

# Annual report and accounts 2020/21



# Human Tissue Authority

## Annual report and accounts 2020/21

Presented to Parliament pursuant to Schedule 2(16) of the Human Tissue Act 2004.

Laid before the Welsh Parliament by Welsh Ministers pursuant to Schedule 2(16) of the Human Tissue Act 2004

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# Chief Executive's foreword

It seems almost unnecessary to state that the last business year has been perhaps the most challenging in this organisation's history. The impact of COVID 19 on our stakeholders and staff, and the limitations on undertaking site visit inspections (one of our key regulatory tools) have proved a significant test of our business continuity and critical incidents plans. That we have been able to respond to our stakeholders and adopt new ways of working concurrently is a testament to our forward planning and agility as an organisation, but most significantly is due to the effort and willingness of our staff to do whatever was required to ensure the HTA continued to operate in a way that supported the sector we regulate.

2020/21 was the third year of our three-year strategy cycle and our plans were necessarily adapted to enable us to respond to the changed environment. In terms of adapting our business as usual activities the HTA was able to:

- Move immediately to a remote working approach, all staff were able to work remotely with all functionality of HTA systems available and governance meetings proceeded as planned through virtual means.
- An immediate response to supporting the regulation of the Post-mortem sector, which has been under particular stress during this period, introducing a revised emergency licensing process and responding to a significant increase in enquiries and requests for advice relating to capacity.
- Restrictions on site visits required a substantial re-working of one of the mainstays of our regulatory assurance toolkit. The introduction of self-assessment questionnaires to provide assurance during the first lockdown led to the development of a Virtual Regulatory Assessment process that now allows us to undertake a thorough assessment of compliance within establishments. The HTA retained the option to undertake site visits where it was felt there was substantial risk to public confidence or patient safety.

Whilst rethinking our core business activities over this period the HTA still delivered a number of strategic development objectives, as well as implementing wider changes in response to the UK's transition from the European Union. In particular the HTA successfully delivered:

- Sector readiness of all HTA stakeholders for changes resulting from the UK's transition from the European Union.
- The full migration of HTA physical servers to cloud based servers, providing more resilience and flexibility.
- The implementation of an upgraded Electronic Document Records and Management System.
- The successful relocation of our physical office from Central London to the new DHSC hub in Stratford, East London.
- The development of new HTA Intranet and Internet sites providing more focussed information and ensuring compliance with new accessibility requirements.

Throughout this trying year we have retained and enhanced the confidence of our stakeholders and sponsor Department. We have received positive feedback from our sponsor and from the Cabinet Office for our support during the first few months of the pandemic; in particular, for the

provision of data in support of response planning. More widely our approach over this year with our wider stakeholders has been described as both pragmatic and supportive.

We have also prepared for the future by delivering further enhancements to our infrastructure and by reframing our transformation programme into a development programme. We have implemented a number of systems improvements and progressed other initiatives to provide the foundations for further improvements in the next twelve to eighteen months. Our development programme includes a thorough review of our operating model and our approach to regulation, looking to embed some of the new ways of working we have developed over the past 12 months, exploit the opportunities for improvement allowed by better data use and adopting new technology, and consider where regulation might be improved by legislative change.

Our staff have proved to be resilient and have demonstrated the high levels of engagement and commitment over this demanding year that we have seen from them in more normal operating conditions. On the whole, we have had positive response to the wellbeing surveys we have undertaken this year with staff feeling supported in terms of their work and their wider health. We are conscious that we will need to carefully balance our ambition with the demands on our staff and not underplay the importance of allowing staff to recover as we return to more normal life patterns over the coming months. As ever, for an organisation of our size, staff retention poses a risk to our operational capacity and capability. We intend that our development programme will mitigate this risk in the medium term. The HTA has historically attracted and retained hugely talented staff which contributes significantly to the organisation's reputation as a responsive and expert regulator. We will need to remain competitive in our offering to recruit and retain the skills we require in the future.

It is a tribute to all my colleagues in the HTA, supported by the management team and the Board, that HTA was able to face the challenges of the past twelve months and finds itself better prepared for further change ahead. I would like to end by thanking them for all their hard work over these past 12 months in delivering our core business, an ambitious programme of change and responding to the other challenges that the last business year have brought.



**Allan Marriott-Smith**  
Chief Executive

# Performance



# Overview

We are a Non-Departmental Public Body (NDPB) sponsored by the Department of Health and Social Care (DHSC), established and domiciled in England. Our registered office is 2 Redman Place, Stratford, London E20 1JQ. We were established under the Human Tissue Act (HT Act) 2004 – which covers England, Wales and Northern Ireland – to regulate activities relating to the removal, storage, use and disposal of human tissue.

## What we do

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent, in accordance with the provisions of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

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

## Our role:

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended);
- We license organisations involved in organ donation and transplantation as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended);
- We monitor and inspect or audit organisations to ensure they comply with the requirements of the legislation and our Codes of Practice;
- We use our powers to take regulatory action where we identify non-compliance;
- We assess living organ donation to ensure donors are protected from duress or coercion, and that no reward is offered or given;
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit;
- We monitor developments relating to activities within our remit and advise Government on related issues.

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

## Our remit

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

Our remit under the Human Tissue Act 2004 extends to England, Wales and Northern Ireland; however, we also carry out some activities in relation to the approval of living organ donations on behalf of the Scottish Government. Our remit under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) extends to the whole of the UK.

We license approximately 855 premises across the six sectors that we regulate and publish standards and requirements that those working within the regulated fields must meet.

Whilst the HTA has a statutory duty to superintend compliance and an influential role in promoting good practice, public confidence in the use of human tissue cannot be safeguarded by the HTA alone. Public confidence is also dependent on individuals and organisations undertaking activities within the HTA's remit to act within the standards and requirements of the legislation.

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

- *Consent* – and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- *Dignity* – is paramount in the treatment of human bodies and tissue.
- *Quality* – must underpin the management of human bodies and tissue.
- *Honesty and openness* – are the foundation of communications in matters pertaining to the use of human tissue and bodies.

The HTA's non-executive Board – consists of: a chair and twelve Members, 10 of which are appointed by the Secretary of State for Health and Social Care; one Member appointed by the Welsh Government's Cabinet Secretary for Health, Well-Being, and Sport and; one by the Minister for Health in Northern Ireland. The professional Members of our Board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial and public sector experience.

The Board's primary role is to ensure that the HTA discharges its statutory responsibilities effectively. It achieves this by setting the HTA's strategic direction and providing both support

and challenge to our Executive team, which is responsible for the delivery of these responsibilities on a day-to-day basis.

Below are our strategic aims for 2019-2022

Strategic Aims	High level objectives are to continue to:
<p>Delivery – To deliver the right touch and in line with the principles of better regulation and the Regulators’ Code.</p>	<ul style="list-style-type: none"> <li>• Deliver a right touch program of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety;</li> <li>• Deliver effective regulation of living donation</li> <li>• Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;</li> <li>• Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards;</li> <li>• Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us;</li> <li>• Maintain our strategic relationships with other regulators operating in the health sector.</li> </ul>
<p>Development – To ensure the HTA’s regulatory approach remains relevant, we actively prepare for the future.</p>	<ul style="list-style-type: none"> <li>• Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively</li> <li>• Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk;</li> <li>• Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements</li> <li>• Begin work on implementing a future operating model, which builds agility, resilience and sustainability as an organisation.</li> </ul>
<p>Deployment – To make the most effective use of people and resources in pursuit of our goals</p>	<ul style="list-style-type: none"> <li>• Manage and develop our people in line with the People Strategy;</li> </ul>

- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money;
- Provide a suitable working environment and effective business technology, with due regard for data protection and information security;
- Plan and prioritise our resources to carefully balance activity across the organisation.

## Key issues in 2020/21

### COVID-19

The HTA deployed its Critical Incident Response Plan at the end of the last financial year to manage its response to the COVID-19 pandemic. The plan proved effective in responding to the situation and business continuity was maintained. However, our site visit inspections were suspended for the first half of the 2020/21 financial year. This resulted in the failure to fulfil our statutory duty to inspect establishments in the Human Application sector every two years. Our Board, Department of Health and Social Care (DHSC) sponsors are aware of this issue and the risk it poses. In response, work was undertaken on developing Virtual Regulatory Assessments (VRAs) or non-site visit inspections. There began their pilot phase in Quarter 3 of the financial year.

Staff wellbeing during the last year has been a central concern, particularly for those with caring responsibilities, or those who have suffered bereavement as a result of the virus. Arrangements were put in place ranging from revised special leave arrangements and adjustments to working patterns to help with those with caring responsibilities.

### UK Transition

Considerable work has been undertaken to implement the Northern Ireland Protocol with the next phase of work focusing on the new licensing arrangements for end users importing directly from the European Economic Area (EEA). Work around fee proposals will commence once we have established how this sector will be regulated.

### Office relocation

The DHSC signed the lease for 2 Redman Place, London on 15 January 2021, however staff are not formally attending the office except for specific tasks relating to the relocation of IT infrastructure. There are further tasks remaining to be completed before this project closes. Given the on-going restrictions across the country, it is unlikely that there will be a return to office working until June 2021 at the earliest.

## Development Programme


The HTA is committed to a multi-year development programme whose benefits include improvements to systems and processes that facilitate a more targeted and risk-based approach to regulation. Additional funding from our reserves for this could not be secured, so the modest investments made in 2020/21 were made from within existing budgets. The HTA will undertake further work funded in the same way and linked to the office relocation in the coming year.



Where funds are available from existing budgets, incremental pieces of work are undertaken to improve our processes and systems. Examples include implementing an electronic document management system (EDRMS) which facilitates the storage, retrieval and management of documents.



## Risks as at 31 March 2021


The HTA aims to take all reasonable steps in the management of risk with the overall objective of achieving strategic and business objectives and protecting staff, stakeholders, the public and assets.

As at 31 March 2021, the HTA had six strategic risks:

Risk associated with Development	Mitigating activities	Risk severity and direction of risk trend
<b>R1: Failure to regulate in a manner that maintains public safety and confidence and is appropriate</b>	<ul style="list-style-type: none"> <li>• Fortnightly Transition Period oversight meetings</li> <li>• Regulatory decision-making framework in place</li> <li>• Annual scheduled review of the Strategy</li> <li>• Approved HTA Business Plan which balances core regulatory functions, development priorities and resource deployment considerations</li> <li>• Well established processes which support our core regulatory business</li> <li>• HTA People Strategy substantially amended and approved by the Board</li> <li>• Training and development of professional competence</li> <li>• Specialist expertise identified at recruitment to ensure a broad range of knowledge is maintained across all sectors and developing areas</li> </ul>	

	<ul style="list-style-type: none"> <li>• Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC and stakeholders during the transition period</li> </ul>	
<p><b>R2: Inability to manage an incident that impacts upon the delivery of HTA strategic objectives.</b></p>	<ul style="list-style-type: none"> <li>• Critical Incident Response Plans are regularly reviewed and communicated to staff who are trained annually;</li> <li>• Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve the Comms Team.</li> <li>• Comms Team have embedded media handling and development of lines to take into business as usual.</li> <li>• IT security controls and risk management in place and Critical Incident Response Plan is regularly reviewed and tested.</li> <li>• Ensuring Designated Individuals (DIs) or equivalent in the ODT sector are aware of and follow the incident reporting procedure for incidents reportable to the HTA.</li> </ul>	
<p><b>R3: Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach</b></p>	<ul style="list-style-type: none"> <li>• Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (update, amendments or emerging issues) to inform the DHSC and manage messages</li> <li>• Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope</li> <li>• Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence</li> <li>• Action where we believe it will support public confidence.</li> <li>• Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</li> </ul>	

	<ul style="list-style-type: none"> <li>• Significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent.</li> <li>• Professional Evaluation Survey (conducted in Q 2019/20) results used to inform further developments</li> <li>• Communications work package set up as part of the UK Transition project to ensure we are managing our licenced establishments' expectations of what is required at the end of the transition period. As part of this work package, we will also attempt to reach out to unknown end users to make them aware of their new regulatory licensing requirements and timelines.</li> </ul>	
<p><b>R4: Failure to utilise people, data and business technology capabilities effectively</b></p>	<ul style="list-style-type: none"> <li>• Full suite of people policies and procedures (including performance management).</li> <li>• People Strategy for the period 2019 to 2021 in effect</li> <li>• External assessment of utilisation of capabilities</li> <li>• Adherence to the HTA Workforce Capability Development Framework</li> <li>• Investment in the development of the HTA leadership team</li> <li>• Handover process formalised via a checklist to ensure corporate knowledge is retained.</li> <li>• Data relating to establishments securely stored within our Customer Relationship Management system (CRM)</li> <li>• Appropriate procedures to manage personal data including GDPR compliance</li> <li>• Staff training in key business systems</li> <li>• IT systems protected and assurances received from third party suppliers that protection is up to date.</li> </ul>	
<p><b>R5: Insufficient, or ineffective management of financial resources</b></p>	<ul style="list-style-type: none"> <li>• Budget management framework exists to control, and review spend and take early action</li> </ul>	

	<ul style="list-style-type: none"> <li>• Financial projections, cash flow forecasting and monitoring, reviewed monthly by executive team;</li> <li>• Reserves policy and levels are reviewed frequently and reported to the executive team and Authority;</li> <li>• Internal audit and annual external audit of finance are undertaken each year;</li> <li>• Fee modelling which provides cost/income information for planning;</li> <li>• Rigorous debt recovery procedures in place.</li> </ul>	
<b>R6: Failure to achieve the benefits of the HTA Development Programme</b>	<ul style="list-style-type: none"> <li>• SMT expertise in organisational change, programme and project management</li> <li>• Procurement and contract management experience within SMT</li> <li>• Well established corporate governance and financial controls.</li> <li>• Existing mechanisms for engaging staff</li> <li>• A phased delivery approach implemented to avoid all or nothing investment and aligned with available funding.</li> </ul>	

At the end of the 2019/20 business year, we identified a risk of continuity relating to risks three, four and six, as several of our Board Members were due to step down in the latter part of the 2020/21 business year. This emerging risk has reduced as two new members have been appointed at the end of the 2020/21 business year with a third commencing in April 2021. We are in constant contact with our Departmental sponsors to ensure this risk is fully mitigated.

Further information on the HTA's approach to managing risk can be found in the Annual Governance Statement.

### Going concern

The HTA annual report and accounts have been prepared on a going concern basis. The HTA is funded from two sources; grant in aid provided by the Department of Health and Social Care who are in turn are funded through Parliament and Parliament has demonstrated its commitment to continue to fund DHSC for the foreseeable future; and licence fees from both the private and public sector which represent around 80%.

Our funding from DHSC has been agreed for the next year and our licence fees which are charged in line with statute creating a guaranteed income source. These fees are set in December each year, prior to billing our establishments in the April and September of the



following year. We also hold £1.5m in reserves which allows the HTA to continue its core operational activities.

In addition, there is no expectation that the services of the HTA will not continue or that the organisation is subject to any review that may result in it being abolished or subsumed.

Based on the above, the Board has reasonable expectation that it has adequate resources to continue in operational existence for the foreseeable future. For this reason, the Board continues to adopt the going concern basis for preparing the financial statements.

## Performance analysis

### Measuring performance

Each year, we agree a business plan with the Department of Health and Social Care (DHSC) that includes strategic aims, high level objectives and key performance indicators (KPIs) covering delivery of our statutory remit and public accountability.

The HTA records achievement of key performance indicators monthly and reviews achievement and action needed at the HTA Management Group (HTAMG) meeting. Our KPIs detailed below measure non-financial performance to provide an overview of our activities.

Each quarter a report is made to the Board and DHSC providing assurance. This year, there has been a change in the way we report performance. The restrictions that came into force at the end of 2019/20 have impacted upon our ability to conduct site visits. This was a risk that the executive, the Board and sponsor team are aware of, and have tolerated. The adoption of virtual non-site assessments known as Virtual Regulatory Assessments (VRAs) is deemed a suitable alternative in medium to long-term. Previously we had reported against a target number of site visits. Due to the restrictions over the year, the decision was taken to defer the site visits to 2021/22 and therefore the KPI for this activity has been removed.

### Analysis of performance over the year

#### Performance indicators 2020/21

Performance indicators	Target 2020/21	Performance 2020/21	Target 2018/19	Performance 2019/20
<b>Delivery</b>				
Take appropriate action for all regulatory non-compliance <sup>1</sup>	100% of Corrective and Preventative Actions	98.5% <sup>1</sup>	100% of Corrective and Preventative Actions	100%

<sup>1</sup> Target missed due to 2 CAPA's that remained open due to insufficient information

	(CAPAs) implemented within 28 days		(CAPAs) implemented within 28 days	
Make appropriately evidenced decisions to agreed quality standard	100% of non-panel cases turned around with 5 working days	100%	100% of non-panel cases turned around with 5 working days	100%
Respond to enquiries in a timely way	95% of enquiries answered within 10 working days	95% <sup>2</sup>	95% of enquiries answered within 10 working days	94%
<b>Deployment</b>				
Reduce attrition rates through improved selection and targeted measures to retain staff	Attrition rate to be no more than 18%	14% <sup>3</sup>	Attrition rate to be no more than 18%	29%

## Financial review

We have generated the income needed to cover the cost of licensable activities and delivered within the budget set for the year. We have a comprehensive fees model that enables us to set our fees according to the regulatory workload and allocate our costs according to our activities as set out in legislation.

### Summary position as at 31 March 2021

		2020/21	2019/20
	Note	£'000s	£'000s
<b>Income</b>			
From devolved Governments		134	133
Licence fees		3,997	3,728
Other income	(a)	418	454
<b>Total income<sup>4</sup></b>		<b>4,549</b>	<b>4,315</b>
<b>Expenditure</b>			
Staff costs		3,356	3,343
General administrative and non-cash costs		2,019	2,032
<b>Total expenditure<sup>4</sup></b>		<b>5,375</b>	<b>5,375</b>
<b>Net (expenditure)/income for the year</b>	(b)	<b>(826)</b>	<b>(1,060)</b>

(a) Other income is made up of rental income from NHS Resolution and seconded staff costs.

(b) Net expenditure for the year reflects our financial position excluding the Grant-in-aid (GIA) funding received from Department of Health and Social Care. The table below reflects the revenue GIA received from DHSC, to arrive at the Net operating surplus for HTA.

<sup>2</sup> Target has been met during a period of change and some uncertainty

<sup>3</sup> An increase in the number of leavers compared to last year. Due to our size, a small movement in numbers causes a larger increase in percentages.

<sup>4</sup> Figures differ from financial statements due to rounding in both financial years

Net (expenditure) /income for the year	(b)	(826)	(1,060)
Revenue Grant in Aid	(c)	771	693
Pension contribution increase	(d)	0	129
Ring-fenced RDEL	(e)	206	198
Surplus/(deficit) for the year		151	(40)

(c) GIA is treated as financing within statutory accounts and it is a requirement to report it this way. GIA is therefore excluded in the Statement of Comprehensive Net Expenditure (SoCNE) on page 62 within the financial statements and included in the Statement to Changes in Taxpayers Equity (SoCTE) on page 65.

(d) This represents payments made to the NHS Pension Scheme by DHSC on the HTAs behalf.

(e) In addition, the HTA received cover for its non-cash expenditure (depreciation and amortisation) of £206k. It is not cash and therefore not shown in the accounts.

Against the above surplus our operating expenditure is £5.37m. Our staff costs at £3.3m were in line with that of last year.

Income from contracts with customers (Licence fee income) of £4m is 7% higher than our 2019/20 fee income (just over £3.7m), and 1.5% higher than the budget. This increase largely due to increased application fees in 2020/21.

During 2020/21 the HTA managed its income to ensure drawdowns were kept within the DHSC's cash allocation. The total available cash allocation for revenue and capital expenditure was £771,000 and £100,000 respectively, (2019/20 £693,000 and £100,000).

## Supplier payments

The HTA is committed to the Better Payment Practice Code. We aim to pay suppliers within ten days of receipt of a valid invoice. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

HTA Target	2020/21	2019/20
90% of payments made within 10 days of receipt of undisputed invoice. (Better Payment Practice Code Target is 95% in 30 days)	<b>383 invoices received of which 346 (92.3%) were paid within 10 days</b>	813 invoices received of which 806 (99.1%) were paid within 10 days

The reduction in invoices received (53%) is due to the reduction in activities due to the COVID-19 pandemic and its resulting restrictions. We continue to meet our target and exceed the Better Payment Practice Code Target of 95%.

## Counter fraud and corruption

In January 2019 the Cabinet Office launched a revised Functional Standards for Counter Fraud Bribery and Corruption (GovS 013) and announced its extension to all Arm's Length Bodies (ALBs). These standards set expectations for the management of fraud, bribery and corruption risk in government organisations. The standards represent the minimum that organisations should have in place and will evolve over time. The Cabinet Office assesses the performance of organisations against these standards and assigns a maturity level indicating how sophisticated they are in their approach.

Achieving compliance with the functional standard required a revised and expanded counter fraud, bribery and corruption strategy, policy and response plan that were approved in Quarter 3 of 2019. A formal fraud risk assessment was conducted twice during the last year. From the 1 April 2020 we submitted our first consolidated data request (CDR) of losses and errors from fraud to the Cabinet Office.

Whilst the HTA is yet to receive feedback on the actions taken as part of the Functional Standards, we will continue to ensure awareness of fraud is made across the business and by all staff. Short training sessions on bribery and corruption have been taken in the last quarter of the 2020/21 business year with completion in quarter one of 2021/22.

## Staff involvement and wellbeing

The HTA keeps all members of staff informed about organisational, management and policy issues. There is a weekly briefing for all staff and in addition all-staff meetings are held at least every three months. Directorate team meetings are also held regularly. Members of staff can raise any issues with a member of the SMT during the weekly "SMT drop-in" session.

The impact of the COVID-19 pandemic highlighted issues around staff mental health and wellbeing. During this time, our focus increased on ensuring that staff felt supported whilst working remotely. The introduction of our new intranet (WAVE) is used to keep staff informed of the latest developments around restrictions and their impact on the work of the HTA. A "Wellbeing" page was designed where varied topical guidance and support is provided. Staff are able to access recommended training and links to information around Childcare support during COVID-19, topics around staying motivated, content and resilient.

As a response to the restrictions in place over the last year and after a consultation, the HTA has implemented flexible working and opportunities to become home-workers, timed to coincide with the relocation of the HTA to its new offices in Stratford in January 2021. The actual date that staff can return to office working is yet to be established, however where it can be achieved safely,

staff who have struggled with remote working were also given the opportunity to attend the offices.

The HTA has a staff forum to ensure that all staff have their say and have an opportunity to raise issues, make suggestions and give opinions. The chair of the staff forum is also the staff Freedom to Speak Up champion, to provide a secure mechanism for staff to raise any concerns.

A Board Member, the chair of the Audit and Risk Assurance Committee (ARAC), also acts as a Freedom to Speak Up champion and meets with the chair of the staff forum at least three times a year coinciding with ARAC meetings.

The HTA maintains an up-to-date health and safety policy and we set out our responsibilities in the Statement of Intent. The HTA has appointed first aiders and fire wardens and has online training modules and assessments to ensure staff are working in a safe environment that protects their health. No health and safety incidents were reported in the year.

The HTA also have Mental Health First Aiders (MHFAs) who act as a point of contact for any member of staff who is feeling or experiencing any form of mental health or emotional distress.

## **Learning and development**

The HTA actively promotes the development of staff by offering a wide range of corporate and specific training. Individual needs are set out in personal development plans and are met through training events, participation in projects, observing activities the HTA oversees and shadowing. This year, investment in staff training events has continued albeit virtually. Staff have also conducted training sessions called “Lunch and Learn”, sharing their expertise across the sectors we regulate and other areas of learning. Feedback is always sought from staff, with most attendees indicating that the skills and knowledge gained at such events are relevant to their roles.

Our Career Investment Scheme launched over eight years ago, to assist staff members to obtain professional qualifications or undertake training to enhance their skills and knowledge to aid their career, continues to be used. In 2020/21 six members of staff benefitted from the scheme, in addition to the 36 previous beneficiaries since the scheme began. We also have access to training Astute training platform. Here staff can access short online training sessions, ranging from Health and Safety to Information governance. The Civil Service Learning portal which provides training resources for public sector staff is also available.

## **Equality Act 2010 – equality and diversity and human rights**

The HTA is committed to providing equal opportunities for all staff. Our aim is to ensure that all staff are aware that any form of discrimination against people, because of their race, disability, gender, gender identity, religion/belief, age, sexual orientation or any other protected characteristic is prohibited within the HTA, and to ensure that the Authority abides by the

statutory regulations regarding human rights and discrimination. We periodically monitor our performance in this area with reports discussed at management meetings. Any new policies and those subject to review are considered from an equality impact assessment perspective.

During 2020/21 the HTA became accredited to the **Race at Work Charter**. In order to gain this, the HTA had to meet amongst other things five charter principles:

Principle	HTA response
Appoint a Sponsor for race	We have an Executive Sponsor for race to provide visible leadership on race and ethnicity across the HTA, which is the HTA Chief Executive
Capture ethnicity data and publicise	We capture ethnicity data via IRIS (HR system) and measure our progress and aim to publish this in our annual report.
Commit at board level to zero tolerance of harassment and bullying	We have full commitment from our board and SMT to zero tolerance of any form of harassment or bullying and we have policies in place to support this.
Make clear that supporting equality in the workplace is the responsibility of all leaders and managers.	We have a shared responsibility to ensure performance objectives for leaders and managers cover their responsibilities to support fairness for all staff.
Take action that supports ethnic minority career progression	We have a culture of coaching and mentoring with a plan for a more formalised mentoring programme when the immediate needs of the pandemic have eased.

## Disabled employees

We have a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making any reasonable adjustments to the workplace or work processes and having advice available through the occupational health service.

## Gender mix as at 31 March 2021

An analysis of gender mix for the headcount as at 31 March 2021 is provided below. The figures exclude the Shared Director who is accounted for within the Human Fertilisation and Embryology (HFEA) and temporary staff.

Gender	Male	Female	Total 2020/21	Total 2019/20
Authority Members	4	6	10	13
Directors	1	2	3	3
Total staff (including Directors, excluding Members) <sup>5</sup>	12	33	45	47

Of the 19 staff who declared, one reports themselves as disabled. An analysis of other characteristics of all staff, as at 31 March 2021, is provided below.

### Staff mix according to age as at 31 March 2021

Age range	2020/21	2019/20
< 34	8	11
35-44	17	21
45-54	14	10
>55	6	5

Ethnicity	2020/21	2019/2
White British	39	29
Asian [Indian]	0	3
Black [African]	1	1
White [European]	3	1
White [Irish]	0	1
Other	0	2
Undefined	2	10
<b>TOTAL</b>	<b>45</b>	<b>47</b>

### Social, community, sustainability and environmental issues

The HTA recognises the work-related benefits of staff joining together outside work for various events. We encourage a social committee to organise informal and more formal gatherings. This

<sup>5</sup> Last year (Male 11/Female 37)

year has seen virtual events that have brought staff together whilst restrictions on travelling to the office remained.

During 2020/21 HTA staff have engaged in events to raise funds for charities. The HTA has supported staff in these endeavours.

Once restrictions are lifted, the HTA will occupy space within a multi tenanted building on 2 Redman Place. We share floor space with the Care Quality Commission (CQC), National Institute for Health and Care Excellence (NICE), the Human Fertilisation and Embryology Authority and the Health Research Authority (HRA). This co-habitation has enabled us to achieve the 2014 Government Estates Strategic target for space utilisation of 8 sqm / full-time equivalent (FTE) staff member. The new offices provide a fully inclusive, flexible and collaborative working environment supporting all organisations.

Our landlords, the British Council, provide services and encourage behaviour that meets sustainability requirements. This includes recycling, energy efficiency and other facilities. HTA performance is not monitored separately.

Whilst the HTA may be exempt from formal reporting on a number of Greening Government Commitments, as it has fewer than 250 FTE staff, we still consider environmental and sustainability issues when procuring goods and services. Staff and Members are encouraged to travel on HTA business in the most sustainable and cost-effective way.

The HTA is a member of the Cycle to Work scheme, which provides tax efficient incentives for employees to use cycles to travel to work.

We are aware of the green agenda in relation to procurement and we use the Crown Commercial Service and other frameworks which have sustainability factored in.

During this extraordinary time of the COVID-19 pandemic The HTA has successfully relied on its technology to enable us to collaborate and conduct our business seamlessly.



**Allan Marriott-Smith**  
**Chief Executive**  
**Accounting Officer**

**9 July 2021**



# Accountability

# Corporate governance report

## Directors' report

### The Board

Our Board consists of 13 Members (including the Chair) appointed through an open public process. At 31 March there were 10 Board Members with an additional member taking up post in April 2021. Authority Members during 2020/21 are set out below. Biographies for each can be found on our website.

Authority member	Type	Appointment start date	Appointment end date
<b>Lynne Berry CBE (Chair)</b>	Lay	18 November 2019	17 November 2022
<b>William Horne<sup>6</sup></b>	Lay	1 August 2014	31 March 2021
<b>Professor Andy Hall</b>	Professional	20 October 2014	11 February 2021
<b>Hossam Abdalla</b>	Lay	20 October 2014	11 February 2021
<b>Amanda Gibbon</b>	Lay	20 October 2014	11 February 2021
<b>Professor Anthony Warrens</b>	Professional	20 October 2014	11 February 2021
<b>Glenn Houston</b>	Lay	5 May 2015	4 May 2022 (extended in March 2021)
<b>Dr Lorna Williamson OBE</b>	Professional	1 April 2016	31 March 2022 (re-appointed February 2019)
<b>Professor Penney Lewis</b>	Lay	1 April 2016	31 March 2022 (re-appointed February 2019)
<b>Dr Stuart Dollow</b>	Professional	1 April 2016	31 March 2022 (re-appointed February 2019)
<b>The Right Reverend Graham Usher</b>	Lay	1 April 2016	Resigned 5 November 2020
<b>Professor Gary Crowe</b>	Lay	1 September 2019	31 August 2022
<b>Dr Charmaine Griffiths</b>	Lay	1 September 2019	31 August 2022
<b>Professor Deborah Bowman</b>	Lay	4 January 2021	3 January 2024
<b>Jan Williams OBE</b>	Lay	4 January 2021	3 January 2024

Member biographies are on the HTA website: <https://www.hta.gov.uk/about-hta/meet-our-board-and-executive-team>

<sup>6</sup> William Horne became acting Chair from 10 January to 18 November 2019

## Senior Management Team

Our Chief Executive and Directors during 2020/21 are set out below.

Senior Management	Post
Allan Marriott Smith	Chief Executive
Richard Sydee <sup>1</sup>	Director of Resources
Nicolette Harrison	Director of Regulation
Louise Dineley	Director of Data, Technology & Development

<sup>1</sup> Director of Resources is shared and seconded 2.5 days a week from the Human Fertilisation and Embryology Authority (HFEA)

## Interests of Board Members and senior staff

The HTA maintains a Register of Interests. All Board Members and staff declare any company directorships and other significant interests held by them or their close family and friends which may conflict with their HTA responsibilities.

Potential conflicts of interest are managed by all Board Members, and staff, declaring in a register of interests any company directorships and other significant interests held by them or their close family and friends which may conflict with their HTA responsibilities.

Members also declare their interest in any items being discussed at Board and ARAC meetings. The Chair decides whether there is a conflict of interest and whether the Member concerned should remain involved in the discussion.

Members interests are published on our website <https://www.hta.gov.uk/about-hta/committees-and-working-groups/authority-board>

## Pensions

Pension benefits are provided by the National Health Service (NHS) Pension Scheme. The HTA recognises the contributions payable for the year. Full details are set out in the remuneration and staff report and note 1.11 to the accounts.

## Data incidents

Arrangements for data security and any personal data-related incidents are set out in the annual governance statement.

## Our auditors

The Comptroller and Auditor General is the external auditor for the HTA's accounts. The external auditor's remuneration in 2020/21 was £27,800. No fees were incurred for non-audit work.

## Statement of the Authority and Accounting Officer's responsibilities

Under the Human Tissue Act 2004, the HTA is required to prepare a statement of accounts in the form and basis set out in the Accounts Direction for each financial year, in conformity with the Secretary of State's direction Schedule 2 (paragraph 16), 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 income and expenditure, Statement of Financial Position and cash flows for the financial year.

In preparing the accounts, the Authority and the Accounting Officer are required to comply with the requirements of the Government Financial Reporting Manual prepared by HM Treasury, and in particular to:

- observe the Accounts Direction issued by DHSC, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- 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;
- prepare the accounts on a going concern basis;
- confirm that the Annual Report and Accounts as a whole is fair, balanced and understandable and I take personal responsibility for the Annual Report and accounts and the judgements required for determining that it is fair, balanced and understandable.

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

The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances, for which the Accounting Officer is answerable, for keeping

proper records and safeguarding the HTA's assets, are set out in the Accounting Officers' Memorandum, issued by the DHSC, and in Managing Public Money published by HM Treasury.

As Accounting Officer, I have taken all the 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 that information. So far as I am aware, there is no relevant audit information of which the auditors are unaware.

## **Accounts direction**

The Annual Accounts have been prepared and issued by the HTA, under directions given by the Secretary of State for Health and Social Care, with the approval of HM Treasury, in accordance with Schedule 2 (paragraph 16) of the HT Act. The Accounts report the resources that have been used by the HTA to deliver its objectives. These Annual Accounts have been prepared in accordance with the guidance set out in the Department of Health and Social Care (DHSC) Group Accounting Manual (GAM) 2020/21.

## **Authority statement**

The Senior Management team (SMT) of the HTA and the ARAC, on behalf of the Authority, has reviewed the Annual Report and Accounts.

# Governance statement

## Introduction

This statement sets out the governance and control framework at the HTA and the risks to HTA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HTA's resources in 2020/21.

This year has seen many challenges due to the impact of the COVID-19 pandemic, that affected and continues to affect many organisations. We set our priorities for the 2020/21 business year in the last quarter of 2019/20. At that point we, like many, were unaware of the significant changes to come.

## Governance framework

### The Human Tissue Authority

The Human Tissue Authority is a regulator set up in 2005 following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent. The legislation that established us not only addressed this issue but also updated and brought together other laws that relate to human tissue and organs. The HTA was established by the Human Tissue Act 2004 as an arm's length body of the Department for Health and Social Care and is overseen by a Board of lay and professional members appointed by Government.

The Permanent Secretary nominates a Senior Departmental Sponsor (SDS) who acts as the HTA's designated, consistent point of contact within the Department. The SDS acts as the link at executive level between the HTA and the senior officials of the Department and Ministers. The SDS also supports the Permanent Secretary in holding the HTA to account and in providing assurance on its performance.

A Departmental sponsor team supports the SDS by undertaking the principal day-to-day liaison between the Department and the HTA.

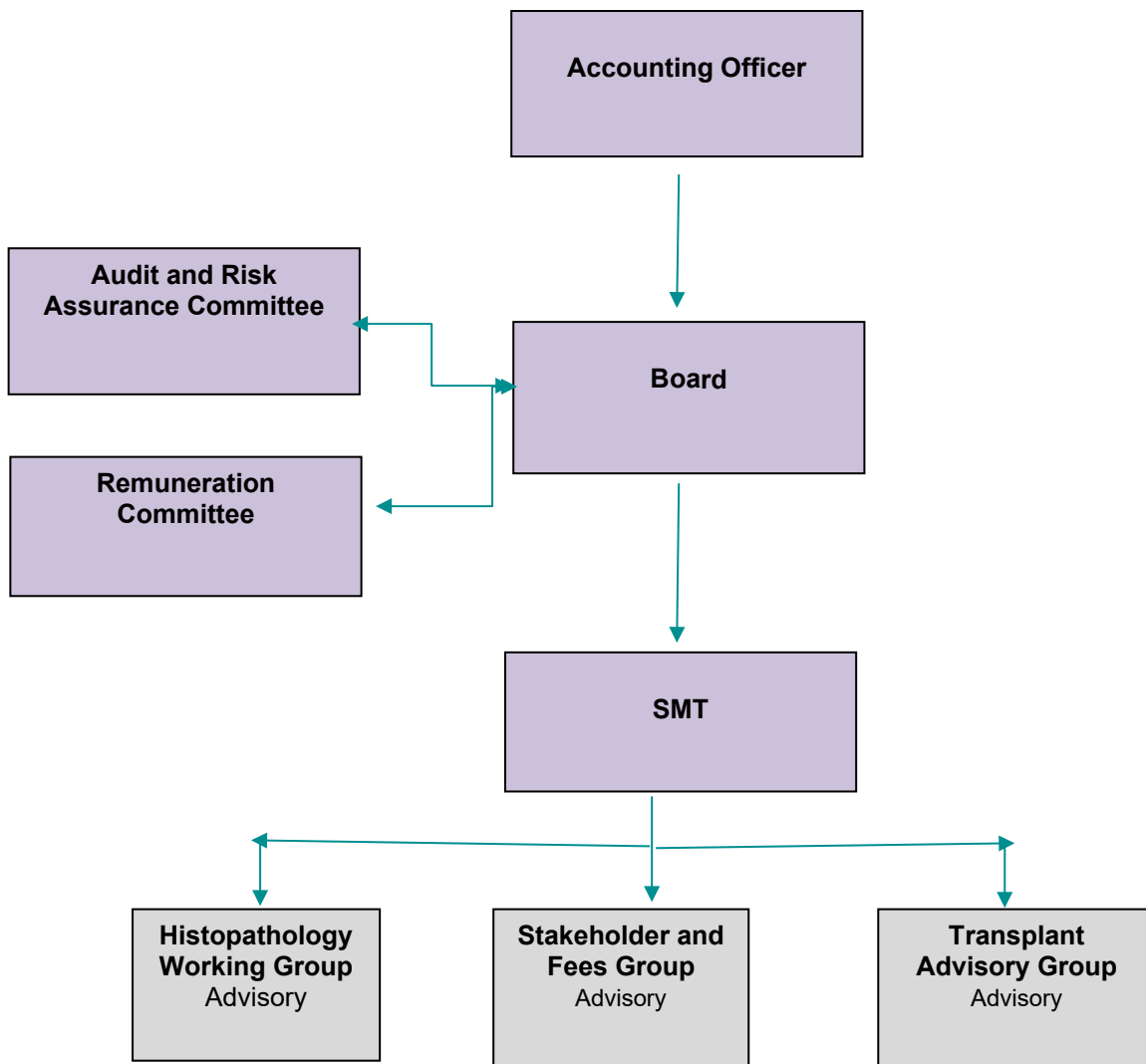
The Secretary of State has delegated some of his statutory responsibilities to the HTA.

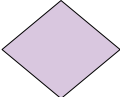
As Accounting Officer, I am responsible for ensuring the HTA business is conducted in accordance with the law and proper standards, and that public money is safeguarded and properly accounted for, and used efficiently, effectively, and economically.

In discharging this overall duty, I am responsible for putting in place proper arrangements for the governance of HTA's affairs and facilitating the effective exercise of its functions which includes the management of risk.

As the HTA's Chief Executive, I am responsible for service delivery and resources. There are structures and processes in place to ensure accountability and give the HTA a framework for risk management.

### The Governance Structure



 Decision making

 Advisory

## The Board

The Board (the HTA's statutory non-executive board) comprises 13 Members including the Chair who are appointed by the Secretary of State for Health and Social Care, with the exception of one Member appointed by the Welsh Government Cabinet Secretary for Health, Well-Being and Sport and one by the Minister of Health in Northern Ireland. Members are appointed for a three-year term of office initially.

At the end of 2020/21 there were 9 Members plus the Chair who come from a variety of medical, scientific, legal, administrative and ethical backgrounds. This ensures that the Board draws on a wide range of experience relevant to the governance of the HTA. By law, at least half must be lay Members.

This year has seen the terms of office end for five Members, these were; The Right Reverend. Graham Usher, Professors Andy Hall and Anthony Warrens, Hossam Abdalla and Amanda Gibbon, the out-going Chair of the Audit, Risk and Assurance Committee (ARAC).

We welcomed two new Members in February 2021; Professor Deborah Bowman and Jan Williams OBE and a third who will take up post in April 2021.

The Board's primary role is to ensure that the HTA's statutory responsibilities are met. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an executive that is responsible for the discharge of these responsibilities on a day-to-day basis. At every meeting the Board receives reports aligned with our strategic themes of Delivery, Development and Deployment and these include reports on our financial priorities and an updated assessment of strategic risk.

## Highlights of Board reports

Key areas of business considered by the Board, in addition to standing items over the reporting period such as performance reporting (including financial performance) and risk management, included:

- business continuity risk and issues being faced from the start of the coronavirus pandemic; contingency arrangements and re-build strategies
- feedback on staff wellbeing and support
- sector activities, risks and oversight and our regulatory response
- emergency mortuary licensing (during the first wave)
- virtual regulatory assessments (pilot) in response to the cessation of site visits due to government restrictions
- development of the Board's risk appetite and tolerance statements
- update on plans post the internal audit review of corporate governance arrangements
- development programme (formerly transformation programme) and progress on the six priority areas and the impact the pandemic has had on progress.



The Board ensures that statutory functions are delivered appropriately, in line with the [Harris review](#). It has a clear understanding of the statutory basis of work undertaken by the HTA, ensuring there is direction or clarification from the DHSC where required.

The HTA is committed to transparency and public accountability and therefore Board agendas, papers and minutes are published on our website, along with other policies and reports.

The Board met 4 times during the year. The Chief Executive and Executive Directors (the SMT), attend Authority meetings. Representatives from the DHSC also attend, and other HTA staff attend as required. Member attendance at ordinary Board meetings in 2020/21 is listed below.

Authority Member	Number of meetings attended
Lynne Berry CBE	4/4
William Horne	4/4
Professor Andy Hall	4/4
Hossam Abdalla	4/4
Amanda Gibbon (ARAC Chair)	4/4
Professor Anthony Warrens	4/4
Glenn Houston	3/4
Dr Lorna Williamson OBE	4/4
Professor Penney Lewis	4/4
Dr Stuart Dollow	4/4
The Right Reverend Graham Usher <sup>7</sup>	2/3
Professor Gary Crowe	4/4
Dr Charmaine Griffiths	4/4
Professor Deborah Bowman	2/2
Jan Williams OBE	2/2

## Committees and groups

The Board is supported in its work by Committees and groups which include Members. Committees review the work of the HTA and make decisions or recommend a decision to the full Authority where necessary. Groups include stakeholders and provide input to emerging strategies and approaches. The following committees and groups were in place in 2020/21.

Committees of Members:

<sup>7</sup> Graham Usher resigned from the Board 5 November 2020

- Audit and Risk Assurance Committee (ARAC)
- Remuneration Committee

Groups consisting of Members with external stakeholder representation:

- Transplantation Advisory Group (TAG)
- Histopathology Working Group (HWG)
- Stakeholder and Fees Group

Having external stakeholder representation on groups enables the Board to work directly with stakeholders to review developing issues and advise the Executive. These discussions improve Members' understanding of operational activity which enhances the Authority's ability to scrutinise the actions of the Executive. Groups also provide Members and stakeholders with the chance to contribute views to the early stages of significant regulatory policy development, resulting in better decision making.

TAG is a forum for the discussion of issues arising in living and deceased organ donation. In particular, the Group considers new policy issues and emerging novel areas in transplantation; identifies revisions required to current HTA or NHS Blood and Transplant (NHSBT) policies; discusses the complex ethical issues in transplantation; and reviews guidance on issues surrounding Independent Assessors (IAs), including recruitment and performance issues identified during the reaccreditation process.

HWG exists to maintain a positive and long-lasting impact on the delivery of post-mortem services, working with the sector to help drive up standards. Consultation with HWG helps ensure that advice provided by the HTA remains current and in line with professional guidance. In addition, the HWG considers issues facing post-mortem sector establishments, in order to inform the continued development of HTA regulatory policy affecting the sector and its overlap with the research sector.

The Stakeholder and Fees Group provides a forum for regular consultation on our approach to regulatory activities, including fee-setting and an opportunity for stakeholders to make their views known to the Authority. The Stakeholder and Fees Group was established to ensure the HTA continues to improve transparency and accountability and maintain effective working relationships with establishments we license.

The three advisory groups did not meet during the 2020/21 business year because of the pandemic restrictions. It is expected that if restrictions continue, the group will meet virtually. Engagement was maintained with key external stakeholders through alternative means, including active participation in cross-government, multi-agency groups dealing with the pandemic response.

The ARAC met three times in 2020/21. The Chief Executive, the Director of Resources, the Head of Finance and Governance, the HTA's external and internal auditors and a representative of the Department of Health and Social Care attend meetings. Other Directors and staff are asked to attend to discuss particular risk areas that the ARAC wishes to explore, or other topics

depending on the ARAC's business. The ARAC's terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular, providing scrutiny to support the agreement of the Governance Statement.

Member attendance at ARAC meetings in 2020/21 is listed below.

ARAC member attended	Number of meetings
Amanda Gibbon (Chair)	3/3
Prof. Gary Crowe (Chair) <sup>8</sup>	3/3
Dr Charmaine Griffiths	3/3
Glenn Houston	2/3
Dr Stuart Dollow	3/3

The Audit, Risk and Assurance Committee has received reports from management, internal and external audit in a range of areas.

In 2020/21 the internal audit plan covered six business areas which were all completed by the end of the business year. The areas covered and the assurance ratings given are set out below:

Audit	Scope	Assurance rating
Review of Cyber Security Strategy	Review of the Cyber Security Strategy, including assessing how any changes are being managed	Moderate
Consistency in the Inspection Process	Assessment of how HTA monitors the quality and effectiveness of inspections in a non-inspection regime	Moderate
Risk management including a deep dive on the risk around UK Transition	Assessment and management of risks and the approach to risk tolerance and appetite	Moderate
Corporate Governance (Advisory)	Review of governance and structure of various committees	N/a
Accounts Payable and Receivable	Review of controls and governance in place	Substantial

Areas of particular focus for ARAC during 2020/21 were:

<sup>8</sup>Gary Crowe replaced Amanda Gibbon as Chair in January 2021

- The strategic risk register and in particular tolerance in relation to risk 1-failure to regulate appropriately. The lack of inspections across sectors due to coronavirus was a concern. Mitigations for this included the development of Virtual Regulatory Assessments (VRAs).
- UK transition and planning
- Office relocation project
- Outcomes from internal and external audit reports

In January 2021, ARAC held its annual meeting in private with external and internal auditors to assure themselves there were no other matters of which they should be aware of.

Our internal auditors are the Government Internal Audit Agency who are in the fourth year of their appointment with the HTA. The Head of Internal Audit (HIA), changed in the latter part of the year with Joanne Charlton replacing the interim Head, Anthony Stanley, who oversaw the programme of audit work as detailed above until January 2021.

The Remuneration Committee met twice in 2020 to agree the principles for the 2020 pay award. The Chief Executive, the Director of Resources and the Head of HR attend the Remuneration Committee as appropriate. Members and their attendance are as follows:

Member	Number of meetings attended
Lynne Berry CBE (Chair)	2/2
Hossam Abdalla	2/2
Glenn Houston	2/2
Professor Penney Lewis	2/2

Board Members may also chair and participate in HTA conferences, events, and workshops for stakeholders; participate in working groups covering the work of the Directorates and provide advice to the executive. The Welsh Member has also liaised with the Welsh Government. The Northern Ireland member has liaised with the Department of Health NI, as and when required.

## Effectiveness of the Board

The HTA complies with HMT- *Corporate governance in central government departments: code of good practice*. Members' terms and conditions include adherence to the seven principles of public life: selflessness, integrity, objectivity, accountability, openness, honesty and leadership, and these are demonstrated in Authority meetings.

The Chair of the Board assesses the performance of each member annually. DHSC forms a view on the effectiveness of the Board by attending meetings and of the HTA's performance through quarterly accountability meetings. No significant issues have been raised.

ARAC makes a self-assessment of its performance annually using the NAO Audit Committee checklist. During the year a flexible approach was needed in planning the meeting agendas,

informed by emerging risks and issues given the impact of the COVID-19 pandemic. The same agile approach was taken in regularly self-assessing committee effectiveness each time the committee met remotely, rather than completing the formal year end assessment using the NAO framework.

Training sessions are usually scheduled at the end of ARAC meetings to aid understanding of current topics although these have not occurred this year due to the logistics of virtual meetings during the pandemic. The newer ARAC members attended a training session for Audit Committee members on 18 March conducted by the Government Internal Audit Agency. This was to facilitate the Members understanding of role and responsibilities as Audit Committee members.

## The Executive

The Executive implements the policy and strategic goals set by the Board. It is led by the SMT consisting of the Chief Executive and three Directors.

The SMT meets weekly to consider a regular programme of business, ad hoc items and to exchange information. The SMT provides leadership to the staff of the HTA and makes decisions on how the strategies agreed by the Authority are to be implemented. The regular programme of business includes finance reports and reviews of the strategic risk register.

The HTA Management Group (HTAMG) consists of the SMT and the Heads of functions (the next level of management). This group normally meets monthly to review performance and operational risk, agree business plans and projects. Every quarter HTAMG considers operational risks alongside strategic risks. This, however, was paused due to the need to focus on business delivery during the pandemic.

During the last year, HTAMG consisting of Heads of functions met weekly also to discuss operational business plans and priorities in light of the coronavirus pandemic and its subsequent impact on the business plan including licensing of emergency mortuaries and supporting the pandemic response to excess deaths, moving to remote working, developing virtual replacements for site visits, maintaining priority operational delivery and development activity.

The Accounting Officer follows the requirements of *Managing Public Money* and the delegations issued by the DHSC. To ensure compliance with the Framework Agreement agreed with DHSC the HTA ensures:

- the provision of the HTA's strategic and business plans for approval by the DHSC
- that the HTA submits quarterly performance and risk reports to the timetable outlined by the DHSC and other returns (e.g. finance and headcount) as required
- participation in quarterly accountability reviews held between the HTA's SMT and the senior department sponsor.

## Whistleblowing arrangements

The HTA's Whistleblowing policy sets out how any concerns can be raised by staff and what action would be taken. It aims to reassure staff that they should raise concerns openly and that there will be no repercussions for them if they raise concerns in good faith. The policy has been communicated to staff through newsletters and all staff meetings.

As well as line management and HR channels, the HTA has both a staff and Board Member Freedom to Speak Up champion with whom staff can raise concerns. The Board Member is the Chair of ARAC who meets the staff member before each ARAC meeting to review what has been discussed at staff forum meetings and give the staff Freedom to Speak Up champion an opportunity to discuss any concerns that they or any other staff member may have. Contact details for the DHSC, National Audit Office (NAO) and the Whistleblowing Helpline are also provided.

During the year, there has been one issue raised under the HTAs whistleblowing arrangements, this is currently an on-going investigation.

## The control framework

The HTA understands the importance of risk management and internal control. All Members of the Board and the Executive have responsibility for risk management.

The Board is ultimately responsible for overseeing management of the HTA's strategic risks. The Board is supported by the ARAC and monitors risks through reports from the Executive and quarterly updates of the strategic risk register. The Chief Executive is responsible for providing leadership for management of risk within the organisation, supported by the Director of Resources, and all members of the SMT are responsible for managing the strategic risks that may impact the delivery of policies and objectives in their areas of work. Heads of functions manage the operational risks to the delivery of their areas of work and are required to report to the HTAMG on how they manage/mitigate particular risks.

There is an ongoing process designed to:

- identify and prioritise the risks to the achievement of HTA policies and aims and objectives
- evaluate the likelihood of those risks being realised, the possibility of new risks emerging, and the impact should they be realised
- manage them efficiently, effectively, and economically

The HTA Risk Management Strategy and Policy set out the principles and approach to managing risk at the HTA. In quarter four of the business year, a significant review of the Risk Management Policy alongside the Strategic Risk Register commenced. This year also saw the development of the Board's risk appetite and tolerance statement. This work is expected to be complete in early April. Refresher training on management of risk was undertaken in March which has ensured that existing and new Heads of function are aware of both the policy and process.

In order to ensure proper procedures are consistently followed, the control framework also includes policies and standard operating procedures that are reviewed and updated regularly. During the 2020/21 business year a detailed review of the governance documents including policies and standard operating procedures was conducted.

This framework has been in place in the HTA for the year ended 31 March 2021 and up to the date of approval of the Annual Report and Accounts and accords with HM Treasury guidance. The framework will continue to be refined and enhanced in order to ensure the HTA meets best practice for an established public body. The HTA will build on advice from our external and internal auditors as well as other professional sources to ensure it remains fit for purpose to meet the changing nature of our business.

The HTA is aware of the Macpherson report but does not use analytical models that inform government policy.

## **Risk assessment**

Our risks reflect the strategy for 2019-2022 and there are six strategic risks which over the year have been broadly stable in terms of their status, notwithstanding the impact and risk of COVID-19. At the end of March 2021, there were three risks that were rated Amber which means they have a scoring of between 12 and 16 and three risks that were rated yellow with scores between 5 and 10. All of the risks have been impacted by the coronavirus pandemic to varying degrees.

At the beginning of the 2020/21 business year, the HTA along with many other organisations were required to respond quickly to the impact of the COVID-19 pandemic. This risk, placed on both the sector and organisation, was incorporated into our strategic risk register at the beginning of the year.

To oversee the continued operations of the HTA we established a business continuity team who met daily to discuss the organisations capability and respond to changing advice from government and queries from the sector and aligned professional bodies. The Board held two extraordinary meetings with the Executive to scrutinise its response to the pandemic and the plans to continue oversight of the sectors we regulate.

The Strategic risk register was reviewed by the SMT monthly alongside control actions to mitigate risks.

The three amber risks were failure to regulate appropriately; failure to manage expectation of regulation and failure to utilise our capabilities effectively.

Risk one is failure to regulate appropriately, which had been amber rated for the year and was increased in March 2020 as the pandemic escalated. The risk level remained high (rating of 16) due to the managed issue of the cessation of site visit inspections in the Human Application sector, which are a key regulatory tool and is a statutory requirement. Alternative non-site visit inspection assessments (Virtual Regulatory Assessments (VRAs) were piloted in the HA sector in quarter three and continued in Quarter 4 following a detailed evaluation exercise with the

intention of extending their use to sectors next year. The VRAs have provided a level of assurance that establishments are compliant, coupled with last year's internal audit review of key regulatory processes that gave substantial assurance, it is felt that this risk is being managed and its rating is acceptable to the HTA.

The second amber risk is failure to manage expectations of regulation and has been assessed at amber throughout the year. This risk arises through the public's expectation of the HTA's regulatory reach, and where these expectations may be at variance with our remit under the current legislation. We continue to communicate our remit to stakeholders and the public and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit, but which may adversely impact on public confidence is challenging. The rate of growth in the number of perimeter issues shows no sign of decreasing. On the 31 December 2020 the Transition Period ended. The HTA has developed, amended processes and provided advice to stakeholders who import and export material from/to the EU, and those affected by movements between GB and Northern Ireland through the Northern Ireland Protocol, to be aware of and respond to the new regulatory requirements. This activity continued in Quarter 4 as some of these new licensing obligations did not take effect until after the end of June 2021 under the relevant UK Transition Statutory Instruments.

One notable issue at our regulatory boundary has been responding to concerns from Members of the House of Lords about the consent provisions for bodies and body parts imported for the purposes of public display, with progress made during Quarter 4 on making relevant changes for a revised Code of Practice for Public Display.

Failure to utilise our capabilities effectively is the final amber risk and has been assessed at this level for most of the year with increases in November and January in line with the changes in restrictions. This risk is centered around the deployment of our resources (staff and use of data and business technology). Issues around staff recruitment of specialist roles were an issue early in the year, however the status improved over the autumn. Further mitigations include the implementation of our EDRM system at the end of the year which is one of the workstreams of the Development Programme and is the pre-work needed for achieving implementation of our records management process and policies.

The three yellow risks are failure to manage an incident; insufficient or ineffective management of financial resources; failure to achieve the benefits of the HTA Development Programme; and failure to manage an incident were assessed as low throughout the year.

Our financial risk – insufficient or ineffective management of financial resources remained low over the year. Early in the year issues around our establishments' ability to meet their licence fee payments was raised and the reputational issue of billing during the pandemic did not materialise. The risk remains low as funds were released in year through carrying of vacancies and reduction in inspection costs. There may be a small risk of debt collection being a little slower than normal as our establishments' cashflow may be impacted by the pandemic.



In conjunction with a stable financial position, the final risk – failure to achieve the benefits of the HTA Development Programme benefited from the surplus funds released. Key workstreams were commenced with the completion of phase one of the EDRMS implementation and the transfer of electronic data into the cloud.

With regard to the final yellow risk relating to incident management, the speed and effectiveness of our shift to remote working and continuation of core business activities was a demonstration that our current plans work. An internal audit review of our Business Continuity and Critical Incidence Response plans, conducted in 2019/20, provided moderate assurance.

Assurance sources are identified for all risks and these reports and feedback provide assurance to the SMT and the Authority that the controls in place are as expected and that the risks are as stated.

## Pensions

As an employer with staff entitled to membership of the NHS Pension Scheme, control measures are in place to ensure all employer obligations contained within the Scheme regulations are complied with. This includes ensuring that deductions from salary, employer contributions and payments into the Scheme are in accordance with Scheme rules, and that member Pension Scheme records are accurately updated in accordance with the timescales detailed in regulations.

## Data security

In accordance with our responsibilities under Schedule 2 (paragraph 16) of the Human Tissue Act and the provisions of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the HTA has in place various robust and specific arrangements to maintain high standards of information security, including data protection. These include an information governance and cyber risk policy that applies to all staff, Members and contractors. There were no reportable personal data losses in 2020/21.

A Cyber Security Essentials audit was carried out in quarter three of 2020/21 by internal audit. The objective of this audit was to provide assurance that our Cyber Security Strategy including any recent or future changes are being managed, controlled and implemented effectively to meet defined objectives. This audit was given moderate assurance with four low level and two medium recommendations. The medium recommendations related to periodic audits of user devices deployed across the HTA network and production of incident response plans to restore IT services in the event of a service outage or disruption. The Cyber Security Strategy has been updated and progress towards achieving the National Cyber Security Centre (NCSC) Cyber Security minimum standards by 2023 was reported to ARAC in October 2020.

The internal audit review of our Records Management undertaken in 2018/19 made eight recommendations, of which five were high priority. These were the finalisation of a records management policy, the linking of the policy to the Information Asset Register, the development of a risk assessment methodology, the provision of training for staff and the appointment of a

Departmental Records Officer. The remainder related to retention of records and led to an overall opinion of Limited Assurance. Of the eight recommendations, three are outstanding and have been deferred to be picked up as part of the development programme and upgrading of our existing Records Management system and are considered at present a low priority.

The Director of Resources holds the role of Senior Information Risk Owner (SIRO). This is one of the requirements to strengthen controls around information security set out in the report of the Data Handling Review, which was carried out in 2008 for the Cabinet Office. The SIRO makes an annual report of compliance with the requirements for protecting information and an assessment of information risk management to the Accounting Officer and the ARAC which contributes to this Statement.

Historically the HTA has conducted the annual review of its arrangements against the Cabinet Office's mandatory requirements using the Security Policy Framework and 10 steps to cyber security and reports compliance to the ARAC and DHSC. This year we used the National Cyber Security Centre (NCSC) Minimum Cyber Security Standard to assess compliance. The overall assessment from the SIRO is that there are no areas of non-compliance that put information security at risk and that there are appropriate processes in place to minimise the risk to our information.

## **Accounting Officer Responsibilities and assurance**

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, the executive directors within the organisation who have responsibility for the development and maintenance of the internal control framework, risk management reports 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 the reviews of the effectiveness of the system of internal control by the Board's ARAC and appropriate plans to address any weaknesses and ensure continuous improvement of the system are in place.

During the year, the HTA engaged its internal auditors to review the areas of Consistency in the Inspection process, Cyber Security Essentials, Payable and Receivables, UK Transition – risk management and advisory reviews of our Corporate Governance Effectiveness. Each audit were rated as follows:

- Consistency in the Inspection process (four recommendations in total of which 3 were low – 1 medium recommendation relating to the assessment of risk 1 within the strategic risk register. The reduction in on-site inspections is a risk that is being mitigated by the introduction of Virtual Regulatory Assessments (VRA's). This involves remotely assessing compliance – desktop inspection as such.
- Review of Cyber Security (six recommendations in total of which 4 were low) – 2 medium recommendations relate to the audit of all user devices. This risk is controlled through the annual audit of IT laptops which takes place each year in January. There is room to conduct spot checks throughout the year. The second medium recommendation relates to the production of an IT Incidence Response Plan. This will be incorporated within the

newly updated Critical Incidence Response Plan (CRiP) and our Business Continuity Plan (BCP).

- Payables and Receivables audit received a Substantial rating with 3 low level recommendations, with the most important being the review and update of our SOPs which has now been done.
- Risk Management – EU Transition (four recommendations in total of which 3 were low – 1 medium recommendation which required due dates to be added to the Risks Assumptions Issues and Dependencies (RAID) Log. Again, this action has been taken.

Where high, medium, or low priority recommendations have been made I am assured that appropriate action plans are in place and good progress is being made against the agreed actions. The Head of Internal Audit has concluded that they can give “moderate assurance to the Accounting Officer that the HTA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2020/21”.

From this, internal audit’s annual opinion of moderate assurance, and the other sources stated on the risk registers (Board and ARAC reports, reviews with staff and feedback from DHSC and stakeholders), I am confident that the necessary assurances have been gained over the key areas, as set out above.

This enables me to confirm that the HTA’s systems are effective and working, to ensure that we have fulfilled and continue to fulfill our remit and our objectives.

There have been no significant internal control problems in the HTA up to 31 March 2021 and up to the date of this report.



**Allan Marriott-Smith**  
**Accounting Officer**  
**Human Tissue Authority**

**Date: 9 July 2021**

# Remuneration report

This report contains details on the remuneration of Members of our Board and the Executive for the year ended 31 March 2021. It is based upon the provisions contained within the Government Financial Reporting Manual 2020/21. It also provides an analysis of staff and sickness absence data.

## Audit

Specific areas of the Remuneration report are audited by NAO, the HTA's external auditors. These sections cover salary and pension data in the tables, non-cash benefits and amounts payable to third parties for services of senior staff.

## Salary and benefits in kind of Authority Members

Members of the Board receive an annual remuneration that is agreed by 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 DHSC. Members also receive travel and subsistence expenses which are deemed a benefit in kind (see later section).

Overleaf are the payments made to Members in the financial year 2020/21 and those benefits in kind that are subject to tax and national insurance.

## Trade Unions

Under the Facility Time Publication Requirements Regulations of 2017, the HTA is required to disclose the number of staff, cost and time spent on facility time by an employee who is a relevant union official if it meets certain criteria.

The HTA does not employ any staff who devote time to a trade union.

## The Authority (Audited)

Name	2020/21			2019/20		
	Salary range	Expenses (to nearest £100) <sup>9</sup>	Total	Salary range	Expenses (to nearest £100)	Total
	£'000s	£	£'000s	£'000s	£	£'000s
Lynne Berry CBE	40-45	0	40-45	15-20 (Fye 40-45)	0	15-20 (Fye 40-45)
William Horne	5-10	0	5-10	25-30	3,300	30-35
Amanda Gibbon	5-10	0	5-10	10-15	0	10-15
Hossam Abdalla	5-10	0	5-10	5-10	0	5-10
Professor Andy Hall	5-10	0	5-10	5-10	3,000	10-15
Professor Anthony Warrens	5-10	0	5-10	5-10	0	5-10
Glenn Houston	5-10	0	5-10	5-10	2,700	10-15
Dr Lorna Williamson OBE	5-10	0	5-10	5-10	400	5-10
Professor Penney Lewis	5-10	0	5-10	5-10	0	5-10
Dr Stuart Dollow	5-10	0	5-10	5-10	0	5-10
The Right Reverend Graham Usher	0-5	0	0-5	5-10	500	5-10
Professor Gary Crowe <sup>10</sup>	10-15	0	10-15	0-5	1,000	5-10
Dr Charmaine Griffiths	5-10	0	5-10	0-5	N/a	0-5
Professor Deborah Bowman	0-5 (Fye <sup>11</sup> 5-10)	0	0-5 (Fye 5-10)	N/a	N/a	N/a
Jan Williams OBE	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)	N/a	N/a	Na

<sup>9</sup> Members' expenses relate solely to their attendance at HTA committees, meetings and training events. During 2020/21 all meetings were conducted virtually therefore no member were reimbursed costs of travel and subsistence.

<sup>10</sup> Gary Crowe replaced Amanda Gibbon as Chair on 12 February 2021.

<sup>11</sup> Fye – Full year equivalent

## The Senior Management Team

Name	Position	Appointed	Until
Allan Marriott Smith	Chief Executive	6 July 2015	N/a
Richard Sydee <sup>12</sup>	Director of Resources	1 November 2016	N/a
Nicolette Harrison	Director of Regulatory Delivery	4 June 2018	N/a
Louise Dineley	Director of Data, Digital and Technology	28 October 2019	N/a

The remuneration for SMT is agreed by the HTA Remuneration Committee and DHSC, following the very senior managers' pay framework and in-line with HM Treasury requirements.

Later sections provide details of the remuneration, pension interests and benefits in kind of SMT.

These details are shown in accordance with the Department of Health and Social Care (DHSC) Group Accounting Manual (GAM). '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

### Staff remuneration policy

The HTA provides for staff salaries to be uplifted annually in August. Any uplifts are in line with HM Treasury pay guidance and approved by DHSC. The HTA have made awards each year to eligible staff who are performing satisfactorily that do not exceed 1% of the pay-bill.

### Duration of contract, notice periods and termination payments on contracts of employment

Members of staff in Bands 1 – 2 (Assistants and Officers) are required to give the HTA six weeks' notice for termination of contract. Members of staff in Bands 3 – 4 (Managers and Heads) and Directors are required to give three months' notice. The HTA is required to give the notice period of between one and twelve weeks in line with the Employment Rights Act 1996.

<sup>12</sup> Richard Sydee is shared with the HFEA and is seconded to HTA 2.5 days per week.

Termination payments are made only in appropriate circumstances and may arise where staff are not required to work their notice period. No payments were made in 2020/21 (and nil in 2019/20).

## Benefits in kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the HMRC as a taxable emolument. The HTA has agreed a PAYE Settlement Agreement (PSA) with HMRC for taxable emoluments of HTA Board Members. This covers travel and subsistence.

Information regarding travel and subsistence claimed by Authority Members and senior management has been published on the HTA's website [www.hta.gov.uk](http://www.hta.gov.uk)

No benefits in kind were received by senior staff members in 2020/21.

## Senior Management remuneration (Audited)

Senior Manager	2020/21					2019/20				
	Salary £000s	Bonus £000s	B i K £	Pension Benefits £000s	Total £000s	Salary £000s	Bonus £000s	B i K £	Pension Benefits £000s	Total £000s
Allan Marriott-Smith	120-125	0	0	42.5-45	165-170	110-115	0-5	0	12.5-15	130-135
Nicolette Harrison	95-100	0-5	0	22.5-25	125-130	95-100	0-5	0	22.5-25	120-125
Richard <sup>14</sup> Sydee	45-50 (Fte 95-100)	0-5	0	22.5-25	70-75	45-50 (Fte 90-95)	0	0	17.5-20	65-70
Louise Dineley	95-100	0-5	0	0	95-100	40-45 (Fye 90-95)	0	0	0-2.5	40-45 (Fye 90-95)

The factors used to calculate CETV increased on 29 October 2018. This has affected the calculation of the real increase in CETV.

<sup>13</sup>The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less the contributions made by the individual.

<sup>14</sup> Richard Sydee is seconded to the HTA from the HFEA for 2.5 days a week and this is reflected above. The figures shown above represent 50% of his salary, bonus and pension that HTA has paid to the HFEA.

## Median pay and multiples (Audited)

Band of highest paid director's gross salary only	2020/21 (£'000)		2019/20 (£'000)	
	120	125 <sup>15</sup>	120	125
	(full year equivalent)		(full year equivalent)	
Median remuneration of staff	45.0		45.0	
Ratio	2.72		2.72	

Under reporting requirements, public sector bodies are required to disclose the relationship between the total remuneration of the highest-paid Director in their organisation and the median remuneration of the organisation's workforce including temporary staff.

The highest paid Director for this comparison was the Chief Executive. There has been no change in the median remuneration of staff since last year. We are a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay remains higher than that for a number of other public sector bodies.

In 2020/21, no employees (2019/20, 0) received remuneration in excess of the highest paid director. Remuneration ranged from £25k to £120-£125k.

Total remuneration includes salary, non-consolidated performance related pay, benefits-in-kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

## Staff costs (Audited)

The HTA is structured as follows: thirteen Authority Members including the Chair and an Executive of 51 staff. For 2020/21, the HTA staff costs were:

	Permanently employed staff	Members	Seconded Staff	Temporary staff	Total 2020/21	Total 2019/20
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Wages and salaries	2,287	138	123	87	<b>2,635</b>	2,627
Social security costs	257	5	15	0	<b>277</b>	278
Pension costs	420	0	24	0	<b>444</b>	438

<sup>15</sup> Represents the contractual full-time salary



Subtotal	2,964	143	162	87	<b>3,356</b>	3,343
Less recoveries in respect of outward secondments	0	0	(50)	0	<b>(50)</b>	(47)
<b>Total net costs</b>	2,964	143	112	87	<b>3,306</b>	3,296

For 2020/21 all contributions were paid to the NHSPS at rates prescribed by HM Treasury. The current employer's rate for the NHSPS is 20.68% of pensionable pay according to salary level. The most recent revaluation of the NHS Pension Scheme resulted in a 6.3% increase in the employer contribution rate for the NHS Pensions Scheme. In 2019-20, this was funded and paid over to the pension scheme centrally by the Department of Health and Social Care, with a notional adjustment to the HTA grant in aid. However, in 2020-21, the HTA has received additional grant in aid funding which covers 3.8% of this increase.

### Average number of persons employed (Audited)

The average number of whole-time equivalent (Wte) persons employed or outwardly seconded during the year was as follows.

	Permanently employed staff	Seconded Staff	Total 2020/21	Total 2019/20
SCS	3	0	3	3
Other	43	1	44	47
<b>Total staff</b>	<b>46</b>	<b>1</b>	<b>47</b>	<b>50</b>
<b>Temporary staff</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>

Staff reported in the above table are only those directly employed by the HTA. During the year, one staff member was on secondment to the HFEA for approximately half of their time. As at 31 March 2021, the HTA employed 45 WTE staff (2019/20, 47).

### Expenditure on consultancy

During the year we spent £128,594 on consultancy services which includes legal fees, technical consultancy and HR consultancy.

### Sickness and absences

During the year ended 31 March 2021 the total number of whole-time equivalent days (Wte) lost to sickness absence was 83 days (2019/20 143 days). This information is disclosed in accordance with the Department of Health and Social Care (DHSC) Group Accounting Manual (GAM).

## Off-payroll assurance statement

The HTA seeks to ensure that any engagements of more than six months in duration, for more than a daily rate of £245, include contractual provisions that allow us to seek assurance regarding the income tax and National Insurance Contribution obligations of the person engaged, and to terminate the contract if that assurance is not provided.

For all new off-payroll engagements, or those that reached six months duration, between 1 April 2020 and 31 March 2021, for more than £245 per day and that last for longer than six months:

<b>Number of existing engagements as of March 2021</b>	<b>1</b>
Of which....	
Have existed for less than 1 year at time of reporting	1
Have existed for between 1 and 2 years at time of reporting	0
Have existed for between 2 and 3 years at time of reporting	0
Have existed for between 3 and 4 years at time of reporting	0
Have existed for 4 or more years at time of reporting	0

For all new off-payroll engagements, or those that reached six months duration, between 1 April 2020 and 31 March 2021, for more than £245 per day and that last for longer than six months

<b>Number of existing engagements as of March 2021</b>	<b>1</b>
Of which....	
No. assessed as caught by IR35	0
No. assessed as not caught by IR35	1
No. engaged directly (via PSC contracted to department) and are on the department payroll	0
No. of engagements reassessed for consistency/assurance purposes during the year	0
No. of engagements that saw a change to IR35 status following the consultancy review	0

For any off-payroll engagements of board members, and/or, senior officials with significant financial responsibility, between 1 April 2020 and 31 March 2021.

<b>No. of off-payroll engagements of board members, and/or senior officials with significant financial responsibility, during the finance year</b>	<b>0</b>
Total no. of individuals on payroll and off-payroll that have been deemed “board members, and/or senior officials with significant responsibility”, during the financial year.	3

## Staff pensions

Since 1 December 2009, employees have been covered by the provisions of the National Health Service (NHS) Pension Scheme.

## NHS pension scheme

Past and present employees are covered by the provisions of the two NHS Pension Schemes. Details of the benefits payable and rules of the Schemes can be found on the NHS Pensions website at [www.nhsbsa.nhs.uk/pensions](http://www.nhsbsa.nhs.uk/pensions). Both are unfunded defined benefit schemes that cover NHS employers, GP practices and other bodies, allowed under the direction of the Secretary of State for Health and Social Care in England and Wales. They are not designed to be run in a way that would enable NHS bodies to identify their share of the underlying scheme assets and liabilities. Therefore, each scheme is accounted for as if it were a defined contribution scheme: the cost to the NHS body of participating in each scheme is taken as equal to the contributions payable to that scheme for the accounting period.

In order that the defined benefit obligations recognised in the financial statements do not differ materially from those that would be determined at the reporting date by a formal actuarial valuation, the FReM requires that “the period between formal valuations shall be four years, with approximate assessments in intervening years”. An outline of these follows::

### a) Accounting valuation

A valuation of scheme liability is carried out annually by the scheme actuary (currently the Government Actuary’s Department) as at the end of the reporting period. This utilises an actuarial assessment for the previous accounting period in conjunction with updated membership and financial data for the current reporting period, and is accepted as providing suitably robust figures for financial reporting purposes. The valuation of the scheme liability as at 31 March 2021, is based on valuation data as 31 March 2020, updated to 31 March 2021 with summary global member and accounting data. In undertaking this actuarial assessment, the methodology prescribed in IAS 19, relevant FReM interpretations, and the discount rate prescribed by HM Treasury have also been used.

The latest assessment of the liabilities of the scheme is contained in the report of the scheme actuary, which forms part of the annual NHS Pension Scheme Accounts. These accounts can be viewed on the NHS Pensions website and are published annually. Copies can also be obtained from The Stationery Office.

## b) Full actuarial (funding) valuation

The purpose of this valuation is to assess the level of liability in respect of the benefits due under the schemes (taking into account recent demographic experience), and to recommend contribution rates payable by employees and employers.

The latest actuarial valuation undertaken for the NHS Pension Scheme was completed as at 31 March 2016. The results of this valuation set the employer contribution rate payable from April 2019 to 20.6% of pensionable pay. The 2016 funding valuation was also expected to test the cost of the Scheme relative to the employer cost cap that was set following the 2012 valuation. In January 2019, the Government announced a pause to the cost control element of the 2016 valuations, due to the uncertainty around member benefits caused by the discrimination ruling relating to the McCloud case.

The Government subsequently announced in July 2020 that the pause had been lifted, and so the cost control element of the 2016 valuations could be completed. The Government has set out that the costs of remedy of the discrimination will be included in this process. HMT valuation directions will set out the technical detail of how the costs of remedy will be included in the valuation process. The Government has also confirmed that the Government Actuary is reviewing the cost control mechanism (as was originally announced in 2018). The review will assess whether the cost control mechanism is working in line with original government objectives and reported to Government in April 2021. The findings of this review will not impact the 2016 valuations, with the aim for any changes to the cost cap mechanism to be made in time for the completion of the 2020 actuarial valuations..

## Pension Benefits – Senior Management Team (Audited)

Name of Officer	Real increase in pension at age 60 (a)	Real increase in pension lump sum at age 60 (b)	Total accrued Pension at 31/03/2020 (c)	Lump sum at age 60 at 31 March 2020 (d)	CETV at 31/03/2021 (e)	Real increase in CETV as funded by employer 2020/21 (f)	CETV at 31/03/2020 (g)	Employers contribution to stake holder pension
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£,000
Allan Marriott Smith	2.5-5.0	N/a	20-25	N/a	318	27	269	0
Nicolette Harrison	0-2.5	N/a	5-10	N/a	77	16	47	0
Richard Sydee <sup>16</sup>	0-2.5	0-2.5	35-40	80-85	673	13	573	0
Louise Dineley	0-2.5	-2.5-0	30-35	60-65	523	0	513	0

<sup>16</sup> Richard Sydee is a member of the Civil Service Pension Scheme. The above figures represent 50% of his pension costs of the HFEA.

The factors used to calculate a CETV increased on 29 October 2018. This affects the calculation of the real increase in CETV but does not affect the real increase in pension benefits.

### Cash equivalent transfer value (CETV)

Column (f) 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 staff 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 National Health Service Pension Scheme /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 are calculated using common market valuation factors for the start and end of the period.



**Allan Marriott-Smith**  
**Accounting Officer**  
**Human Tissue Authority**

**Date: 9 July 2021**

# Parliamentary accountability and audit report

## Accountability (the details below are subject to audit)

### Fees charging and cost allocation

Our licence fees are set to recover the full cost incurred in the granting of licences and regulation. The table below shows the income from each sector, other income for licensing activities and the costs of licensing activities. The income shown is that which relates to licensable activities and therefore excludes an element of rent and income from secondments.

We confirm that we have complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

SECTOR	31 March 2021	31 March 2020
	£'000s	£'000s
Applications	70	84
Anatomy	105	98
Post-Mortem	1,281	1,174
Public Display	21	22
Research	723	671
Human Application	1,482	1,382
Organ Donation/ Transplantation	315	298
Other income for licensing activities <sup>17</sup>	372	473
<b>Total Income from contracts with Customers<sup>18</sup></b>	<b>4,369</b>	<b>4,202</b>
Costs allocated to licensing activities	(4,423)	(4,233)
<b>Surplus/(Deficit) on activities</b>	<b>(54)</b>	<b>(31)</b>

In addition, there are elements of our work that do not relate directly to the cost of regulating the sectors above. The DHSC accordingly contributes to the funding of these activities through the provision of Grant-in-aid.

### Losses and special payments

Losses and special payments are items that Parliament would not have contemplated when it agreed funds for the health service or passed legislation. By their nature they are items that ideally should not arise. They are therefore subject to special control procedures compared with the generality of payments. They are divided into different categories, which govern the way that individual cases are handled.

There were no losses or special payments of £300,000, either individually or in aggregate, made in 2020/21.

### Remote contingent liabilities

There were no remote contingent liabilities in 2020/21.

<sup>17</sup> Figure includes income from Devolved Governments and rental of excess office space.

<sup>18</sup> This is the total income allocated to licensable activities and therefore differs from that on page 18.

## THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

### Opinion on financial statements

I certify that I have audited the financial statements of the Human Tissue Authority for the year ended 31 March 2021 under the Human Tissue Act 2004. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. The financial reporting framework that has been applied in their preparation is applicable law and the Department of Health and Social Care Group Accounting Manual.

I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion, the financial statements:

- give a true and fair view of the state of the Human Tissue Authority's affairs as at 31 March 2021 and of the Human Tissue Authority's net expenditure for the year then ended;
- have been properly prepared in accordance with the Human Tissue Act 2004 and Secretary of State directions issued thereunder.

### Opinion on regularity

In my opinion, in all material respects the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

### Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK), applicable law and Practice Note 10 'Audit of Financial Statements of Public Sector Entities in the United Kingdom'. My responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of my certificate.

Those standards require me and my staff to comply with the Financial Reporting Council's Revised Ethical Standard 2019. I have also elected to apply the ethical standards relevant to listed entities. I am independent of the Human Tissue Authority in accordance with the ethical requirements that are relevant to my audit of the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements.



I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

### **Conclusions relating to going concern**

In auditing the financial statements, I have concluded that the Human Tissue Authority's use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work I have performed, I have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Human Tissue Authority's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

My responsibilities and the responsibilities of the Authority and the Accounting Officer with respect to going concern are described in the relevant sections of this certificate.

The going concern basis of accounting for the Human Tissue Authority is adopted in consideration of the requirements set out in the Department of Health and Social Care Group Accounting Manual, which require entities to adopt the going concern basis of accounting in the preparation of the financial statements where it anticipated that the services which they provide will continue into the future.

### **Other Information**

The other information comprises information included in the annual report, but does not include the parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's certificate thereon. The Authority and the Accounting Officer are responsible for the other information. My opinion on the financial statements does not cover the other information and except to the extent otherwise explicitly stated in my certificate, I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If I identify such material inconsistencies or apparent material misstatements, I am required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact.

I have nothing to report in this regard.

### **Opinion on other matters**

In my opinion, based on the work undertaken in the course of the audit:

- the parts of the Accountability Report to be audited have been properly prepared in accordance with Secretary of State directions made under the Human Tissue Act 2004; and

the information given in the Performance and Accountability Reports for the financial year for which the financial statements are prepared is consistent with the financial statements.

### **Matters on which I report by exception**

In the light of the knowledge and understanding of the Human Tissue Authority and its environment obtained in the course of the audit, I have not identified material misstatements in the Performance and Accountability report. I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Accountability Report to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual are not made; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

### **Responsibilities of the Authority and Accounting Officer for the financial statements**

As explained more fully in the Statement of Authority and Accounting Officer's Responsibilities, the Authority and the Accounting Officer, are responsible for:

- the preparation of the financial statements in accordance with the applicable financial reporting framework and for being satisfied that they give a true and fair view;
- such internal controls as the Authority and the Accounting Officer determine are necessary to enable the preparation of financial statements to be free from material misstatement, whether due to fraud or error.
- assessing the Human Tissue Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Authority and the Accounting Officer anticipate that the services provided by the Human Tissue Authority will not continue to be provided in the future.

### **Auditor's responsibilities for the audit of the financial statements**

My responsibility is to audit, certify and report on the financial statements in accordance with the Human Tissue Act 2004.

My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a certificate that includes my opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if,

individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulation, including fraud.

My procedures included the following:

- Inquiring of management, the audited entity's head of internal audit and those charged with governance, including obtaining and reviewing supporting documentation relating to the Human Tissue Authority's policies and procedures relating to:
  - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance;
  - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud; and
  - the internal controls established to mitigate risks related to fraud or non-compliance with laws and regulations including the Human Tissue Authority's controls relating to Managing Public Money;
- discussing among the engagement team regarding how and where fraud might occur in the financial statements and any potential indicators of fraud. As part of this discussion, I identified potential for fraud in the following areas: revenue recognition, posting of unusual journals.
- obtaining an understanding of the Human Tissue Authority's framework of authorities as well as other legal and regulatory frameworks that the Human Tissue Authority operates in, focusing on those laws and regulations that had a direct effect on the financial statements or that had a fundamental effect on the operations of the Human Tissue Authority. The key laws and regulations I considered in this context included the Human Tissue Act 2004, Managing Public Money, employment legislation and regulations and tax legislation.

In addition to the above, my procedures to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with relevant laws and regulations discussed above;
- enquiring of management and the Audit and Risk Assurance Committee concerning actual and potential litigation and claims;
- reading minutes of meetings of those charged with governance and the Board;
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and

evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business; and

- in addressing the risk of fraud in revenue recognition, reviewing the volume and value of credit notes and debt write-offs processed during the year and after the year-end for any unusual trends; substantive testing of any journal entries which impact the income lines, particularly those around the year-end; testing of pre-year-end and post-year-end receipts, to confirm whether revenue has been recognised in the correct financial year; and a comparative review of income collected from individual entities.

I also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists and significant component audit teams and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

A further description of my responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: [www.frc.org.uk/auditorsresponsibilities](http://www.frc.org.uk/auditorsresponsibilities). This description forms part of my certificate.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the income and expenditure reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

## Report

I have no observations to make on these financial statements.

**Gareth Davies**  
**Comptroller and Auditor General**

**Date 12 July 2021**

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

# Financial statements

**Human Tissue Authority**  
**Annual Report and Accounts 2020/21**

**Statement of Comprehensive Net Expenditure for the year ended 31 March 2021**

	Note	<u>2020/21</u> <u>£'000s</u>	<u>2019/20</u> <u>£'000s</u>
<b>Income from sale of goods and services</b>			
Revenue from contracts with customers	4	3,997	3,728
Other Operating Income	4	<u>552</u>	<u>587</u>
<b>Total operating income</b>		<u>4,549</u>	<u>4,315</u>
<b>Expenditure</b>			
Purchase of goods and services	3	782	919
Staff costs	3.1	3,356	3,343
Depreciation, amortisation and impairment charges	3	100	294
Loss on disposal of fixed assets	3	110	1
Movement in provisions	3	(70)	120
Other operating expenditure	3	<u>1,097</u>	<u>698</u>
<b>Total operating expenditure</b>		<u>5,375</u>	<u>5,375</u>
<b>Net (Income)/Expenditure</b>		<u>826</u>	<u>1,060</u>

There are no items of expenditure that should be shown as Other Comprehensive Expenditure. All items of income and expense arise from continuing activities.

Notes 1 to 14 on pages 66 to 80 form part of these financial statements

**Human Tissue Authority**  
**Annual Report and Accounts 2020/21**

**Statement of Financial Position as at  
31 March 2021**

	Note	<u>31-Mar-21</u> <u>£'000s</u>	<u>31-Mar-20</u> <u>£'000s</u>
<b>Non-current assets:</b>			
Property, plant and equipment	5	55	204
Intangible assets	6	24	91
<b>Total non-current assets</b>		<b>79</b>	<b>295</b>
<b>Current assets:</b>			
Trade and other receivables	8	174	414
Cash and cash equivalents	9	4,071	3,696
<b>Total current assets</b>		<b>4,245</b>	<b>4,110</b>
<b>Total assets</b>		<b>4,324</b>	<b>4,405</b>
<b>Current liabilities</b>			
Trade and other payables	10	807	763
Provisions	12	25	40
<b>Total current liabilities</b>		<b>832</b>	<b>803</b>
<b>Total assets less current liabilities</b>		<b>3,492</b>	<b>3,602</b>
<b>Non-current liabilities</b>			
Provisions	12	25	80
<b>Total Non-current liabilities</b>		<b>25</b>	<b>80</b>
<b>Total assets less total liabilities</b>		<b>3,467</b>	<b>3,522</b>
<b>Taxpayers' Equity</b>			
I&E Reserve		3,467	3,522
<b>Total equity</b>		<b>3,467</b>	<b>3,522</b>

Notes 1 to 14 on pages 66 to 80 form part of these financial statements

The financial statements were signed on behalf of the Human Tissue Authority by:



(Signed) .....  
Allan Marriott-Smith  
(Accounting Officer)

9 July 2021

**Human Tissue Authority**  
**Annual Report and Accounts 2019/20**

**Statement of Cash Flows for the year to  
31 March 2021**

	<b>2020/21</b>	2019/20
	<b>Total</b>	Total
<b>Note</b>	<b>£'000s</b>	£'000s
<b>Cash flows from operating activities</b>		
Net operating expenditure	SoCNE (826)	(1,060)
Adjustment for depreciation and amortisation	3 106	214
Adjustments for non-cash transactions	3.1 0	129
Adjustment for loss on disposal of property, plant and equipment	3 110	1
Decrease in trade and other receivables	8 240	67
Increase/(Decrease) in provision	12 (70)	120
Increase in trade payables	10 44	129
<b>Net cash (outflow) inflow from operating activities</b>	<b>(396)</b>	<b>(400)</b>
<b>Cash flows from investing activities</b>		
Purchase of non-financial assets	5 0	(45)
<b>Net cash outflow from investing activities</b>	<b>0</b>	<b>(45)</b>
<b>Cash flows from financing activities</b>		
Grants from sponsor department	1.7 771	693
<b>Net financing</b>	<b>771</b>	<b>693</b>
<b>Net increase/(decrease) in cash and cash equivalents in the period</b>	<b>375</b>	<b>248</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>9 3,696</b>	<b>3,448</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>4,071</b>	<b>3,696</b>

Notes 1 to 14 on pages 66 to 80 form part of these financial statements



**Human Tissue Authority  
Annual Report and Accounts 2020/21**

**Statement of Changes in Taxpayers' Equity  
For the year ended 31 March 2021**

	Note	<u>I &amp; E Reserve</u> £'000s
<b>Balance at 1 April 2019</b>		3,760
<b>Changes in taxpayers' equity for 2019/20</b>		
Retained surplus/(Deficit)		<u>(1,060)</u>
<b>Total recognised Income and expense for 2019/20</b>		(1,060)
Grant from sponsor department		<u>822</u>
<b>Balance at 31 March 2020</b>		<u><b>3,522</b></u>
<b>Changes in taxpayers' equity for 2020/21</b>		
Retained surplus/(Deficit)		<u>(826)</u>
<b>Total recognised Income and expense for 2020/21</b>		(826)
Grant from sponsor department	1.7	<u>771</u>
<b>Balance at 31 March 2021</b>		<u><b>3,467</b></u>

Notes 1 to 14 on pages 66 to 80 form part of these financial statements

**Human Tissue Authority  
Annual Report and Accounts 2020/21**

## Notes to the accounts

These notes form an integral part of and should be read in conjunction with the accompanying financial statements.

### 1. Statement of accounting policies

These financial statements have been prepared pursuant to the Human Tissue Act 2004, Schedule 2 (paragraph 16) and in accordance with the Department of Health and Social Care (DHSC) Group Accounting Manual (GAM). The accounting policies contained in the GAM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context. Where the GAM permits a choice of accounting policy, the accounting policy which is judged to be most appropriate to the particular circumstances of the Human Tissue Authority (HTA) for the purposes of giving a true and fair view has been selected. The particular policies adopted by the HTA for the year ended 31 March 2021 are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

#### 1.1 Going concern

The HTA is financed in part through Grant in Aid funding provided by the Department of Health and Social Care (DHSC), which is approved annually by Parliament. The Secretary of State for Health and Social Care has directed that Parliamentary funding has been voted to permit relevant activities to continue. Grant in Aid has been secured from the DHSC for the 2021-22 year. In addition the HTA has set its licence fees for the coming year and expects these to be collected, therefore the Board of the HTA has prepared these financial statements on a going concern basis. Further information can be found in the Accountability report on page 16.

#### 1.2 Accounting convention

The accounts have been prepared under the historical cost convention.

#### 1.3 Non-current assets

Non current assets are property, plant and equipment and intangible assets including the costs of acquiring or developing computer systems and software. Only items or groups of related items costing £5,000 or more are capitalised. Items costing less are treated as revenue expenditure in the year of acquisition.

All property, plant and equipment and intangible assets held by the HTA at 31 March 2021 are carried in the Statement of Financial Position at depreciated historical cost. The depreciated or amortised historical cost is used as a proxy for fair value, for the classes of assets listed below, since the useful life over which the asset class is depreciated or amortised is considered to be a realistic reflection of the consumption of that asset class. Depreciation and amortisation are provided on a monthly basis from the date of deemed economic benefit, at rates calculated to write off the costs of each asset evenly over its expected useful life.

##### Plant and Equipment

Information Technology	4 years
Furniture and fittings	3 or 5 years
Refurbishment Costs	5 or 10 years

##### Intangible assets

Information Technology	5 years
Websites	3 years

#### 1.4 Assets under Construction (Development expenditure)

These are the costs related to the upgrade of HTA systems whether that be the hardware or applications that are yet to be deployed. These assets are not depreciated.

## Human Tissue Authority Annual Report and Accounts 2020/21

### 1.5 Impairments

The simplified approach to impairment, in accordance with IFRS 9, measures the loss allowance for trade receivables at an amount equal to lifetime expected credit losses (stage 1).

For other financial assets, the loss allowance is measured at an amount equal to lifetime expected credit losses if the credit risk on the financial instrument has increased significantly since initial recognition (stage 2).

An assessment of all of the HTA's financial assets has resulted in movement in the value of the impairment of receivables. In carrying out the assessment of licence fee debtors, account is taken of the sector, economic climate (past and future) and previous losses and the impact of COVID-19. A default rating (weighted) is applied to debts aged over a period of 28, 42 and 56 days.

DHSC provides a guarantee of last resort against debts of its arm's length bodies and NHS bodies and as such the HTA does not recognise stage 1 or 2 losses against these bodies.

A movement in the provision for expected credit losses of £6,063 was credited to the SoCNE.

### 1.6 Critical accounting judgements and key sources of estimation uncertainty

In the application of the HTA accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered relevant. Actual results may differ from those estimates. The estimates and underlying assumptions are reviewed annually. Revisions to accounting estimates are recognised in the period of the revision and future periods if the revision affects both current and future period. The judgements that management has made in the process of applying HTA's accounting policies and that may have significant effect on the amounts recognised in the financial statements are:

IAS 17 Leases – the most significant judgement relates to whether the newly signed lease for 2 Redman Place, Stratford should be classified as an Operating or Finance lease and therefore its impact and treatment in the 2020/21 accounts. The HTA management believe that the new lease does not meet the definition of a finance lease for the following reasons: the lease is a 10 year lease where ownership at its conclusion does not transfer to the HTA; there is no option to purchase the building and importantly, the lease term is not a major part of the economic life of the lease. Therefore, the lease is classified as an operating lease under IAS 17 and as such rental costs have been charged to the SoCNE, on a straight-line basis over the term of the lease.

### 1.7 Government Grants and Grant-in-aid

Grant-in-aid (GIA) received is used to finance activities and expenditure which support the statutory and other objectives of the HTA. Grant-in-aid is treated as financing and credited to the income and expenditure reserve, because it is regarded as contributions from a controlling party.

### 1.8 Leases

#### Operating leases as the lessee

Leases are classified as finance leases when substantially all the risks and rewards of ownership are transferred to the lessee. All other leases are classified as operating leases. The HTA had one lease assessed to be an operating lease.

Operating lease payments are recognised as an expense on a straight-line basis over the lease term.

#### Operating leases as the lessor

Rental income from operating leases is recognised as income on a straight-line basis over the term of the lease.

## Human Tissue Authority Annual Report and Accounts 2020/21

### 1.9 Income

Our main source of income takes the form of fees for licences from establishments who have human tissue on their premises and fixed fees from devolved administrations, for work on policies and transplants.

There is a contractual arrangement between the HTA and its establishments as per IFRS 15 and the 5-step model. The underlying legislation is deemed to enforce contractual obligations on both parties, and thus these arrangements are viewed as contracts under IFRS 15. Performance obligations exist between the HTA and its establishments, where the establishments are obligated to comply with certain standard conditions and in return the HTA will grant them a licence for a fixed period of 1 year. A transaction price (licence fee) is chargeable which is different for each type of licence. Licences fees are charged for the financial year April through March reflecting regulatory activity being carried out. We recognise this income in the financial year it is invoiced, this being the point in time at which the performance obligation (the work undertaken by HTA to grant a licence) is satisfied.

Other income received by HTA relates to rental income and seconded staff. Income is recognised on an accruals basis, with the performance obligation deemed to be the point at which these goods or services are delivered.

### 1.10 Employee benefits

Salaries, wages and employment-related payments are recognised in the period in which the service is received from employees. The cost of leave earned but not taken by employees at the end of the period is recognised in the financial statements to the extent that employees are permitted to carry forward leave into the following period.

### 1.11 Pensions

Past and present employees are covered by the provisions of the NHS Pensions Scheme (NHSPS). Details of the benefits payable under these provisions can be found on the NHS Pensions website at [www.nhsbsa.nhs.uk/pensions](http://www.nhsbsa.nhs.uk/pensions). The Scheme is an unfunded, defined benefit scheme that covers NHS employers, General Practices and other bodies, allowed under the direction of the Secretary of State, in England and Wales. The Scheme is not designed to be run in a way that would enable NHS bodies to identify their share of the underlying Scheme's assets and liabilities. Therefore, the Scheme is accounted for as if it were a defined contribution scheme: the cost to the HTA of participating in the Scheme is taken as equal to the contributions payable to the Scheme for the accounting period.

### 1.12 Financial assets

Financial assets are recognised when HTA becomes party to the financial instrument contract or, in the case of contract receivables, when the goods or services have been delivered. Financial assets are derecognised when the contractual rights have expired or the asset has been transferred.

Under IFRS 9 a new approach to classification and measurement of financial assets was introduced. Under the new classification, our receivables are classified according to how they are subsequently measured in this case at amortised cost using the 'business model test'.

### 1.13 Financial liabilities

Financial liabilities are recognised on the statement of financial position when HTA becomes party to the contractual provisions of the financial instrument or, in the case of trade payables, when the goods or services have been received. Financial liabilities are de-recognised when the liability has been paid or expired.

## Human Tissue Authority Annual Report and Accounts 2020/21

### 1.14 Cash and cash equivalents

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours. Cash equivalents would be investments that mature in 3 months or less from the date of acquisition and that are readily convertible to known amounts of cash with insignificant risk of change in value.

### 1.15 IFRS issued but not yet effective

The Treasury FReM (as adopted by the DHSC GAM) does not require the following Standards and Interpretations to be applied in 2020/21. The application of the Standards as revised would have a material impact on the accounts in 2020/21, were they applied in that year.

IFRS 16 Leases replaces IAS 17 and is effective for the public sector from 1 April 2022. The new standard amends the accounting for lessees, removing the distinction between recognising an operating lease (off balance sheet) and a finance lease (on balance sheet). The new standard requires recognition of most leases which last more than 12 months to be recognised on balance sheet.

The new lease for the 2 Redman Place, Stratford is for a 10 year period and based upon the value of the operating lease at note 11, the impact on the accounts is likely to be material.

### 1.16 Provisions

Provisions are recognised when the HTA has a present legal or constructive obligation as a result of a past event, it is probable that the HTA will be required to settle the obligation, and a reliable estimate can be made of the obligation.

The amount recognised as a provision is the best estimate of expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties.

## 2. Analysis of Net Expenditure by Segment

Under the definition of IFRS 8 the HTA is a single operating segment whose objectives are the licensing and inspection of premises involved in the storage and use of human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions.

The HTA also gives approval for organ and bone marrow donations from living people.

The HTA charges fees for its licensing activities which, along with Grant-in-aid from the DHSC, its sponsoring body, are applied in pursuit of these objectives.

**Human Tissue Authority  
Annual Report and Accounts 2020/21**

**3. Other Expenditure**

	Notes	2020/21 £'000s	2019/20 £'000s
<b>Staff Costs</b>	3.1	3,356	3,343
<b>Purchase of goods and services</b>			
Computer running costs	(a)	336	417
Staff recruitment, training and welfare		93	145
Consultancy		21	15
Office and administration costs		36	43
Maintenance Contracts		80	52
Travel subsistence and hospitality		46	103
Conferences & Events		1	33
Stationery and publications		17	22
Auditors Remuneration	(b)	71	66
Legal and professional fees	(c)	81	23
		782	919
<b>Other operating costs</b>			
Accommodation	(d)	934	578
Project Costs		135	91
Telecommunications		28	29
		1,097	698
<b>Non-cash items</b>			
Depreciation and amortisation	5,6	106	214
Expected credit losses	8	(6)	80
(Gain)/Loss on disposal of non-current assets		110	1
Provision provided/(released) in year	12	(70)	120
		140	415
<b>Total</b>		<b>5,375</b>	<b>5,375</b>

**Notes**

(a) Computer running cost include costs incurred for cloud-based working which is part of the Development Programme (formerly the Transformation Programme).

(b) Audit fees	Internal	43	38
	External	28	28
		71	66

(c) Increase in legal costs due to advice around EU Exit and Transition

(d) Accommodation costs include the rent payments for 151 Buckingham Palace Road. Costs relating to the HTA's new offices in Stratford have been accrued for the period November 2020 to March 2021.

**Human Tissue Authority  
Annual Report and Accounts 2020/21**

**3.1 Staff numbers and related costs****Staff costs comprise:**

	<b>2020/21</b>	2019/20
	<b>Total</b>	Total
	<b>£,000</b>	£'000
Wages and salaries	<b>2,635</b>	2,627
Social security costs	<b>277</b>	278
Pension costs	<b>444</b>	438
Sub Total	<b>3,356</b>	3,343
Less recoveries in respect of outward secondments	<b>(50)</b>	(47)
Total net costs	<b>3,306</b>	3,296

Details of remuneration paid to Members and the Senior Management team are given in the Remuneration Report.

For 2020/21 contributions of £302,720 (2019/20, £294,991) were paid to the NHS Pensions (NHSPS) at rates prescribed by the Treasury. The current rate for the NHSPS is 20.68% of pensionable pay according to salary level.

**Average number of persons employed**

The average number of whole-time equivalent (Wte) persons employed or seconded during the year was as follows.

	<b>2020/21</b>	2019/20
	<b>Total</b>	Total
Directly Employed	<b>47</b>	50
Subtotal	<b>47</b>	50
Temporary staff	<b>1</b>	1
Total	<b>48</b>	51

All staff are directly employed by HTA. During the year, one staff was on secondment for part of their time to the HFEA for two and a half days per week. As at 31 March 2021 the HTA employed 47 Wte staff (2019/20, 47).

**Human Tissue Authority  
Annual Report and Accounts 2020/21**

**4. Income**

	Note	<u>2020/21</u> <u>£'000s</u>	<u>2019/20</u> <u>£'000s</u>
Revenue from contracts:			
Licence Fee Income		3,997	3,728
Income from devolved administrations		<u>134</u>	<u>133</u>
		4,131	3,861
Other Operating Income	4.1	<u>418</u>	<u>454</u>
		<b><u>4,549</u></b>	<b><u>4,315</u></b>

The HTA's remit is to regulate the removal, storage, use and disposal of human organs and tissue from the living and deceased. In accordance with section 16, schedule 3, paragraph 2 (4) (f) and paragraph 13 of the Human Tissue Act 2004, the HTA may grant licences to other organisations and charge fees for those licences.

**4.1 Other Operating Income**

	<u>2020/21</u> <u>£, '000</u>	<u>2019/20</u> <u>£'000</u>
Other Income - Rent	368	407
Other Income - Outward secondees	<u>50</u>	<u>47</u>
	418	454

Other income - outward secondees relates to a single member of staff who worked for another organisation part-time.



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## 5. Property, Plant and Equipment

	Information Technology Hardware £'000	Furniture & Fittings £'000	Assets Under Construction £'000	Refurbishment Costs £'000	Total £'000
<b>Cost or valuation</b>					
At 1 April 2020	360	148	0	1,094	1,602
Additions	0	0	0	0	0
Disposals	(235)	(148)	0	(1,086)	(1,469)
Adjustments/Transfers	0	0	0	(8)	(8)
<b>At 31 March 2021</b>	<b>125</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>125</b>
<b>Depreciation</b>					
At 1 April 2020	243	139	0	1,015	1,397
Charge for the year	39	0	0	0	39
Disposals	(212)	(139)	0	(1,007)	(1,358)
Adjustments/Transfers	0	0	0	(8)	(8)
<b>At 31 March 2021</b>	<b>70</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>70</b>
<b>Net book value at 31 March 2021</b>	<b>55</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>55</b>
Net book value at 1 April 2020	117	9	0	79	205
All assts are owned by the HTA					

<b>Cost or valuation</b>					
At 1 April 2019	307	148	25	1,094	1,574
Additions	45	0	0	0	45
Disposals	(17)	0	0	0	(17)
Reclassifications	25	0	(25)	0	0
<b>At 31 March 2020</b>	<b>360</b>	<b>148</b>	<b>0</b>	<b>1,094</b>	<b>1,602</b>
<b>Depreciation</b>					
At 1 April 2019	222	130	0	902	1,254
Charge for the year	38	9	0	113	160
Disposals	(17)	0	0	0	(17)
Reclassifications	0	0	0	0	0
<b>At 31 March 2020</b>	<b>243</b>	<b>139</b>	<b>0</b>	<b>1,015</b>	<b>1,397</b>
<b>Net book value at 31 March 2020</b>	<b>117</b>	<b>9</b>	<b>0</b>	<b>79</b>	<b>205</b>
Net book value at 1 April 2019	85	18	25	192	320
<b>Net book value at 31 March 2020</b>	<b>117</b>	<b>9</b>	<b>0</b>	<b>79</b>	<b>205</b>
All assts are owned by the HTA					

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**6. Intangible Assets**

	<b>Information Technology</b>	<b>Websites</b>	<b>Total</b>
	<b>£'000</b>	<b>£'000</b>	<b>£'000</b>
<b>Cost or valuation</b>			
At 1 April 2020	1,156	0	1,156
Additions	0	0	0
Disposals	(32)	0	(32)
Adjustments/Transfers	8	0	8
<b>At 31 March 2021</b>	<b>1,132</b>	<b>0</b>	<b>1,132</b>
<b>Amortisation</b>			
At 1 April 2020	1,065	0	1,065
Charged in year	67	0	67
Disposals	(32)	0	(32)
Adjustments/Transfers	8	0	8
<b>At 31 March 2021</b>	<b>1,108</b>	<b>0</b>	<b>1,108</b>
<b>Net book value at 31 March 2021</b>	<b>24</b>	<b>0</b>	<b>24</b>
Net book value at 1 April 2020	91	0	91

All assts are owned by the HTA

The gross cost of our Customer Relationship Management(CRM) system is £1,118k and it's net book value is £23k. The CRM is an internally generated asset and has a remaining useful life of one year.

<b>Cost or valuation</b>			
At 1 April 2019	1,156	58	1,214
Additions	0	0	0
Disposals	0	(58)	(58)
<b>At 31 March 2020</b>	<b>1,156</b>	<b>0</b>	<b>1,156</b>
<b>Amortisation</b>			
At 1 April 2019	1,012	57	1,069
Charged in year	53	0	53
Disposals	0	(57)	(57)
<b>At 31 March 2020</b>	<b>1,065</b>	<b>0</b>	<b>1,065</b>
<b>Net book value at 31 March 2020</b>	<b>91</b>	<b>0</b>	<b>91</b>
Net book value at 1 April 2019	144	1	145

All assts are owned by the HTA

The gross cost of our Customer Relationship Management(CRM) system is £1,118k and it's Net book value is £86k. The CRM is an internally generated asset and has a remaining useful life of two years.

## 7. Financial instruments

IFRS 7 Financial Instruments Disclosure requires disclosure of the role that financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Financial instruments play a much more limited role in creating or changing risk at the HTA than would be typical of the listed companies to which IFRS 7 mainly applies. Financial assets and liabilities are generated by day-to-day operational activities rather than being held to change the risks facing the HTA in undertaking activities.

### Liquidity risk

The HTA receives the majority of its income from annual licence fees payable by establishments mainly in the public sector. Other revenue resource requirements are financed by a grant from the DHSC. These, together with a robust debt recovery, cash flow forecasting and payment process, ensure that the HTA is not exposed to significant liquidity risk.

### Market and interest rate risk

At 31 March 2021 the HTA's financial liabilities carried nil rates of interest. The HTA's financial assets relate to receivables and cash balances held at 31 March 2021 within the Royal Bank of Scotland bank account and Barclays commercial current account, which are not interest bearing. Interest on cash balances are set by the banks. The HTA is therefore not exposed to significant interest-rate risk.

### Credit risk

The HTA receives most of its income from licence fees from within both the NHS and non-NHS market. It has in place and operates a fit for purpose credit control policy and, where applicable, provides for the risk of debts not being discharged by those establishments it licenses. The HTA is therefore not exposed to significant credit risk.

The aged debtor report for NHS and non-NHS receivables at the 31 March 2021 was:

	<b>£'000s</b>
Not past due	0
Past due 0-28 days	0
Past due 29 days	187

### Foreign currency risk

There were no foreign currency transactions conducted by the HTA during the period ended 31 March 2021. There was therefore no significant foreign currency risk during the year.

Human Tissue Authority  
Annual Report and Accounts 2020/21**Financial instruments held by the HTA**

<b>By category</b>	<b>Receivables and other financial assets</b>
	<b>31-Mar-21</b>
	£'000
<b>Financial assets measured at amortised cost</b>	<b>103</b>
Contract receivables (net of provisions)	103
Cash at bank and in hand	4,071
<b>Total at 31 March 2021</b>	<b>4,174</b>
Contract receivables (net of provisions)	332
Other receivables	7
Cash at bank and in hand	3,696
<b>Total at 31 March 2020</b>	<b>4,035</b>

**Financial liabilities**

<b>By category</b>	<b>Other financial liabilities</b>
	<b>31-Mar-21</b>
	£'000
<b>Financial liabilities measured at amortised cost</b>	<b>35</b>
Contract payables	35
Other payables	11
Accruals	760
<b>Total at 31 March 2021</b>	<b>806</b>
Contract payables	40
Other payables	7
Accruals	717
<b>Total at 31 March 2020</b>	<b>764</b>

As at 31 March 2021, none of the HTA's liabilities carried a floating rate of interest.

**Fair values**

The fair value of the financial assets and liabilities was equal to book value.

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**8. Trade receivables and other current assets**

	<b>31-Mar-21</b>	31-Mar-20
	<b>£'000</b>	£'000
<b>Amounts falling due within one year:</b>		
Contract receivables (contracts with customers)	188	424
Impairments for credit losses	(85)	(91)
Other Receivables	0	7
Prepayments and contract assets	71	74
	<u>174</u>	<u>414</u>

**Amounts falling due after more than one year:**

There are no debtors falling due after more than one year.

**9. Cash and cash equivalents**

	<b>£'000</b>
Balance at 31 March 2020	3,696
Net change in cash and cash equivalent balances	375
Balance at 31 March 2021	<u>4,071</u>

	<b>31-Mar-21</b>	31-Mar-20
	<b>£'000</b>	£'000
The following balances were held at:		
Commercial banks	3,864	3,363
Government Banking Services	207	333
	<u>4,071</u>	<u>3,696</u>

**10. Trade payables and other current liabilities**

	<b>31-Mar-21</b>	31-Mar-20
	<b>£'000</b>	£'000
<b>Amounts falling due within one year</b>		
Contract payables	35	40
Other payables	12	7
Accruals	760	716
	<u>807</u>	<u>763</u>

The cash balances as at 31 March 2021 carried a floating rate.

There are no creditors falling due after one year.

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## 11. Commitments under leases

### Operating leases

#### 11.1 Operating Lease Payments

Commitments under operating leases to pay rentals during the year following the year of these accounts are given below, analysed according to the period in which the lease expires.

A new MOTO for the new offices at 2 Redman Place was agreed and signed in June 2021 with the Department of Health and Social Care (DHSC). This is the only lease the HTA now holds.

<b>Total future minimum lease payments</b>	<b>Buildings</b>	<b>31-Mar-21</b>	<b>31-Mar-20</b>
	<b>£'000</b>	<b>Total</b>	<b>Total</b>
	<b>£'000</b>	<b>£'000</b>	<b>£'000</b>
Payable:			
Not later than one year	91	91	461
Later than one year not later than five years	364	364	0
Later than five years	418	418	0
<b>Total</b>	<b>873</b>	<b>873</b>	<b>461</b>

#### 11.2 Sub-lease receipts recognised as revenue

<b>Total future minimum lease receivables</b>	<b>31-Mar-21</b>	<b>31-Mar-20</b>
	<b>£'000</b>	<b>£'000</b>
Receivable:		
Not later than one year	0	368
Later than one year not later than five years	0	0
<b>Total rental revenue</b>	<b>0</b>	<b>368</b>

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## 12. Provisions

<b>Total future minimum lease payments</b>	<b>Office Relocation(Travel) £'000</b>	<b>Total £'000</b>
Balance at 1 April 2020	120	120
Provided in year	0	0
Provisions utilised in year	0	0
Release of provision for the period	<u>(70)</u>	<u>(70)</u>
<b>Balance at 31 March 2021</b>	<b><u>50</u></b>	<b><u>50</u></b>

### Analysis of expected timing of cashflows

	<b>Office Relocation(Travel) £'000</b>	<b>Total £'000</b>
Not later than one year	25	25
Later than one year and not later than five years	25	25
	<b><u>50</u></b>	<b><u>50</u></b>

The provision provided this year reflects the cost of additional travel the HTA has committed to reimburse its staff over a three year period as a result of the office relocation. It is expected that the provision will be released equally each year, however this may change when the next annual review takes place.

The relocation of HTA to new offices is a constructive obligation under IAS 37. The HTA has consulted its staff and expects there to be a transfer of economic benefits. The estimate of the provision is based upon the number of staff who have applied to work flexibly. The provision will be reviewed at an appropriate point in the 2021/22 financial year.

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### **13. Related party transactions**

During the period none of the Department of Health and Social Care Ministers, HTA Board members or members of the key management staff, or parties related to any of them, has undertaken any material transactions with the HTA.

The Department of Health and Social Care is regarded as a related party. During the year HTA has had a significant number of material transactions with the Department, and with other entities for which the Department is regarded as the parent Department, including:

NHS Blood and Transplant  
NHS Resolution  
Human Fertilisation and Embryology Authority

The HTA has also had material transactions with the Government Property Agency (GPA) throughout the year.

### **14. Events after the reporting period**

In accordance with the requirements of International Accounting Standard 10, reports after the accounting period are considered up to the date the accounts are authorised for issue. This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

The MOTO for the new office 2 Redman Place, Stratford, was signed on 7 June 2021.



