authority to carry out this work and report back its findings to the Authority on a regular basis.
12. The HTA is now in the process of finalising and agreeing its corporate risk management strategy. The strategy will set out:
 - How the HTA will proactively identify, evaluate and manage risks to delivery of its policies, aims and objectives
 - Roles and responsibilities in relation to risk management and how these will be communicated;
 - How the HTA will involve its stakeholders in identifying and managing risk
 - How the HTA will determine the levels of risk it is willing to tolerate (risk appetite)
 - How the risk management process itself will be reviewed and continually improved
 - How business continuity will be addressed through the production of a Business Continuity Plan
13. A key part of the strategy will be the introduction of a formal risk registers for strategic and operational risks. Once the strategy has been agreed, these risk registers will be periodically reviewed by the Senior Management Team, Authority and Audit Committee.

Review of effectiveness

14. As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of Internal Control. My review of the effectiveness of the system of Internal Control is informed by the work of the internal auditors and the executive managers within the department who have responsibility for the development and maintenance of the Internal Control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of Internal Control by the board, the Audit Committee and a plan to address weaknesses and ensure continuous improvement of the system is in place.
15. The Director of Resources and I have kept the current system of Internal Control under review during 2005/06.
16. The Audit Committee will review the management of risk across the HTA during 2006/07 and I will commission a review of the corporate risk management strategy within six months of it being introduced.
17. No significant internal control issues have been identified.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

30 June 2006

Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of the Human Tissue Authority for the year ended 31 March 2006 under the Human Tissue Act 2004. These comprise the income and expenditure account, the balance sheet, the cash flow statement and statement of total recognised gains and losses and the related notes. These financial statements have been prepared under the accounting policies set out within them.

Respective responsibilities of the Authority, Chief Executive and auditor

The Authority and Chief Executive are responsible for preparing the Annual Report, the remuneration report and the financial statements in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with approval of Treasury made for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the Authority's and Chief Executive's Responsibilities.

My responsibility is to audit the financial statements in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the remuneration report to be audited have been properly prepared in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of the Treasury. I also report whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. I also report to you if, in my opinion, the Annual Report is not consistent with the financial statements, if the Authority has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by relevant authorities regarding remuneration and other transactions is not disclosed.

I review whether the statement on pages 35 to 37 reflects the Authority's compliance with HM Treasury's guidance on the Statement on Internal Control, and I report if it does not. I am not required to consider whether the Accounting Officer's statements on Internal Control cover all risks and controls, or form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises only the titles included within the Annual Report, the unaudited part of the remuneration report and the management commentary. I consider the implications of my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinions

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the remuneration report to be audited. It also includes an assessment of the significant estimates and judgements to be made by the Authority and Chief Executive in preparation of the financial statements, and of whether the accounting policies are most appropriate to the Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the remuneration report to be audited are free from material misstatement, whether caused by fraud or error and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the remuneration report to be audited.

Opinions

In my opinion:

- the financial statements give a true and fair view, in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury, of the state of the Human Tissue Authority's affairs as at 31 March 2006 and of its surplus for the year there ended;
- the financial statements and the part of the remuneration report to be audited have been properly prepared in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury; and
- in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

I have no observations to make on these financial statements.



John Bourn
Comptroller and Auditor General

6 July 2006

National Audit Office
157–197 Buckingham Palace Road
Victoria
London SW1W 9SP

Financial accounts 2005/06

Presented pursuant to the Human Tissue Act 2004 Section 36 and Schedule 2 (Section 16)

The Human Tissue Authority

Financial accounts 2005/06
(For the year ended 31 March 2006)

30 June 2006

Income and expenditure account

For the year ended 31 March 2006

	Note	2005/06 £
Income		
Amount already accounted for by Department of Health	2	91,956
Grant drawn down	2	1,132,000
Total income		1,223,956
Administration costs		
Staff costs	3	540,060
Other administration costs	4	660,581
Total expenditure		1,200,641
Net operating surplus		
Notional interest	1.7	1,133
Surplus on ordinary activities		
Write back of notional interest		(1,133)
Surplus for the financial year		23,315

Statement of recognised gains and losses

For the year ended 31 March 2006

As the HTA owns no fixed assets, there were no recognised gains or losses for the year 2005/06.

The notes on pages 43 to 49 form part of these accounts.

Balance sheet

As at 31 March 2006

	Note	£	31 March 2006	£
Current assets				
Debtors	5	29,315		
Cash at bank and in hand	14	88,070		
			117,385	
Creditors				
(Amounts falling due within one year)	6	(94,070)		
Total assets less current liabilities				23,315
				23,315
Financed by				
Income and expenditure reserve	8			23,315
				23,315



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

30 June 2006

The notes on pages 43 to 49 form part of these accounts.

Cash flow statement

For the year ended 31 March 2006

	Note	2005/06 £
Net cash inflow/(outflow) from operating activities	15	88,070
Increase/(decrease) in cash in the period		88,070

The notes on pages 43 to 49 form part of these accounts.

Notes to the accounts

1. Statement of accounting policies

The financial statements have been prepared pursuant to the Human Tissue Act 2004, Schedule 2, Section 16 and in accordance with the Government Finance Reporting Manual (FReM) 2005/06 issued by HM Treasury. The accounting policies contained in the FReM follow UK generally accepted accounting practice for companies (UK GAAP) to the extent that it is meaningful and appropriate to the public sector. The particular accounting policies adopted by the Human Tissue Authority are described below. They have been applied consistently in dealing with items considered material in relation to the accounts.

1.1 Accounting convention

These accounts have been prepared under the historical cost convention. As the Authority has no fixed assets, stocks or current asset investments, hence there is no need to account for revaluation.

1.2 Fixed assets

The Authority does not have any fixed assets included in its balance sheet.

Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

Computer equipment and software are leased from GAD, as are the office premises under operating leases, and therefore these are not included on the balance sheet. Furniture was donated by the Department of Health, but does not satisfy the capitalisation criteria set out above, and therefore is not included on the balance sheet

1.3 Foreign currency transactions

There were no transactions in foreign currency in 2005/06.

1.4 Leases

The Authority has no finance leases. The Authority has operating leases with the Government Actuary's Department with regards to the rent and hire of premises plus the lease of computer equipment. The Authority also has an operating lease with DANKA in respect of photocopying equipment. Commitments under operating leases are detailed in note 10.

1.5 Income

Income is received in a form of a grant from the sponsoring department, the Department of Health and is credited to income in the year to which it relates. From 2006/07 income will also take the form of fees for licences from bodies which have Human Tissue on their premises. Licence fee income will be recognised at point of sale. This operating income will be shown net of value added tax.

1.6 Administration expenditure

Administration costs reflect the costs of running the HTA.

1.7 Notional charge

In accordance with Treasury Guidance, notional interest at 3.5 per cent of the average capital employed, excluding balances held in cash and in hand, has been credited in the Income and Expenditure Account amounting to £1,133

1.8 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS.) The defined benefit elements of the schemes are unfunded and are non-contributory except in respect of dependents' benefits. The HTA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the schemes, the HTA recognises the contributions payable for the year.

1.9 Value Added Tax

The Authority was not registered for VAT during the financial year 2005/06. The HTA will begin issuing licences in 2006/07 and as such will be able to offset its output tax chargeable against its fees for said licences against the input tax it already pays for goods and services received.

2. Total income

Gross income is made up of Government grants received in the year. In 2006/07 the Authority will be charging fees for licences.

	2005/06 £
Administration income	
Amount already accounted for by Department of Health	91,956
Grant drawn down (received from Department of Health)	1,132,000
Total	1,223,956

3. Staff numbers and related costs

a) Staff costs comprise:

	2005/06 £
Wages and salaries – HTA staff	428,518
Social Security costs	34,409
Pension costs – HTA staff	66,556
Agency / temporary staff	10,577
Total	540,060
Of which members emoluments	110,155

More details on remuneration policy can be found at in the remuneration report.

For 2005/06, contributions of £66,556 were paid to the PCSPS at rates prescribed by the Treasury. These rates were in the range of 16.2 – 24.6 per cent of pensionable pay, according to salary level.

b) Average number of persons employed

All staff are seconded through other Government bodies, these include Department of Health, Human Fertilisation and Embryology Authority and the National Patient Safety Agency. As HTA was in set-up year, the vast majority of staff did not take up their employment with the HTA until the second half of the year, leading to a very low average over the year. As of 31 March 2006 the HTA employed 19 staff (18 WTE). The average number of whole-time equivalent persons employed (including senior management), during the year was as follows:

	2005/06
Seconded management staff	3
Seconded administrative staff	4
Total	7

4. Other administration costs

	2005/06 £
Rent of building	117,271
Utilities	10,244
Facilities management services	120,626
Project costs	136,473
Travel, subsistence and hospitality	49,168
Recruitment	24,400
Training	26,946
Consultancy	17,715
Stationery and publications	7,082
Photocopier leasing costs	659
Shared services (IT support, finance, payroll, legal)	95,364
Operating lease on computer equipment	17,411
Computer running costs	3,540
Telecommunications	4,803
Auditor's remuneration	12,500
Other costs	16,379
Total	660,581

5. Debtors

	2005/06 £
Prepayments	29,315
Total	29,315

Debtors – Intra government balances

	2005/06 £
Balance with central government bodies	20,522
Balance with bodies external to government	8,793
Total	29,315

6. Creditors

	2005/06 £
Amounts falling due within one year	
Trade creditors	851
Accruals	93,219
Total	94,070

There are no creditors falling due after one year.

Creditors – Intra government balances

	2005/06 £
Balance with central government bodies	65,850
Balance with bodies external to government	28,220
Total	94,070

7. Post-balance sheet events

- (i) A credit note in respect of rent was received after the balance sheet due date. This necessitated an adjustment to the final accounts whereby expenditure was reduced and prepayments were increased by £20,552.
- (ii) There were no further post balance sheet events to report.

8. Income and expenditure reserve

The income and expenditure reserve represents the total net assets less liabilities of the HTA, to the extent that the total is not represented by other reserves.

	2005/06 £
Balance at 1 April 2005	-
Surplus for the year	23,315
Income and expenditure reserve at 31 March 2006	23,315

9. Capital commitments

There were no capital commitments as at 31 March 2006.

10. Commitments under operating leases

	Land and buildings £	Other £
Leases which expire within 1 year	-	-
Leases which expire within 2–5 years	140,725	22,338
Leases which expire after 5 years	-	-
Total	140,725	22,338

11. Contingent liabilities

There were no contingent liabilities as at 31 March 2006.

12. Related party transactions

The Department of Health is regarded as a related party and had various material transactions with the Authority during the year. This mainly related to the provision of the grant-in-aid.

The HTA lets a floor of a building paying its rent to GAD. During the year the rent payable amounted to £117,271. HTA also made a prepayment of £20,552 to GAD in respect of rent. GAD also provides services to HTA in respect of Finance, Facilities Management, Utilities, Members Payroll and IT services. A breakdown of services provided by GAD is shown below:

	2005/06 £
Rent and hire of premises	117,271
Facilities management	120,160
Utilities	10,244
IT support	24,818
Lease of computer equipment	17,411
Finance services	24,050
Members payroll	1,954
Internal audit	141
Total	316,049

Three staff are on secondment from the Department of Health. One member of staff is on secondment from the National Patient Safety Agency. All remaining staff are on secondment to the HTA through the HFEA. HFEA manage this arrangement.

Baroness Hayman is a member of the HFEA. Dame Suzi Leather and Sharmila Nebhrajani are respectively the Chair and Deputy Chair of the HFEA.

The HFEA provide legal, payroll, HR services plus costs for all staff totalling £476,869. At the year end the HTA had accrued payments owing to the HFEA totalling £53,350 in respect of staff costs.

The Authority paid £176 in respect of a meeting at the University of Birmingham. Professor El-Nasir Lalani, an Authority member, is the Head of Pathology at the University of Birmingham. The Authority paid £1,450 in respect of two separate conference fees to the National Bereavement Partnership. Michaela Willis, an Authority member, is the Chief Executive of the National Bereavement Partnership

None of the remaining Authority members, key managerial staff or other related parties has undertaken any material transactions with HTA during the year.

13. Performance against key financial targets

During 2005/06 the Authority managed to stay within an acceptable level of its allotted budget.

Since October 2005, 85.0 per cent of invoices were paid within 30 days. This result was lowered significantly by the delay in the transfer of a number of invoices from the Department of Health during the first three months of outsourcing. It is hoped that through implementing a more rigorous procurement process, this figure will improve next year and enable the Authority to fulfil the criteria of the Better Payment Practice Code.

14. Cash at bank and in hand

	2005/06 £
Balance at 1 April	-
Net change inflow	88,070
Balance at 31 March 2006	88,070
The following balances at 31 March 2006 are held at:	
Office of HM Paymaster General plus cash in hand	88,070
	88,070

The Office of HM Paymaster General provides a current account banking service. During the year, the Authority held a small amount of cash in hand – at year end this was £94.

The balance of funds held in the HM Paymaster General account on 31 March 2006 was £87,976.

15. Notes to the Cash Flow Statement

a) Reconciliation of operating surplus to operating cash flows

	2005/06 £
Operating surplus	23,315
(Increase)/decrease in debtors	(29,315)
Increase/(decrease) in creditors	94,070
Net cash inflow/(outflow) from operating activities	88,070

16. Financial instruments

FRS13, Derivatives and Other Financial Instruments, requires disclosure of the role which financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Because of the nature of its activities and its means of funding the HTA is not exposed to the degree of financial risk faced by business entities. Moreover, financial instruments play a much more limited role in creating or changing risk than would be typical of the listed companies to which FRS13 mainly applies. The HTA has very limited powers to borrow or invest surplus funds and financial assets and liabilities are generated by day-to-day operational activities and are not held to change the risks facing the HTA in undertaking its activities.

As permitted by FRS13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from the currency profile.

Liquidity risk

The Authority's net revenue resource requirements are financed by a Grant from the Department of Health. The HTA is not therefore exposed to significant liquidity risks.

Interest rate risk

The HTA's financial assets and liabilities are not exposed to interest rate risks.

Interest rate profile

The following table shows the interest rate and currency profiles of the HTA's financial assets.

Table 2 – Financial assets

	Total	Fixed-rate financial assets			Non-interest bearing financial assets		
		Floating rate financial assets	Fixed-rate financial assets	Non-interest bearing financial assets (i)	Weighted-average interest rate	Weighted-average period until maturity	
	£	£	£	£	%	Years	Years
At 31 March 2006:							
Sterling	88,070	-	-	88,070	-	-	Note (i)
Other	-	-	-	-	-	-	-
Gross financial assets	88,070	-	-	88,070	-	-	-

(i) The HTA's non-interest bearing financial assets comprises cash at bank and in hand of £88,070.

Foreign currency risk

There was no foreign currency expenditure in 2005/06. Foreign currency expenditure in 2006/07 is expected to be minor.

Fair values

Set out below is a comparison by category of book values and fair values of the HTA's financial assets and liabilities as at 31 March 2006.

Table 3 – Fair values

	Book value	Fair value (i)	Basis of fair valuation
	£'000	£'000	
At 31 March 2006			
Primary financial instruments:			
Financial assets:			
Cash at bank	88,070	88,070	Note (i)
Financial liabilities:			
None Held	-	-	Note (i)

(i) Fair value is not significantly different from book value since, in the calculation of book value, the expected cash flows have been discounted by the Treasury discount rate of 2.2% a year in real terms.

17. Losses and special payments

There were no losses or special payments during the financial year.

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