

# Annual report and accounts 2021/22



# Human Tissue Authority

## Annual report and accounts 2021/22

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

The Human Tissue Authority is a UK-wide body which regulates the safe and consented use of human tissue and organs. This encompasses regulating nearly 800 licensed establishments across a broad range of medical, scientific, research and education settings: as well as the provision of advice to Ministers and officials at the Department of Health and Social Care, devolved administrations, and to the public and stakeholders in relation to our remit.

2021/22 saw the continued impact of Covid19 across our regulatory landscape but we were able to build on innovations necessitated by the pandemic in 2020/21 business year and during the latter part of 2021/22 resumed a full programme of regulatory activity. As a result, we delivered a programme of reviews in over 150 licensed establishments – numbers not far short of performance prior to the pandemic. We also continued to deliver against our internal change programme, working to update our systems and improve our use of digital information to assist our regulatory goals, with more details provided later in this report.

Having taken up the post of Chief Executive and Accounting Officer of the HTA on 1 January 2022, I have been able to use my first few months (Q4 of 2021/22) to take stock and plan for the future with the development of the 2022/23 business plan. This builds on the plans progressed in 2021/22 and I am grateful to the work of my predecessor, the Executive team, and colleagues over the first 9 months of the year in helping to deliver within budget and against the organisation's objectives. The HTA has been a successful in 2021/22 and continues to perform well on a small budget and staff cadre, and I have been impressed with the general standing the organisation has with its sponsor department and stakeholders.

It will be critical that we capitalise on the foundational developments made during this year, as we continue to strive to regulate in a more risk-based and proportionate way, being efficient and effective, making it straightforward for compliant licence-holders whilst challenging those with key shortfalls to improve. Whilst I acknowledge the good work that has been done, I am keen we accelerate our development and deliver further change to our regulatory approach in the next business year. We will look to achieve these ambitions as we also interact with our stakeholders more often as we deploy our new stakeholder engagement strategy.

We face other demands as we enter 2022/23, there are changes to regulations and codes of practice as we assist our sponsor Department and other government bodies to implement deemed consent for organ donation in Northern Ireland and other regulatory changes. We will also continue to fully support the work of Sir Jonathan Michael's Independent inquiry into the issues raised by the Fuller case through the first and second phases of its review. More broadly, we will continue to support the growth of the UK's life sciences as we strive to be an excellent, proportionate and accountable regulator.

It has been a privilege to take on the role of Chief Executive of the HTA, and I wish to record my thanks to colleagues all across the organisation for their continued dedication, hard work and commitment to the work of the HTA.

A handwritten signature in black ink, appearing to read 'Colin Sullivan', with a long horizontal flourish extending to the right.

**Dr Colin Sullivan**  
**Chief Executive**

# Performance Report



# 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 both within our remit, and in areas related to (but not covered by) our current legislation and advise Ministers on these. This is particularly important in areas of emerging technology and cutting-edge research not originally envisaged when the Human Tissue Act was enacted.

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

Areas which we regulate are:

- 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 over 800 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 2021-2024

Strategic Aims	High level objectives are to continue to:
<p>Delivery – To deliver the right mix of operational activity to maintain public and professional confidence</p>	<ul style="list-style-type: none"> <li>• Deliver a risk-based, data-driven, and proportionate programme 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 professionals and the public in matters that are important to them and influence them in matters that are important to us.</li> <li>• Maintain and further develop our strategic relationships with other regulators operating in the health sector.</li> </ul>
<p>Development – To make the right investment to continuously improve delivery and deployment.</p>	<ul style="list-style-type: none"> <li>• Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.</li> </ul>

	<ul style="list-style-type: none"> <li>• Make continuous improvements to systems and processes to minimise waste or duplicated effort as well as 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>• Implement and embed a future operating model, which builds our agility, resilience, and sustainability as an organisation.</li> </ul>
Deployment – To make the most effective use of people and resources in pursuit of our goals	<ul style="list-style-type: none"> <li>• Manage and develop our people in line with the HTA’s People Strategy</li> <li>• Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money</li> <li>• Provide a suitable working environment and effective business technology, with due regard for data protection and information security</li> <li>• Plan and prioritise our resources to carefully balance activity across the organisation</li> </ul>

## Key issues in 2021/22

In October 2021 our Chief Executive of over five years left the HTA. There was a gap until January 2022, when the new Chief Executive commenced. Our Director of Resources temporarily filled the position of Accounting Officer over this period. This left a few challenges such as to how best to deploy underspent resources by the end of the financial year and the finalisation of our business plans for the coming business year. However, with concerted effort in Q4, the business plan for 22/23 was completed and shared with the Board and the Department ahead of year end in March 2022.

## Development Programme

For the last 3 years the HTA Strategy has been committed to strengthening the use of data and developing our technology to support the delivery of effective regulation. Progress in the achievement and realisation of the intended benefits had been constrained due to the availability of resources (financial and people). Hence, during Q4 21/22, proposals for a review of the prioritisation of key work packages and deployment of resources was proposed. The Board has

subsequently agreed to pause some activities and review the current focus and structure of the Development Programme.

## COVID-19

The impact of the pandemic over the last 2 years has not only impacted upon staff well-being which continues to be an area of focus, however it also impacted upon our ability to fulfil our statutory duty to inspect establishments within the Human Application sector every two years. Whilst our Board and our sponsors within the Department of Health and Social Care (DHSC) have been aware of this and the risks it poses, it continues to be an area of concern for the senior management team. The introduction of Virtual Regulatory Assessments (VRAs) has helped to reduce the risk posed and with the recommencement of a full range of inspections during 2021/22, we are seeking to recover to meet the requirement for the bi-annual cycle of inspections in the Human Application Sector during 22/23.

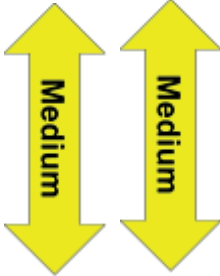
## Office relocation

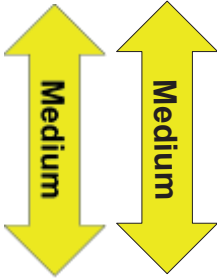
We have now taken up residence in new purpose-built offices in Stratford, East London. Although many staff are working across the country on regulation visits and less than a third are on office-based contracts, we are using the space to convene for collaborative work and to strengthen the culture of the HTA. We will also be looking to use the opportunity of co-location with other Health Sector regulators to build partnerships and collaborations which benefit patients, the public and those we regulate. Full access to the office recommenced early in 2021/22 and we are utilising the space to encourage staff to come together. As well as regular team meetings, we have introduced quarterly all-staff meetings in Redman Place.

## Risks as at 31 March 2022

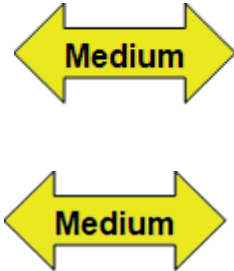
The HTA aims to take all reasonable steps in the management of risk with the overall objective of achieving strategic and business objectives and protecting staff, stakeholders, the public and assets.

As at 31 March 2022, the HTA had six strategic risks:

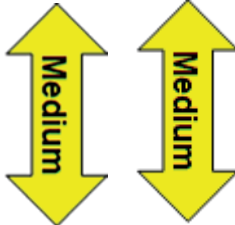
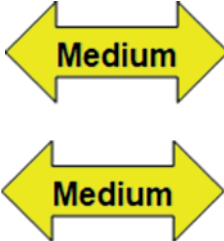
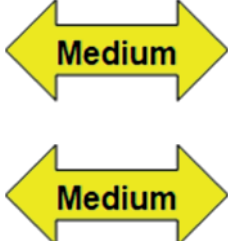
Risk associated with Development	Mitigating activities	Risk severity and direction of risk trend last 2 quarters
<b>R1: Failure to regulate in a manner that maintains public safety and confidence and is appropriate</b>	<ul style="list-style-type: none"> <li>Regulatory model comprising a mixture of proactive regulatory assessments (e.g. through site visit inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc);</li> <li>Process for consideration of police referral maintained and used;</li> <li>Annual collection of activity data in Human Application (HA) sector; biennial collection of compliance updates data from other sectors;</li> <li>Regulatory decision-making framework in place;</li> <li>The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment consideration;</li> <li>Well established processes which support our core regulatory business;</li> <li>HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model;</li> <li>Adherence to the HTA People Strategy which has been substantially amended and approved by the Board;</li> </ul>	

	<ul style="list-style-type: none"> <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> <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 Plan, SOPs and guidance in place, are regularly reviewed and communicated to staff who are trained annually;</li> <li>• All specific roles identified in the Critical Incident Response Plan are filled;</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>• Availability of legal advice;</li> <li>• Fit for purpose Police Referrals Policy;</li> <li>• Onward delegation scheme and decision making framework agreed by the Board;</li> <li>• Regulatory decision-making framework</li> <li>• IT security controls and information risk management in place and Critical Incident Response Plan is regularly reviewed and tested.</li> <li>• Ensuring Designated Individuals (DIs) or equivalent in the Organ Donation and Transplantation (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</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> </ul>	



<p><b>particular stemming from limitations in current legislation or misperception of HTA regulatory reach</b></p>	<ul style="list-style-type: none"> <li>• Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope;</li> <li>• Active management of issues raised by the media – including the development of the HTA position on issues;</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> <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 quarter four of 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> <li>• Regular meetings with DHSC Policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures.</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>• Current People Strategy;</li> <li>• External assessment of utilisation of capabilities;</li> <li>• Adherence to the HTA Workforce Capability Development Framework;</li> </ul>	



	<ul style="list-style-type: none"> <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 and mandatory training on policies and required controls;</li> <li>• IT systems protected and assurances received from third party suppliers that protection is up to date;</li> <li>• System performance analytics available and reported.</li> </ul>	
<b>R5: Insufficient, or ineffective management of financial resources</b>	<ul style="list-style-type: none"> <li>• Budget management framework exists to control, and review spend and take early action;</li> <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 audits 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 organisational Development Programme</b>	<ul style="list-style-type: none"> <li>• SMT expertise in organisational change, programme and project management;</li> <li>• HTA approach to the management of change projects (underpinned by project management methodologies);</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> </ul>	

	<ul style="list-style-type: none"> <li>• A phased delivery approach implemented to avoid all or nothing investment and aligned with available funding;</li> <li>• Monthly reporting to the SRO.</li> </ul>	
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The end of the 2021/22 business year has seen overall a stable risk profile. Risks 1 and 4 have seen a reduction in status at the end of the year and, in addition, both are below their tolerance levels, as restrictions were removed enabling an increase in inspections (on-site) and a healthy recruitment campaign that has seen key vacancies filled.

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

### Going concern

The HTA is funded from two sources; grant in aid provided by the Department of Health and Social Care who are funded through Parliament. Parliament has demonstrated its commitment to continue to fund DHSC for the foreseeable future. We are also funded by licence fees from both the private and public sector.

Our funding from DHSC has been agreed for the next year and our licence fees which are charged in line with statute create a guaranteed income source. Licence fees are set in December each year, prior to billing our establishments in the April and September of the following year. We also hold over £1m 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 and the organisation is not subject to any review in 2022/23 that may result in it being abolished or subsumed. The organisation is expected to be reviewed in 2023/24 as part of the rolling Public Bodies Review Programme of regular reviews.

Based on the above, the Board has reasonable expectation that it has adequate resources to continue in operational existence for a period of at least 12 months from the date the financial statements are authorised for issue. For this reason, the Authority and the Accounting Officer continue 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.

A monthly management report is produced and shared with the SMT and Heads of Service. The report is management information used by the Heads of Service to view what work is in the pipeline; any workload pinch-points or risks to the business plan deliverables. The report is also designed to give SMT assurance that resources are being allocated correctly.

During the last two years we have amended how we reported to our Board. A Chief Executive's Performance Report was tabled at each meeting. This report focused more upon updates of a financial and regulatory nature rather than KPIs. The pandemic affected the number of inspections and site visits we were able to carry out. This resulted in no targets being set for inspections in 2020/21. This year (2021/22) has seen restrictions lifted which has enabled a staggered approach to site visits and the addition of Virtual Risk Assessments (VRAs) that complement on-site inspections.

Below are some of the KPIs reported to the Board in the 2021/22 business year.

## Analysis of performance over the year

### Performance indicators 2021/22

Performance indicators	Target 2021/22	Performance 2021/22	Target 2020/21	Performance 2020/21
<b>Delivery</b>				
Undertake a risk-based inspection/audit program	140 inspections	157 inspections	Not measured in 2020/21	N/a
Take appropriate action for all regulatory non-compliance <sup>1</sup>	100% of Corrective and Preventative Actions (CAPAs) implemented within 28 days	92%	100% of Corrective and Preventative Actions (CAPAs) implemented within 28 days	98.5% <sup>2</sup>
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%

<sup>1</sup> 2021/22 target missed due to 5 CAPA's that have remained open as agreed by the Regulation team. 4 relate to one establishment

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

Respond to enquiries in a timely way	95% of enquiries answered within 10 working days	91% <sup>3</sup>	95% of enquiries answered within 10 working days	95% <sup>4</sup>
<b>Deployment</b>				
Reduce attrition rates through improved selection and targeted measures to retain staff	Attrition rate to be no more than 18%	14%	Attrition rate to be no more than 18%	14.3%

## Financial review

We have generated the income needed to cover the cost of the activities we licence 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 2022

		2021/22	2020/21
	Note	£'000s	£'000s
<b>Income</b>			
From devolved Governments		134	134
Licence fees		4,079	3,997
Other income	(a)	50	418
<b>Total income<sup>5</sup></b>		<b>4,263</b>	<b>4,549</b>
<b>Expenditure</b>			
Staff costs		3,500	3,356
General administrative and non-cash costs		1,394	2,019
<b>Total expenditure<sup>4</sup></b>		<b>4,894</b>	<b>5,375</b>
<b>Net (expenditure) for the year</b>	(b)	<b>(631)</b>	<b>(826)</b>

(a) Other income is seconded staff costs. In 2020/21 it included rent also.

(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>3</sup> The 91% represents enquiries answered within 5 days. 10 day target was unavailable.

<sup>4</sup> Target has been met during a period of change and some uncertainty

Net (expenditure) /income for the year	(b)	(631)	(826)
Revenue Grant in Aid	(c)	911	771
Ring-fenced RDEL	(d)	56	106
Surplus for the year		336	51

(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 66 within the financial statements and included in the Statement of Changes in Taxpayers Equity (SoCTE) on page 69.

(d) In addition, the HTA received cover for its non-cash expenditure (depreciation and amortisation) of £56k. It is not cash and therefore the cover is not shown in the accounts.

Against the above surplus our operating expenditure is £4.89m. Our staff costs at £3.5m which is 4.3% higher than last year and reflects the increase in whole-time equivalent staff employed.

Income from contracts with customers (Licence fee income) of £4m is 2% higher than our 2020/21 fee income (just over £3.99m), and 3.2% higher than the budget. This increase is largely due to increased application fees in 2021/22.

During 2021/22 the HTA ensured that drawdowns of grant in aid were kept within the DHSC's cash allocation. The total available cash allocation for revenue and capital expenditure was £911,000 and £100,000 respectively, (2020/21 £771,000 and £100,000).

## Supplier payments

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	2021/22	2020/21
90% of payments made within 10 days of receipt of undisputed invoice.	<b>502 invoices received of which 422 (83.6%) were paid within 10 days</b>	383 invoices received of which 346 (92.3%) were paid within 10 days

We missed our target due to some issues with invoices and extended time to pay.

The HTA is committed to the Better Payment Practice Code and its target of 95% of payments made within 30 days. 502 invoices were received of which 99% (497 invoices) were paid within 30 days.

## Counter fraud, bribery and corruption

During 2021/22, we continued to make submissions to the Cabinet Office in compliance with the Government Functional Standards GovS 013: Counter Fraud.

Regular fraud risk assessments are conducted as part of achieving compliance with the functional standards as is the training modules around fraud, bribery and corruption that are mandatory for all staff.

In order to keep abreast of the fraud landscape, we are also members of the DHSC's Counter Fraud Liaison Group. This group also provides guidance and training around reporting of fraud and error.

## Staff involvement and wellbeing

The HTA keeps all members of staff informed about organisational, management and policy issues. There is a weekly exchange call for all staff introduced by the new Chief Executive. This brings staff together and facilitates discussion around the latest issues/news items that may impact on the HTA. It enables staff to have their say and be heard. Quarterly all-staff meetings (in person for most participants) have also been introduced in our new offices allowing staff to connect. There are also informal weekly drop-in sessions with members of the Senior Management Team (SMT) where staff can raise any issues of concern or interest.

We undertook our staff survey in February 2022, had a participation rate of 83% (88%, 2019/20) compared to the Civil Service average of 62% in 2019/20. We are committed to engaging staff and strive to maintain and build on high staff engagement and satisfaction scores from each staff survey.

We have a social committee who continue to deliver various staff events. Added to this list of activities, is the new "Friday Superbowl" which gives staff the opportunity to quiz another member of staff in a friendly and light-hearted manner. Our focus on wellbeing is now a business as usual programme of events. Each month we have introduced themes such as Renew and Assess, where staff are encouraged to be reflective of their own well-being and to consider self-development and mental fitness going forward. During Q4 the Wellbeing Charter was launched. The Wellbeing Charter is a set of working practices that aim to ensure wellbeing is supported at the HTA.

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

The chair of the Audit and Risk Assurance Committee (ARAC) who is also a Board Member, 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 has eight 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

Staff are encouraged to have personal development plans; this remains an essential part of our appraisal process. We have 3 types of training programmes; Corporate Training including compliance training, role specific training and our Career Investment Scheme.

Our Career Investment Scheme which continues to be used was 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. In 2021/22 2 (6, 2020/21) members of staff benefitted from the scheme, in addition to the 42 previous beneficiaries since the scheme began. We also have access to the 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.

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.

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

The HTA is committed to equality of opportunity for both current and prospective employees, and in the recruitment of working group members. All who work for the HTA, applies to work at the HTA or applies to join a group are treated fairly and valued equally.

We revised our Equality, Diversity and Inclusion (EDI) and Human Rights policy in Q4 of 2021/22 on the back of an Internal Audit on EDI which concluded in January 2022. The audit identified three areas for improvement which were; updating our ED&I page on our intranet; updating or removal of references to an annual equal opportunities audit and a report on ED&I should be made to our Audit Committee on a regular basis.

Our values make clear that we are committed to providing equal opportunities for all staff. 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 we seek to ensure that the Authority abides by all 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. We are working with other health regulators to determine better ways of pooling resources to help improve promoting inclusion.

## 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. We keep abreast of any changes in the law or any tribunal rulings that may impact on our policies. The latest is the consideration of menopause symptoms as a disability. In order to ensure staff are aware and understand, we have conducted awareness sessions through our “lunch and learn” sessions.

Disability - of the 17 staff who declared, one reports themselves as disabled. An analysis of other characteristics of all staff, as at 31 March 2022, is provided below.

## Gender mix as at 31 March 2022

An analysis of gender mix for the headcount as at 31 March 2022 is provided below. The figures exclude the Shared Director who is accounted for within the Human Fertilisation and Embryology Authority (HFEA) and temporary staff.

Gender	Male	Female	Total 2021/22	Total 2020/21
Authority Members	3	6	9	10
Directors	1	2	3	3
Total staff (including Directors, excluding Members) <sup>6</sup>	14	31	45	45

## Staff mix according to age as at 31 March 2022

Age range	2021/22	2020/21
< 34	4	8
35-44	21	17
45-54	13	14
>55	7	6

<sup>6</sup> Last year (Male 11/Female 37)



<b>Ethnicity</b>	<b>2021/22</b>	<b>2020/2021</b>
White British	26	39
Asian [Indian]	4	0
Black [African]	1	1
White [European]	3	3
White [Irish]	2	0
Other	2	0
Undefined	7	2
<b>TOTAL</b>	<b>45</b>	<b>45</b>

## Social, sustainability and environmental issues

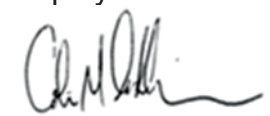
The HTA is committed to reducing its environmental impact. Where possible staff are encouraged to use greener modes of transport. The relocation to our offices in Stratford in early 2021 has helped us reduce our energy usage. The new offices have excellent environmental credentials, awarded 'Outstanding' by BREEAM, one of the world's most highly recognised industry standards for best practice in design and construction. We have reduced our paper usage initially due to the pandemic which required all staff to work virtually but reduced levels continue in the period without COVID restrictions.

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.

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.

Whilst the HTA may be exempt from formal reporting on a number of Greening Government Commitments, as it has fewer than 50 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.



**Dr Colin Sullivan**  
**Chief Executive**  
**Accounting Officer**

**18 July 2022**

# 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 2022 there were 9 Board Members with an additional member leaving in April 2022. Authority Members during 2021/22 are set out below. Biographies for each existing member 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 (extended to November 2025)
<b>Professor Gary Crowe</b>	Lay	1 September 2019	31 August 2022 (extended to September 2025)
<b>Glenn Houston</b>	Lay	5 May 2015	30 April 2022 (term ended)
<b>Dr Lorna Williamson OBE</b>	Professional	1 April 2016	31 March 2022 (term ended)
<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 (term ended)
<b>Ellen Donovan</b>	Lay	1 April 2021	31 March 2024
<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	2022 January 2024 (Resigned 28 February 2022)

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

## Senior Management Team

Our Chief Executive and Directors during 2021/22 are set out below.

Senior Management	Post
<b>Dr Colin Sullivan</b>	Chief Executive (appointed 1 January 2022)
<b>Allan Marriott Smith</b>	Chief Executive (resigned 31 October 2021)
<b>Richard Sydee<sup>7</sup></b>	Director of Resources (Accounting Officer from 1 <sup>st</sup> November 2021 – 31 <sup>st</sup> December 2021)
<b>Nicolette Harrison</b>	Director of Regulation
<b>Louise Dineley</b>	Director of Data, Technology & Development

## 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.

<sup>7</sup> Richard Sydee – Director of Resources was acting Accounting Officer for the period November 2021 to January 2022 when Dr Colin Sullivan joined as the new Chief Executive. Richard is also shared and seconded 2.5 days a week from the Human Fertilisation and Embryology Authority.

## 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 2021/22 was £30,000. 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) 2021/22.

### **Authority statement**

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

# Governance statement

## Overview

This statement sets out the governance and control framework at the HTA and the risks to HTA performance. It explains how I, and my predecessors in 2021/22, have discharged the responsibility of being Accounting Officer, so as to manage and control the HTA's resources in 2021/22.

## Governance framework

### The Human Tissue Authority

The HTA is an independent regulator established in 2005 following events in the 1990s that revealed incidents of removal and retention of 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 Authority (our Board)

The Authority oversees the strategic direction and delivery of objectives and ensures that the core purpose and values of the organisation are upheld. The Authority is led by the Chair and comprises Non-Executive Directors (NEDs). The Board is advised by the Executive Directors who are the Chief Executive, Director of Resources, Director of Regulation and Director of Data, Technology and Development.

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 Department of Health in Northern Ireland. Members are appointed for a three-year term of office initially.

The Board met 4 times during the year and had a Strategic Planning Day in April 2021. The Chief Executive and Executive Directors (the SMT), attend Authority meetings. Representatives from the DHSC also attend, and other HTA staff attend as required.

Details of Authority members and attendance are below.

Authority Member	Number of meetings attended	Total number of meetings in 2021/22
Lynne Berry CBE	4	4
Professor Gary Crowe	4	4
Dr Charmaine Griffiths	4	4
Professor Penney Lewis	4	4
Dr Stewart Dollow	4	4
Glen Houston	3	4
Dr Lorna Williamson OBE	4	4
Jan Williams OBE	4	4
Professor Deborah Bowman	3	4
Ellen Donovan	4	4

At the end of 2021/22 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.



The end of the 2021/22 business year saw the terms of office end for three Members, with one Member's term ending in quarter one of 2022/23. In April 2022, four new Board Members will join the Authority.

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/priorities and these include reports on our financial priorities and an updated assessment of strategic risk.

### **Quality of data used by the Board**

The papers received by the Board are subject to refinement through a rigorous internal assurance process overseen by SMT. In Q4 of 2021/22, we reviewed this process and made further improvements. In 2021/22, all Board Meetings took place virtually and were chaired effectively with challenge and discussion being encouraged.

An effective secretariat service was provided to the Board to ensure the sound administration of the Board and its activities.

### **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 but not limited to:

- Development programme – regular updates on key deliverables; gaining assurance on the governance and leadership of the programme;
- Codes of Practice Code D – code has been updated brought about due to differences in legislative consent requirements for the public display of bodies imported into England, Northern Ireland and Wales;
- Virtual Regulatory Assessments (VRAs) – feedback on pilots conducted in the Human Application sector and roll-out to the other sectors;
- Fee proposals for 2022/23 – the introduction of two new fees; Import and Export of relevant material moved between Great Britain & Northern Ireland under UK Transition Protocols, and proposals for increasing fees rather than a full fee review;
- COVID-19 restrictions – impact on site visits, staff returning to the office and the opportunities presented from co-locating;
- Communication and Stakeholder Engagement Strategy – proposed improvements to the way HTA conducts or responds to these activities ;
- Fuller Independent Inquiry – regular feedback on the HTA's work to support the inquiry and its impact on the HTA's resource.

The Board ensures that statutory functions are delivered appropriately, and 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. In order to demonstrate our commitment to openness and transparency we will make more policies and reports publicly available during 2022/23.

### Committees and groups

The Board is supported in its work by Sub-Committees and groups which have included Members. The Sub-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 2021/22.

Committee	Membership at 31 March 2022	Number of meetings 2021/22	Attendance rate
Audit and Governance Committee	3	3	100%
Remuneration Committee	3	0	N/a

Groups	Membership at 31 March 2022
Transplantation Advisory Group (TAG)	N/a
Histopathology Working Group (HWG)	N/a
Stakeholder and Fees Group	N/a

Having engagement with external stakeholders is key to the way the HTA operates, however, the 3 advisory groups did not meet during 2021/22. The coverage, format and membership of the HTA's stakeholders groups is under review and this work is expected to conclude in 2022/23 business year.

## The Executive

Dr Colin Sullivan (appointed 1 <sup>st</sup> Jan 2022)	Chief Executive
Richard Sydee	Director of Resources (shared with HFEA)
Nicolette Harrison	Director of Regulation
Louise Dineley	Director of Data, Technology and Development

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 Heads Management Team (HMT) consists of the Heads of functions (the next level of management). This is a business delivery group and a formal operational management team established by the Chief Executive and its purpose is to identify, assess, manage and/or escalate key corporate or emerging risks, provide operational leadership, oversee a working environment that supports effective achievement of goals and priorities, and maintains all necessary standards. The group also develops and implements SMT-approved operational plans and standards.

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.

## Audit, Risk and Assurance Committee

The ARAC met three times in 2021/22. 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 2021/22 is listed below.

ARAC member attended	Number of meetings
Prof. Gary Crowe (Chair)	3/3
Dr Charmaine Griffiths	3/3
Glenn Houston <sup>8</sup>	1/1
Dr Stuart Dollow	3/3
Jan Williams	2/3

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

In 2021/22 the internal audit plan covered seven 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
Staff Wellbeing	Review assess the adequacy and effectiveness of the processes in place to support employee wellbeing	Substantial
Business Planning and Performance reporting (advisory)	Assessed the adequacy of business planning and performance arrangements in place with the HTA and the extent to which they support delivery of the strategic plan	N/a
Financial Management: Budgeting	Assessment of the adequacy and effectiveness of the budget setting and ongoing budget management	Moderate
Governance Statement	Review assess the adequacy of the arrangements in place to draw assurances and develop the Governance Statement included in the Annual Report and Account	Moderate
Effectiveness of the Inspection Process	A follow-on review from the Virtual Inspection Process conducted in	Moderate

<sup>8</sup> Glenn Houston was replaced by Jan Williams after the June 2021 meeting. Jan Williams resigned from the Board in February 2022.

	20/21 assessing the effectiveness of inspection arrangements once virtual inspections have embedded.	
Data Security & Protection Toolkit (20-21 submission)	The objective of this audit is to understand and help address security and data protection risk; identify opportunities for improvement; whilst satisfying the annual requirement for an independent assessment of the Toolkit submission.	Limited
Equality Diversity and Inclusion	The objective of this audit is to assess the adequacy of the arrangements in place to sufficiently support and embed an effective ED&I landscape	Moderate

Areas of particular focus for ARAC during 2021/22 were:

- Deep dive conducted into Strategic Risk 4 – failure to utilise capabilities effectively; the committee receiving assurance that plans are in place to mitigate any resource stretch;
- Development programme – updates on deliverables over the remainder of the business year; in particular impact of key staff changes (Head of Business Technology);
- Horizon Scanning and the COVID enquiry;
- Outcomes from internal and external audit reports and progress on meeting audit recommendations;
- Internal Audit Plan for 2022/23
- Cyber Security – the committee reviewed the dashboard and proposed amendments to it reflecting best practice in areas such as staff awareness training and staff working remotely
- Operational risk – assurance that operational risks are being managed appropriately and the introduction of a new risk operational risk register template;
- Policy review – specifically the Anti-Fraud and Whistleblowing policies.

The ARAC holds an annual meeting in private with external and internal auditors to assure themselves there were no other matters of which they should be aware of. This meeting was held in January 2022.

Our internal auditors are the Government Internal Audit Agency who are in the fifth year of their appointment with the HTA.

## Remuneration Committee

The Remuneration Committee usually meets twice a year to agree the principles for pay awards. The Committee did not meet in 2021/22 due to a freeze on pay awards. The Chief Executive, the Director of Resources and the Head of HR attend the Remuneration Committee as appropriate. The Remuneration Committee Terms of Reference are subject to review and discussion at the May meeting of the HTA Board.

Members of the committee in the last business year are detailed below. Due to pay restrictions, no meetings were had in 2021/22.

Member	Number of meetings attended
Ellen Donovan (replaced Lynne Berry CBE as Chair)	N/a
Glenn Houston	N/a
Professor Penney Lewis	N/a

When appropriate, Board Members may also 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 the requirements of HM Treasury Corporate Governance in Central Government Departments: Code of Good Practice (2017)<sup>9</sup> insofar as they relate to public bodies. The HTA is compliant against the provisions of the code, with the following exceptions:

Ref	Code Provision	Exception
4.7	The permanent secretary should support the chair to ensure that board members have the skills, knowledge and familiarity with the department required to fulfil their role on the board and its committees.	This responsibility is shared between the Chair and the Chief Executive.
4.11	The Board Secretary's responsibilities include: arranging induction and professional development of Board Members	This responsibility is shared between the Chair, Chief Executive and Board Secretary

<sup>9</sup> It should be noted that the following provisions in the code are not applicable to the Human Tissue Authority: Sections 1,2,3,3,3,7,3.8,3.9,3.13,3.14,3.19,4.9,4.12,4.13,4.14,5.7,5.8

5.5	The Head of Internal Audit is periodically invited to attend Board meetings, where key issues are discussed relating to governance, risk management or control issues across the department and its ALBs.	The Head of Internal Audit always attends meetings of the ARAC but does not attend Board meetings.
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## 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 regular 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 21/22 year, there have been no cases progressed under the HTAs whistleblowing arrangements.

## The risk and control framework

In 2021/22 we have continued to embed our risk management framework to ensure that all staff follow a single process for identifying and managing risks that may threaten delivery and achievement of objectives. Our framework is aligned with the overarching principles of HM Treasury's Orange Book.

In continuing to implement the framework, our risk function and directorate risk leads have continued to provide information on new and existing risks, and co-ordinate and support the embedding of an appropriate risk management culture. Improvements in the quality of directorate risk registers have continued throughout 2021/22. We aim to improve our risk management maturity and risk culture year-on-year. This framework has been in place in the HTA for the year ended 31 March 2022 and up to the date of approval of the Annual Report and Accounts and accords with HM Treasury guidance.

## Risk appetite and tolerance

In 2020/21, we developed an approach to risk appetite which has been defined as 'the total amount and types of risk the HTA is willing to take in the achievement of its objectives'.



The HTA believe no risk exists in isolation from others and that risk management is about finding the right balance between risks and opportunities to act in the best interests of our stakeholders and taxpayers. Our approach to risk appetite involves risk trade-off conversations and a consideration of the counterfactual – giving us a flexible framework within which we can try new things, make agile decisions and find a balance between boldness and caution, risk and reward, cost and benefit. It also aims to provide a balance between an approach which is excessively bureaucratic and burdensome and one which lacks rigour.

When balancing risks, we will tolerate some more than others. For example, we may explore innovative ways of regulating in line with better regulation principles, and will have a clear view on its regulatory risk and areas of oversight, however, we would not tolerate any action that could cause reputational damage.

Our risk appetite and tolerance statement is to be reviewed by the Board at its meeting in the autumn of 2022.

Categories of risk and stated tolerances are summarised in the table below:

Category of risk	Risk tolerance
Regulation	Low
Corporate Governance	Low
Reputational	Low
Capabilities	Moderate
Information and security management	Low
Finance	Low

## Risk assessment

The HTA strategic risk register captures the high-level significant risks which could impact on the delivery of the HTA's strategic objectives. This is reviewed at each Audit, Risk and Assurance Committee and Board meeting. Also, each directorate holds its own risk register and reviews it on a regular basis. Any significant risks are subsequently escalated to the Senior Management Team for discussion and further escalation to the Board, to Audit, Risk and Assurance Committee and the DHSC sponsor team, if required.

Our risks reflect against implementation of the 2021 to 2024 Strategy and there are six strategic risks of which four have remained relatively stable over the year. The pressures that the COVID-19 pandemic presented and restrictions placed upon many organisations at its start have reduced somewhat during this last business year.

At the end of 2021/22, the HTA had six strategic risks (see table on pages 14-18) that were rated Yellow which means they have a scoring of between 5 and 10.



Failure to regulate appropriately – risk one, was increased at the end of 2020/21 in response to the COVID-19 position and heightened activity within the post-mortem sector. The risk reduced at the end of Q1 in 2021/22 as the roll-out of our Virtual Regulatory Assessments (VRAs) across the HT Act Sectors had a positive impact. Quarter four saw a full schedule of inspections which included site visits and VRAs and hybrid inspections, thus providing assurance that establishments remain compliant.

The Inability to manage an incident - risk two saw an increase in Q3 in response to what was then a confidential matter which subsequently became public in the autumn of 2021. The resulting inquiry (Fuller Independent Inquiry) after the individual was tried and convicted, placed demands on the senior management team, the Communications and Media teams and those staff working within the postmortem sector.

Failure to manage regulatory expectations risk three – was high (a risk score of 12) for the first 5 months of the business year as the HTAs UK Transition Project team proactively managed regulatory changes up to the June 2021 deadline. There were anticipated resource pressures, but these were effectively managed. The workload also included responding to issues raised by Members of the House of Lords concerning the consent provisions for material imported for the purposes of public display. The HTA response to this was a review and update of the Code of Practice Code D: Public Display. The revised Code D was laid before Parliament in June 2021 with publication in July 2021.

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.

Failure to utilise our capabilities effectively is the fourth risk and was assessed as high (a scoring of 12-16) for most of the year as recruitment to permanent roles had been placed on hold. At the start of 2021/22, a partial implementation of organisational redesign took place to address capability gaps identified during the previous year and saw the introduction of an ambitious recruitment campaign for ten posts including that of a Deputy Director adding further support and resilience to the Senior Management Team. In Q4, some key vacancies remain relating to planning and portfolio manager and Chief Information and Technology Officer. Interim appointments have been made to both posts. The rating at the end of the year was reduced to medium (yellow) with posts being filled and with the commencement of the new Chief Executive in January 2022, which is a clear mitigation of some organisation risk.

Insufficient or ineffective management of financial resources - risk five, our financial risk has been consistently low over the year. We have seen reductions in expenditure around accommodation where we have relocated to new offices in East London; the impact of restrictions early in the year affecting our site visits, meetings and events contributed to this reduction. There is a possible risk around the savings we are required to make as part of the

Spending Review 21, and we are planning a review of our fees in 22/23. Also, the outcome of bids for additional funding from DHSC for support on work associated with the Fuller Independent Inquiry and the COVID-19 inquiry responses are yet to be agreed. We continue to monitor this closely.

Failure to achieve the full benefits of the Organisational Development Programme – risk six, our final risk has been rated yellow (medium) for the year. This risk has been impacted by a lack of available resources due to other priorities. At the start of Q4, agreement was given for resourcing and investment to a re-prioritised set of commissions and deliverables. These commissions include targeted work to strengthen our data and intelligence, support the development of the target operating model and stakeholder engagement, thus justifying this risk's lower rating.

Assurance sources are identified for all risks and these reports and feedback provide assurance to the SMT and Board Members 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 2021/22.

From the Cyber Security Essentials audit, carried out in Q3 of 2020/21 by internal audit, the two recommendations that stemmed from this audit which were 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 have been addressed with the latter included within our Business Continuity Policy. A Cyber Security dashboard has been developed giving an overview of cyber security risks to the HTA and is reported to ARAC, the last being in January 2022.

An internal audit review of our Data Security & Protection Toolkit (DSPT) submission was conducted at the start of quarter two in 2021/22. This audit was required to help address data security and data protection risk and identify opportunities for improvement in addition to

satisfying the annual requirement for an independent assessment of the Toolkit submission. This was the first time the HTA has undertaken populating the DSPT and was demonstrated by the 'Limited' assurance we received. The recommendations from this audit were one high and two medium. The high rating reflected the lack of familiarisation with the toolkit and the lack of documentation. Further work is planned to develop the HTA's understanding of the evidence required. The two medium recommendations related to development of a structured approach to the future population of the toolkit and conducting a formal lessons learned exercise using gap analysis of the toolkit content; reaching out to organisations that have been through the process. It is expected that both these recommendations will be actioned before the next submission period which is June 2022.

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. During this financial year we identified one instance of a failure to obtain DHSC ministerial approval in advance of letting a contract for consultancy. Retrospective approval was obtained, and this requirement is now appropriately identified in our control processes.

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.

The process that has been applied in maintaining and reviewing the effectiveness of the governance framework includes the following:

- the Authority's internal management processes, such as performance monitoring and reporting; the staff performance appraisal framework; monitoring of policies;

- the Authority's internal audit coverage, which is planned using a risk-based approach. The outcome from the internal audit coverage helps inform the Head of Internal Audit's opinion on the overall adequacy of the Authority's internal control framework, which is reported in her annual report.

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.

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 2022 and up to the date of this report.



**Dr Colin Sullivan**  
**Accounting Officer**  
**Human Tissue Authority**

**Date: 18 July 2022**

# Remuneration and Staff Report

This report contains details on the remuneration of Members of our Board and the Executive for the year ended 31 March 2022. It is based upon the provisions contained within the Department of Health and Social Care, Group Accounting Manual (DHSC GAM) 2021/22. It also provides an analysis of staff and sickness absence data.

## Audit

Specific areas of the Remuneration and Staff Report are audited by the HTA's external auditors. These sections are labelled 'Audited' within the Remuneration and Staff Report.

## 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 and Social Care. 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 2021/22 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	2021/22			2020/21		
	Salary range	Expenses (to nearest £100) <sup>10</sup>	Total	Salary range	Expenses (to nearest £100)	Total
	£'000s	£	£'000s	£'000s	£	£'000s
Lynne Berry CBE	40-45	0	40-45	40-45	0	40-45
Professor Gary Crowe	10-15	0	10-15	10-15	0	10-15
Glenn Houston	5-10	0	5-10	5-10	0	5-10
Dr Lorna Williamson OBE	5-10	0	5-10	5-10	0	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
Dr Charmaine Griffiths	5-10	0	5-10	5-10	0	5-10
Professor Deborah Bowman	5-10	0	5-10	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)
Jan Williams OBE	5-10	0	5-10	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)
Ellen Donovan	5-10	0	5-10	N/a	0	N/a

## The Senior Management Team

Name	Position	Appointed	Until
Dr Colin Sullivan	Chief Executive	1 January 2022	N/a
Allan Marriott Smith	Chief Executive	6 July 2015	31 October 2021
Richard Sydee <sup>11</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

<sup>10</sup> Members' expenses relate solely to their attendance at HTA committees, meetings and training events. During 2021/22 all meetings were conducted virtually therefore no member were reimbursed costs of travel and subsistence.

<sup>11</sup> Richard Sydee is shared with the HFEA and is seconded to HTA 2.5 days per week.

The remuneration for SMT is agreed by the HTA Remuneration Committee and DHSC, following the Executive and Senior Managers (ESM) 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. There were no pay awards in the 2021/22 financial year.

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

Members of staff in Bands 1 – 3 (Assistants, Officers and Managers) are required to give the HTA eight weeks' notice for termination of contract. Members of staff in Bands 4 and above (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.

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 2021/22 (and nil in 2020/21).

### **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 prior to COVID-19 pandemic was published on the HTA's website [www.hta.gov.uk](http://www.hta.gov.uk) ([archive](#)). In 2021/22, one senior staff member received a payment classed as a benefit in kind.

## Senior Management remuneration (Audited)

Senior Manager	Salary	Bonus	B i K	Pension Benefits <sup>12</sup>	Total	Salary	Bonus	B i K	Pension Benefits	Total
	2021/22					2020/21				
	£000s	£000s	£	£000s	£000s	£000s	£000s	£	£000s	£000s
Colin Sullivan <sup>13</sup>	30-35 (Fye 135-140)	0	300	7.5-10	40-45 (Fye 140-145)	N/a	N/a	N/a	N/a	N/a
Allan Marriott-Smith	80-85 (Fye 120-125)	0	0	37.5-40	115-120 (Fye 160-165)	120-125	0	0	42.5-45	165-170
Nicolette Harrison	95-100	0	0	22.5-25	120-125	95-100	0-5	0	22.5-25	125-130
Richard <sup>14</sup> Sydee	45-50 (Fte 95-100)	0	0	20-22.5	70-75	45-50 (Fte 95-100)	0-5	0	22.5-25	70-75
Louise Dineley	95-100	0	0	25-27.5	120-125	95-100	0-5	0	0	95-100

## Pay ratio (Audited)

Reporting bodies are required to disclose the relationship between the remuneration of the highest paid director / member in their organisation against the 25th percentile, median and 75th percentile of remuneration of the organisation's workforce.

Total remuneration is further broken down to show the relationship between the highest paid director's salary component of their total remuneration against the 25th percentile, median and 75th percentile of salary components of the organisation's workforce.

The banded remuneration of the highest paid director in the Human Tissue Authority in the financial year 2021/22 was £135-£140k (2020/21, £120-£125k). The relationship to the remuneration of the organisation's workforce is disclosed in the table below.

<sup>12</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>13</sup> Dr Sullivan joined the HTA in the January of 2022

<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.



Year	25 <sup>th</sup> percentile total remuneration	25 <sup>th</sup> percentile Salary ratio <sup>15</sup>	Median total remuneration ratio	Median salary ratio	75 <sup>th</sup> percentile total remuneration ratio	75 <sup>th</sup> percentile salary ratio
2021-22	3.19 : 1	3.19 : 1	2.99 : 1	2.99 : 1	2.31 : 1	2.31 : 1
2020-21	2.86 : 1	2.86 : 1	2.72 : 1	2.72 : 1	2.16 ; 1	2.16 : 1

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 2021-22, 1 (2020-21, 0) employee received full year equivalent remuneration in excess of the highest-paid director. Full year equivalent remuneration ranged from £25,000 to £192,000 (2020/21 £25,000 to £125,000).

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

The figures have not changed in the above table due to small payments of benefits-in-kind that have not impacted on the total remuneration.

### Percentage change in remuneration of the highest paid director (Audited)

	2021/22	2020/21	Change
	£000s	£000s	
Director – salary range	137.5	122.5	12.2%
Director – performance pay	None	None	N/a
All staff – salaries	54.2	49.4	9.7%
All staff – performance pay	None	None	N/a

In line with Cabinet Office pay policy no pay award was made to HTA staff during the reporting year. The 12.2% increase in directors pay is due to an increase in salary on appointment, the all-staff increase is driven through the inclusion of contract and fixed term contract appointments. No additional payments were made in years 2020/21 and 2021/22.

<sup>15</sup> The figures for 2020/21 and the current year are salary only as there were no payments related to performance made.

## Staff costs (Audited)

The HTA is structured as follows: thirteen Authority Members including the Chair and an Executive of 51 staff. For 2021/22, the HTA staff costs were:

	Permanently employed staff	Members	Seconded Staff	Temporary staff	Total 2021/22	Total 2020/21
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Wages and salaries	2,170	118	118	393	<b>2,799</b>	2,635
Social security costs	247	5	14	0	<b>266</b>	277
Pension costs	406	0	29	0	<b>435</b>	444
<b>Subtotal</b>	<b>2,823</b>	<b>123</b>	<b>161</b>	<b>393</b>	<b>3,500</b>	<b>3,356</b>
Less recoveries in respect of outward secondments	0	0	(50)	0	<b>(50)</b>	(50)
<b>Total net costs</b>	<b>2,823</b>	<b>123</b>	<b>111</b>	<b>393</b>	<b>3,450</b>	<b>3,306</b>

For 2021/22 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 years 2019-20, 2020/21 and 2021/22, 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.

## 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 2021/22	Total 2020/21
SCS	3	0	3	3
Other	42	1	43	44
<b>Total staff</b>	<b>45</b>	<b>1</b>	<b>46</b>	<b>47</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 2022, the HTA employed 45.5 WTE staff (2020/21, 47). The total number of contract (temp) staff in 2021/22 was 5 (2020/21, 1).

### Staff Turnover (not Audited)

Staff turnover was 15% (2020/21, 13%).

### Expenditure on consultancy

During the year we spent £444,338 on consultancy services which includes legal fees, technical consultancy and HR consultancy.

### Sickness and absences

During the year ended 31 March 2022 the total number of whole-time equivalent days (Wte) lost to sickness absence was 143 days (2020/21 83 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, 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, as at 31 March 2022, for more than £245 per day:

<b>Number of existing engagements as of 31 March 2022</b>	<b>7</b>
Of which....	
Have existed for less than 1 year at time of reporting	6
Have existed for between 1 and 2 years at time of reporting	1
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 between 1 April 2021 and 31 March 2022, for more than £245 per day.

<b>Number of existing engagements as of 31 March 2022</b>	<b>7</b>
Of which....	
No. assessed as caught by IR35	7
No. assessed as not caught by IR35	0

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 2021 and 31 March 2022.

<b>No. of off payroll engagements of board members, and/or senior officials with significant financial responsibility, during the financial year</b>	<b>3</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 2022, is based on valuation data as 31 March 2021, updated to 31 March 2022 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 also tested the cost of the Scheme relative to the employer cost cap that was set following the 2012 valuation. There was initially 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.

HMT published valuation directions dated 7 October 2021 (see Amending Directions 2021) that set out the technical detail of how the costs of remedy are included in the 2016 valuation process. Following these directions, the scheme actuary has completed the cost control element of the 2016 valuation for the NHS Pension Scheme, which concludes no changes to benefits or member contributions are required. The 2016 valuation reports can be found on the NHS Pensions website at <https://www.nhsbsa.nhs.uk/nhs-pension-scheme-accounts-and-valuation-reports>.

## 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 31/03/2022 (c)	Lump sum at age 60 at 31 March 2022 (d)	CETV at 31/03/2022 (e)	Real increase in CETV as funded by employer 2021/22 (f)	CETV at 01/04/2021 (g)	Employers contribution to stake holder pension
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£,000
Colin Sullivan	0-2.5	N/a	0-5	N/a	9	4	0	0
Allan Marriott Smith	0-2.5	N/a	25-30	N/a	359	29	318	0
Nicolette Harrison	0-2.5	N/a	5-10	N/a	108	17	77	0
Richard Sydee <sup>16</sup>	0-2.5	0-2.5	35-40	80-85	667	7	623 <sup>17</sup>	0
Louise Dineley	0-2.5	0-2.5	30-35	60-65	562	23	523	0

### 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.

<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.

<sup>17</sup> CETV value at 1 April 2021 has been restated following a recalculation by the Civil Service Pension Administrators.

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.

# 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 2022	31 March 2021
	£'000s	£'000s
Applications	102	70
Anatomy	112	105
Post-Mortem	1,280	1,281
Public Display	20	21
Research	762	723
Human Application	1,485	1,482
Organ Donation/ Transplantation	317	315
Other income for licensing activities <sup>18</sup>	107	372
<b>Total Income from contracts with Customers<sup>19</sup></b>	<b>4,185</b>	<b>4,369</b>
Costs allocated to licensing activities	(3,938)	(4,423)
<b>Surplus/(Deficit) on activities</b>	<b>247</b>	<b>(54)</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 2021/22 (2020/21: none).

<sup>18</sup> Figure includes income from Devolved Governments and rental of excess office space.

<sup>19</sup> This is the total income allocated to licensable activities and therefore differs from that on page 20.

**Remote contingent liabilities**

The HTA has no Remote Contingent Liabilities.

A handwritten signature in black ink, appearing to read 'Colin Sullivan', enclosed in a thin black rectangular border.

**Dr Colin Sullivan**  
**Accounting Officer**  
**Human Tissue Authority**

**Date: 18 July 2022**

## 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 2022 under the Human Tissue Act 2004.

The financial statements comprise the Human Tissue Authority's

- Statement of Financial Position as at 31 March 2022;
- Statement of Comprehensive Net Expenditure, Statement of Cash Flows and Statement of Changes in Taxpayers' Equity for the year then ended; and
- the related notes including the significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and UK adopted International Accounting Standards.

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 2022 and its net expenditure for the year then ended; and
- 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 HM Treasury's Government Financial Reporting 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 financial statements nor my auditor's certificate and report. 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, the part of the Remuneration and Staff Report to be audited has been properly prepared in accordance with Secretary of State directions issued under the Human Tissue Act 2004;

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

- the parts of the Accountability Report subject to audit 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 and is in accordance with the applicable legal requirements.

### **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:

- I have not received all of the information and explanations I require for my audit; or
- adequate accounting records have not been kept by the Human Tissue Authority 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 subject to audit are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual have not made or parts of the Remuneration and Staff Report to be audited are not in agreement with the accounting records and returns; 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:

- maintaining proper accounting records;
- the preparation of the financial statements and Annual Report in accordance with the applicable financial reporting framework and for being satisfied that they give a true and fair view;
- ensuring that the Annual Report and accounts as a whole is fair, balanced and understandable;
- 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; and
- 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.

### **Extent to which the audit was considered capable of detecting non-compliance with laws and regulations including fraud**

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulations, including fraud. The extent to which my procedures are capable of detecting non-compliance with laws and regulations, including fraud is detailed below.

### **Identifying and assessing potential risks related to non-compliance with laws and regulations, including fraud**

In identifying and assessing risks of material misstatement in respect of non-compliance with laws and regulations, including fraud, I considered the following:

- the nature of the sector, control environment and operational performance including the design of the Human Tissue Authority's accounting policies;
- Inquiring of management, the Human Tissue Authority'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 the Human Tissue Authority's compliance with the Human Tissue Act 2004 and 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 a result of these procedures, I considered the opportunities and incentives that may exist within the Human Tissue Authority for fraud and identified the greatest potential for fraud in the following areas: revenue recognition, posting of unusual journals, complex transactions and bias in management estimates. In common with all audits under ISAs (UK), I am also required to perform specific procedures to respond to the risk of management override of controls.

I also obtained an understanding of the Human Tissue Authority's framework of authority as well as other legal and regulatory frameworks in which the Human Tissue Authority operates, focusing on those laws and regulations that had a direct effect on material amounts and disclosures in 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 law, pensions legislation and tax legislation.

### **Audit response to identified risk**

As a result of performing the above, the procedures I implemented to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with the provisions of relevant laws and regulations described above as having direct effect on the financial statements;
- enquiring of management and the Audit and Risk Assurance Committee concerning actual and potential litigation and claims;
- reading and reviewing minutes of meetings of those charged with governance and the Board and internal audit reports;
- 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, substantive testing of journal entries which meet high risk characteristics impacting the income lines, particularly round 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 risk-based 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 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.

### **Other auditor's responsibilities**

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: 19 July 2022**

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



# Financial statements

**Human Tissue Authority**  
**Annual Report and Accounts 2021/22**

**Statement of Comprehensive Net Expenditure for the year ended 31 March 2022**

	Note	<u>2021/22</u> <u>£'000s</u>	<u>2020/21</u> <u>£'000s</u>
<b>Income from sale of goods and services</b>			
Revenue from contracts with customers	4	(4,079)	(3,997)
Other Operating Income	4	(184)	(552)
<b>Total operating income</b>		<u><b>(4,263)</b></u>	<u><b>(4,549)</b></u>
<b>Expenditure</b>			
Purchase of goods and services	3	1,078	782
Staff costs	3.1	3,500	3,356
Depreciation, amortisation and impairment charges	3	7	100
Loss on disposal of fixed assets	3	0	110
Movement in provisions	3	(25)	(70)
Other operating expenditure	3	334	1,097
<b>Total operating expenditure</b>		<u><b>4,894</b></u>	<u><b>5,375</b></u>
<b>Net Expenditure</b>		<u><b>631</b></u>	<u><b>826</b></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 70 to 85 form part of these financial statements.

**Human Tissue Authority  
Annual Report and Accounts 2021/22**

**Statement of Financial Position as at  
31 March 2022**

	Note	<u>31-Mar-22</u> <u>£'000s</u>	<u>31-Mar-21</u> <u>£'000s</u>
<b>Non-current assets:</b>			
Property, plant and equipment	5	42	55
Intangible assets	6	0	24
<b>Total non-current assets</b>		<b><u>42</u></b>	<b><u>79</u></b>
<b>Current assets:</b>			
Trade and other receivables	8	358	174
Cash and cash equivalents	9	4,078	4,071
<b>Total current assets</b>		<b><u>4,436</u></b>	<b><u>4,245</u></b>
<b>Total assets</b>		<b><u>4,478</u></b>	<b><u>4,324</u></b>
<b>Current liabilities</b>			
Trade and other payables	10	706	807
Provisions	12	25	25
<b>Total current liabilities</b>		<b><u>731</u></b>	<b><u>832</u></b>
<b>Total assets less current liabilities</b>		<b><u>3,747</u></b>	<b><u>3,492</u></b>
<b>Non-current liabilities</b>			
Provisions	12	0	25
<b>Total Non-current liabilities</b>		<b><u>0</u></b>	<b><u>25</u></b>
<b>Total assets less total liabilities</b>		<b><u>3,747</u></b>	<b><u>3,467</u></b>
<b>Taxpayers' Equity</b>			
I&E Reserve		<u>3,747</u>	<u>3,467</u>
<b>Total equity</b>		<b><u>3,747</u></b>	<b><u>3,467</u></b>

Notes 1 to 14 on pages 70 to 85 form part of these financial statements.

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



(Signed) .....  
Dr Colin Sullivan  
Accounting Officer

18 July 2022

**Human Tissue Authority  
Annual Report and Accounts 2021/22**

**Statement of Cash Flows for the year to  
31 March 2022**

		<b>2021/22</b>	2020/21
		<b>Total</b>	Total
<b>Note</b>		<b>£'000s</b>	£'000s
<b>Cash flows from operating activities</b>			
Net operating expenditure	SoCNE	(631)	(826)
Adjustment for depreciation and amortisation	3	56	106
Adjustment for loss on disposal of property, plant and equipment	3	0	110
(Increase)/Decrease in trade and other receivables	8	(184)	240
Increase/(Decrease) in provision	12	(25)	(70)
Increase/(Decrease) in trade payables	10	(101)	44
<b>Net cash (outflow)/ inflow from operating activities</b>		<b>(885)</b>	<b>(396)</b>
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment	5	(19)	0
<b>Net cash outflow from investing activities</b>		<b>(19)</b>	<b>0</b>
<b>Cash flows from financing activities</b>			
Grants from sponsor department	1.7	911	771
<b>Net financing</b>		<b>911</b>	<b>771</b>
<b>Net increase/(decrease) in cash and cash equivalents in the period</b>			
		<b>7</b>	<b>375</b>
<b>Cash and cash equivalents at the beginning of the period</b>			
	9	<b>4,071</b>	<b>3,696</b>
<b>Cash and cash equivalents at the end of the period</b>			
		<b>4,078</b>	<b>4,071</b>

Notes 1 to 14 on pages 70 to 85 form part of these financial statements.

**Human Tissue Authority  
Annual Report and Accounts 2021/22**

**Statement of Changes in Taxpayers' Equity  
For the year ended 31 March 2022**

	Note	<u>I &amp; E Reserve</u> £'000s
<b>Balance at 1 April 2020</b>		3,522
<b>Changes in taxpayers' equity for 2020/21</b>		
Net Expenditure		(826)
<b>Total recognised Income and expense for 2020/21</b>		<u>(826)</u>
Grant from sponsor department		771
<b>Balance at 31 March 2021</b>		<u><b>3,467</b></u>
<b>Changes in taxpayers' equity for 2021/22</b>		
Net Expenditure		(631)
<b>Total recognised Income and expense for 2021/22</b>		<u>(631)</u>
Grant from sponsor department	1.7	911
<b>Balance at 31 March 2022</b>		<u><b>3,747</b></u>

Notes 1 to 14 on pages 70 to 85 form part of these financial statements.

**Human Tissue Authority  
Annual Report and Accounts 2021/22**

## 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 2022 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 2022-23 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 Performance report on page 18.

#### 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 2022 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 2021/22

### 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.

### 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 signed lease for 2 Redman Place, Stratford should be classified as an Operating or Finance lease and therefore its impact and treatment in the 2021/22 accounts. The HTA management believe that the 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.

There is a rent-free period that has been accounted for on a straight-line basis over the life of the lease.

## Human Tissue Authority Annual Report and Accounts 2021/22

### 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 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 an approach to classification and measurement of financial assets was introduced a few years ago. Under this 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 2021/22

### 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 adapted by the DHSC GAM) does not require the following Standards and Interpretations to be applied in 2021/22. The application of the Standards as revised would have a material impact on the accounts in 2021/22, 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.

On transition to IFRS 16 on 1 April 2022, the HTA will apply the standard retrospectively with the cumulative effect of initially applying the standard recognised in the Income and Expenditure Reserve at that date. For existing operating leases with a remaining lease term of more than 12 months and an underlying asset value of £5,000, a lease liability will be recognised equal to the value of remaining lease payments discounted on transition at the HTA's incremental borrowing rate. The HTA's incremental borrowing rate will be a rate defined by HM Treasury. Currently this rate is 0.95% but this may change between now and adoption of the standard. The related right of use asset will be measured equal to the lease liability adjusted for any prepaid or accrued lease payments.

The lease for 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.

The HTA has estimated the impact of applying IFRS 16 in 2022/23 on the opening statement of financial position and the in-year impact on the statement of comprehensive net expenditure and capital additions as follows:

<b>Estimated impact on 1 April 2022 statement of financial position</b>	<b>£000</b>
Additional right of use assets recognised for existing operating leases	763
Additional lease obligations recognised for existing operating leases	763
<b>Net impact on net assets 1 April 2022</b>	<b>0</b>
<b>Estimated in-year impact in 2022/23</b>	
Additional depreciation on right of use assets	87
Additional finance costs on lease liabilities	7
Lease rentals no longer charged to operating expenditure	(109)
<b>Estimated impact on surplus/deficit in 2022/23</b>	<b>(15)</b>

These figures are estimates based on our current rent agreement and uses the HM Treasury discount rate in force at that time.

## Human Tissue Authority Annual Report and Accounts 2021/22

### 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 2021/22**

### 3. Other Expenditure

	Notes	2021/22 £'000s	2020/21 £'000s
<b>Staff Costs</b>	3.1	3,500	3,356
<b>Purchase of goods and services</b>			
Computer running costs		329	336
Staff recruitment, training and welfare		142	93
Consultancy		323	21
Office and administration costs		28	36
Maintenance Contracts		90	80
Travel subsistence and hospitality		37	46
Conferences & Events		0	1
Stationery and publications		18	17
Auditors Remuneration	(a)	83	71
Legal and professional fees		28	81
		<u>1,078</u>	<u>782</u>
<b>Other operating costs</b>			
Accommodation	(b)	165	934
Project Costs		162	135
Telecommunications		7	28
		<u>334</u>	<u>1,097</u>
<b>Non-cash items</b>			
Depreciation and amortisation	5,6	56	106
Movement in impairment for expected credit loss	8	(49)	(6)
(Gain)/Loss on disposal of non-current assets		0	110
Provision provided/(released) in year	12	(25)	(70)
		<u>(18)</u>	<u>140</u>
<b>Total</b>		<u><b>4,894</b></u>	<u><b>5,375</b></u>
<b>Notes</b>			
(a) Audit fees	Internal	53	43
	External	30	28
		<u>83</u>	<u>71</u>

(b) Accommodation costs are significantly reduced due to relocation to the new shared Stratford hub which has recognised costs savings.

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### 3.1 Staff numbers and related costs

**Staff costs comprise:**

	<b>2021/22</b>	2020/21
	<b>Total</b>	Total
	<b>£,000</b>	£'000
Wages and salaries	<b>2,799</b>	2,635
Social security costs	<b>266</b>	277
Pension costs	<b>435</b>	444
Sub Total	<b><u>3,500</u></b>	<u>3,356</u>
Less recoveries in respect of outward secondments	<b>(50)</b>	(50)
Total net costs	<b><u>3,450</u></b>	<u>3,306</u>

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

For 2021/22 contributions of £405,629 (2020/21, £302,720) were paid to the NHS Pensions (NHSPS) at rates prescribed by HM 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>2021/22</b>	2020/21
	<b>Total</b>	Total
Directly Employed	<b>46</b>	47
Total WTE staff	<b><u>46</u></b>	<u>47</u>
Temporary staff	<b>5</b>	1
Total	<b><u>51</u></b>	<u>48</u>

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 2022 the HTA employed 45.5 Wte staff (2020/21, 47). The number of contractors engaged during the year was 9.

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**4. Income**

	Note	<u>2021/22</u> <u>£'000s</u>	<u>2020/21</u> <u>£'000s</u>
Revenue from contracts:			
Licence Fee Income		(4,079)	(3,997)
Income from devolved administrations		<u>(134)</u>	<u>(134)</u>
		(4,213)	(4,131)
Other Operating Income	4.1	<u>(50)</u>	<u>(418)</u>
		<b><u>(4,263)</u></b>	<b><u>(4,549)</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>2021/22</u> <u>£,000</u>	<u>2020/21</u> <u>£'000</u>
Other Income - Rent	0	(368)
Other Income - Outward secondees	<u>(50)</u>	<u>(50)</u>
	(50)	(418)

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 2021	125	0	0	0	125
Additions	10	0	9	0	19
Disposals	0	0	0	0	0
Adjustments/Transfers	0	0	0	0	0
<b>At 31 March 2022</b>	<b>135</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>144</b>
<b>Depreciation</b>					
At 1 April 2021	70	0	0	0	70
Charge for the year	32	0	0	0	32
Disposals	0	0	0	0	0
Adjustments/Transfers	0	0	0	0	0
<b>At 31 March 2022</b>	<b>102</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>102</b>
<b>Net book value at 31 March 2022</b>	<b>33</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>42</b>
Net book value at 1 April 2021	55	0	0	0	55
All assets are owned by the HTA					
<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)
Adjustment/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)
Reclassifications	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
<b>Net book value at 31 March 2021</b>	<b>55</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>55</b>
All assets are owned by the HTA					

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**6. Intangible Assets**

	<b>Information Technology</b>	<b>Total</b>
	<b>£'000</b>	<b>£'000</b>
<b>Cost or valuation</b>		
At 1 April 2021	1,132	1,132
<b>At 31 March 2022</b>	<u>1,132</u>	<u>1,132</u>
<b>Amortisation</b>		
At 1 April 2021	1,108	1,108
Charged in year	24	24
<b>At 31 March 2022</b>	<u>1,132</u>	<u>1,132</u>
<b>Net book value at 31 March 2022</b>	<u>0</u>	<u>0</u>
Net book value at 1 April 2021	24	24
All assets 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 nil. The CRM is an internally generated asset and came to the end of its useful life in March 2022. It will remain on the fixed asset register as decisions around what is required going forward are made.

<b>Cost or valuation</b>		
At 1 April 2020	1,156	1,156
Disposals	(32)	(32)
Adjustments/Transfers	8	8
<b>At 31 March 2021</b>	<u>1,132</u>	<u>1,132</u>
<b>Amortisation</b>		
At 1 April 2020	1,065	1,065
Charged in year	67	67
Disposals	(32)	(32)
Adjustments/Transfers	8	8
<b>At 31 March 2021</b>	<u>1,108</u>	<u>1,108</u>
<b>Net book value at 31 March 2021</b>	<u>24</u>	<u>24</u>
Net book value at 1 April 2020	91	91
All assets are owned by the HTA		

## 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 2022 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 2022 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 2022 was:

	<b>£'000s</b>
Not past due	0
Past due 0-28 days	7
Past due 29 days	302

### Foreign currency risk

There were no foreign currency transactions conducted by the HTA during the period ended 31 March 2022. There was therefore no significant foreign currency risk during the year.



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**Financial instruments held by the HTA**

<b>By category</b>	<b>Receivables and other financial assets</b>
	<b>31 March</b>
	£'000
<b>Financial assets measured at amortised cost</b>	
Contract receivables (net of provisions)	273
Other receivables	4
Cash at bank and in hand	4,078
<b>Total at 31 March 2022</b>	<b>4,355</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>

**Financial liabilities**

<b>By category</b>	<b>Other financial liabilities</b>
	<b>31 March</b>
	£'000
<b>Financial liabilities measured at amortised cost</b>	
Contract payables	9
Other payables	21
Accruals	676
<b>Total at 31 March 2022</b>	<b>706</b>
Contract payables	35
Other payables	12
Accruals	760
<b>Total at 31 March 2021</b>	<b>807</b>

As at 31 March 2022, 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-22</b>	31-Mar-21
	<b>£'000</b>	£'000
<b>Amounts falling due within one year:</b>		
Contract receivables (contracts with customers)	309	188
Impairments for credit losses	(36)	(85)
Other Receivables	4	0
Prepayments and contract assets	81	71
	<u><b>358</b></u>	<u>174</u>

Contract receivables at the end of March 2022 have increased by 64%. This is due to challenges around credit control and ascertaining who the correct contacts are for payment when there are staff changes within our establishments.

**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 1 April 2021	4,071
Net change in cash and cash equivalent balances	7
Balance at 31 March 2022	<u><b>4,078</b></u>

	<b>31-Mar-22</b>	31-Mar-21
	<b>£'000</b>	£'000
The following balances were held at:		
Commercial banks	3,799	3,864
Government Banking Services	279	207
	<u><b>4,078</b></u>	<u>4,071</u>

The cash balances as at 31 March 2022 carried a floating rate.

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

	<b>31-Mar-22</b>	31-Mar-21
	<b>£'000</b>	£'000
<b>Amounts falling due within one year</b>		
Contract payables	9	35
Other payables	21	12
Accruals	676	760
	<u><b>706</b></u>	<u>807</u>

There are no creditors falling due after more than 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.

<b>Total future minimum lease payments</b>	<b>Buildings</b>	<b>31-Mar-22</b>	31-Mar-21
	<b>£'000</b>	<b>Total</b>	Total
	<u>£'000</u>	<u>£'000</u>	<u>£'000</u>
Payable:			
Not later than one year	109	109	109
Later than one year not later than five years	437	437	437
Later than five years	391	391	502
<b>Total</b>	<b><u>937</u></b>	<b><u>937</u></b>	<b><u>1,048</u></b>

The future minimum lease payments payable as of 31 March 2021 have been re-stated to include irrecoverable VAT payable.

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## 12. Provisions

	<b>2021/22</b>	2020/21
	<b>Office</b>	Office
	<b>Relocation(Travel)</b>	Relocation(Travel)
	<b>£'000</b>	£'000
Balance at 1 April 2021	50	120
Release of provision for the period	(25)	(70)
<b>Balance at 31 March 2022</b>	<b><u>25</u></b>	<b><u>50</u></b>

Analysis of expected timing of cashflows

	<b>Office</b>	Total
	<b>Relocation(Travel)</b>	£'000
	<b>£'000</b>	£'000
Not later than one year	25	25
Later than one year and not later than five years	0	25
	<b><u>25</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 consulted its staff in 2020/21 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 remains unutilised in 2021/22 due to restrictions early in the year. A decision was taken to release half of the remaining provision with a further review to be undertaken in the 2022/23 business 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 BT)  
Human Fertilisation and Embryology Authority (HFEA)  
Care Quality Commission (CQC)

### **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.





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