NHS
Health Research Authority

Health Research Authority
Annual Report and Accounts

For the 15 Months from 01 January 2015 to 31 March 2016

NHS

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1.0 Introduction: The Health Research Authority

On 01 January 2015 the Health Research Authority (HRA) became a Non Departmental Public Body (NDPB) established under the provisions of the Care Act 2014. The timing of this change in status is the rationale behind presenting this Annual Report for the fifteen months period from 01 January 2015 to 31 March 2016 as previously the HRA was required to present its final report as a Special Health Authority (SpHA) for the nine month period 1 April 2014 to 31 December 2014.

The HRA is tasked with protecting and promoting the interests of patients and the public in health and social care research, including publishing policy and guidance on the good management and conduct of research and promoting transparency in research. In accordance with the Care Act 2014, its main purposes are to co-ordinate and standardise practice relating to the regulation of health and social care research, recognise and establish Research Ethics Committees (RECs), be a member of UK Ethics Committee Authority (UKECA); and provide approvals for the processing of confidential information relating to patients.

The HRA appoints and manages 68 RECs, and works with colleagues in the Devolved Administrations to provide a UK wide REC service working to HRA Standard Operating Procedures (SOPs).

It also appoints and manages the independent Confidentiality Advisory Group (CAG) which provides advice about the appropriate use of confidential patient information without consent in the National Health Service (NHS) for research and other purposes; such as the commissioning of health services. The HRA is formally responsible for approving CAG's advice for applications relating to research and for advising the Secretary of State for purposes outside of research.

The HRA's ambition is to be a successful organisation that is:

- driven by the key purpose of protecting and promoting the interests of patients and the public in health and social care research;
- underpinned by strong leadership focussed on creating a streamlined and efficient framework for the approval and management of research; and
- acknowledged as successful by key stakeholders, as well as through demonstrably improved performance, increased numbers of research participants and greater confidence in health research.

The HRA will actively work with all relevant partners to help create an environment where:

- greater numbers of patients and the public can and do take part in health and social care research and continue to feel safe when they do;
- applying to do research is simpler, decision making is quicker and more predictable;
- researchers find it easier to do high-quality, ethical research;
- commissioners and providers appreciate how research benefits the public, patients, staff and industry;
- industry sees the UK as a great place to do health research;
- more money from charities and other funders goes into carrying out research rather than getting through unnecessary bureaucratic hoops before it starts; and
- clinical trials get registered and research results get published.

1.1 Strategic Objectives

The HRA's overall strategic goal is to make the UK a global leader for health and social care research and works with a wide range of partners to help create an environment where more money invested in research goes into carrying out relevant, good quality research that is registered and published. Its other strategic aims are:

- leading improvements that make it easier to conduct good quality research in the UK;
- improving efficiency and effectiveness of systems and of advice and guidance;
- building and consolidating productive relationships with public and professional stakeholders;
- having a skilled, dedicated and motivated workforce and HRA volunteer committee members; and
- ensuring the HRA is managed and governed effectively and provides value for money to the tax payer

A key initiative in the forthcoming year is to revisit and refresh this strategic direction in light of achievements to date and to ensure the HRA's direction of travel continues to be in harmony with current and projected political, economic, technological and social trends and its ambitions to be a leader in the research environment.

i. Protecting the Interests of the Public

The HRA will help increase public participation in research by continuing to ensure it is explained well, conducted safely and transparently and to appropriate ethical standards including trial registration and publication of research results.

As well as protecting the public interest through our system of RECs and the CAG, the HRA manages The Over-Volunteering Prevention System (TOPS), to prevent healthy volunteers from taking part too often in trials of new medicines.

HRA Approval will further protect the interests of the public by providing a transparent and efficient approval system for research in the NHS.

ii. Streamlining Research

The HRA continues to make the approval and management of health research even simpler and more efficient to help attract global research to the UK. This, in turn, will help speed up the adoption of proven new treatments.

The HRA is continuing to reduce bureaucracy within the framework for the approval and management of research in the UK to ensure a greater proportion of research funds are used for direct research purposes to inform improvements to patient treatments and care.

As you will see in the following pages, The HRA has set out and made good steps in delivering an ambitious programme of work to improve the framework and processes for the approval and management of research in the NHS with many of our projects involving collaboration with partners, some of which are led by them. These partners include National Institute for Health Research (NIHR), Medicines and Healthcare Products Regulatory Agency (MHRA) and the Devolved Administrations to provide a UK wide system for research that is proportionate and effective for approving research.

iii. Promoting Transparency

The HRA recognises that transparency of research is essential so that participants and patients are protected from unnecessary research and patients benefit from improved outcomes and care informed by high quality research. As a consequence we have committed to a range of actions to improve transparency in health and social care research.

This work will provide important reassurances to the public and are part of the duty to support good quality, ethical research. This includes the registration of clinical trials as a formal condition of REC approval, working with partners to understand what is meant by publication of results and developing standards for publication to ensure findings are available for participants, patients, the public, researchers, clinicians and commissioners.

A summary of health research projects conducted in the UK that require ethical approval through the UK wide service is published with the REC opinion.

iv. Working in Collaboration

Whilst the HRA's remit covers England, in accordance with the Care Act's duty to collaborate, collaborative working with the devolved administrations in Scotland, Wales and Northern Ireland to provide a UK wide ethics service and support UK-wide compatibility for the governance and management of research is an important and continuing activity.

The HRA provides the **Integrated Research Application System** (IRAS) on behalf of partners, including the Devolved Administrations.

1.2 History

There have been some significant milestones leading to the establishment of the HRA. Some key points in this history are:

- The formal establishment of RECs in the NHS in England in 1991, following the publication of Department of Health guidance HSG(91)5 (known as 'The Red Book');
- The establishment of Multi-centre Research Ethics Committees (MRECs) in 1997, following the publication of Department of Health guidance HSG (97)23;
- The establishment of the Central Office for Research Ethics Committees (COREC) in 2000;
- The publication of Governance Arrangements for NHS Research Ethics Committees (GAfREC) in July 2001;
- The provision of a single UK-wide ethical opinion, following the implementation of version 1.0 of the SoPs for RECs in the United Kingdom on 1 March 2004;
- The implementation of the EU Clinical Trials Directive 2001/20/EC on 1 May 2004
- 'Building on Improvement' plan in 2006 to deliver the ideas on REC operation and the interfaces with other research approvals processes set out by the advisory group chaired by Lord Warner;
- The establishment of NRES on 1 April 2007, which incorporated COREC and NHS RECs (in England);
- An independent review of medical research regulation and governance by the Academy of Medical Sciences, which reported in January 2011, recommended rationalising research regulation into a new arm's length body;
- The legislation to establish the HRA as a Special Health Authority and provide a new pathway for the regulation and governance of health research was laid before

Parliament on 27 September 2011 and the HRA was formally established on December 2011; and

- On 31 March 2013 all functions that advised on the use of confidential patient information without consent, according to regulations made under section 251 of the NHS Act 2006, transferred from the National Information Governance Board (NIGB) to the HRA. To undertake the work, the HRA established the CAG, replacing the Ethics and Confidentiality Committee (ECC).
- On the 01 January 2015 the HRA became a NDPB.

1.3 Governance

i. The Board

The HRA is governed by a Board that is its corporate decision-making body. It is composed of five non-executive directors (including the Chair) and three executive directors (including the Chief Executive). Three further directors attend the Board:

Chair	Professor Jonathan Montgomery
Non-Executive Directors	Dr Allison Jeynes-Ellis, Professor Deirdre Kelly, Professor Nalin Thakkar and Graham Clarke
Chief Executive	Dr Janet Wisely
Executive Director	Ian Cook (from January 2015)
Executive Director	Debbie Corrigan
Director	Joan Kirkbride
Director	Tom Smith
Director	Dr Janet Messer

The HRA is committed to openness and transparency with Board meetings held in public and papers and minutes available on the HRA website.

The HRA Board's Audit and Risk Management Committee, which meets quarterly to scrutinise audit services and programmes, risk management, the annual governance statement, statutory annual accounts and corporate governance arrangements. It provides assurance to the Board that the HRA is meeting its statutory and regulatory requirements in these areas.

ii. Executive Functions

HRA's Senior Executive team have the day-to-day responsibility of managing the organisation and have specific executive responsibilities to deliver both strategic, operational and tactical objectives and functional, statutory or mandatory requirements. They are accountable, primarily through the Chief Executive, to the Board for delivery.

The HRA's Executive Management Team (EMT) comprise three executive Directors (Chief Executive, Director of Finance, Procurement and Estates and Director of Corporate Services) and three non-voting Directors namely Director of Operations, Director of Research Systems, Standards and HRA Approval Programme and Director of Quality, Guidance and Learning.

2.0 Performance Report

2.1 Overview

i. Chief Executive's Perspective

This year has been a year of considerable achievement for the HRA, during which we successfully implemented a major programme that has seen the mechanism for receiving approval for research in the NHS in England transformed. Building on our previous record of success with research ethics and through effective partnership working with the National Institute of Health Research (NIHR) Clinical Research Network (CRN) and others, HRA Approval is a shared endeavour which will benefit all that are funding, managing and delivering health research; and of course the patients and future patients in the NHS who will ultimately benefit from improved clinical care and health outcomes.

Much of our credibility is drawn from the confidence others have in our ability to design and implement solutions. Whilst it is too early to claim full benefit realisation from the new approach we can certainly celebrate the success in delivery. The recruitment and training of new staff, the Information System requirements, the change management and engagement and not forgetting the continued delivery of existing key functions including RECs and CAG. With linked policy developments and achievements, not least the issue for formal consultation of a new policy framework for health and social care research which will further enable us, our colleagues in the devolved administrations and others to continue to strive to ensure the UK is a great place to do health research. Our key performance indicators demonstrate that success across all areas of business.

We can also applaud our success in maintaining an engaged workforce through that change and the results of our staff survey which demonstrated the commitment of our staff to the work we do and the value of it. The HRA also appoints some 1000 volunteers on our committees whose contribution must also be recognised, these serve on our committees looking at and assessing the ethics of applications and judgements of patient and public interests on an entirely voluntary basis whilst showing considerable commitment to the service.

With thanks to staff, our Board and the volunteer members we can all reflect on a very successful year.

ii. HRA Purpose and Activities

As laid out in the Care Act 2014, the HRA's main functions are:

- Co-ordination and standardisation of practice relating to the regulation of health & social care research;
- Recognising and establishing Research Ethics Committees;
- Being a member of UKECA; and
- Providing approvals for processing confidential information relating to patients.

The main objectives in exercising these functions are to:

- Protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical; and

- Promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical - including promoting transparency in research.

Transparency in research includes the registration of research, the publication and dissemination of research findings and conclusions, the provision of access to data on which research findings or conclusions are based, the provision of information at the end of research to participants in the research and the provision of access to tissue used in research, for use in future research

Key activities undertaken during the accounting period include:

Public Involvement

The HRA has continued to made good progress with work to implement its public involvement strategy, which was approved by the Board in 2013/14. Members of the HRA's Public Involvement Network, a panel of more than 70 people interested in being involved in our work, have been working on a project to co-design and co-produce new content for the patient and public area of the HRA's web site.

Collaborative work has been initiated to better understand how the HRA can influence researchers to involve the public effectively in their studies through the process of ethical review. This is being informed by the third joint project with INVOLVE analysing the amount and nature of public involvement reported in applications for ethical review. Data has been analysed from all applications in 2014 in addition to the sample from 2010 and 2012 from the first two projects. As well as this work showing a steady and continued increase in the amount of public involvement reported for all studies, especially non-commercial funded ones, it has provided data that will help improve guidance for applicants on what is required and ways in which to better assess what is submitted.

During 2015/16 work has been undertaken with others on activities aimed at supporting the further spread of effective public involvement in health and social care research. This included: being part of a consortium of funders providing a helpline for public contributors who are in receipt of State benefits; contributing to discussion and debate at cross-NIHR groups and meetings; contributing to a workshop and wider debate on ethical issues related to involvement; and reviewing and updating the joint statement with INVOLVE on ethics and public involvement.

UK Policy Framework for Health and Social Care Research

The HRA and the devolved administrations are developing a new UK Policy Framework for Health and Social Care Research which sets out the high-level principles of good practice in the management and conduct of health and social care research in the UK, as well as the responsibilities that underpin high-quality ethical research. The formal consultation period ended in March 2016. The policy team has also progressed a number of new policy areas through a programme of active engagement, including policy guidance on making the findings of research accessible to those that participate in research and proportionate approaches for consent and identification of patients who may be invited to participate in health research.

HRA Approval Programme

During 2015/16 the HRA has delivered HRA Approval as a radical new system to simplify the regulatory system for health research in England. Building on the creation of the programme team, governance structure and plans in 2014/15, we

moved to implementation of HRA Approval starting roll out by study type in May 2015. A new team within the HRA has been recruited and trained to deliver the new assessment and Approval service. The iterative approach has allowed careful internal management of the new system, with opportunity for feedback and learning. Extensive change management activity with stakeholders, particularly the NHS, has been crucial to delivery. Webinars have been delivered and shared reaching over a 1000 participants in the NHS and NIHR. The readiness of the NHS has been supported and assessed at a Trust level through our regional change leads. Extensive guidance has been developed and published, and training to external stakeholders has been delivered (reaching over 500 participants and with material provided for further cascade) in collaboration with industry and non-commercial partners. The Information System changes required to deliver were implemented successfully by the HRA and the NIHR CRN which has closed the Coordinating System for NHS permissions as part of this transition. Implementation was completed at 31st March 2016 and 2016 will see a period of embedding, continued evaluation and further refinement to the new process for obtaining approval for research in the NHS in England. Metrics and targets have been established to monitor performance and will be published in our business plan. Performance is being measured carefully in these early stages of implementation with application numbers now rising rapidly (approaching 500) as expected with full roll out complete.

Collaborative Projects

The testing of pharmacy and radiation assurances has been completed in collaboration with Cancer Research UK and the Experimental Cancer Medicine Centres, and processes have been revised based on feedback. These assurances will be incorporated into HRA Approval in due course.

Building on the UK-wide system for management of protocol amendments, a single system for all protocol amendments involving the NHS in England has been designed and implemented. This process will be used for all studies originally processed through historic systems as well as those processed through the new HRA Approval process.

Collaboration with the Department of Health and the NIHR Clinical Research Network was initiated to agree a suite of data points for measuring and managing the performance of the set-up and delivery of research in the NHS.

The HRA continues to work closely with the devolved administrations to collectively improve the research environment across the UK, ensuring that systems are compatible for companies and researchers undertaking research across the UK.

The Confidentiality Advisory Group

The CAG is an advisory group of volunteer members appointed by the HRA, which provides expert and independent advice to the HRA on access to confidential patient information for medical research purposes under Section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 in line with the HRA Directions 2013.

Since becoming an NDPB, the CAG has taken on new statutory responsibilities as part of a package of broader governmental safeguards to improve public confidence in the appropriate handling of data. It continues to engage with the key bodies as these aspects develop.

In line with the additional responsibilities outlined above, the CAG has established a second Confidentiality Advisory Group and recruited new staff and seven new members. This now means that the CAG will meet twice per month in London and Manchester and will provide more flexibility for those applicants submitting applications for medical research which require S251 support.

There has been a review and streamlining of existing application guidance to further support applicants and provide greater clarity of process.

It has also worked closely with the Health and Social Care Information Centre (HSCIC) at all levels to provide clarity of process to applicants and reduce duplication, and has engaged with national bodies to maintain awareness of key changes so that its recommendations remain fully informed.

Research Ethics Committees

Research Ethics Committees (RECs) provide an ethical review of applications submitted to the HRA for research which involve patients and the public, the use of their tissue and data. They are comprised of a maximum of 18 volunteer members. The HRA has 68 RECs, including the Social Care REC which transferred into the HRA in 2015-16

The number of applications reviewed was 3102***** in England (3918 UK wide) and proportionate review applications (low risk applications through sub-committee 1870 in England (2280 UK wide). The average review time for full applications is 28 calendar days; proportionate review 11 days; and substantial amendments 16 days. Applications submitted to the Gene Therapy Committee continue to be reviewed well within statutory (90 day) timelines (average 33 days). This represents excellent performance against statutory timelines and stretched targets across all submissions.

The number of full meetings was reduced from 11 to 10 per annum and has resulted in cost savings to the organisation whilst maintaining services to applicants and reducing the burden placed on REC members.

The member portal for REC members was developed and tested by a small group of members. Following feedback and refinement this facility is available to all those members who wish to use the portal. This will provide for a more efficient review of applications and will also provide financial savings. We have already seen a reduction in the volume of documents being printed and posted out to REC members. This will become the default route to transmit papers as one of the cost saving strategies identified across the whole service.

Transparency

The HRA has long recognised that transparency within research is not only an important area for the UK but that this is a global issue, of interest to the public, research participants, patients and also the wider research community. The HRA is committed to taking a pragmatic approach so that the UK remains a competitive place to do research, and patient and public confidence is maintained.

*****_Please note: Information given refers to April 2015 to March 2016 data collection period_

Over the past year the HRA has;

- Continued to require trial registration as a condition of the REC approval and offered a simple deferral mechanism for Sponsors, where issues of commercial confidence or intellectual property are such that deferral is requested, with 44 such requests in year;
- Seen the publication of "Can UK NHS research ethics committees effectively monitor publication and outcome reporting bias?" by Rasheda Begum and Simon Kolstoe, supported by the HRA (http://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-015-0042-8); and
- Continued to publish for the purpose of its own transparency REC and CAG opinions, including summaries of the research and, where appropriate,links to the full clinical trial registration.

Partnership Working

The HRA has continued to work with the Phase 1 (trials that are first testing new drugs in humans) community to develop the service we provide. This year has seen an agreement reached on the documents used by companies working in this sector to recruit volunteers which may be submitted for generic review to facilitate a more consistent approach across the sector and an efficiency saving with documents being reviewed once for all studies.

Within the HRA's commitment to work effectively with other stakeholders, support has been provided to the Ministry of Defence REC (MoDREC) in relation to management input to develop their administrative services, providing speakers for their annual training event and arranging for them to have access to co-opted members when reviewing clinical trials.

Close working with the MHRA, Human Tissue Authority (HTA) and Human fertilisation and Embryology Authority (HfEA) continued. As examples, it was identified that there was a gap in the legislation which did not require the ethical review of DNA analysis from non-relevant material. UKECA has agreed to a joint HRA / HTA proposal that this type of research does require ethical review. New training has been developed to help distinguish between project and research tissue bank approvals. The HRA is also working closely with the MHRA to ensure UK wide readiness for the forthcoming EU clinical trial regulations (scheduled to be implemented in 2018)

Integrated Research Application System (IRAS) and HRA Assessment and Review Portal (HARP)

Following a full tender and procurement process a contract for the supply of IRAS and HARP is in place from April 2016 for a period of three years with optional extension for a further two years.

This re-procurement of the supplier for IRAS and HARP during 2015 allowed a significant series of developments during the course of 2015/16. These were delivered to time and budget and were all successfully released to live.

Although many of the developments were to support the implementation of HRA Approval, there were also incremental improvements to HARP for RECs and the CAG. Different secure portals into HARP now allow REC members to review applications online and NHS organisations to confirm the Approval status of research projects.

IRAS developments have supported the UK partners. An electronic interface is being developed between IRAS and the NIHR Central Portfolio Management System.

Financial Balance and Budgeting

The HRA remained within agreed revenue, capital cash and resource limits and ensured that budgets were managed throughout the organisation. We achieved this by delivering:

- A published Financial Plan for 2015/16 and agreed budgets being in place;
- Submissions for the 4 year Spending Review which will form the basis for a strategic 5 year financial plan ;
- Financial reports within 4 working days and reporting to the EMT and the Board as agreed;
- Forecasts which are reviewed monthly through close finance to service partnering;
- Improved payment performance, not only meeting the Better Payment Practice Code of 95% of invoices paid within 30 days but achieving 98%, 63% of which were in 10 days.
- Continued improvements in early travel bookings (2 weeks or more ahead) to take advantage of discounted ticket rates; and
- Near 100% use of recycled copying paper (better value and 'environmentally friendly').

iii. Key Issues and Risks

The key issues for the HRA have been to maintain existing services to the high standards set, through a period of considerable change and the delivery of a major programme of activity which has seen full implementation of a new streamlined approach for the approval of research in the NHS in England. The changes in England have required further negotiation with the devolved administrations so that the UK wide provided service for RECs was maintained to UK wide agreed standard operating procedures and commitments to broader compatibility for the governance and approvals within the NHS also preserved. The HRA was also subject to challenge on the transparency provisions set through judicial review, this process diverted considerable management resource although the essence of the challenge – the need for transparency and the HRA's role to promote it - was successfully defended with the HRA losing in just one aspect regarding clarity of information on its website and being ordered to pay part of the claimants costs.

iv. Performance Summary

The HRA's headline achievement for performance against Key Performance Indicators for the Period January 2015 – March 2016 are set out below:

Ethical Review

Mandatory Targets	Comment
95% of applications to full research ethics committee meetings to receive final decisions within 60 calendar days	Exceeded or met performance for each month
95% of amendments on approved applications submitted to research ethics committee meetings to receive a decision within 35 calendar days	Exceeded or met performance for each month

To note that 100% of research summaries and REC opinion being published within 90 days has also been met

HRA Targets	Comment
95% of applications to research ethics proportionate review service to receive decision within 14 calendar days	Achieved an overall average performance in the 15 months of 95%
95% of applications to full research ethics committee meetings to receive final decisions within 40 calendar days	Each month in 2015/16 exceeded performance of same month in 2014/15
95% of amendments on approved applications submitted to research ethics committee meetings to receive a decision within 28 calendar days	Achieved an overall average performance in the 15 months of 93.77%

Confidentiality Advisory Group

HRA Targets	Comment
CAG/CAT – 75% of full applications to be processed in 60 days	Target met for 14 out 15 months
CAG/CAT 75% of Precedent Set review applications to be processed in 30 days	Target met for 12 out 15 months

System Availability

HRA Targets	Comment
All systems to achieve agreed contractual availability targets	Met for all systems each month

Response to requests/complaints/FOI's

HRA Targets	Comment
100% of response to requests/complaint/FOIs met within agreed timescales	Met for each quarter apart from Q3 in 2015/16 when 90% of valid FOI requests to received final response within 20 working days of receipt was recorded

Finance

HRA Targets	Comment
95% of all invoices to paid within 30 days Better Payment Practice Code (BPPC) Target	Achieved 98% average in the 15 months Jan 2015 to Mar 2016.
95% of value of all invoices paid within 30 days	Achieved 97% average in the 15 months Jan 2015 to Mar 2016
60% (increased from 50% in 2014/15) of all invoices to be paid within 10 days (HRA Target)	Achieved average score of 58% for the 15 month period Jan 2015 to March 2016
60% (increased from 50% in 2014/15) of value all invoices to be paid within 10 days (HRA Target)	Average score of 59% for the 15 month period Jan 2015 to March 2016

2.2 Performance Analysis

i. Performance reporting

The HRA has a set of operational indicators that it monitors closely to determine and demonstrate progress against key objectives. Each director is responsible for managing and measuring performance against objectives. The HRA recognises that these measures can form a core component on an overall indicator but that success in many areas is much more than a simple quantitative measure. As such, success is regarded as not only as an achievement of a stated objective but also that the achievement has led to a tangible benefit realised and valued by stakeholders including patients, the public, researchers, others involved in the regulation and management of research in the UK and other opinion formers. Through our performance management regime therefore, we aim to make judgements about our ultimate ambition to make the UK a great place to do health research and to build patient confidence in health research.

The HRA Board reviews progress against delivery of objectives quarterly with the HRA Executive Management Team (EMT) reviewing progress bi-monthly. To support these processes, a performance management framework has been developed to report progress against each objective.

The HRA has set out key performance indicators for each high level business objective, together with the component measures that will be used to make judgements on the successful improvement and delivery of these indicators.

Individual staff objectives that complement and reflect these organisational objectives are developed during the Appraisal process and monitored during regular 1-1s between staff and line managers.

ii. Better regulation

a. HRA Approval

A major programme of work to streamline research applications has just been completed. HRA Approval has been designed as a system to streamline the regulatory process for research in England. Following an iterative development and roll out it was fully implemented on 31 March 2016. It includes a single assessment of legal and compliance matters on behalf of the NHS undertaken by staff in the NHS. This frees up NHS staff to focus on supporting the set-up of research in the NHS, and avoiding duplication of checks at individual NHS organisations.

A single application is submitted to the HRA for both the independent ethical review and the assessment of legal and compliance matters in England, removing the need for two separate applications to different bodies which was previously needed.

This single application is processed within the HRA for ethical review and legal and compliance assessment using a single information system, HARP. By incrementally developing the existing information system used for ethical review, we have been able to implement a significant change to business processes without needing to build a new information system from scratch. In doing so it has already been possible to close applications to a separate information system hosted by the NIHR Clinical Research Network, and in due course it will be possible to decommission that separate system.

HRA Approval also removes the need for separate application forms to be completed and submitted to each participating NHS organisation in England, instead there is a consistent document package that researchers are expected to provide to participating NHS organisations so that they can undertake research projects. This change prepares England for the implementation of the EU Clinical Trial Regulation (planned 2018). We are liaising with colleagues in the devolved administrations to see if they wish to consider such a move.

The above measures benefit both industry, NHS and academic researchers as well as freeing up resource in NHS organisations hosting research.
A further component is in the process of being rolled out where a single technical assurance conducted by a trained NHS professional will remove the need for individual professionals at each NHS participating organisation to conduct their own reviews of the technical pharmacy and radiation components of research studies. This process is being rolled out during the course of 2016.

A project to review the information governance assurances of NHS organisations in relation to research is being undertaken. This will enable one set of information to be provided by researchers about the data collection, processing and security arrangements for their study, removing the current duplication where individual NHS organisations each assess the information governance arrangements for research projects (often using individual local forms).

Previously NHS organisations were expected to record and report different data points in relation to their performance in setting up research studies: one set to the NIHR CRN, and a separate set to the Department of Health. The implementation of HRA Approval provided an opportunity to review this performance information and the HRA, DH and NIHR CRN collectively agreed a single set of metrics that NHS organisations would be expected to record and report.

With other Arm's Length Bodies (ALBs) and review bodies in the health and social care research system we are exploring how we may further simplify application forms for research by further development of IRAS. This includes consideration of the separate applications researchers need to make currently to access patient information held by various bodies.

b. Establishing Principles for Good Research

Upon becoming a non-Departmental public body (NDPB) in 2015, the HRA became responsible for publishing guidance for research in England, in place of the Research Governance Framework.

The HRA and the devolved administrations in Wales, Scotland and Northern Ireland committed to the ambition of having a single framework for research across the UK and established a UK-wide steering group to lead this work, with membership from the HRA and the devolved administrations, plus observers from the Department of Health.

We worked with the three devolved administrations to develop a draft UK-wide policy framework that sets out principles of good practice in the management and conduct of health and social care research. This work took account of what we and our partners had heard since the four separate

Research Governance Frameworks were issued in each UK country over ten years ago. In particular, we reflected what we had learned from a series of projects that looked into key known issues affecting good practice in the management and conduct of research. These issues included educational research, social care, risks to research, risk in research, risk perception and proportionate consent.

This new policy framework addresses key known issues affecting good practice in the management and conduct of research. It supports appropriate safeguards while avoiding the ambiguity in the current Research Governance Frameworks and the obstacles to which that has contributed. The policy framework focuses on the real risks in research, the benefits of research, and proportionate risk assessment and management. This will ensure that people continue to feel safe when they take part in research, that researchers find it easy to do high-quality ethical research, and that funding goes into carrying out research, not into getting through unnecessary hoops before it starts.

In spring 2015, we invited comments from English organisations on the draft UK policy framework for health and social care research. The comment period closed in May 2015. Parallel exercises were conducted by the devolved administrations. The comments received were broadly similar across the four UK countries. A summary of the comments we received and our responses can be found in the report published on the HRA web site.

These comments, along with those received by the devolved administrations and further learning from follow-on engagement with the social care research community and contract research organisations, informed the development of a revised draft of the policy framework, issued for formal public consultation from December 2015 to March 2016. The consultation responses are now being analysed by the HRA and each devolved administration to inform a UK-wide perspective. We will publish a summary of the responses we received. The steering group that is overseeing this work will agree a revision of the policy framework in light of the analyses. That version is intended to be published in summer 2016, replacing the Research Governance Frameworks previously issued by each of the four UK health departments.

iii. Complaints

The HRA received four complaints during the accounting period. Of these two were upheld. One related to new systems that were being put in place for HRA Approval with the other concerning the management of a REC meeting. In the former, immediate action was taken to address the system issues to the satisfaction of the complainant and future users, and in the latter, the REC was suspended.

One complaint was referred to the Parliamentary and Health Service Ombudsman in November 2015, though the initial complaint was made in the 2013 – 14 accounting period. The investigation is yet to be completed.

iv. Equal Opportunities

The HRA is committed to ensuring that all its practices are carried out in a fair, reasonable and consistent manner and will promote human rights and equality and diversity and will not discriminate against any staff, potential staff, members, partners, service users or anyone that deals with the HRA in any way.

The HRA's Equality Policy is at the heart of enabling it to deliver its core values. Through implementation of the policy, the HRA ensures that commitment to fairness and equality is evident at every level throughout the organisation and that

everyone is treated fairly, reasonably and consistently regardless of background or personal characteristics.

The HRA will promote equality and integrate an anti-discriminatory approach into all areas of its work. It will ensure that barriers to accessing services and employment are identified and removed, and that no person is treated less favourably on the grounds of their race, ethnicity, religion or belief, age, gender, marital status, trans status, disability, sexual orientation, mental health status, caring responsibilities or socio-economic background.

The HRA recognises the importance of this policy in both the employment relationship and service provision, and reflects these commitments in all HRA policies.

Anyone that deals with the HRA will receive equitable treatment whether they are staff, members, receiving a service, providing a service, tendering for a contract or any other relationship and the HRA will uphold the Human Rights of all service users, staff and anyone else with a relationship to it. These include practices that reflect the principles of respect for private and family life and freedom of thought, conscience and religion.

v. Sustainability Report

Whilst the HRA may potentially be exempt from formal reporting on a number of Greening Government Commitments as it has less than 250 FTE, it has already demonstrated its commitment to the sustainability agenda. Since its establishment in December 2011 it has reduced the number of its regional offices from seven to five, and introduced video conferencing in its remaining offices to reduce the need to travel

The HRA has also updated its travel and accommodation policies to generally ensure a more rigorous approach to managing the amount of travelling that staff have to do. It is also coming to the end of a programme of work which has committed to the government standard of eight desks to ten staff as well as offering opportunities for an enhanced level of flexible working which once again will reduce the amount of travelling required.

These factors taken together have and will continue to reduce costs as well as contribute to the reduction of the HRA's carbon footprint.

The HRA has also moved to over 80% usage of recycled paper in QTR 4 2015/16 which represents a significant increase on 14/15. Alongside this, the implementation of the managed print service has seen a measurable reduction in paper use

The HRA has also introduced a portal to enable REC members to review applications electronically and to avoid the need for papers to be printed and posted to members. This is available for all members and during 2016 will become the default method for members to access the applications they review.

Janet Wisely
Chief Executive
Health Research Authority
29 June 2016

3.0 Accountability Report

3.1 Directors report

i. Governance

The HRA was established in December 2011 by Statutory Instrument signed by the authority of the Secretary of State for Health

The HRA's relationship with the Department of Health acting on behalf of the Secretary of State, is regulated by a Framework Agreement that sets out the respective roles and responsibilities of each party, the shared principles that underpin the relationship and the arrangements for ensuring that the Department is able to discharge its responsibilities as sponsor and in relation to accountability. It also explains the HRA's governance arrangements as well as clarifying the lines of accountability for its performance.

As an ALB, the HRA works in close partnership with the Department to deliver its objectives. Whilst the HRA is responsible for its operational decisions and the way in which it discharges its functions, the Framework Agreement helps to describe how the Department will assure itself of the HRA's performance without interfering in its day-to-day decision making.

The Department's Research and Development Directorate act as Sponsors for the HRA and provide assurance to the Department's Permanent Secretary and the Secretary of State that it is meeting its obligations.

ii. Pension Liabilities

Past and present employees of the HRA are covered by the provisions of the NHS Pensions Scheme. Note 3 of the accounts presents how pension liabilities have been treated.

iii. Declaration of Interests

The HRA maintains a formal register of Board member's interests as set out in the Code of Accountability for the NHS. Board members are asked to confirm any declarations of interest at each Board meeting and at any time that changes take place. This includes any interests in relation to specific items on a Board agenda. Board members are also asked to declare any spouse / partner interests. The register, showing current declarations made by the Board, is updated on a regular basis and made available to the public on the HRA website at: http://www.hra.nhs.uk/wp-content/uploads/2013/09/HRA-Board-Declaration-of-interest-register-April-2016.xlsx

iv. Remuneration to Auditors

The accounts have been prepared according to accounts direction of the Secretary of State, with approval of HM Treasury. The accounts have been audited by the Comptroller and Auditor General in accordance with the Care Act 2014 at the cost of £35,000. The audit certificate can be found on page 41.

v. Personal Data related Incidents

No significant personal information incidents have occurred throughout 2015-16 resulting in a submission to the Information Commissioner. There have been eight

minor breaches (the majority comprising of e-mails sent to wrong address) which have all been investigated and appropriate action taken.

vi. Financial Instrument

Financial instruments relating to the HRA can be found in Note 18 of the accounts Page 61.

3.2 Statement of the Accountable Officer's responsibilities

Under the Care Act 2014, the Secretary of State has directed the HRA to prepare a financial statement of accounts for each year in the form and on the basis set out in the Accounts Direction.

The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the HRA and of its net resource outturn, application of resources, changes in tax payers' equity and cash flows for the financial year.

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

- observe the Accounts Direction issued by the Secretary of State, with the approval of HM Treasury, including the relevant accounting and disclosure requirements and apply sensible 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; and
- prepare the accounts on a going concern basis.
- confirm that the annual report and accounts as a whole is fair, balanced and understandable
- confirm that the Accounting Officer takes personal responsibility for the annual report and accounts and the judgments required for determining that it is fair, balanced and understandable.

The Accounting Officer of the Department of Health has designated the Chief Executive as Accounting Officer of the HRA. 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 for safeguarding the HRA's assets, are set out in Managing Public Money published by the HM Treasury.

So far as the Chief Executive is aware, there is no relevant audit information of which the entity's auditors are unaware, and the Chief Executive has taken all the steps that they ought to have taken to make them aware of any relevant audit information and to establish that the entity's auditors are aware of that information.

3.3 Governance Statement

This Governance Statement sets out the framework utilised by the HRA to regulate its activities and to ensure delivery of its functions and objectives. In addition to setting out the governance structure, it outlines the way in which performance is managed and reviewed; the risk management processes; and the process for setting Directors Remuneration. The HRA complies with the requirements of the Corporate Governance in

Central Government Departments: Code of Good Practice (2011) insofar as they relate to public bodies.

Responsibilities of Accounting Officer

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the HRA's policies, aims and objectives, whilst safeguarding public funds and its assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Managing Public Money.

I have been the Accounting Officer for the period reported in the Annual Report and Accounts, 01 January 2015 to 31 March 2016. I am accountable for the discharge of my functions to the Authority's Board and appropriate arrangements are in place for the appropriate discharge of all statutory functions attached to the HRA. The HRA is aware of the findings from the Harris Report and ensures it has the capacity and capability to comply with the statutory functions.

I am also accountable to the Minister of State at the Department of Health. This line of accountability is managed through a Framework Agreement between the Department of Health and the HRA, an Annual Accountability Review with the Minister through monthly reviews with officials at the Department of Health and close working on a day-to-day basis between my staff and those in the Sponsor Branch at the Department.

i. Governance Structure

a. The Board

The HRA is governed by a Board that functions as a corporate decision-making body. The Board is composed of the Chair and four Non-Executive Directors (NEDs) and three executive directors (including the Chief Executive). The Board therefore conforms to the recommendations set out in the Corporate Governance in Central Government Departments: Code of Good Practice (2011). Other Non-voting directors (listed below) are required to attend the board meetings.

Ten public HRA Board meetings have been held between 01 January 2015 and 31 March 2016. One additional part 2, confidential meeting was held to discuss a major organisational change to the HRA which Directors (non-voting) did not attend.

The Board membership attendance over the period was as follows:
Professor Jonathan Montgomery (Chair) (attend 11 out of 11 meetings), Graham Clarke (NED) (11/11), Dr Allison Jeynes-Ellis (NED) (9/11), Professor Deirdre Kelly (NED) (9/11), Professor Nalin Thakkar (NED) (11/11), Dr Janet Wisely (Executive Director) (10/11), Debbie Corrigan (Executive Director) (11/11), Ian Cook (Executive Director) (11/11), Joan Kirkbride (Director – Non voting) (9/10) Dr Janet Messer (Director – Non voting) (9/10), Tom Smith (Director – Non voting) (8/10).

Key areas of business considered by the Board, in addition to standing items including finance reporting, key performance indicators and risk management, over the reporting period include:

- Establishing the HRA as a NDPB;
- Findings from the perception audit and key opinion leaders survey;
- Providing approval for England for the consultation for the new UK policy Framework for Health & Social Care;
- Agreeing NED portfolios (critical friend role to EMT);
- Governance to deliver the major programme activity for HRA Approval;
- Receiving Health Check reports regarding HRA Approval Programme; and
- Agreeing Stakeholder Engagement and Communications Strategy.

The Board is committed to improving its performance and effectiveness with seminars often held prior to the main Board meeting. Topics covered in these seminars include:

- Board behaviours and culture;
- Board development;
- Stakeholder mapping and analysis;
- Reputation; and
- Public involvement.

The Board has started the work to revisit and refresh the strategic objectives for the HRA and to work with stakeholders on the development of the HRA's 3-5 strategic plan; specifically considering how the HRA can build public confidence in health research.

The HRA has developed a key performance indicator report which is reviewed on a quarterly basis. The report provides the Board with an overview of the RAG status of the HRA Business Plan 2014-15 and 2015-16 objectives plus detailed management information relating to these objectives.

Corporate level risks and their mitigation and management are considered via the HRA Corporate risk register on a quarterly basis by the Board. The Board will consider if the appropriate risks are captured on the register with the mitigations detailed appropriately and the strategic and reputational impacts discussed fully.

Declaration of interests are declared and formally recorded (can be made available upon request) and all Board members' expenses are published.

The Board has two sub committees: the Audit and Risk Committee and the Pay and Remuneration Committee.

b. Audit and Risk Committee

The HRA Audit & Risk Committee has continued to deliver its role to advise the HRA's Accounting Officer and the HRA Board on risk management, corporate governance and assurance arrangements in the HRA.

The HRA Audit & Risk Committee has met six times during the period 01 January 2015 to 31 March 2016. The Committee membership attendance over the period was as follows: Graham Clarke (Chair, NED) (6/6), Professor Deirdre Kelly (NED) (5/6), Professor Nalin Thakkar (NED) (5/6), Shelley Dolan (Chief Nurse, the Royal Marsden NHS Foundation Trust) (0/6).

In addition, individuals from the HRA, Health Group Internal Audit, External Audit and the National Audit Office were invited and regularly attended the Committee.

Once a year, the Committee will review the annual report and accounts, including the consideration of related reports from auditors and an annual report on the activities and effectiveness of the committee. The Terms of reference, audit manual and audit timetable have all been reviewed and approved both for 2015 and 2016. The HRA Audit and Risk Committee regularly reviews the HRA Corporate Risk Register , Audit reports, Corporate Gift and Hospitality reports, Single tender actions and loss and compensation reports.

Following the establishment of the HRA as a Non-Departmental Public Body from 1st January 2015 a hand over meeting was held between the outgoing and incoming

Audit and Risk Committee Chairs to ensure an appropriate transition took place with any outstanding matters conveyed.

c. Pay and Remuneration Committee

The membership of the Pay and Remuneration Committee is made up of the Chair and NEDs with the Chief Executive normally invited to attend. The business conducted by the Remuneration Committee over the period includes:

(a) advising the Board about appropriate remuneration and terms of service for the Chief Executive and any Directors on Very Senior Managers Terms and Conditions of Service to ensure they are fairly rewarded for their individual contribution to the Authority, having proper regard to the Authority's circumstances and performance and to the provisions of any national arrangements for such staff including:
   i. all aspects of salary (including any performance-related elements/bonuses);
   ii. provisions for other benefits, including pensions and cars;
   iii. arrangements for termination of employment and other contractual terms;

(b) having oversight in relation to remuneration and terms of service for those Directors and other staff who are covered under Agenda for Change terms and conditions who are direct line reports of the Chief Executive; and

(c) proper calculation and scrutiny of termination payments taking account of such national guidance as is appropriate, advise on and oversee appropriate contractual arrangements for such staff.

The committee met seven times in the reporting period in order to deliver its functions for the HRA.

d. HRA Executive Management Team

The HRA is committed to ensuring there are robust and transparent reporting frameworks in place, which are also proportionate and appropriate to the nature of the HRA business.

The Executive Management Team (EMT) is the senior executive decision making body of the HRA responsible for managing HRA business within agreed objectives, resources and according to the HRA / DH framework agreement and standing orders. The EMT is accountable to the Chief Executive.

ii. Effectiveness

The system of performance monitoring in place throughout the period is designed to ensure appropriate delegation and segregation of duties. The following sections describe the operation.

a. The Risk and Control Framework

The Board has overall responsibility for risk management and for clear lines of individual accountability for managing risk throughout the organisation, leading up to the Board. There is a Risk Management policy and procedure in place. The Board reviews the HRA Corporate risk register on a quarterly basis.
The HRA aims to maximise the impact of its operations within the resources available to it. In so doing it aims to manage risks at all levels in the

organisation from the top strategic level to the bottom operational / project levels without dampening innovation, including the projects delivered by partner organisations. This requires consideration of a full cross section of risks to the organisation including; reputation risks, financial risks, organisational risks, health and safety risks and risks to the achievement of the organisation's objectives

In addressing issues relating to risk, the HRA seeks to be as transparent and open as possible and, through this approach, aims to identify and address those areas where there is a need for improvement in the risk management processes and/or controls and contingencies.

The Audit and Risk Committee is the Board's sub-committee that reviews risk and ensures that the systems are in place to ensure effective risk management. The Board retains overall responsibility for risk management and governance. There are clear lines of responsibility of individual accountability for managing risk throughout the Authority, leading up to the Board. I have delegated the day-to-day responsibility for maintaining the system of risk management and risk reporting to the Board Secretary and Chief Executive Business Manager.

As agreed in the Business Plan, senior managers lead on the objectives of the Authority and, as such, they are responsible for managing risk at the project delivery and day-to-day operational level, as well as relating to transition planning. Each Directorate holds its own risk register and reviews it on a regular basis. A risk register is also held by the EMT for additional risks which do not sit with any one Director. The risk registers report the escalated risks and risk scores, risk owners, mitigating actions and due dates, as well as residual risk and assurances.

Any risks reaching agreed thresholds by the Director are raised to the Executive Management Team and reviewed on a quarterly basis. The EMT will review each risk and determine whether the risk is significant enough to be added to the HRA Corporate Risk Register which is reviewed in a public session of the Board. The HRA also has a confidential corporate risk register for any risks which are confidential in nature and need to be reviewed by the Board in its confidential, part 2 session. The Corporate risk register is shared with the Audit and Risk Committee and DH sponsor team on a quarterly basis.
Any risks rated high on thresholds are also escalated to the DH sponsor team.

The Audit and Risk Committee reviews and ensures that systems are in place to ensure effective risk management. The Internal Audit function forms part of the review process and provides assurance on the risk management process, and advises the Audit Committee accordingly.

The risks that have been considered and managed by the Board this year include those relating to:

- The judicial review, as a pressure on management time and resources and in needing to address the findings relating to clarity and management of information on the HRA website
- Delivery of HRA Approval as a major programme of activity with considerable external dependencies for the wider NHS, DH, devolved administrations and NIHR.

- Workload for the CAG and negotiation of new roles and responsibilities for CAG and the HRA
- The extended remit to adult social care and unknowns regarding the current landscape and impact therefore on the HRA

The majority of risks on the HRA Corporate Risk register related to the HRA Approval Programme. The HRA Approval Programme Board provides assurance to the HRA Board regarding the progress of this key area of work with independent Health Checks conducted. For the latest version of the HRA Corporate Risk Register and to review those risks relating to HRA Approval Programme, please see the HRA Board page of the website.

b. Quality Assurance

The HRA has given careful consideration to the requirements and coverage of the Macpherson recommendations, including direct discussions with the modelling oversight committee within DH. With the endorsement of that committee we have confirmed that the HRA does not operate any business critical models. We have sought separate views on our broader quality assurance processes and to the extent they are able to comment, the modelling oversight committee has observed that the processes appear thorough and well developed. We are therefore fully compliant with the Macpherson recommendations.

c. Information Governance

The HRA has an established Information Governance structure:

- The Board has designated the Corporate Secretary as Senior Responsible Information Officer (SIRO) with responsibility for the system of safeguarding and protecting personal identifiable, confidential and sensitive data;
- the Information Governance Lead is also the Corporate Secretary;
- Ian Cook, Director of Corporate Services was the Caldicott Guardian to April 2015 with Sheila Oliver (Head of NRES and a retired nurse clinician) to take within her role a formal responsibility for leading and advising on correspondence with patients and for providing support to the Caldicott Guardian as required; and
- Directors, REC Centre managers and Heads of Department are Information Asset Owners (IAOs) as appropriate.

The Information Governance Steering Group (IGSG) is a formal sub-committee of the EMT. Its purpose is to coordinate, supervise and direct the work of others, as appropriate, to ensure the HRA maintains a coordinated approach to Information Governance. It implements organisational and managerial structures that support appropriate consideration of Information Governance issues to sustain continual improvement.

Data security risks are managed and monitored within the overall risk management framework overseen by the Information Governance Lead and IGSG to ensure security threats are followed up and appropriately managed.

The key risks the Steering Group has addressed include:

- Through the QA programme, risk that small issues identified in isolated areas when combined and may pose a larger risk are not identified;
- Unauthorised staff may access confidential information; and
- Organisational under-reporting of IG incidents.

All information assets and associated systems are identified and included in an Information Asset Register and are subject to annual information asset assessments. These assessments inform the Corporate and Information Risk Registers and an associated Action Plan.
No significant information incidents have occurred throughout 2015/16 resulting in a submission to the Information Commissioner.

The Board regularly reviews the quality of the data it receives with recommendations made to improve the design and content at each meeting. For example the Key Performance Indicator document has evolved to meet the needs of the Board and the organisation after recommendations made whenever the document is presented

The Corporate Secretary as SIRO for the HRA has completed and submitted the Information Assurance Annual Return to the Department of Health.

d. The System of Internal Control

As Accounting Officer, I have responsibility, for reviewing the effectiveness of the system of internal control, which has been in place in the HRA for the period 01 January 2015 to 31 March 2016 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

The EMT, led by myself, reviews and monitors progress with other management groups providing input as required. These include a recruitment control panel and management groups specifically for the information systems we provide and major programmes (HRA Approval) or steering groups for significant projects (including the new policy framework).

Senior managers within the organisation who have responsibility for the development and maintenance of the system of internal control provide me with assurance. The Assurance Framework itself provides me with evidence that the effectiveness of controls that manage the risks to the organisation achieving its principal objective have been reviewed and this aspect of the Authority's activities has been subject to external review.
A Business Plan for 2016/17 has been developed and approved by the Board which will set out a clear purpose and business objectives for the HRA. Our controls assurance and risk management processes are closely aligned to the twin objectives of maintaining on-going activities and managing significant transition issues.

Reports are provided to the Board on a quarterly basis on achievements and progress against the objectives and plans, and this report includes risks and controls in place to mitigate them.

I am not aware of any significant internal control issues.

The effectiveness of the system of internal control has been, and continues to be, subject to review by our internal auditors who, in liaison with HRA management, plan and carry out a programme of work that has been approved by the Audit and Risk Committee which external audit attends, to review the design and operation of the systems of internal control.

Where weaknesses are identified, these are reported to the Audit and Risk Committee and an action plan agreed with management to implement the recommendations agreed as part of this process.

The Head of Internal Audit provides me with an opinion, in accordance with Public Sector Internal Audit Standards, on the overall arrangements for gaining assurance through the Assurance Framework and on the controls reviewed as part of the internal audit work.

Head of Internal Audit Opinion 2015/16

I have received the following opinion from the Head of Internal Audit.

"In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

My opinion is based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year and on the follow up action from Internal Audits conducted in the previous reporting year. There have been no undue limitations on the scope of audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned.

For the three areas on which I must report, I have concluded the following:

- In the case of **risk management and governance** - **satisfactory**. During 2015/2016 the HRA has continued to undertake a key programme of change regarding the Approval Programme. There have been appropriate and proportionate systems in place during the structured programme of change. The HRA has continued work to develop and strengthen accountability including roles and responsibilities and an audit of 'HRA Board Effectiveness and Governance arrangements' was undertaken which concluded that effective arrangements are in place.

- In the case of **control – satisfactory.** 10 assurance based reviews have been conducted; of which most were rated as 'moderate or substantial opinion'. We also concluded that good progress had been made in implementing internal audit recommendations. For the two limited rated reviews, we are satisfied that HRA management have instigated action or developed plans to remediate the issues identified.

In summary, my overall opinion is that I can give **reasonable assurance** to the Accounting Officer that the HRA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2015/16".

e. Capacity to Handle Risk

The Board of the HRA has overall responsibility for risk management throughout the HRA. Its responsibilities include:

- agreeing the Risk Management Policy;
- assigning a Responsible Senior Manager with oversight of Risk Management and who is responsible for championing risk management at HRA;
- ensuring risk management is embedded into all processes;
- reviewing significant programme, strategic and operational / project risks;

- reviewing critical risk management activities / controls and their verification; and
- ensure that the appropriate structure exists within the HRA to ensure risk management processes are effective at dealing with risks, controls, contingencies and action plans, including defined audit committee and people responsibilities.

Currently responsibilities are as follows:

- ensuring all required risk management systems, policy and strategy and support are in place: Chief Executive, Director of Finance, Board Secretary;
- scheduling and facilitating Internal Audit activities: Director of Finance;
- regularly reviewing and following-up risk management activities with all parties. This will include ensuring the verification / assurance of risk management activities and key controls/contingencies: Board Secretary;
- writing the Governance Statement: Chief Executive supported by Board Secretary;
- ensuring the appropriate risk structure is in place including the Audit and Risk Committee: Board Secretary; and
- monitoring risk performance. As part of the routine progress reports the Audit and Risk Committee receives information on the risk performance in terms of the current risk profile, risk management activity performance, and implementation and verification of risk management controls and contingencies: Board Secretary.

iii. Compliance with NHS Pension Scheme Regulations

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 the Scheme rules, and that member Pension scheme records are accurately updated in accordance with the timescales detailed in regulations.

iv. Summary

The HRA has delivered a substantive programme of work this year to improve the framework and processes for the approval and management of health research in the NHS. This has involved collaboration with others to achieve our continued aim of making the UK a great place to do research whilst building confidence and participation in health research and so improve the nation's health. Core services have been maintained with key performance indicators achieved. The HRA has demonstrated the effective delivery of governance requirements will all key corporate governance functions being managed effectively, robustly and efficiently.

Janet Wisely
Chief Executive
Health Research Authority
29 June 2016

3.4 Remuneration and Staff Report

Sections 3.4.i to v(b) are all subject to audit. Details of losses and special payments can be found in note 15 of the financial statements.

i. Remuneration Policy

The Chairman and Non-Executive Director Board members are remunerated in line with DH guidance that applies to all NHS bodies. Details of the senior managers' remuneration are given below in section 3.4.ii. Pay for one Executive is set and reviewed in line with the DH guidance 'Pay Framework for Very Senior Managers (VSM) in Strategic and Special Health Authorities, Primary Care Trusts and Ambulance Trusts. Senior managers employed under the VSM framework are under stated contracts of employment as set out by NHS Employers.

Pay for the other Executives employed and contained in the report is set and reviewed in line with Agenda for Change terms and conditions.

All those contained in the senior managers remuneration table below are subject to annual appraisals on their performance.

ii. Remuneration and Pension for Directors

To note the first table below presents the 15 month remuneration. The second presents the 9 month remuneration.

	Salaries and Allowances			
	15 months to 31 March 2016 (* Annualised 12 month salaries 1 April 15 – 31 March 16)			
Name and Title of Directors	**Salary (bands of £5,000)**	**Performance related bonuses (bands of £5,000)**	**All Pension related benefits (bands of £2500)**	**Total (bands of £5,000)**
	£000	**£000**	**£000**	**£000**
Non-Executive Directors				
Jonathan Montgomery, Chairman (*)	55-60	0	0	55-60
Graham Clarke, Non-Executive Director and Audit Chair (from 1 January 2015) (*)	15-20	0	0	15-20
Allison Jeynes-Ellis, Non-Executive Director (*)	5-10	0	0	5-10
Deirdre Kelly, Non-Executive Director (from 1 January 2015) (*)	5-10	0	0	5-10
Nalin Thakkar, Non-Executive Director (from 1 January 2015) (*)	5-10	0	0	5-10
Directors				
Janet Wisely, Chief Executive (*)	160-165	5-10	0	170-175
Deborah Corrigan, Director of Finance, Procurement & Estates (*)	95-100	0	35-37.5	130-135
Joan Kirkbride, Director of Operations (*)	110-115	0	20-22.5	130-135
Tom Smith, Director of Quality, Guidance and Learning (*)	75-80	0	32.5-35	110-115
Ian Cook, Director of Corporate Services (*)	105-110	0	30.32.5	135-140
Stephen Robinson, Corporate Secretary (from 1 August 2015) (*)	45-50	0	17.5-20	65-70
Janet Messer, Director of Research Systems, Standards & HRA Approval Programme (*)	90-95	0	37.5-40	125-130

(*) Jonathan Montgomery (£45k - £50k); Graham Clarke (£10k - £15k); Allison Jeynes-Ellis (£5k - £10k); Deirdre Kelly (£5k - £10k); Nalin Thakkar (£5k - £10k); Janet Wisely (£135k - £140k); Deborah Corrigan (£75k - £80k); Joan Kirkbride (£85k - £90k); Tom Smith (£60k - £65k); Ian Cook (£80k - £85k); Stephen Robinson (£45k - £50k); Janet Messer (£70k - £75k)

	Salaries and Allowances			
	9 months to 31 December 2014 (* Annualised 12 month salaries 1 April 14 to 31 March 15)			
Name and Title of Directors	**Salary (bands of £5,000)**	**Performance related bonuses (bands of £5,000)**	**All Pension related benefits (bands of £2500)**	**Total (bands of £5,000)**
	£000	**£000**	**£000**	**£000**
Non-Executive Directors				
Jonathan Montgomery, Chairman (*)	30-35	0	0	30-35
Sally Cheshire, Non-Executive Director and Audit Chair (left 31 December 2014) (*)	5-10	0	0	5-10
Allison Jeynes-Ellis, Non-Executive Director (*)	5-10	0	0	5-10
Julie Stone, Non-Executive Director (left 31 December 2014) (*)	5-10	0	0	5-10
Directors				
Janet Wisely, Chief Executive (*)	90-95	0	7.5 - 10.0	100 - 105
Deborah Corrigan, Director of Finance, Procurement & Estates (*)	50-55	0	22.5 - 25.0	70 - 75
Joan Kirkbride, Director of Operations (*)	65-70	0	2.5 - 5.0	70 - 75
Tom Smith, Director of Quality, Guidance and Learning (*)	45-50	0	20 .0 - 22.5	65 - 70
Ian Cook, Director of Corporate Services (*)	60-65	0	0	60 - 65
Shaun Griffin, Director of Communication (left 9th January 2015) (*)	25-30	0	See note 1	25-30
Janet Messer, Director of Research Systems, Standards & HRA Approval Programme (*)	20-25	0	10.0 - 12.5	30 - 35

(*) Jonathan Montgomery (£45k - £50k); Sally Cheshire (£5k - £10k); Allison Jeynes-Ellis (£5k - £10k); Julie Stone (£5k - £10k); Janet Wisely (£120k - £125k); Deborah Corrigan (£65k - £70k); Joan Kirkbride (£85k - £90k); Tom Smith (£60k - £65k); Ian Cook (£80k - £85k); Janet Messer (£40k - £45k)

Note 1: Shaun Griffin, Director of Communication, was seconded to the HRA for two days a week. He was employed by the Human Tissue Authority, who re-charge the Health Research Authority for his services. In the 9 months to 31 December 2014, the HRA has paid the Human Tissue Authority £26,555.70 in respect of his services. Details of his remuneration are included in the Annual Report of the Human Tissue Authority.

The claimed expenses of the Board members are disclosed on the HRA website. There were no other benefits in kind.

To note the table below presents the 15 month pension benefits.

Name and Title	Pension Benefits 15 months to 31 March 2016 Real Increase in pension at age 60 (bands of £2,500)	Real increase in pension lump sum at aged 60 (bands of £2500)	Total accrued pension at age 60 at 31 March 2016 (bands of £5,000)	Lump sum at age 60 related to accrued pension at 31 March 2016 (bands of £5,000)
	£000	£000	£000	£000
Deborah Corrigan, Director of Finance, Procurement & Estates	0 – 2.5	0 – 2.5	20 - 25	55 - 60
Joan Kirkbride, Director of Operations	0 – 2.5	2.5 – 5.0	35 - 40	110 - 115
Tom Smith, Director of Quality, Guidance and Learning	0 – 2.5	0 -2.5	10 - 15	30 - 35
Janet Messer, Director of Research Systems, Standards & HRA Approval Programme	0 – 2.5	0 – 2.5	10 - 15	30 - 35
Ian Cook, Director of Corporate Services	0 – 2.5	0	0 - 5	0
Stephen Robinson, Corporate Secretary (from 1 August 2015)	0 – 2.5	0	5 - 10	0

Name and Title	Pension Benefits 15 months to 31 March 2016 Cash Equivalent Transfer Value at 31 March 2016	Cash Equivalent Transfer Value at 31 December 2014	Real Increase in Cash Equivalent Transfer Value	Employer's contribution to stakeholder pension	Total pension entitlement at 31 March 2016 (Bands of £5,000)
	£000	£000	£000	£000	£000
Deborah Corrigan, Director of Finance, Procurement & Estates	354	327	23	0	80 - 85
Joan Kirkbride, Director of Operations	823	623	193	0	150 - 155
Tom Smith, Director of Quality, Guidance and Learning	177	149	27	0	45 – 50
Janet Messer, Director of Research Systems, Standards & HRA Approval Programme	192	166	24	0	40 - 45
Ian Cook, Director of Corporate Services	19	0	19	0	0 - 5
Stephen Robinson, Corporate Secretary (from 1 August 2015)	80	57	15	0	5 - 10

Notes:

(1) Janet Wisely, Chief Executive, is not currently a member of the NHS Pension Scheme.

(2) NHS Pensions did not provide lump sum figures for senior managers who only have membership in the 2008 section, unless they chose to move their 1995 section benefits under the Choice option.

iii. Cash Equivalent Transfers

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capital value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV 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 disclosures applies. The CETV figures and the other pension details include the value of any pension benefits in another scheme or arrangement which the individual has transferred to the NHS pension scheme. 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. CETVs are calculated within the guidelines and framework prescribed by the Institute of Faculty of Actuaries.

On 1 October 2008, a change in the way the factors used to calculate CETVs came into force as a result of the Occupational Pension Scheme (Transfer Value Amendment) regulations. These placed responsibility for the calculation method for CETVs (following actuarial advice) on Scheme Managers or Trustees. Further regulations from the Department of Work and Pensions to determine cash equivalent transfer values (CETV) from Public Sector Pensions Schemes came into force on 13 October 2008.

In his budget of 22 June 2010 the Chancellor announced that the uprating (annual increase) of public sector pensions would change from the Retail Prices Index (RPI) to the Consumer Prices Index (CPI) with the change expected from April 2011. As a result, the Government Actuaries Department undertook a review of all transfer factors. The new CETV factors have been used in our calculations.

iv. Fair Pay Disclosures

Reporting Bodies are required to disclose the relationship between the remuneration of the highest-paid director in their organisation and the median remuneration of the organisations workforce, including temporary staff.

The remuneration of the highest paid Director in the HRA in the period 01 January 2015 to 31 March 2016 was 4.89 times the median remuneration of the workforce, which was £27,090. The ratio has increased slightly compared to the 9 month period to the 31 December 2014.

	15 months to 31 March 2016	9 months to 31 December 2014
Band of Highest Paid Directors Total Remuneration (£000's) annualised	130-135	120-125
Lowest pay range	10-15	15-20
Median Total	27,090	26,822
Remuneration ratio	4.89	4.57

There were no staff employed by the HRA who received remuneration at a higher level than the highest paid director.

v. Staff Report

a. Exit Packages

Exit package cost band	15 months to 31 Mar 2016			9 months to 31 Dec 2014		
	Number of compulsory redundancies	Number of other departures agreed	Total cost of exit packages by cost band (£000)	Number of compulsory redundancies	Number of other departures agreed	Total cost of exit packages by cost band (£000)
<£20,001	0	1	16	0	0	0
£20,001 - £40,000	0	0	0	0	0	0
£40,001 - £100,000	0	0	0	0	0	0
£100,001 - £150,000	0	0	0	0	0	0
£150,001 - £200,000	0	0	0	0	0	0
£200,001 - £250,000	0	0	0	0	0	0
£250,001 - £300,000	0	0	0	0	0	0
£300,001 - £350,000	0	0	0	0	0	0
Total number and cost of exit packages	**0**	**1**	**16**	**0**	**0**	**0**

There are no redundancy costs for the 15 month period to 31 March 2016 (£nil 9 month period to 31 December 2014). The exit package relates to payment in lieu of notice and annual leave within contractual arrangements.

b. Analysis of Staff Costs

	15 months to 31 Mar 2016			9 months to 31 Dec 2014		
	Total	**Permanently employed**	**Other**	Total	Permanently employed	Other
	£000	**£000**	**£000**	£000	£000	£000
Salaries and wages	**8,586**	7,034	1,552	3,848	3,293	555
Social security costs	**576**	576	0	264	264	0
Employer contributions to NHSPA	**878**	878	0	424	424	0
Redundancies/notice	**0**			0	0	**0**
Total	**10,040**	**8,488**	**1,552**	4,536	3,981	555

The costs and average numbers of staff include the costs of staff employed by other NHS bodies that are recharged to the HRA. These are included within the 'Other' column. These figures include social security costs and employer contributions to the NHSPA.

The HRA received approval for the HRA Approval Business Case on the 31 March 2014. During 2014-15 phased recruitment took place to appoint staff into posts identified in the Business Case, and the full year effect of these posts will have increased the average staff numbers, as well as further recruitment during 2015-16 impacting on an increase in staff numbers.

The average number of persons employed during the period was:

	15 months to 31 Mar 2016			9 months to 31 Dec 2014		
	Total Number	**Permanently Employed Number**	**Other Number**	Total Number	Permanently Employed Number	Other Number
Total	**180**	**164**	**16**	143	132	11

c. Off payroll engagements

Following the Review of Tax Arrangements of Public Sector Appointees published by the Chief Secretary to the Treasury on 23 May 2012, the Health Research Authority must publish the following tables of information on their highly paid and/or senior off-payroll engagements**.**

Table 1: For all off-payroll engagements as at 31 March 2016, for more than £220 per day and that last longer than six months:

	Number
Number of existing engagements as of 31 March 2016	7
Of which, the number that have existed:	
for less than one year at the time of reporting	3
for between one and two years at the time of reporting	4
for between 2 and 3 years at the time of reporting	0
for between 3 and 4 years at the time of reporting	0
for 4 or more years at the time of reporting	0

The HRA can confirm that all existing off-payroll engagements have at some point been subject to a risk based assessment as to whether assurance is required that the individual is paying the right amount of tax and, where necessary, that assurance has been sought.

Table 2: For all new off-payroll engagements between 1 January 2015 and 31 March 2016, for more than £220 per day and that last longer than six months:	
	Number
Number of new engagements, or those that reached 6 months in duration, between 1 January 2015 and 31 March 2016	6
Number of new engagements which include contractual clauses giving the HRA the right to request assurance in relation to income tax and National insurance obligations	1
Number for whom assurance has been requested	6
Of which:	
assurance has been received	6
assurance has not been received	0
engagements terminated as a result of assurance not being received	0
Number of off-payroll engagements of board members, and/or senior officers with significant financial responsibility during the year	0
Number of Individuals that have been deemed "board members, and/or senior officers with significant financial responsibility" during the financial year. This figure includes both off-payroll and on-payroll engagements	12

d. Consultancy expenditure

There was no consultancy expenditure.

e. Staff Composition

2016 (as at 31/03/16)	Male	Female	Ethnicity	Disability	Age Range
On payroll	52 27%	142 73%	40 of those declared (Non White British)	3.5% of those declared	Under 20 =0 (0%) 20 – 29 = 46 (24%) 30 – 39 = 61 (31%) 40 – 49 = 38 (20%) 50 – 59 = 33 (17%) 60 and above = 16 (8%)

NB: percentages are of all staff

	Male	Female	Total
Directors	2 (33%)	4 (66%)	6
Other Senior Managers	15 (41%)	22 (59%)	37
Employees	35 (23%)	166 (77%)	201

f. Sickness Absence Data

Statistics Produced by HSCIC from Electronic Staff Record (ESR) Data Warehouse		
Quarterly Sickness Absence Publications	Monthly Workforce Publication	
Average FTE 2015-16	FTE-Days Lost to Sickness Absence	Average Sick Days per FTE
160	1164	7.3
Source: hscic - Sickness Absence and Workforce Publications - based on data from the ESR Data Warehouse		
Period covered: January to December 2015		
Data items: ESR does not hold details of normal number of days worked by each employee. (Data on days lost and days available produced in reports are based on a 365-day year.)		
The number of FTE-days lost to sickness absence has been estimated by multiplying the estimated FTE-days available by the average sickness absence rate.		
The average number of sick days per FTE has been estimated by dividing the estimated number of FTE-days sick by the average FTE.		
Sickness absence rate is calculated by dividing the sum total sickness absence days (including non-working days) by the sum total days available per month for each member of staff).		

g. Staff Policies

No.	Harmonised HR policies
1	HRA Adoption policy and procedure
2	HRA Annual Leave policy and procedure
3	HRA Dress Code policy and procedure
4	HRA Flexible Working policy and procedure
5	HRA Grievance and Disputes policy and procedure
6	HRA Lone Worker policy and procedure
7	HRA Maternity policy and procedure
8	HRA Paternity policy and procedure
9	HRA Prevention of Bullying and Harassment policy and procedure
10	HRA Sickness Absence Management policy and procedure
11	HRA Raising Concerns policy and procedure
12	HRA Home Working policy and procedure
13	HRA Probationary Review policy and procedure
14	HRA Disciplinary policy and procedure
15	HRA Capability policy and procedure
16	HRA Appeals policy and procedure
17	HRA Organisational Change policy and procedure

18	HRA Recognition of Service policy and procedure
19	HRA Special Leave policy and procedure
20	HRA Pay Protection policy
21	HRA Recruitment & Selection of Staff policy
22	Shared Parental Leave NHS Business Services Authority (NHSBSA) policy for HRA use)

All HRA policies include provision for making reasonable adjustments for disabled staff.

3.5 Parliamentary Accountability and Audit report

i. Regularity of Expenditure

The Authority achieved its financial targets and remained well within its revenue resource limit during the 15 month period. During that time £15.9 million was spent against a revenue resource limit of £19.7 million with an expected £3.8 million under spend. The table below sets out the actual financial performance against budgeted performance. The information is presented for the 3 month and 12 month periods that make up the 15 months covered by this report.

Comparison of actual financial performance against budgetted performance

Net Expenditure	3 months Jan 2015 to Mar 2015			12 months Apr 2015 to Mar 2016			15 months Jan 15 to Mar 16		
	Budget	Actual	Variance	Budget	Actual	Variance	Budget	Actual	Variance
Staff costs	1,967	1,955	(12)	8,534	8,195	(339)	10,501	10,150	(351)
Premises & Fixed plant (incl IT)	751	754	3	2,652	2,675	23	3,403	3,429	26
Establishment expenses (travel, training, REC meeting costs)	3,248	454	(2,794)	1,872	1,324	(548)	5,120	1,778	(3,342)
Supplies & services (eg Chairs allowance)	84	64	(20)	395	379	(16)	479	443	(36)
Capital depreciation and amortisation	45	45	0	283	253	(30)	328	297	(31)
Miscellaneous expenditure (Internal audit, fruitless payments)	25	23	(2)	116	98	(18)	141	121	(20)
Auditors remuneration	35	5	(30)	35	30	(5)	70	35	(35)
Transport and moveable plant (Taxis)	0	5	5	2	6	4	2	11	9
Income (non Grant in Aid)	(132)	(133)	(1)	(196)	(198)	(2)	(328)	(331)	(3)
Total Expenditure (funded by GIA)	**6,023**	**3,172**	**(2,851)**	**13,693**	**12,762**	**(931)**	**19,716**	**15,933**	**(3,783)**

The welcome but late decision on the HRA Approval business case in March 2014 resulted in the HRA rapidly having to implement unprecedented recruitment plans for the organisation in order to attract the resources required to deliver the HRA Approval Programme. As a result the 2014/15 HRA financial plans presented in July 2014 highlighted an early forecast underspend, the majority of which would be as a result of reserves set aside for HRA Approval Programme posts not being utilised and which were reflected in the £2.8million underspend reported at the end of March 2015.

The timing of recruitment and resulting impact on the financial position continued into 2015/16. Reserves are categorised within establishment expenses and this is where the under spend is reported. The 15 months of this annual report have seen 88 members of staff recruited (38.68 WTE) in phases.

Regular reports and forecasts were provided to both the DH Sponsor and finance colleagues.

Financial control is achieved across the HRA through budgetary allocations, which are flexed during the year as required. Financial performance is monitored through high level reports to DH on a quarterly basis and through the HRA Board and Executive Management Team on a Directorate basis each month, and by detailed reports to individual budget holders within 5 days of the end of the month.

ii. Fees and Charge

The main source of funding (98%) is Grant in Aid (GIA) Parliamentary grant from the Department of Health.

Fees and charges for services provided to the Devolved Administrations, as well as income from NHS and non NHS organisations are the other sources of income.

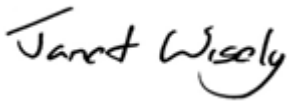
iii. Remote Contingent Liabilities

The HRA did not have any remote contingent liabilities.

iv. Long-term Expenditure Trends

We recognise we are operating in a challenging economic climate but we consider that we are well placed to continue to manage resources and deliverables in line with the requirements of anticipated future funding settlements and the recent spending review. Expenditure will be reviewed regularly as part of the efficient management of the organisation.

The operating expenditure of the HRA will continue to be met largely through GIA from DH.



Janet Wisely
Chief Executive
Health Research Authority
29 June 2016

v. The Certificate and Report of the Comptroller and Auditor General

I certify that I have audited the financial statements of The Health Research Authority for the 15 month period ended 31 March 2016 under the Care Act 2014. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration and Staff Report and the Parliamentary Accountability Disclosures that is described in that report as having been audited.

Respective responsibilities of the Accounting Officer and auditor

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Care Act 2014. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Health Research Authority's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by The Health Research Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by me in the course of performing the audit. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income 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.

Opinion on regularity

In my opinion, in all material respects the expenditure and income 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.

Opinion on financial statements

In my opinion:

- the financial statements give a true and fair view of the state of the Health Research Authority's affairs as at 31 March 2016 and of the net expenditure for the year then ended; and
- the financial statements have been properly prepared in accordance with the Care Act 2014 and Secretary of State directions issued thereunder.

Opinion on other matters

In my opinion:

- the parts of the Remuneration and Staff Report and the Parliamentary Accountability disclosures to be audited have been properly prepared in accordance with Secretary of State directions made under the Care Act 2014, and
- the information given in the Performance Report and Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or

- the financial statements and the parts of Remuneration and Staff Report and the Parliamentary Accountability Disclosures to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Sir Amyas C E Morse **Date 6 July 2016**

Comptroller and Auditor General

National Audit Office

157-197 Buckingham Palace Road

Victoria

London

SW1W 9SP

4.0 The Accounts of the Health Research Authority for 15 months to March 2016

Statement of Comprehensive Net Expenditure for the 15 months as at 31 March 2016

	Notes	**15 months as at 31 Mar 2016**	9 months as at 31 Dec 2014
		£'000	£'000
Administration			
Expenditure			
Staff Costs	3, 4	**10,150**	**4,596**
Amortisation and Depreciation	4	**297**	**117**
Other Expenditure	4	**5,817**	**2,652**
		16,264	**7,365**
Income			
Income from Activities	6	**331**	**193**
		331	**193**
Net Expenditure for the period		**15,933**	**7,172**
Net Resource outturn		**15,933**	**7,172**

The notes on pages 48 to 62 form part of these accounts.

Statement of Financial Position as at 15 months as at 31 March 2016

	Notes	**15 months as at 31 March 2016**	9 months as at 31 December 2014
		£'000	£'000
Non Current Assets			
Information Technology Assets	7.1	**51**	**78**
Intangible Assets	7.2	**1,459**	**753**
Total non-current assets		**1,510**	**831**
Current assets			
Trade and other receivables	8	**270**	**183**
Cash and cash equivalents	9	**3,485**	**2,394**
Total current assets		**3,755**	**2,577**
Total Assets		**5,265**	**3,408**
Current Liabilities			
Trade and other payables	10	**1,296**	**1,189**
Other liabilities	10	**0**	**225**
Total current liabilities		**1,296**	**1,414**
Non-current assets less net current liabilities		**3,969**	**1,994**
Assets less liabilities		**3,969**	**1,994**
Taxpayers' Equity			
General Fund		**3,969**	**1,994**
Total Taxpayers' Equity		**3,969**	**1,994**

The notes on pages 48 to 62 form part of these accounts.

The financial statements on pages 44 to 47 were signed on behalf of the Health Research Authority by:

Chief Executive
29 June 2016

Statement of Cash Flows for the 15 months as at 31 March 2016

	Notes	**15 months as at 31 Mar 2016**	9 months as at 31 Dec 2014
		£'000	£'000
Cash flows from operating activities			
Net expenditure for the period after interest		**(15,933)**	(7,172)
Adjustments amortisation and depreciation	4	**297**	117
(Increase)/Decrease in trade and other receivables	8	**(87)**	0
Increase/(Decrease) in trade payables	10	**(118)**	117
Less: liabilities assumed not passing through Statement of Comprehensive Net Expenditure	11	**0**	0
Net cash (outflow) from operating activities		**(15,841)**	(6,938)
Cash flows from investing activities			
Purchase of plant, property and equipment	7.1	**0**	**(8)**
Purchase of intangible assets	7.2	**(976)**	**(229)**
Net cash inflow/(outflow) from investing activities		**(976)**	(237)
Cash flows from financing activities			
Net Parliamentary funding		**17,908**	**5,750**
Net financing		**17,908**	5,750
Net increase/(decrease) in cash and cash equivalents		**1,091**	(1,425)
Cash and cash equivalents at the beginning of the period		**2,394**	3,819
Cash and cash equivalents at the end of the period	9	**3,485**	2,394

The notes on pages 48 to 62 form part of these accounts.

Statement of Changes in Taxpayers' Equity for the 15 months as at 31 March 2016

	General Fund £'000	Total Reserves £'000
Balance as at 12 months to 31 March 2014	**3,416**	**3,416**
Net Expenditure 9 months to 31 Dec 2014	(7,172)	(7,172)
Total recognised income and expenditure for the period	**(7,172)**	**(7,172)**
Parliamentary funding for resources for the 9 months to 31 December 2014	**5,750**	**5,750**
Total Parliamentary Funding from Department of Health	**5,750**	**5,750**
Balance as at 9 months to 31 December 2014	**1,994**	**1,994**
Net Expenditure 15 months to 31 March 2016	(15,933)	**(15,933)**
Total recognised income and expenditure for the period	**(15,933)**	**(15,933)**
Parliamentary funding for resources for the 15 months to 31 March 2016	**17,908**	**17,908**
Total Parliamentary Funding from Department of Health	**17,908**	**17,908**
Balance as at 15 months to 31 March 2016	**3,969**	**3,969**

The notes on pages 48 to 62 form part of these accounts.

Notes to the Accounts

1. Accounting Policies

These financial statements have been prepared in accordance with the Government Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be most appropriate to the particular circumstances of the Health Research Authority has been selected for the purpose of giving a true and fair view. The particular policies adopted by the Health Research Authority are described below. They have been applied consistently in dealing with items considered material in relation to the accounts. There have been no revisions of estimation techniques. Accruals are estimated with reference to available documentation advice from management and from information gained from similar previous events and are the best estimate at the date of these financial statements. Staff holiday is recorded and therefore the holiday pay accrual calculation is an accurate assessment. Useful economic lives are reviewed at least annually. The basis for estimating useful economic life include experience of previous similar assets, the condition and performance of the asset and the knowledge of technological advances and obsolescence.

1.1 Accounting Conventions

This account is prepared under the historical cost convention, modified to account for the revaluation of fixed assets at their value to the business by reference to current costs. This is in accordance with directions issued by the Secretary of State for Health and approved by HM Treasury. On the 1st January 2015 the HRA became a Non Departmental Public Body. The main source of funding continues to be from the Department of Health. The timing of this change in status is the rationale behind presenting these accounts for the fifteen month period from 01 January 2015 to 31 March 2016 as previously the HRA was required to present its accounts as a Special Health Authority (SpHA) for the nine month period 1 April 2014 to 31 December 2014.

1.2 Income

Income is accounted for applying the accruals convention. The main source of funding for the Non Department Public Body is Parliamentary grant from the Department of Health, which is credited to the general fund. Parliamentary funding is recognised in the financial period in which it is received.

Operating income is income which relates directly to the operating activities of the authority. It principally comprises fees and charges for services provided to the Devolved Administrations, as well as income from NHS and non NHS organisations. Where income is received for a specific activity which is to be delivered in the following financial year, that income is deferred.

1.3 Taxation

The Authority is not liable to pay corporation tax. Expenditure is shown net of recoverable VAT. Irrecoverable VAT is charged to the most appropriate expenditure heading or capitalised if it relates to an asset.

1.4 Tangible assets - Information Technology

(a) Capitalisation

Information Technology which is capable of being used for more that one year and they:

- individually have a cost equal to or greater than £5,000; or
- collectively have a cost of at least £5,000 and an individual cost of more than £600, where the assets are functionally interdependent, they have broadly simultaneous purchase dates, are anticipated to have simultaneous disposal dates and are under single managerial control.

(b) Valuation

Information technology assets are capitalised initially at cost. They are carried on the Statement of Financial Position at cost net of depreciation and impairment, or at depreciated replacement cost where materially different.

(c)Depreciation

IT Assets are depreciated evenly over the expected useful life:

	Years
Tangible Information Technology	5

1.5 Intangible Assets

(a) Capitalisation

Intangible assets with a useful economic life of more than a year and a cost of at least £5,000 are capitalised initially at cost.

(b) Valuation

Intangible assets are capitalised initially at cost. They are carried on the Statement of Financial Position at cost net of amortisation and impairment, or at amortised replacement cost where materially different.

(c)Amortisation

Amortisation is charged on each individual component of intangible assets.

Other than while under construction, all intangible assets are amortised.

Intangible Assets are currently grouped under Information Technology and the lives of these assets are assessed as set out below. They are amortised on a straight line basis over the estimated lives of the assets.

Purchased computer software licences are amortised over the shorter of the term of the licence and their useful economic lives.

	Years
Software Licences	3 – 5
Bespoke software licence	7
Intangible information technology	5 – 7

1.6 Cash and Cash Equivalents

Cash is the balance held with the Government Banking Service. The Health Research Authority does not hold any petty cash.

1.7 Employee Benefits

Short term 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 in into the following period.

Retirement benefit costs

Past and present employees are covered by the provisions of the two NHS Pensions Schemes. The schemes are 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 schemes 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, the scheme is accounted for as if it were a defined contribution scheme: the cost to the NHS body of participating in the scheme is taken as equal to the contributions payable to the scheme for the accounting period.

For early retirements other than those due to ill health the additional pension liabilities are not funded by the scheme. The full amount of the liability for the additional costs is charged to expenditure at the time the Authority commits itself to the retirement, regardless of the method of payment.

1.8 Leases

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

Operating lease payments are recognised as an expense on a straight-line basis over the lease term. Lease incentives are recognised initially as a liability and subsequently as a reduction of rentals on a straight-line basis over the lease term.

Where arrangements are in place that imply a lease arrangement the costs have been charged as an expense on a straight-line basis and disclosed as part of note 13.

Contingent rentals are recognised as an expense in the period in which they are incurred.

1.9 Provisions

The Authority has no provisions.

1.10 Financial Instruments

Financial Assets

Loans and receivables are non-derivative financial assets with fixed or determinable payments which are not quoted in an active market. They are included in current assets. The Authority's loans and receivables comprise: cash at bank and in hand, NHS Receivables, prepayments and accrued income and 'other receivables.

Loans and receivables are recognised initially at fair value, net of transaction costs, and are measured subsequently at amortised cost, using the effective interest method. The effective interest rate is the rate that discounts exactly estimated future cash receipts through the expected life of the financial asset or, when appropriate, a shorter period, to the net carrying amount of the financial asset. Interest on loans and receivables is calculated using the effective interest method and credited to the Statement of Net Comprehensive Expenditure.

Financial Liabilities

Financial liabilities are recognised on the Statement of Financial Position when the Authority 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 derecognised when the liability has been discharged, that is, the liability has been paid or has expired. The Authority's financial liabilities comprise: NHS Payables, other payables and accruals.

Financial liabilities are initially recognised at fair value.

1.11 IFRS Disclosure

Early adoption of IFRS's, amendments or interpretations

The Health Research Authority has not adopted any IFRS's, amendments or interpretations early.

IFRS's, amendments and interpretations in issue but not yet effective or adopted

The following is a list of changes to IFRS that have been issued but which were not effective in the reporting period.

IAS 19 Post-Employment Benefits (Pensions)

IFRS 9 Financial Instruments

IFRS 13 Fair Value Measurement

These would have no material impact on the HRA financial statements.

2. Analysis of Net Expenditure by segment

The Health Research Authority currently reports the financial information to the Board as one segment and therefore no segmental analysis is disclosed.

3. Staff numbers and related costs

The tables for the staff numbers and staff costs are included on page 36 within the Remuneration report section.

Expenditure of staff benefits

There was no expenditure made on staff benefits in the period to the 31st March 2016 (9 month period to 31 December 2014 - £0)

Retirements due to ill-health

This note discloses the number and additional pension costs for individuals who retired early on ill-health grounds during the year. There were no such retirements in the 15 month period to 31 March 2016 (9 month period to 31 December 2014 - £0). This information has been supplied by NHS Pensions.

Exit packages agreed in the period to 31st March 2016

The table for the exit packages agreed in the period is included on page 36 within the Remuneration report section.

3.2 Pension costs

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. Both are unfunded defined benefit schemes that cover NHS employers, GP practices and other bodies, allowed under the direction of the Secretary of State 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 the 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 are accepted as providing suitably robust figures for financial reporting purposes. The valuation of the scheme liability as at 31 March 2016, is based on valuation data as 31 March 2015, updated to 31 March 2016 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 scheme actuary report, which forms part of the annual NHS Pension Scheme (England and Wales) Pension Accounts. These accounts can be viewed on the NHS Pensions website. 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 its recent demographic experience), and to recommend the contribution rates payable by employees and employers.

The last published actuarial valuation undertaken for the NHS Pension Scheme was completed for the year ending 31 March 2012

The Scheme Regulations allow for the level of contribution rates to be changed by the Secretary of State for Health, with the consent of HM Treasury, and consideration of the advice of the Scheme Actuary and appropriate employee and employer representatives as deemed appropriate.

4 Expenditure

The Health Research Authority costs all relate to Administration costs

	Note		**15 months as at 31 Mar 2016**		9 months as at 31 Dec 2014
			£'000		£'000
Non-executive members' remuneration			110		60
Other salaries and wages	3		10,040		4,536
Redundancies and notice not worked	3		0		0
Total Staff Costs			**10,150**		**4,596**
Supplies and Services - general			442		237
Establishment expenses			1,780		869
Transport and moveable plant			11		2
Premises and fixed plant			3,429		1,487
Auditors' remuneration: (*) Audit fees			35		33
Miscellaneous			120		24
Total Other Expenditure			**5,817**		**2,652**
Capital: Depreciation	7.1	27		16	
Amortisation	7.2	270		101	
Total Depreciation and Amortisation			**297**		**117**
Total expenditure			**16,264**		**7,365**

(*) The Audit Fee for the 15 month period to the 31st March 2016 is £35,000 (9 month period to 31st December 2014 £33k).
The Authority did not make any payments to External Auditors for non audit work

4.1 Better Payment Practice Code - measure of compliance

	15 months to 31 Mar 2016 Number	9 months to 31 Dec 2014 Number
Total Non-NHS trade invoices paid in the year	**5,240**	**3,068**
Total Non-NHS trade invoices paid within target	**5,160**	**3,011**
Percentage of Non-NHS trade invoices paid within target	**98.5**	98.1
Total NHS trade invoices in the year	**405**	**167**
Total NHS trade invoices paid within target	**386**	**158**
Percentage of NHS trade invoices paid within target	**95.3**	94.6

5.1 Reconciliation of net operating cost to revenue resource limit

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Net operating costs for the financial year	**15,933**	7,172
Change in level of Provisions		
Charge Against Revenue Resource Limit	15,933	7,172
Revenue Resource Limit (full year)	**(19,716)**	(7,421)
Underspend against Revenue Resource Limit	**(3,783)**	**(249)**

5.2 Reconciliation of gross capital expenditure to capital resource limit

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Gross Capital Expenditure	**976**	237
Less: Net Book Value of assets disposed of	**0**	0
Charge against the Capital Resource Limit	**976**	237
Capital Resource Limit (full year)	**(1,373)**	(237)
Underspend Against Capital Resource Limit	**(397)**	0

6. Operating revenue

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Administration		
Fees & charges to external customers	**3**	**2**
Income received from Scottish Parliament	**130**	**92**
Income received from National Assembly for Wales	**87**	**57**
Income received from Northern Ireland Assembly	**44**	**31**
Income received from other Departments	**67**	**11**
Total Administration revenue	**331**	**193**

7. Non-current assets

7.1 Tangible assets - Information Technology

	Information Technology £'000	Total 15 months as at 31 March 2016 £'000
Cost or Valuation at 1 January 2015	111	111
Additions - purchased	0	0
Gross cost at 15 months as at 31 March 2016	111	111
Depreciation		
Accumulated depreciation at 1 January 2015	33	33
Charged during the year	27	27
Accumulated depreciation at 15 months as at 31 March 2016	60	60
Net book value at 9 months as at 31 December 2014	78	78
Net book value at 15 months as at 31 March 2016	51	51

	Information technology £'000	Total 0 £'000
Cost or Valuation at 1 April 2014	103	103
Additions - purchased	8	8
Gross cost at 9 months as at 31 December 2014	111	111
Depreciation		
Accumulated depreciation at 1 April 2014	17	17
Charged during the year	16	16
Accumulated depreciation at 9 months as at 31 December 2014	33	33
Net book value at 31 March 2012	86	86
Net book value at 9 months as at 31 December 2014	**78**	**78**

The Health Research Authority did not own any Property, Plant and Equipment assets other than Information Technology at the 15 months as at 31 March 2016. (9 months as at 31 December 2014 : £nil)

7.2 Intangible assets

	Assets under construction £'000	Software licences £'000	Information technology £'000	Total 15 months as at 31 March 2016 £'000
Gross cost at 1 January 2015	0	540	1,292	1,832
Additions - purchased	153	0	823	976
Gross cost at 15 months as at 31 March 2016	153	540	2,115	2,808
Amortisation				
Accumulated depreciation at 1 January 2015	0	81	998	1,079
Charged during the year	0	135	135	270
Accumulated depreciation at 15 months as at 31 March 2016	0	216	1,133	1,349
Net book value at 9 months as at 31 December 2014	0	459	294	753
Net book value at 15 months as at 31 March 2016	153	324	982	1,459

	Assets under construction £'000	Software licences £'000	Information technology £'000	Total 9 months as at 31 Dec 2014 £'000
Gross cost at 1 April 2014	81	540	982	1,603
Additions - purchased	0	0	229	229
Transfers	(81)	0	81	0
Gross cost at 9 months as at 31 December 2014	0	540	1,292	1,832
Amortisation				
Accumulated depreciation at 1 April 2014	0	0	978	978
Charged during the year	0	81	20	101
Accumulated depreciation at 9 months as at 31 December 2014	0	81	998	1,079
Net book value at 31 March 2014	81	540	4	625
Net book value at 9 months as at 31 December 2014	**0**	**459**	**294**	**753**

7.3 Profit / (loss) on disposal of fixed assets

The Health Research Authority did not make any disposals of non-current assets during the 15 month period up to the 31 March 2016 (£nil 9 months to 31st December 2014)

8. Trade Receivables

Amounts falling due within one year

	15 months as at 31 March 2016 £'000	9 months as at 31 December 2014 £'000
Trade Receivables	**52**	21
Other receivables	**84**	57
Accrued income and prepayments	**134**	105
Trade and other receivables	**270**	183

9. Cash and Cash equivalents

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Opening balance	**2,394**	3,819
Net change in period	**1,091**	-1,425
Total	**3,485**	**2,394**
Comprising:		
Held with office of Government Banking Service	3,485	2,394
Commercial banks and cash in hand	0	0
Balance at 15 months as at 31 March 2016	**3,485**	2,394

10. Trade Payables and other current liabilities

Amounts falling due within one year

	15 months as at 31 March 2016 £'000	9 months as at 31 December 2014 £'000
Trade payables	**263**	**268**
Accruals and deferred income	**1,033**	**921**
Trade and other payables	**1,296**	1,189
Other taxation and social security	**0**	**134**
Other Current Liabilities	**0**	**91**
Other Current Liabilities	**0**	**225**
Total Trade Payables and other current liabilities	**1,296**	1,414

11. Contingent Liabilities

At 31 March 2016 there were no known contingent liabilities (31 December 2014 -£nil)

12. Capital Commitments

At 31 March 2016 the HRA has entered into a 3 year contract, with the option to extend for 2 years to the value of £3,123,600 for the 5 years (31 December 2014 - £nil) relating to the development of the HARP and IRAS systems. The capital commitment under the contract is £721,620 relating to the first year of work.

13. Commitments under leases

Operating leases

There is an implied lease between the HRA and the DH for the Authority's occupation of Skipton House. There is no formal agreement relating to the lease but there is a Civil Estate Occupancy Agreement with the authority/ memorandum of term of occupation for use between crown bodies. This is due to expire in December 2016 and negotiations are ongoing to extend the lease period. The commitments below include only those costs to December 2016 as negotiations have not yet been finalised. The HRA have also agreed leases for offices in Nottingham, Bristol and Manchester.

Total future minimum lease payments under this implied operating lease are given in the table below for each of the following periods.

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Obligations under operating leases comprise:		
Buildings		
Not later than one year	274	339
Later than one year and not later than five years	284	235
Later than five years	0	0
	558	574

14. Other financial commitments

The Health Research Authority entered into a contract on 1 April 2012 relating to the provision of financial and accounting and payroll services. The contract was for a year with the option to extend for a further year to 31 March 2014, followed by a further four years if required with a notice period of 12 months. The annual cost of the contract is £165,000. The Health Research Authority entered on 24 February 2016 relating to the maintenance of the HARP and IRAS system and the provision of a helpdesk for these systems. The contract is for 5 years, with a notice period of 3 months after the initial year of the contract.

	15 months as at 31 Mar 2016 £'000	9 months as at 31 Dec 2014 £'000
Not later than one year	285	170
Later than one year and not later than five years	645	382
	930	552

15. 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 each individual case is handled.

Losses and special payments are charged to the relevant functional headings in the operating cost statement on an accruals basis, including losses which would have been made good through insurance cover had the Authority not been bearing their own risks (with insurance premiums then being included as normal revenue expenditure). This note is compiled directly from the losses and special payments register which is prepared on a cash basis.

For the 15 month period to the 31st March 2016, the authority had ten losses totalling £49025.12, of which £48,000 related to the legal costs (part of claimants) that the HRA were ordered to pay as a result of the outcome of a Judicial Review. The other nine smaller losses relate to bad debts written off and a non cancellable travel unused travel ticket (9 months to 31 December 2014: 2 losses £945.71)

16. Related Party Transactions

The Health Research Authority is an NDPB established by order of the Secretary of State for Health. The Department of Health is regarded as a controlling related party. During the year the Health Research Authority 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. All transactions are at arms length. The Health Research Authority has considered materiality in line with the manual for accounts guidelines for agreeing creditor and debtor balances (£50k) and income and expenditure balances (£100k).

	Receivables	Payables	Income	Expenditure
	15 months as at 31 March 2016 £'000	15 months as at 31 March 2016 £'000	15 months as at 31 Mar 2016 £'000	15 months as at 31 Mar 2016 £'000
Department of Health	0	218	0	1,296
NHS Business Services Authority	0	17	0	112
NHS England	0	0	0	117
Oxford University Hospitals NHS Trust	0	0	0	130

No Board Member or key manager has undertaken any material transactions with the Health Research Authority during the year.

17. Events after the reporting period

The result of the referendum held on 23 June was in favour of the UK leaving the European Union. This is a non-adjusting event. A reasonable estimate of the financial effect of this event cannot be made

The annual report and accounts have been authorised for issue on the date the accounts were certified by the Comptroller and Auditor General.

18. Financial Instruments

Financial risk management

Financial reporting standard IFRS 7 requires disclosure of the role that financial instruments have had during the period in creating or changing the risks a body faces in undertaking its activities. As the cash requirements of the Authority are met through Parliamentary Funding, financial instruments play a more limited role in creating risk that would apply to a non-public sector body of a similar size. The Health Research Authority has limited powers to borrow or invest surplus funds and financial assets and liabilities are generated by day-to-day operational activities rather than being held to change the risks facing the Agency is undertaking its activities.

The Authority's treasury management operations are carried out by the finance department, within parameters defined formally within the Authority's Standing Financial Instructions and policies agreed by the Board. The Authority's treasury management activity is subject to review by the Authority's internal auditors.

Foreign Currency risk

The Health Research Authority has no foreign currency risk.

Interest rate risk

100% of the Health Research Authority's financial assets and 100% of its financial liabilities carry nil or fixed rates of interest. The Health Research Authority is not, therefore, exposed to significant interest-rate risk.

Liquidity risk

The Health Research Authority's net operating costs are financed from resources voted annually by Parliament. The Health Research Authority largely finances its capital expenditure from funds made available from Government under an agreed capital resource limit. The Health Research Authority is not, therefore exposed to significant liquidity risks.

Credit risk

The Health Research Authority operates primarily within the NHS market and receives the majority of its income from the Department of Health and Devolved Administrations. Provisions against receivables are calculated based on the type of receivable, ageing or the outstanding debt and knowledge of specific queries on the balances.

Trade receivables are disclosed in Note 8. The Health Research Authority had no trade receivables requiring provision at the 31st March 2016.

Supplier risk

The Health Research Authority operates within both the NHS and non-NHS market for the supplies of goods and services.

The aged creditor report for NHS and non-NHS payables at the reporting date was:

	£000
Not past due	240
Past due 0-30 days	21
Past due 31-120 days	4
More than 121 days	(2)

Fair values

The Health Research Authority has no material long term receivables and payables and therefore the book values are not different from the fair value.

19. Intra-government balances

	15 months as at 31 Mar 2016 Current receivables £'000	9 months as at 31 Dec 2014 Current receivables £'000	15 months as at 31 Mar 2016 Current payables £'000	9 months as at 31 Dec 2014 Current payables £'000
Balances with Department of Health	0	0	218	421
Balances with other central government bodies	50	82	13	102
Balances with local authorities	0	0	0	0
Balances with NHS England	2	0	2	10
Balances with Special Health Authorities	0	0	17	27
Balances with NHS Trusts	0	0	28	64
Balances with Foundation Trusts	0	0	69	57
Balances with public corporations and trading funds	0	0	0	0
Balances with HMRC	55	45	0	134
	107	127	347	815
Balances with bodies external to government	163	56	949	599
Total	270	183	1,296	1,414

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