NHS
Health Research Authority

# Health Research Authority
# Annual report and accounts

HC 312

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# Health Research Authority
# Annual report and accounts
# for the period
# 1 December 2011* to 31 March 2012

Presented to Parliament pursuant to Section 232 (Schedule 15 paragraph 3)
of the National Health Service Act 2006

Ordered by the House of Commons to be printed 5th July 2012

HC 312 LONDON: The Stationery Office £16.00

* The Health Research Authority (HRA) was established on 1 December 2011

The National Research Ethics Service (NRES) transferred to the HRA on 1 December 2011

Any enquiries regarding this publication should be sent to us at HRA, Ground Floor, Skipton House, 80 London Road, London SE1 6LH

This publication is also for download at www.official-documents.gov.uk

This document is also available from our website at www.hra.nhs.uk

ISBN: 9780102977561

Printed in the UK by The Stationery Office Limited
on behalf of the Controller of Her Majesty's Stationery Office

ID: P002488734 07/12

Printed on paper containing 75% recycled fibre content minimum

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# Foreword

I feel privileged to have been appointed to Chair the Health Research Authority on 11th June 2012. I have served as a NHS chair for the past fourteen years and I am a passionate supporter of the Service, who wants it to provide the best evidence-based care that it can. My first public appointment was to a local research ethics committee and I am delighted to be involved in this area again. Research Ethics Committees have a crucial role to play in promoting the interests of research participants, including protecting them from unethical research. Our work extends much further, however, and I am excited to be part of the wider agenda of streamlining governance processes so that good research is easy to do and be involved in.

**Professor Jonathan Montgomery**
**Chair, Health Research Authority**

The UK is a world leader in the research it funds and conducts, and home to some of the most innovative individuals and organisations. The Department of Health and our partners in government, patient and public groups, industry, academia, the NHS and social care have all worked hard to reach this position. But we know that we cannot take this position for granted, the situation can always be improved. We have the potential to do even better. At the Department of Health, we know that the regulation of research has been criticised over the years for being too complex and counterintuitive and for creating barriers where there should be bridges. We recognise the frustration that this has caused the research community over the years. The establishment of the Health Research Authority on 1 December 2011 represented a key milestone for all those who are concerned with the improvement of health research regulation. Coming less than a year since the publication of the Government's *Plan for Growth*, the achievement of the Health Research Authority's establishment is testament to the fruits of hard work and a collective determination to improve the UK's research environment for researchers, industry, patients and the public, to the benefit of both the health and wealth of the nation.

I would like to thank all those involved in the establishment of the Health Research Authority – particularly Dr Janet Wisely, Chief Executive of the Health Research Authority, and her team – for their work in making this go smoothly.

**Candy Morris CBE, Senior Responsible Officer, HRA Development Programme, Department of Health**

# Introduction

The intention to establish a Health Research Authority (HRA) was confirmed by the Government in March 2011 and the HRA was established as a Special Health Authority on 1 December 2011.

With the National Research Ethics Service (NRES) transferring in as the core of the HRA, I was delighted to have the opportunity to lead the new organisation in its early months as the Chief Executive.

The purpose of the HRA is to protect and promote the interests of patients and the public in health research. We do this by supporting and promoting a robust and efficient regulatory and governance framework in the UK and providing the NRES.

In our first four months, we have put in place governance structures to enable the HRA to deliver business effectively, robustly and transparently. The HRA provided welcome stability for the NRES and we have also started work immediately on the wider functions for the HRA. We have agreed plans and started work to deliver the platform for the unified approval process from the Integrated Research Application System and the first phase, which will include electronic submission, will be launched in June 2012. The HRA will not be responsible for all actions within the unified approval process, but it can be responsible for defining them and delivering a culture that supports researchers to conduct good quality research in the NHS. We have agreed principles that will underpin the unified approval process, including no duplication and ensuring that all tasks and actions have a defined purpose and are allocated early to those with the responsibility for them.

This annual report describes the significant progress we have made on the new HRA agenda since it was established on 1 December 2011, as well as a comprehensive summary of the work of the NRES, which is a core service for the HRA. We have created significant momentum, which will see further tangible improvements delivered this year.

I would like to thank all my colleagues within the HRA, the staff and NRES committee members for their continuing support and dedication to the service.

**Janet Wisely**
**Chief Executive**
**Health Research Authority**
**19th June 2012**

## Our vision for the Health Research Authority

Our vision and ambition is to develop a Health Research Authority:

- driven by our key purpose of protecting and promoting the interests of patients and the public in health research;
- underpinned by our leadership in creating a unified health research approval process and promoting consistent, proportionate standards for compliance and inspection;
- with our success being acknowledged by key stakeholders, as well as seen through improved approval times, increased numbers of research participants and projects, and greater confidence in health research.

We will work with all the relevant partners to help create an environment where:

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

## The functions of the Health Research Authority

The HRA has a number of functions. We:

- are the Appointing Authority for research ethics committees (RECs) in England and provide the National Research Ethics Service;
- by agreement with the Devolved Administrations, support a UK-wide system for ethical review in the UK;
- have an on-going programme of work to shape effective national roles for the HRA, within our remit to provide a unified approval process and to promote consistent, proportionate standards for compliance and inspection;
- work in partnership to coordinate our activity with other organisations including the Devolved Administrations, Medicines and Healthcare products Regulatory Agency (MHRA), Human Tissue Authority (HTA), Human Fertilisation and Embryology Authority (HFEA), National Information Governance Board (NIGB), National Institute for Health Research (NIHR) and Administration of Radioactive Substances Advisory Committee (ARSAC);
- provide advice and support through our advice service, published guidance, information and training programmes;

The HRA was established on 1 December 2011. The NRES transferred to HRA on 1 December 2011

- provide the Integrated Research Application System (IRAS), through which applications for regulatory and governance approvals of health research are made in the UK, and have agreed plans to provide a platform for the unified approval process from IRAS.

As a new organisation, we will need to develop structures to accommodate emerging roles for the HRA within our functions, and to prepare to be ready to take on further functions as they are transferred by the DH; in particular, approving use of confidential patient information for research.

This annual report may be read in conjunction with other information published by the HRA on its website; for example, the work to shape effective national roles for the HRA published in our business plans. In addition, previous NRES *Year in Review* publications and numerous publications of advice and guidance may be found on the HRA website.

## HRA success

The HRA has in its first four months:

- successfully established governance structures to enable it to function effectively, and commissioned an external audit of these structures to provide external assurance on effectiveness;
- delivered core business during transition and establishment of HRA;
- communicated a vision and ambition that has built confidence and trust in the HRA;
- established a multi-agency project team to prepare proposals for the HRA role in providing a unified approval process and promoting consistent and proportionate standards for compliance and inspection;
- published proposed principles to underpin the unified approval process;
- agreed plans to provide the platform for the unified approval process from IRAS;
- responded to queries within agreed 4 working day response times (to 90%);
- provided and maintained IRAS as an available system 24 hours a day, 7 days per week (to 99%);
- established a HRA Training and Development Group to plan and steer HRA staff and NRES committee members' training, ensuring consistency in sourcing and delivery and to consider how we provide training to support researchers and others within the HRA remit to provide guidance, training and advice;
- provided welcome stability for the NRES, working within agreed performance indicators;
- Full committee decisions made within an average 40 calendar days;
- 95% of applications to proportionate review service to receive decision within 14 calendar days.

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## Unified approval process and promoting proportionate standards for compliance and inspection

A multi-agency project team has been established to shape the role the HRA will play nationally within our function to provide a unified approval process and to promote proportionate standards for compliance and inspection. Looking at health research conducted in the NHS, the project team carried out a process review of the entire research project journey: from initial idea, development, funding, approval, conduct, compliance, inspection, publication and translation. Going beyond the individual project, the review extended to consider an analysis of other projects involving the same researcher or sponsor.

The review of current systems and improvement programmes and the consideration of roles and behaviours enabled the project team to identify principles and emerging themes for further work, which will be included in business plans for 2012-2013. This work will complement the system improvement implemented through IRAS.

## HRA advice, training and guidance

The establishment of the HRA and the transfer in of the NRES has provided opportunity to enhance and further develop the services provided by the HRA with respect to advice, training and guidance. The HRA has agreed a comprehensive plan that will further transition this service, providing greater and accessible guidance to researchers and others. Events have been held to determine how the HRA may effectively provide advice and guidance in accessible formats.

The HRA has this year provided advice through the queries line, a comprehensive training programme and national events with delegates from a range of disciplines to inform national guidance on key topics within research and research ethics.

### Queries line

The NRES queries line is a centrally managed, front-line email service, which co-ordinates advice provided by HRA staff to the users of our service in a professional and helpful manner; each enquiry is handled on a case-by-case basis.

Management information is provided on a quarterly basis to the management team, highlighting any trends or problems. During 2011/12, a total of 2,739 enquiries were received (a 5% drop on the previous year). The 90% target to answer all queries within 4 working days was successfully met in 2011/12, apart from the Christmas period.

### Training

Following an inclusive NRES training needs analysis, the majority of the 2011-12 training programme was delivered for the NRES, as the core service for the HRA. With the move to the HRA, training is provided as an HRA-wide function.

Our challenges in 2011-12 included working within complex and changing procurement processes and availability of speakers. The training strategy requires value-for-money across delivery of all training. This has been met by procuring external trainers only when

essential via robust procurement methods, recruiting additional internal speakers, using NHS or not-for-profit venues, and phasing out two-day events requiring overnight accommodation. We have therefore ensured value-for-money whilst maintaining a comprehensive and developing training programme. We have provided this year specific training for HRA staff to support REC operation, including training on standard operating procedures and working effectively with the Chair. All members attend induction training and we have held national training days for members and staff, as well as dedicated training on topics including the Mental Capacity Act and use of personal data.

Three training workshops were held to help researchers consider the ethical dimensions of their work and to facilitate REC review of their work. These collaborative events have been well received and are always fully subscribed.

| **Staff training days** | **Number** | **Cost** |
|---|---|---|
| 2009-10 | 25 | £76,395 |
| 2010-11 | 40 | £30,152 |
| 2011-12 | 37 | £37,120 |
| **REC Member training days** | **Number** | **Cost** |
| 2009-10 | 54 | £261,525 |
| 2010-11 | 40 | £82,909 |
| 2011-12 | 53 | £25,229 |

### Developing policy on specific ethical issues

The HRA has an on-going programme of events to support collaborative development of guidance on specific ethical issues. This work will move into the HRA advice framework from 2012. Recent events include:

*Ethics in transplantation research*

A joint meeting with the UK Donor Ethics Committee to consider the ethical issues in transplantation research and establish a uniform approach

*Guidance for research involving infants, children and young people: Practicalities of Ethics*

Work collaborating with the Royal College of Paediatrics and Child Health into facilitating research involving children and young adults

*Reviewing clinical trials of investigational medicinal products*

NRES RECs must review any clinical trial and expertise is obviously crucial; working with industry and the Medicines and Healthcare products Regulatory Agency we have provided collaborative training

*Decisions and risk in research*

Explaining the risk / benefit profile of any research is crucial to informed consent; in this workshop, we worked with researchers in Aberdeen (funded by the Chief Scientist Office, Scotland) and Newcastle Universities to explore this theme. Its work will inform further guidance on the participant information sheet, which is currently under review

*The ethical issues arising from research involving adolescents*

Working with the Alder Hey Children's Hospital, Liverpool and the Medicines for Children Research Network, we hosted a meeting to look at research issues particularly important to young people and adolescents

*A framework for considering continuing care after research*

Working with the Wellcome Trust and King's College London, we have developed guidance on this topic through several consultation meetings

*Peer / Scientific review of research and the role of NRES Research Ethics Committees (RECs)*

A meeting attended by researchers and REC members, to consider scientific review of research and the RECs duties under their governance arrangements (GAfREC) to satisfy themselves that this review has been methodical, robust and commensurate.

## Integrated Research Application System

**The HRA provides the Integrated Research Application System for the IRAS partners:**

- Chief Scientist Office, Scotland
- Department of Health, England
- Health & Social Care Research and Development (HSC R&D), Northern Ireland
- National Institute for Social Care and Health Research (NISCHR), Wales
- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Human Fertilisation and Embryology Authority (HFEA) (will join June 2012)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC), England
- National Institute for Health Research Information Systems (NIHR IS), England
- National Offender Management Service (NOMS)
- National Research Ethics Service
- National Social Care REC
- National Information Governance Board (NIGB)

The IRAS is the established system through which applications for regulatory and governance approvals are made in the UK. Key developments in 2011-12 include:

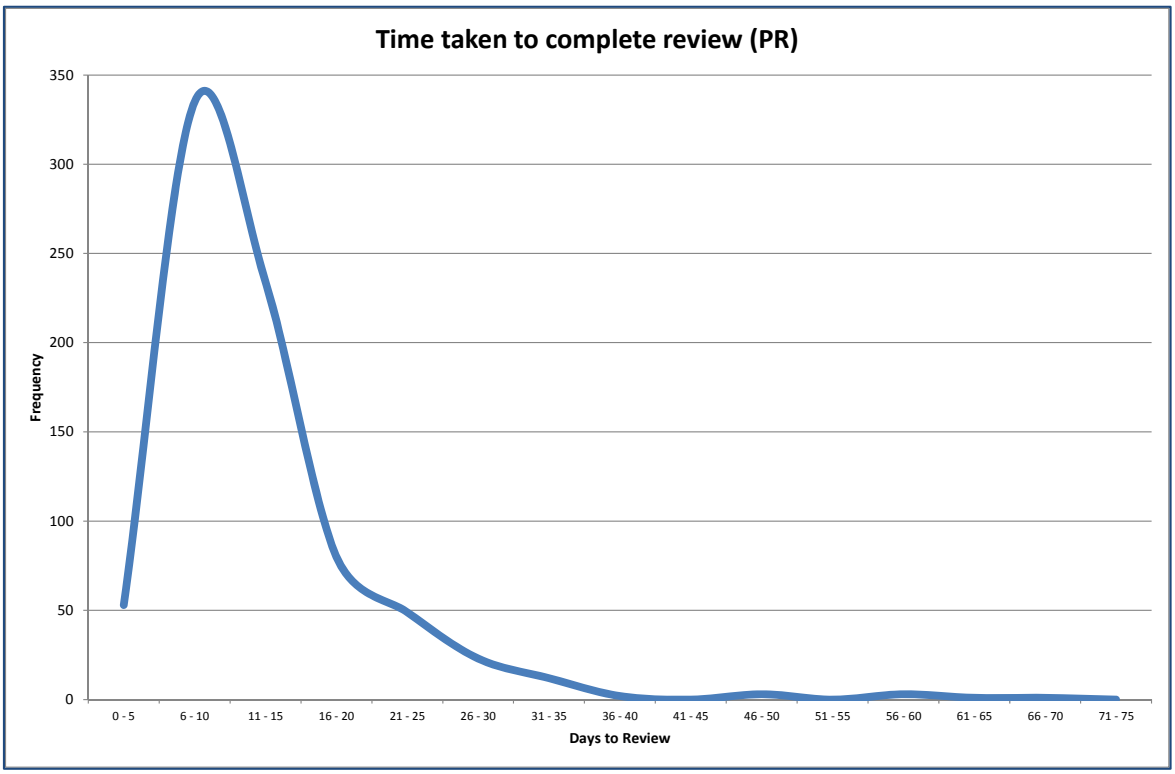
- a significant update of the MHRA Medicines (EudraCT) application form to maintain consistency with European-wide systems;
- revision of project categories in the IRAS filter to expand the available options and provide greater specificity. This enables the system to provide further guidance in terms of the applications required and further tailor the resulting datasets;

- addition of functionality to support the introduction of proportionate review by the National Research Ethics Service;
- introduction of full electronic submission of NHS R&D applications being processed by the National Institute of Health Research Coordinated System for gaining NHS Permissions (NIHR CSP);
- changes and development work to prepare for the wider roll-out of full electronic submission of applications, including enabling of electronic authorisation for wider range of declarations.

## National Research Ethics Service

The NRES is a core service of the HRA in providing ethical review and approval, and protecting research participants. The role of the NRES is to protect the rights, safety, dignity and well-being of research participants and to facilitate ethical research. This year has seen the NRES transfer in to the HRA. This has provided welcome stability and the completion of staff transfers will continue through the next financial year. In 2011-12, the NRES has:

- issued and implemented updated standard operating procedures in line with updated DH-issued Governance Arrangements for Research Ethics Committees and ensure effective delivery against these standards;
- completed the roll out of the Proportionate Review Service for low risk applications with a target review time of 14 days;




- provided application specific advice in a timely and effective manner;
- managed reported potential breaches and reported potential misconduct through agreed standard operating procedures;

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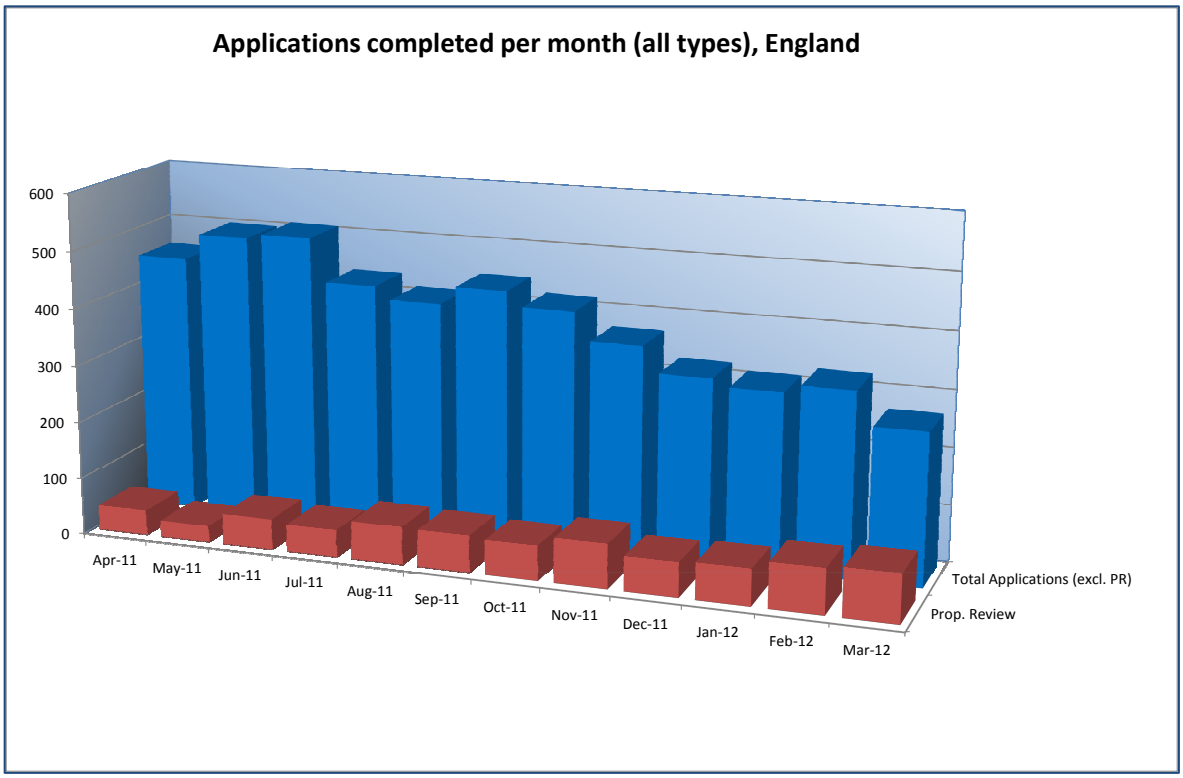
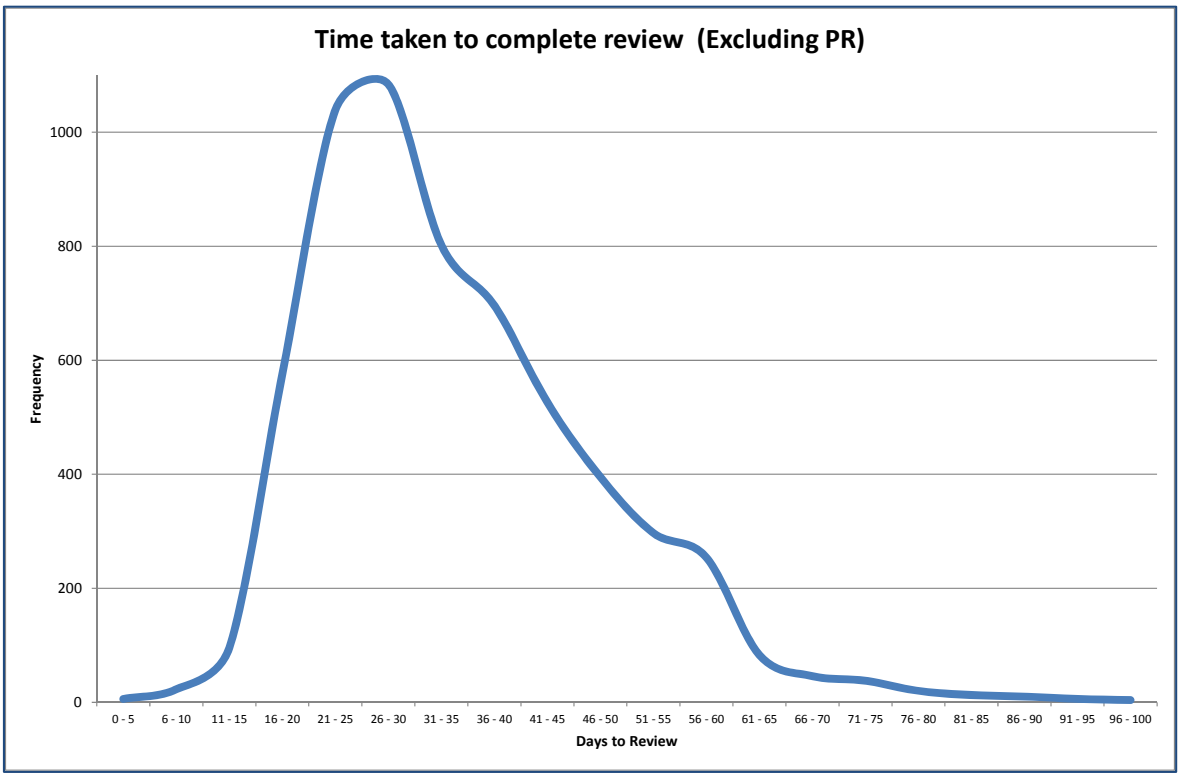
- managed the appeals process for new applications and substantial amendments;
- managed the complaints process for the RECs which now includes follow up on all user feedback;
- continued to manage capacity to demand and reduced the number of RECs ;
- assumed operational management responsibility for the Gene Therapy Advisory Committee;
- providing services within agreements to Devolved Administrations and social care REC;
- assumed responsibility for the former Welwyn Clinical Pharmacology and Reading Independent RECs with the closure of the Appointing Authority for Phase 1 RECs (AAPEC).

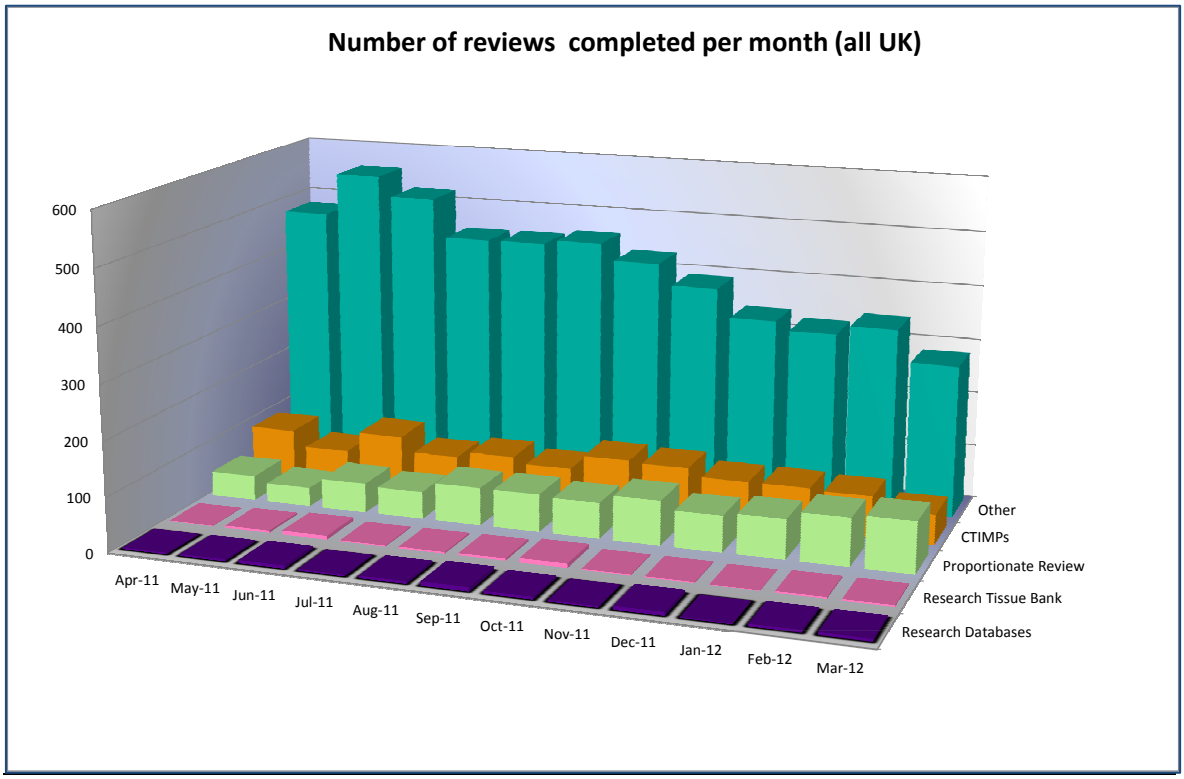



The NRES has an established history of learning and improvement and the HRA will continue to support the NRES in looking for further efficiencies and improvements to the service provided. These improvements have included taking low risk studies out of full committee to sub-committee. The implementation of the updated Governance Arrangements for Research Ethics Committees removed the requirement for ethics committee review for some NHS staff research, such as surveys and questionnaires. This year the NRES has agreed plans and begun work that will:

- test and evaluate the feasibility of further reducing the dataset required for proportionate review service applications;
- evaluate the effectiveness and acceptability of an early assessment of applications received by the NRES, to improve the quality of applications received by committees and enable the early identification of issues that can be conditions of favourable opinion;

- evaluate the effectiveness and acceptability of an officer's review of applications prior to committee consideration to provide advice on relevant legislation, guidance or previous decisions to facilitate improved consistency and standards of ethical review;
- test and evaluate taking some decision-making out of the committee to the officer role, e.g. suitability of the researcher and sponsor, funding, presentation and quality of protocol, insurance provision;
- reduce the timelines for submission of Phase 1 studies.

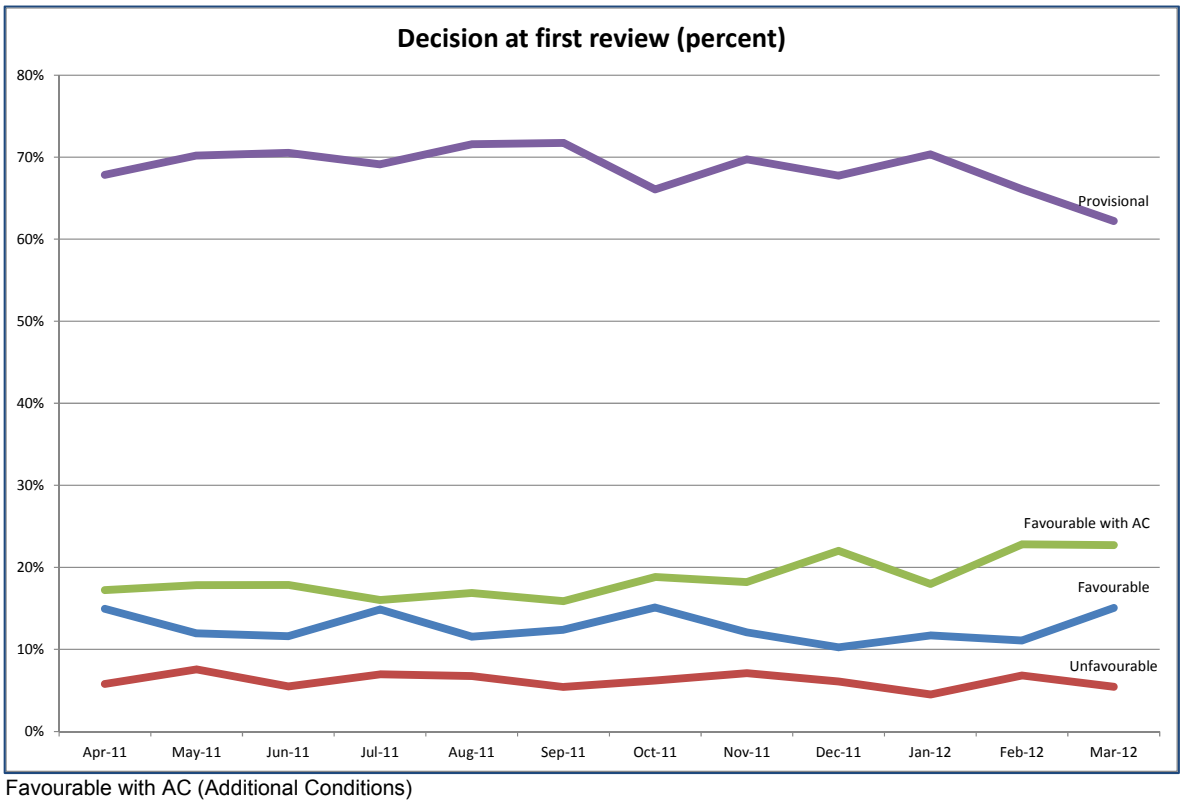


The aims of the improvement programme are to reduce provisional opinion rates, to improve timelines, to reduce the administrative burden on researchers and committees, and to improve quality and consistency of ethical review.

| All UK Committees | First Decision | | | |
|---|---|---|---|---|
| Month Completed | Favourable | Favourable with AC | Provisional | Unfavourable |
| Apr-11 | 85 | 98 | 386 | 33 |
| May-11 | 71 | 106 | 417 | 45 |
| Jun-11 | 74 | 114 | 450 | 35 |
| Jul-11 | 79 | 85 | 367 | 37 |
| Aug-11 | 65 | 95 | 403 | 38 |
| Sep-11 | 71 | 91 | 411 | 31 |
| Oct-11 | 85 | 106 | 372 | 35 |
| Nov-11 | 63 | 95 | 364 | 37 |
| Dec-11 | 47 | 101 | 311 | 28 |
| Jan-12 | 52 | 80 | 313 | 20 |
| Feb-12 | 52 | 107 | 310 | 32 |
| Mar-12 | 61 | 92 | 252 | 22 |
| Total | 805 | 1170 | 4356 | 393 |

Favourable with AC (Additional Conditions)

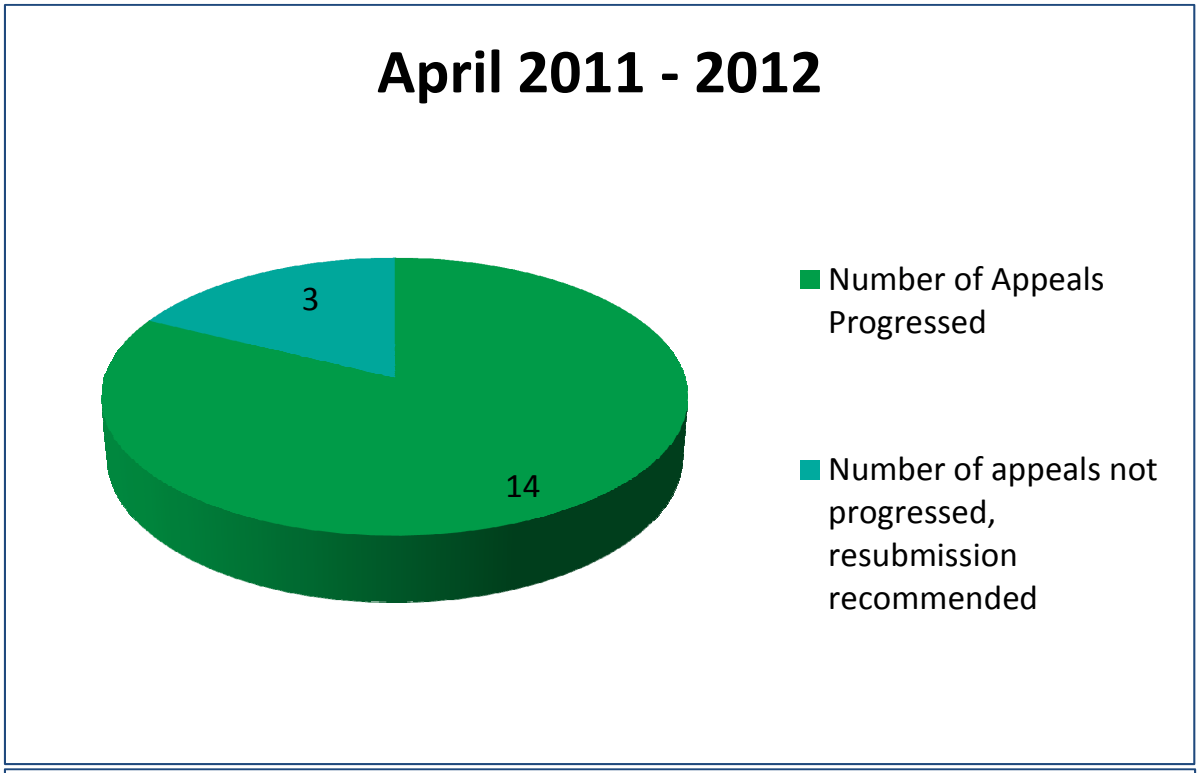


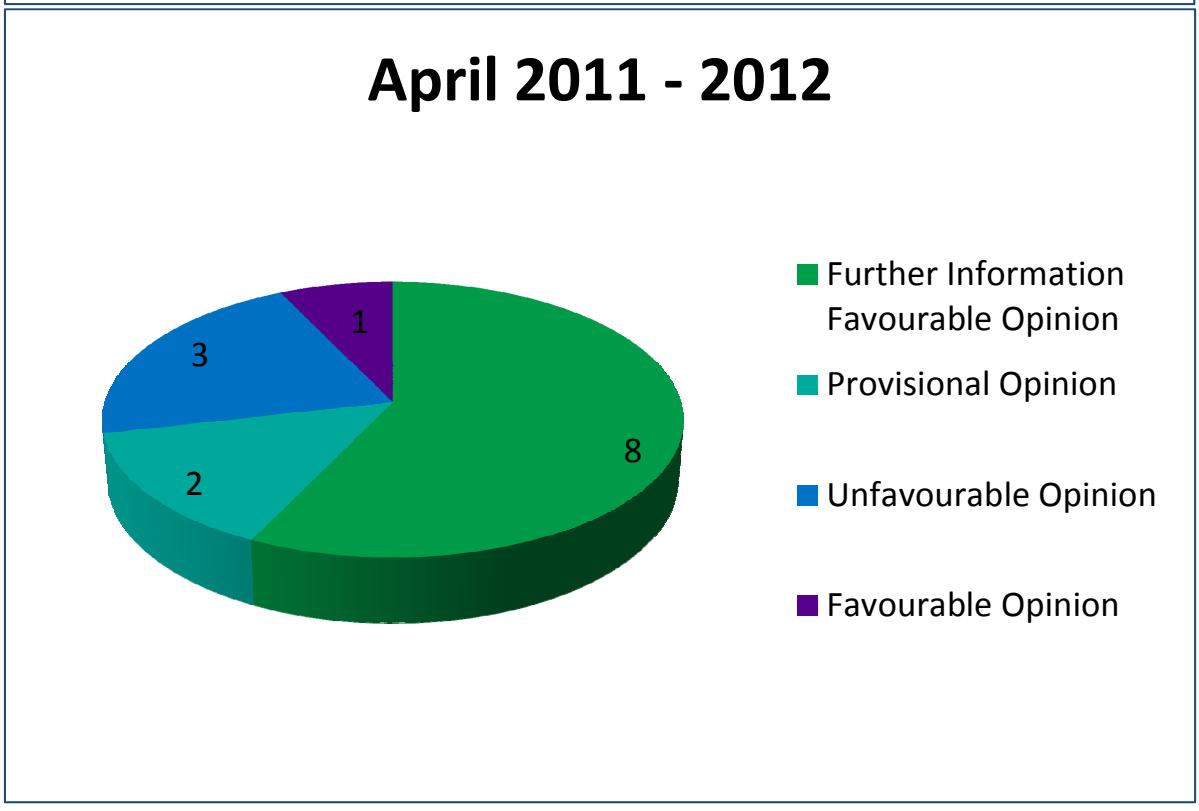

Favourable with AC (Additional Conditions)

The NRES also supports a number of collaborative groups that underpin the work of NRES within a national system for review. These include a UK Clinical Trial Collaborative Group and Phase 1 Advisory Group.

## Appeals

There were seventeen Appeals during 2011 – 2012 compared to twenty eight the previous year.



### NRES quality assurance

The NRES quality assurance function has maintained its ISO 9001 certification having retained certification from the BSI (The British Standards Institute) for a further year in August 2011 without any findings or an action plan.

39 REC accreditation audits have been completed and 35 action plans signed off during the year. The quality assurance function also monitors and supports quality control conducted by the NRES operational teams. The accreditation scheme and supporting quality control have worked together to support RECs and monitor compliance against standard operating procedures. In addition, we have undertaken a number a gap analyses using the approach to inform NRES Operations and RECs taking part of their performance in a constructive but less formal way.

We proactively collect feedback from users of our service and our members by targeting one meeting from each REC per year and seeking feedback from applicants who used that meeting, as well as separately asking REC members if there are any issues they wish to discuss or raise. Feedback has also been collected from the self-selecting group of applicants who chose to complete the feedback form on the NRES website. This year, effort has been put into targeting issues of interest to the operational teams by asking specific questions within an e-mail when seeking targeted feedback from users, e.g. the experience when using application allocation systems. This is to get direct feedback about aspects of our service of particular interest at the time. Effort has also been put into ensuring feedback is used directly to improve our service by asking the consent of some of those who raise issues in the comment section of the form to take up the issue with the REC concerned. This is undertaken by NRES Operations and, where improvements are achieved through this means, it is reported to the appropriate management group and on the NRES website.

Shared ethical debate is a quality assured process supported by the HRA Ethics Advisor, which sends a single-issue or training application to a number of NRES RECs. In the last year, four debates were conducted: one single-issue debate looking at confidentiality in research and three application based debates – a CTIMP (clinical trial of an investigational medicinal product) in children, a Phase 1 study and a qualitative study. We have reviewed this year how to best use the results of shared ethical debates conducted to benefit all RECs by developing training packages and presentations that are sent to all RECs to give feedback from the debates and enable RECs to see the views of others and reflect on their ethical review.

Quality assurance reports are regularly reviewed through the HRA management structures and published on the website.

## UK Ethics Committee Authority

The HRA provides secretariat support to the UK Ethics Committee Authority and the HRA Chief Executive chairs the UKECA by agreement with the Department of Health and Devolved Administrations.

## National Research Ethics Advisors' Panel

Over the past year the National Research Ethics Advisors' Panel (NREAP) has continued to discuss ethical issues faced by research ethics committees, issue guidance and has provided strategic advice and support to NRES. The NREAP is a forum for consultation on proposed changes to the ethics service. The 'NREA-hosted Chairs' Network' meetings have become established as an important forum for dialogue between the Chairs, their committees and the Panel and help to keep the Panel informed of issues that affect RECs at the 'sharp end' of ethical review.

During 2011-12 the Panel issued new guidance regarding:

- *Conflict of Interests/Competing Interests'*(NREAP/04) which sets out a number of principles and possible solutions that might be applied by RECs when considering how conflicts of interests/competing interests should be managed;

and revised its existing guidance on:

- *Follow-up contact of potential participants who have not responded to an initial invitation to take part in research* (initially published 12/07/2010).

In addition, the Panel has:

- contributed to the NRES Report on the shared single-issue ethical debate: *How should RECs consider and decide about the inclusion or exclusion of participants in research who may have difficulties in adequate understanding of English?*; and
- issued a statement on *Presentation of precedents to RECs* which encourages applicants to indicate where particular aspects of a research study have been given ethical approval previously by other RECs. Any committee should consider both the justification and the precedents presented to them and provide clear reasons where they feel unable to agree with the decision of a REC that has previously considered the issue.

Members of the Panel have also contributed to a number of NRES training meetings, as well as to a variety of meetings on behalf of NRES.

The Panel has completed a review of its membership and terms of reference in light of feedback from the first two years of operation and the move of NRES to the HRA. The subsequent revised terms of reference, approved by UKECA on the 15 March 2012, emphasise the Panel's role to help research ethics committees deliver robust, consistent and fair decisions. The Panel will continue to be a resource available to all RECs supported by the UK Health Departments within England and the Devolved Administrations, and will focus on developing the existing links made by the Panel members in order to engage and consult with all stakeholders to inform and deliver appropriate guidance to the REC community.

## National Research Ethics Advisory Panel Members

*Professor Andrew George (Chair)*
Director of the Graduate School and the School of Professional Development, Imperial College London

*Jeremy Butler*
Retired, former pilot and General Manager at British Airways and former Non-Executive Director, NPSA

*Dr Sarah Dyer*
Senior Teaching Fellow, Department of Geography, University of Exeter

*Professor Peter Heasman*
Professor of Periodontology, School of Dental Sciences, Newcastle University.

*Ms Caroline Harrison*
Barrister in the field of clinical negligence and complex personal injury law with expertise in medical research, and the ethical, legal and social implications of human genetic research

*Professor John Saunders*
Professor Saunders, Consultant Physician and Chair of the Committee for Ethical Issues in Medicine, Royal College of Physicians

*Professor Nalin Thakker*
Consultant Oral Pathologist and Chair of Molecular Pathology and Genetics, School of Dentistry, University of Manchester

*Dr Richard Tiner*
President of the Faculty of Pharmaceutical Medicine

*Dr Arthur Tucker*
Principal Clinical Scientist at St. Bartholomew's Hospital and Senior Lecturer in Clinical Pharmacology at Queen Mary University of London

*Professor Charles Warlow*
Professor of Medical Neurology at the University of Edinburgh

*Dr Frank Wells*
Dr Wells is a retired GP and Chairman, EFGCP (European Forum for Good Clinical Practice) Ethics Working Party and its Research Integrity Sub-Group. He worked at the Association of the British Pharmaceutical Industry (ABPI) for 10 years

*Dr Simon Woods*
Senior lecturer and Deputy Executive Director of the Policy, Ethics and Life Sciences Research Centre at Newcastle University

*Professor Sue Wilson*
Chair in Clinical Epidemiology at the University of Birmingham and Deputy Head (Research lead) for the School of Health and Population Sciences

**The Panel held meetings on the following dates during 2011-12**

| | | |
|---|---|---|
| 13 April 2011 | 10 August 2011 | 14 December 2011 |
| 11 May 2011 | 14 September 2011 | 11 January 2012 |
| 08 June 2011 | 12 October 2011 | 08 February 2012 |
| 13 July 2011 | 09 November 2011 | 14 March 2012 |

NREAP meeting papers are published on the NRES section of the HRA website.

## Management commentary

### Summary

The internal focus during 2011/12 has been on setting up the HRA on a legal and stable footing; associated with this have been two main strands of work:

- **Setting up the organisation** – the establishment of the necessary governance arrangements and associated polices
- **Transition** – the effective transfer of NPSA staff to the HRA, the preparation for transfers of staff from the remaining hosts and the implementation of new shared service arrangements.

### Setting up the organisation

The HRA was established as a Special Health Authority under statutory instrument 2011 no 2323 and associated directions on 1 December 2011 with an interim Executive only board. It has already made significant progress in having strong and robust internal organisational policies and procedures in place. The HRA board has formally adopted all key policies (copies of which can be found on the HRA website) and work is on-going to ensure that these policies are understood and implemented across the organisation. A number of these policies are commented on below.

### Information Governance

A comprehensive information governance framework has been produced, consisting of a number of related policies adhering to Cabinet Office guidelines and which will assure the public, users, staff and NRES committee members that information will be managed in compliance with NHS information governance requirements.

The Chief Executive acts as the Senior Information Risk Officer and is supported by Information Asset Owners who include both the Interim Deputy Chief Executive and Heads of Department. A programme of training is being developed to ensure that all staff are aware of their role and responsibilities in relation to information governance.

### Health and Safety

The policy was signed off at the initial board meeting and an implementation plan is currently being developed. An immediate priority will be to set up a Health and Safety Committee to oversee the roll out of the H&S plan and associated training programme.

## Equality and Diversity

The policy was signed off at the initial board meeting and subsequently HRA equality data has been produced along with specific performance targets. An implementation plan is currently being developed to enable the HRA to meet those targets. Furthermore, the Authority will prioritise establishing engagement arrangements with local interest groups to test the continuing relevance and robustness of the policy.

## Sickness Absence

Sickness absence rates for directly employed staff for the HRA for the period 1 December 2011 to 31 March 2012 were 1.5%.

## Freedom of Information

The HRA complies with the Freedom of Information Act.

## Personal Data related incidents

From 1 December 2011 to 31 March 2012 there were no personal data related incidents that required reporting to the Information Commissioner.

## Transition

### *Staff*

NRES staff previously employed by the NPSA have successfully transferred to the HRA and those who were based in Maple Street completed their office move to Skipton in mid-October 2011. Plans are also in place to transfer the remainder of staff from existing hosts by September 2012.

### *Corporate Services*

New shared service arrangements have been successfully set up with the NHS Shared Business Services to deliver finance, payroll and accounting services and with NHS Business Services Authority to deliver HR and Occupational Health Services.

Transition to the DH IT service continues and will be completed in line with the staff transfer timetable.

During the next few months the HRA will also be migrating over to a new cross-government travel and accommodation booking service and will continue to work with the ALB shared services team and the Procurement Centre of Excellence to address continuing procurement requirements.

It should be noted that Finance & Accounting, Human Resources, Occupational Health and Payroll services are currently interim solutions and therefore the HRA may face further changes to providers in the next 12-18 months.

## Resources

The HRA receives two resource limits from the Department of Health (DH), one to cover revenue expenditure and one for capital.

The HRA was established on 1 December 2011. The NRES transferred to HRA on 1 December 2011

The Authority met its financial duties in 2011/12 and spent within the resource limits set. Details of the HRA accounts can be found at the end of this report.

The Authority's total available revenue resources for the period December 2011 to March 2012 were £4.443m. Its capital allocation was £0.095m. The majority of our income comes from DH through a resource limit, with the remainder from the devolved administrations of Scotland, Wales and Northern Ireland and some miscellaneous other income. The resource limit represents the maximum the HRA was permitted to use during the period December 2011 to March 2012.

The Authority's net revenue expenditure totalled £3.445m. There was no capital expenditure.

The Authority underspent the revenue allocation in the year by £0.998m and the capital allocation by £0.095m. The single biggest factor has been the impact on an emerging and small organisation of the expenditure restrictions necessarily placed on the organisation as a result of the economic situation and the timing of the appointment of the permanent Chief Executive. The success in establishing the HRA rapidly by December 2011 following an announcement in March 2011, combined with the effect of the efficiency constraints, has meant that it has not been possible to bring in the additional resources required to both establish the organisation and to deliver all planned HRA-wide objectives.

Restrictions placed on recruitment also led to delays in recruitment to key operational and management vacancies. These had a resulting delay to delivery of some planned developments to the Integrated Research Application System (IRAS) and member portal. Additionally, the delays in recruitment to vacancies mean that some planned training for staff has had to be deferred. The restrictions have also dampened expenditure activity in development areas such as the HRA website and communications function. The cost level and number of redundancies within the NRES has been less than expected.

## Sustainability Report 2011/12

The HRA has been established for 4 months and is working to reduce the environmental impact of its activities.

The majority of the organisations effect on the environment comes from our occupation of office buildings and on the travel our staff undertake. We do not manufacture or consume raw materials.

During the four months our use of offices has reduced as we have rationalised the number of our Research Ethics Committee Centres. Our West Midlands Centre closed in March 2012. During the preceding eight months we closed our Reading Centre and seven other offices in the London and South East area.

As at the end of March, the HRA has nine centres around England and these will reduce to seven by September 2012. Our head office is based within a Department of Health building and the energy and water consumption will therefore from part of the DH report. All our other centres are shared occupation and we are recharged energy and water

costs as part of a service charge and therefore cannot report our consumption of energy and water in these buildings.

Our travel arrangements are managed through an external provider who supplies information on rail and air miles travelled and the carbon effect of them. Over the last four months HRA has used a monthly average of 1,509 kg $CO_2$ in this area. The HRA will monitor usage against this average. HRA is actively working to reduce travel by staff wherever possible and part of our capital plans for the forthcoming year include plans to develop video conferencing capacity to assist in this objective.

We encourage staff to recycle where possible through the provision of facilities to segregate waste. Individual waste bins have also been removed.

## Our organisation – Public Interest

The HRA is responsible for a budget of £10m and has 126 staff, some 1,200 committee members who voluntarily serve on the 81 National Research Ethics Service committees (RECs) and a National Research Ethics Advisors' Panel. Staff are based in London at the HRA office at Skipton House (two other London offices will close by September and relocate to Skipton House) and six other offices across England.

The HRA has put in place interim management structures with a senior management team which meets monthly and through which all business is reviewed and managed, including risk, assurance, financial management and delivery.

The HRA has an involvement strategy which includes a staff partnership forum and established formal feedback routes for the users of our services. The HRA is working with INVOLVE, the Association of Medical Research Charities (AMRC) and others to develop effective mechanisms for active patient and public involvement. The HRA held the first workshop as part of this strategy for involvement in February 2012.

### Complaints

The HRA has a complaints process which has been developed in line with the Ombudsman's "Principles of Complaints Handling".

### Better Payment Practice Code

The HRA seeks to comply with the Better Payment Practice Code by paying our suppliers within 30 days of the receipt of goods or services, or within 30 days of receipt of an invoice. The performance in meeting this objective is disclosed in note 4.3 to the Accounts. This shows that the HRA met the target set in terms of numbers of invoices, however, the HRA missed the target slightly for non-NHS invoice values.

### External audit

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 National Health Service Act 2006 at the cost of £25,000. The audit certificate can be found on page 30.

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 self-aware of any relevant audit information and to establish that the entity's auditors are aware of that information.

### Register of interests

In line with other NHS organisations, the HRA holds a register of interests with information provided by Board members and other staff.

A statement to the effect that 'all Board members should declare interests which are relevant and material to the NHS Board of which they are a member' is contained in the HRA Board agenda and members are expected to declare any interests on any agenda item before discussion commences.

### Pension liabilities

The HRA participates in the NHS Pension Scheme and in doing so makes contributions based on the salary of individual members. The HRA does not have any liability for future pension costs as these are met by the NHS Pensions Scheme.

## Remuneration report

### Sub-Committees

There is one sub-committees of the HRA Board: Audit Committee.

### Pay and Remuneration

Details of the interim executive senior managers' remuneration are given below. Pay for one executive is set and reviewed in line with the DH guidance 'Pay Framework for Very Senior Managers in Strategic and Special Health Authorities, Primary Care Trusts and Ambulance Trusts' (VSM). Senior managers employed under the VSM framework are under stated contracts of employment as set out by NHS Employers.

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

| Salaries and allowances | | | | |
|---|---|---|---|---|
| Name and title of Directors | 2011-12 | | 2010-11 | |
| | Salary (bands of £5,000) | Other Remuneration | Salary (bands of £5,000) | Other Remuneration |
| | £000 | £000 | £000 | £000 |
| Janet Frost (Wisely), Interim Chief Executive (start 01/12/2011) | 30-35 | 0 | N/A | N/A |
| Deborah Corrigan, Deputy Chief Executive / Acting Director of Finance (start 01/12/2011) | 25-30 | 0 | N/A | N/A |
| Band of Highest paid Director's Total Remuneration (£000s) (annualised) | 100-105 | 0 | N/A | N/A |
| Median Total (£) | 38,851 | | | |
| Remuneration Ratio | 2.69 | | | |
| The information above has been subject to audit | | | | |

There were no other benefits in kind

Reporting Bodies are required to disclose the relationship between the remuneration of the highest paid Director in their organisation and the median remunerations of the organisations workforce.

The banded remuneration of the highest paid Director in the HRA in the period December to March 2011/12 (annualised as the organisation has only been established for four months) was £104,481. This was 2.69 times the median remuneration of the directly employed workforce, which was £38,851.

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

Total remuneration includes salary, benefits in kind and severance payments. There were no non-consolidated performance related bonuses. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

| Pension Benefits | | | | |
|---|---|---|---|---|
| **Name and title** | **Real increase in pension at age 60 (bands of £2,500)** | **Lump sum at aged 60 related to real increase in pension (bands of £2,500)** | **Total accrued pension at age 60 at 31 March 2012 (bands of £5,000)** | **Lump sum at age 60 related to accrued pension at 31 March 2012 (bands of £5,000)** |
| | **£000** | **£000** | **£000** | **£000** |
| Janet Frost (Wisely), Interim Chief Executive (start 01/12/2011) | 0 -2.5 | 0-2.5 | 20-25 | 60-65 |
| Deborah Corrigan, Deputy Chief Executive/Acting Director of Finance (start 01/12/2011) | 0 | 0 | 10-15 | 30-35 |

| Pension Benefits (continued) | | | | |
|---|---|---|---|---|
| **Name and title** | **Cash Equivalent Transfer Value at 31 March 2012** | **Cash Equivalent Transfer Value at 31 March 2011** | **Real increase in Cash Equivalent Transfer Value** | **Employer's contribution to stakeholder pension** |
| | **£000** | **£000** | **£000** | **£000** |
| Janet Frost (Wisely), Interim Chief Executive (start 01/12/2011) | 326 | 260 | 20 | 0 |
| Deborah Corrigan, Deputy Chief Executive/Acting Director of Finance (start 01/12/2011) | 167 | 139 | 8 | 0 |
| The information above has been subject to audit. | | | | |

## Cash Equivalent Transfer Values

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 disclosure 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 and 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 for 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.

**Janet Wisely**
**Chief Executive**
**Health Research Authority**
**19 June 2012**

# Statement of Accounting Officers Responsibilities

Under the National Health Service Act 2006, Section 232 (Schedule 15, paragraph 3) the Secretary of State has directed the Health Research Authority to prepare for each year a financial statement of accounts 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 Health Research Authority and of its net resource outturn, recognised gains and losses 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.

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

# Governance Statement

## Introduction

This Governance Statement sets out the framework utilised by the Authority 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 Authority complies with the requirements of the Corporate Governance Code insofar as they relate to public bodies.

A review of governance was undertaken by internal audit during March 2012 to provide assurance to HRA senior management, the Audit and Risk Committee and the Board that current governance arrangements are adequate at this stage of the HRA's evolution.

## Governance Structure

### Responsibilities of accounting officer

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the Health Research Authority policies, aims and objectives, whilst safeguarding public funds and the Authority's 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 this annual report and accounts, 1 December 2011 to 31 March 2012. I am accountable for the discharge of my functions to the Authority's Board. 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 Health Research Authority and 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.

### The Board

The HRA had an Interim Executive Board until June 2012. The Interim Executive Board has been working within the above framework agreement with the Department of Health (DH). The Interim Executive Board includes: Janet Wisely, Interim Chief Executive and Debbie Corrigan, Interim Deputy Chief Executive and Acting Director of Finance. Hugh Davies, the HRA Ethics Advisor, attends by invitation. The HRA Board has met three times on:

01 December 2011

11 January 2012

22 March 2012

At each meeting there are clear agendas and minutes. In addition to receiving updates on current issues, the Board receives reports on progress against our business plan and financial plans and considers our corporate level risks and their mitigation and management.

Both interim executive board members have attended all of the meetings during the period of this report.

HRA Board meetings are held in public, with papers published on the HRA website. Declaration of interests are declared and formally recorded and all Board members expenses are published.

### Sub-Committees

The Board has one sub-committee. The role of the HRA interim Audit & Risk Committee is to advise the HRA's Accounting Officer and the HRA Board on risk management, corporate governance and assurance arrangements in the HRA. The HRA interim Audit & Risk Committee has met three times on:

14 February 2012

01 March 2012

16 March 2012

The HRA Audit and Risk Committee is made up of the following members:

*Shelley Dolan*
Chief Nurse, The Royal Marsden NHS Foundation Trust *(Interim Chair)*

*Michael Fox*
Chair, Barnet, Enfield and Haringey Mental Health NHS Trust

*David May*
Assistant Director of Finance, NHS South West

*Richard Tiner*
President of the Faculty of Pharmaceutical Medicine

The Committee has agreed terms of reference. 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 attendance by members of the committee is shown on the composite table below.

### Attendance at the interim audit and risk committee

The figures in the table below shows attendance at each meeting as compared to the total number of meetings the members were eligible to attend. For instance 2/3 would indicate that two meetings were attended out of three that the member could have attended.

| Name | Audit Committee attendances |
|---|---|
| Shelley Dolan, Chief Nurse, The Royal Marsden NHS Foundation Trust *(Interim Chair)* | 3/3 |
| Michael Fox, Chair, Barnet, Enfield and Haringey Mental Health NHS Trust | 3/3 |
| David May, Assistant Director of Finance, NHS South West | 1/3 |
| Richard Tiner, President of the Faculty of Pharmaceutical Medicine | 3/3 |

### Pay and Remuneration Committee

Prior to the establishment of a Pay and Remuneration committee, the HRA Standing Orders state that any remuneration or terms of service issues affecting the interim Chief Executive or Acting Director of Finance, along with issues outside of agenda for change, will be referred to the Senior Department Sponsor at the Department of Health. In line with the requirements of the NHS Codes of Conduct and Accountability, and more recently the Higgs report, a Pay and Remuneration Committee will be established and constituted by the autumn of 2012 at the latest.

Levels of remuneration for the interim executives are shown in the Remuneration Report above.

## 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.

### 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 and Corporate Assurance policy and guidance in place.

The interim Audit and Risk Committee is the Board's sub-committee that overviews risk and ensures that the systems are in place to ensure effective risk management. The Audit and Risk Committee approved the Risk Management and Corporate Assurance policy and guidance. 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. During the period December 2011 to March 2012, the Authority has continued to focus its risk assessments to include business as usual, as well as transition issues.

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. All risks are recorded in the risk register.

Risks are identified, monitored and managed at departmental level. They are escalated for monitoring through the Senior Management Group. They are entered into the Corporate Assurance Framework.

The Corporate Assurance Framework reports the escalated risks and risk scores, along with the risk mitigation actions and due dates as well as residual risk and assurances put in place to mitigate the risks. The Framework is reviewed by the HRA Senior Management Group and the Audit and Risk Committee to monitor the effective management of risks reporting to the Board.

The Audit and Risk Committee overviews 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.

### Information Governance

As a new organisation the HRA is addressing the requirements of information governance for the first time in its own right and is developing the infrastructure required to manage this task. This commitment is reflected in our business plan. The following information governance roles are in place:

| | |
|---|---|
| **Senior Information Risk Officer (SIRO):** | Dr Janet Wisely, Chief Executive |
| **Information Governance (IG) Lead:** | Sandra Holley, Head of Quality Assurance |
| **Information Asset Owners (IAOs):** | Heads of Department and the Interim Deputy Chief Executive and Acting Director of Finance |

The IG Lead is a member of the Department of Health Information Governance Forum.

The HRA has been established for just four months and has concentrated during that time in establishing an IG infrastructure.

The following Information Governance policies were signed off by the HRA Board on the 1 December 2011.

- HRA Information Risk Policy
- HRA Information Security Policy
- Acceptable Use Guidelines, including guidelines for home working
- FOI, DPA and Confidentiality Policy
- Information Charter
- Records Management Policy
- Forensic Readiness Policy
- A full suite of policies and procedures are in place, including incident reporting processes, and all staff have undertaken Information Security training.

The Chief Executive in her capacity as SIRO for the Health Research Authority has confirmed that the Annual Assessment of Information Risk has been completed and approved by the Board and submitted to the Department of Health.

The Government announced new controls on expenditure shortly after taking office in June 2010 and the Department of Heath revised their delegations to the Authority as a result of these new controls. These were implemented through the National Patient Safety Agency, which NRES was a division of at the time, by introducing new procedures and disseminating these to staff on an *ad hoc* basis and were then consolidated in an Addendum to the Standing Orders and Standing Financial Instructions adopted by the NPSA Board in November 2010. The HRA Standing Orders and Standing Financial Instructions and the scheme of delegation reflect these new controls on expenditure.

## 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 Health Research Authority for the period 01 December 2011 to 31 March 2012 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

As the HRA has been established for just four months, my review of the effectiveness of the system of internal control is informed by the work of internal auditors and the managers within the Authority who have responsibility for the development and

maintenance of the internal control framework, and comments made by external auditors in their management letter and other reports.

The head of internal audit provides me with an opinion, in accordance with Government 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. On the basis of the governance review undertaken and its findings, his opinion is that in the short time the HRA has been in existence quite robust governance arrangements have been put in place, and these will be subject to testing through the delivery of a full year's audit plan.

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.

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 the external auditors, plan and carry out a programme of work that is in the process of being approved by the Audit Committee, to review the design and operation of the systems of internal control. Where weaknesses are identified, these will be reported to the Audit Committee and an action plan agreed with management to implement the recommendations agreed as part of this process.

The Authority prepared a Summary Plan of Activity for December 2011 to March 2012, which set out the purpose of the HRA and focussed on the activity within NRES operations management and improvement. A business plan for 2012/13 has been agreed which sets 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 assured that our arrangements are robust by the reviews undertaken by our Internal Auditors.

I am not aware of any significant internal control issues.

### Capacity to handle risk

The Acting Director of Finance is the designated executive with operational responsibility for maintaining and developing the organisation-wide system of internal control. I am the designated executive with operational responsibility for the system of risk management and risk reporting. I am also the Authority's designated Senior Responsible Information Officer (SIRO) with responsibility for the system of safeguarding and protecting personal identifiable, confidential and sensitive data.

I have delegated the day-to-day responsibility for maintaining the system of risk management and risk reporting to the Interim Board Secretary and Business Manager.

The Senior Management Group, led by myself, reviews and monitors progress with action plans and the Corporate Management Group and the NRES Management Group provide focal points for operating divisions and teams to raise local risk management issues.

The HRA is committed to the shared service programme being driven by the Department of Health. A significant change programme has and is being undertaken.

I have established systems and processes to ensure that the transition of these services is undertaken in an efficient and effective manner. The transition risks have been managed through the Transition Assurance Framework, which has been reviewed frequently by our senior management team and our internal auditor is a member of one of the key projects to transfer finance and accounting services.

The Board takes an active role in risk management, receiving periodic reports and reviewing the Transition Assurance Framework.

The Audit Committee has the role of overseeing the governance process. It has reviewed the Corporate Assurance Framework and any key risks resulting from the transition at its meetings, together with movements in those risks and the management of them.

Risks are managed through Corporate, NRES and IRAS and each prepares risk registers, reviews them at their regular meetings and manages those risks. Risks are referred through to the HRA Senior Management Group and considered for conclusion on the HRA corporate risk register which is shared with Board and DH Sponsor.

### Director's Remuneration

The detail of the remuneration during the year is shown in the remuneration report above.

### 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.

**Janet Wisely**
**Chief Executive**
**Health Research Authority**
**19 June 2012**

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

I certify that I have audited the financial statements of the Health Research Authority for the period ended 31 March 2012 under the National Health Service Act 2006. These comprise the Statement of Comprehensive Net Expenditure the Statement of Financial Position, the Statement of Cash Flows, the Statement of 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 Report that is described in that report as having been audited.

### Respective responsibilities of the Accounting Officer and the 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 National Health Service Act 2006. 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. 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 reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

### Opinion on Regularity

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

### 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 2012 and of its net expenditure for the period then ended; and

- the financial statements have been properly prepared in accordance with the National Health Service Act 2006 and directions issued thereunder by the Secretary of State.

### Opinion on other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with the Secretary of State's directions issued under the National Health Service Act 2006; and
- the information given in the Management Commentary and Sustainability Report included within the Annual Report, for the financial period 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 are not in agreement with the accounting records or 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.

*Amyas C E Morse*
*Comptroller and Auditor General*
*National Audit Office*
*157-197 Buckingham Palace Road*
*Victoria*
*London*
*SW1W 9SP*

*2 July 2012*

# The Accounts of the Health Research Authority 2011/12 for the period 1 December 2011 to 31 March 2012

## Statement of Comprehensive Net Expenditure for the period ended 31st March 2012

| | Notes | 2011-12 £000 |
|---|---|---|
| **Administration** | | |
| **Expenditure** | | |
| Staff Costs | 3 | **2,020** |
| Amortisation | 4.2 | **48** |
| Other Expenditure | 4.2 | **1,488** |
| | | **3,556** |
| **Income** | | |
| Income from Activities | 6 | **111** |
| | | **111** |
| **Net Expenditure and resource outturn** | | **3,445** |

The notes on pages 36 to 55 form part of these accounts.

These accounts include transactions for the period from 1st December 2011 when the organisation was established.

## Statement of Financial Position as at 31st March 2012

| | Notes | 31 March 2012 |
|---|---|---|
| | | £000 |
| **Non-Current Assets** | | |
| Property, plant & equipment | 7.1 | **0** |
| Intangible assets | 7.2 | **212** |
| **Total non-current assets** | | **212** |
| **Current assets** | | |
| Trade and other receivables | 8.1 | **96** |
| Cash and cash equivalents | 9 | **3,574** |
| **Total current assets** | | **3,670** |
| **Total assets** | | **3,882** |
| **Current liabilities** | | |
| Trade and other payables | 10.1 | **2,877** |
| **Total current liabilities** | | **2,877** |
| **Non-current assets plus net current assets** | | **1,005** |
| **Assets less liabilities** | | **1,005** |
| **Taxpayers' equity** | | |
| General fund | | **1,005** |
| **Total taxpayers' equity** | | **1,005** |

*The financial statements on pages 32 to 35 were signed on behalf of the Health Research Authority by:*

Chief Executive :

## Statement of Cash Flows for the period ended 31st March 2012

| | Notes | 2011-12 |
|---|---|---|
| | | £000 |
| **Cash flows from operating activities** | | |
| Net operating costs | | **(3,445)** |
| Adjustments amortisation | | **48** |
| Increase in trade and other receivables | | **(96)** |
| Increase in trade payables | | **2,877** |
| Less: liabilities assumed not passing through Statement of Comprehensive Net Expenditure | | **(2,882)** |
| **Net cash (outflow) from operating activities** | | **(3,498)** |
| **Cash flows from investing activities** | | |
| Purchase of plant, property and equipment | | **0** |
| Purchase of intangible assets | | **0** |
| **Net cash inflow/(outflow) from investing activities** | | **0** |
| **Cash flows from financing activities** | | |
| Net Parliamentary funding | | **7,072** |
| **Net financing** | | **7,072** |
| **Net increase in cash and cash equivalents** | | **3,574** |
| Cash and cash equivalents at 1 December 2011 | | **0** |
| **Cash and cash equivalents at 31 March 2012** | **9** | **3,574** |

The notes at pages 36 to 55 form part of these accounts.

## Statement of Changes in Taxpayers' Equity for the period ended 31 March 2012

| | General Fund |
|---|---|
| | £000 |
| **Balance at 1 December 2011 (on inception)** | **0** |
| Net assets transferred from NPSA (Note 21) | 260 |
| Liabilities assumed from the Department of Health | (2,882) |
| | **(2,622)** |
| Net operating costs | (3,445) |
| **Total recognised income and expenditure for the period** | **(3,445)** |
| Parliamentary Funding for resources | 4,190 |
| Parliamentary Funding for liabilities to NHS hosts | 2,882 |
| **Total Parliamentary Funding from Department of Health** | **7,072** |
| **Balance as at 31 March 2012** | **1,005** |

The HRA was established on 1 December 2011. The NRES transferred to HRA on 1 December 2011

## Notes to the Accounts

### 1 Accounting Policies

These financial statements have been prepared in accordance with the 2011-12 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 for the purpose of giving a true and fair view has been selected. 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.

### 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.

*Acquisitions and Discontinued Operations*

Activities are considered to be 'acquired' only if they are acquired from outside the public sector. Activities are considered to be 'discontinued' only if they cease entirely. They are not considered to be 'discontinued' if they transfer from one NHS body to another.

### 1.2 Income

Income is accounted for applying the accruals convention. The main source of funding for the Special Health Authority is Parliamentary grant from the Department of Health from Request for Resources 1 within an approved cash limit, 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 on a full-cost basis to external customers, as well as public repayment work, but it also includes other income such as that from Devolved Administrations and from other NHS organisations. It includes both income appropriated-in-aid and income to the Consolidated Fund which HM Treasury has agreed should be treated as operating income. 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 Property, Plant & Equipment

### *(a) Capitalisation*

Property, Plant & Equipment is capitalised when it is capable of being used for more than 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 £250, 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; or
- form part of the initial setting-up cost of a new building, irrespective of their individual or collective cost.

### *(b) Valuation*

Property, plant and equipment are capitalised initially at cost. They are carried on the statement of financial position at costs net of depreciation and impairment, or depreciated replacement cost, where materially different.

### *(c) Intangible Assets*

Intangible assets with a useful economic life of more than year and a cost of at least £5,000 are capitalised initially at cost. They are carried on the statement of financial position at cost, net of amortisation and impairment, or depreciated replacement cost, where materially different.

### *(d) Depreciation, amortisation and impairments*

Depreciation is charged on each individual component of non-current assets

Assets under construction are not depreciated.

Intangible assets 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 |
| Bespoke Software licence | 7 |
| Intangible Information Technology | 5 to 7 |

Equipment and IT Assets, furniture and fittings are depreciated on a straight line basis over the estimated lives of the asset:

| | Years |
|---|---|
| Plant & Machinery | 5 |
| Tangible Information Technology | 5 |
| Furniture and fittings | 5 to 10 |

### 1.6 Inventories

Inventories are valued at the lower of cost and net realisable value.

### 1.7 Cash and cash equivalents

Cash is the balance held with the Government Banking Service. Cash in hand are petty cash imprests held within the Health Research Authority.

### 1.8 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 Statement of Comprehensive Net Expenditure 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). However, note 15 is compiled directly from the losses and special payments register which is prepared on a cash basis.

### 1.9 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 into the following period.

*Retirement benefit costs*

Past and present employees are covered by the provisions of the NHS Pensions Scheme. The scheme is an unfunded, defined benefit scheme that covers NHS employers, General Practices and other bodies, allowed under the direction of the Secretary of State, in England and Wales. The scheme is not designed to be run in a way that would enable NHS bodies to identify their share of the underlying scheme 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.

### 1.10 Research and Development

Research and development expenditure is charged against income in the year in which it is incurred, except insofar as development expenditure relates to a clearly defined project and the benefits of it can reasonably be regarded as assured. Expenditure so deferred is limited to the value of future benefits expected and is amortised through the Statement of Comprehensive Net Expenditure on a systematic basis over the period expected to benefit from the project. It should be revalued on the basis of current cost. The amortisation is calculated on the same basis as depreciation, on a quarterly basis.

### 1.11 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.

Where a lease is for land and buildings, the land and building components are separated where possible. Leased land is treated as an operating lease. Leased buildings are assessed as to whether they are operating or finance leases.

### 1.12 Foreign exchange

Transactions which are denominated in a foreign currency are translated into sterling at the exchange rate ruling on the date of each transaction, except where rates do not fluctuate significantly, in which case an average rate for a period is used. Resulting

exchange gains and losses are taken to the Statement of Comprehensive Net Expenditure.

### 1.13 Provisions

The Authority provides for legal or constructive obligations that are of uncertain timing or amount at the Statement of Financial Position date on the basis of the best estimate of the expenditure required to settle the obligation. Where the effect of the time value of money is significant, the estimated risk-adjusted cash flows are discounted using the Treasury's discount rate of 2.2% in real terms.

### 1.14 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, prepayments, NHS receivables, accrued income and 'other debtors'.

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 cast 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 Comprehensive Net 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.

*Financial liabilities at fair value through profit and loss*

Embedded derivatives that have different risks and characteristics to their host contracts, and contracts with embedded derivatives whose separate value cannot be ascertained, are treated as financial liabilities at fair value through profit and loss. They are held at fair value, with any resultant gain or loss recognised in the Statement of Comprehensive Net Expenditure. The net gain or loss incorporates any interest earned on the financial asset.

### 1.15 Transfer of Functions

On 1 December 2011 the functions of NRES, its assets and liabilities transferred from the NPSA to HRA. The HRA also became the appointing authority for research ethics committees in England and assumed the liabilities for NHS Hosts' RECs recharges.

The transfers have been accounted for as acquisitions under IFRS 3, Business Combinations. The identifiable assets acquired and liabilities assumed have been recognised at fair value (equivalent to the book value transferred) on the date of transfer. The reserves acquired have been recognised in the general fund.

## 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

### Executive members and staff costs:

| | Total 2011-12 | Permanently employed | Other |
|---|---|---|---|
| | £000 | £000 | £000 |
| Salaries and wages | **1,613** | 355 | 1,258 |
| Social security costs | **28** | 28 | 0 |
| Employer contributions to NHSPA | **47** | 47 | 0 |
| Redundancies/notice | **332** | 0 | **332** |
| **Total** | **2,020** | **430** | **1,590** |

**The average number of persons employed during the year was :**

| | 2011-12 Total | Permanently employed | Other |
|---|---|---|---|
| | Number | Number | Number |
| **Total** | **126** | **24** | **102** |

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

*Expenditure of staff benefits*

There was no expenditure made on staff benefits to the 31st March 2012.

*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 retirements during 2011-12. This information has been supplied by NHS Pensions.

*Early retirements and redundancies*

£332k has been charged to the revenue account in 2011-12 in respect of redundancies and the cost of notice worked in the new year. All of these staff were employed by other NHS bodies and the costs were recharged to the Health Research Authority.

| Exit package cost band | Number of compulsory redundancies | Total cost of exit packages by cost band (£000's) |
|---|---|---|
| <£20,001 | 5 | 74 |
| £20,001 - £40,000 | 2 | 60 |
| £40,001 - £100,000 | 3 | 171 |
| £100,001 - £150,000 | | |
| £150,001 - £200,000 | | |
| £200,001 - £250,000 | | |
| £250,001 - £300,000 | | |
| £300,001 - £350,000 | | |
| **Total number and cost of exit packages where notice issued in 2011/12** | **10** | **305** |

Redundancy costs have been calculated in accordance with the provisions of NHS Agenda for Change Terms and Conditions. Where there is an entitlement to Early Retirement under those conditions the actuarial cost payable to the NHS Pensions Agency is shown. Exit costs have been accounted for in the year in which the triggering event occurs that will result in that redundancy. The figures above include only those staff who received notice of their redundancy as a result of a triggering event in the year. For those staff who did not receive notice they will be disclosed in the year notice is issued. The triggering events that have led to the redundancies were the announcement by the Department of Health (DH) of the closure of the National Patient Safety Agency and reorganisations in order to reduce costs in line with falls in resources available from the DH.

There are no payments that are Special Payments.

## 4.1 Pension costs

Past and present employees are covered by the provisions of the NHS Pensions Scheme. Details of the benefits payable under these provisions can be found on the NHS Pensions website at www.nhsbsa.nhs.uk/pensions.

The scheme is an unfunded, defined benefit scheme that covers NHS employers, General Practices and other bodies, allowed under the direction of the Secretary of State, in England and Wales. The scheme is not designed to be run in a way that would enable NHS bodies to identify their share of the underlying scheme 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.

The scheme is subject to a full actuarial valuation every four years (until 2004, every five years) and an accounting valuation every year. The last formal actuarial valuation undertaken for the NHS Pension Scheme was completed in 2004. Consequently, a formal actuarial valuation would have been due by 2008. However, formal actuarial variations for unfunded public service pensions schemes have been suspended by HM Treasury on value for money grounds while consideration is given to recent changes to public service pensions and while future scheme terms are developed as part of the reforms to public service pension provision. The primary purpose of the formal actuarial valuations is to set employer and employee contribution rates, and these are currently being determined under the new scheme design.

An outline of these follows:

*a) Full actuarial (funding) valuation*

The purpose of this valuation is to assess the level of liability in respect of the benefits due under the scheme (taking into account its recent demographic experience), and to recommend the contribution rates to be paid by employers and scheme members. The last such valuation, which determined current contribution rates was undertaken as at 31 March 2004 and covered the period from 1 April 1999 to that date. The conclusion from the 2004 valuation was that the scheme had accumulated a notional deficit of £3.3 billion against the notional assets as at 31 March 2004.

In order to defray the costs of benefits, employers pay contributions at 14% of pensionable pay and most employees had up to April 2008 paid 6%, with manual staff paying 5%.

Following the full actuarial review by the Government Actuary undertaken as at 31 March 2004, and after consideration of changes to the NHS Pension Scheme taking effect from 1 April 2008, his Valuation report recommended that employer contributions could continue at the existing rate of 14% of pensionable pay, from 1 April 2008, following the introduction of employee contributions on a tiered scale from 5% up to 8.5% of their pensionable pay depending on total earnings. On advice from the scheme actuary, scheme contributions may be varied from time to time to reflect changes in the scheme's liabilities.

*b) Accounting Valuation*

A valuation of the scheme liability is carried out annually by the scheme actuary as at the end of the reporting period by updating the results of the full actuarial valuation.

Between the full actuarial valuations at a two-year midpoint, a full and detailed member data-set is provided to the scheme actuary. At this point the assumptions regarding the composition of the scheme membership are updated to allow the scheme liability to be valued.

The valuation of the scheme liability as at 31 March 2011, is based on detailed membership data as at 31 March 2008 (the latest midpoint) updated to 31 March 2011 with summary global member and accounting data.

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)

Resource Account, published annually. These accounts can be viewed on the NHS Pensions website. Copies can also be obtained from The Stationery Office.

### *c) Scheme provisions*

In 2008-09 the NHS Pension Scheme provided defined benefits, which are summarised below. This list is an illustrative guide only, and is not intended to detail all the benefits provided by the Scheme or the specific conditions that must be met before these benefits can be obtained.

#### *Annual Pensions*

The Scheme is a "final salary" scheme. Annual pensions are normally based on 1/80th for the 1995 section and of the best of the last three years pensionable pay for each year of service, and 1/60th for the 2008 section of reckonable pay per year of membership. Members who are practitioners as defined by the Scheme Regulations have their annual pensions based upon total pensionable earnings over the relevant pensionable service.

With effect from 1 April 2008 members can choose to give up some of their annual pension for an additional tax free lump sum, up to a maximum amount permitted under HMRC rules. This new provision is known as "pension commutation".

#### *Pensions Indexation*

Annual increases are applied to pension payments at rates defined by the Pensions (Increase) Act 1971, and are based on changes in retail prices in the twelve months ending 30 September in the previous calendar year.

#### *Lump Sum Allowance*

A lump sum is payable on retirement which is normally three times the annual pension payment.

#### *Ill-Health Retirement*

Early payment of a pension, with enhancement in certain circumstances, is available to members of the Scheme who are permanently incapable of fulfilling their duties or regular employment effectively through illness or infirmity.

#### *Death Benefits*

A death gratuity of twice their final year's pensionable pay for death in service, and five times their annual pension for death after retirement is payable.

#### *Additional Voluntary Contributions (AVCs)*

Members can purchase additional service in the NHS Scheme and contribute to money purchase AVC's run by the Scheme's approved providers or by other Free Standing Additional Voluntary Contributions (FSAVC) providers.

#### *Transfer between Funds*

Scheme members have the option to transfer their pension between the NHS Pension Scheme and another scheme when they move into or out of NHS employment.

#### *Preserved Benefits*

Where a scheme member ceases NHS employment with more than two years service they can preserve their accrued NHS pension for payment when they reach retirement age.

*Compensation for Early Retirement*

Where a member of the Scheme is made redundant they may be entitled to early receipt of their pension plus enhancement, at the employer's cost.

## 4.2 Other Operating Costs

The Health Research Authority costs all relate to Administration costs

| | Note | | 2011-12 |
|---|---|---|---|
| | | | £000 |
| Salaries and wages | 3 | | **1,688** |
| Redundancies and notice worked in 2011/12 | 3 | | **332** |
| Total Staff Costs | | | **2,020** |
| Rentals under operating leases | | | **26** |
| Supplies and Services - general | | | **29** |
| Establishment expenses | | | **343** |
| Transport and moveable plant | | | **3** |
| Premises and fixed plant | | | **680** |
| Capital: | | | |
| Amortisation | | **48** | |
| Loss on disposal of non-current assets | | **0** | |
| | | | **48** |
| Auditors' remuneration: (*) | | | **25** |
| Miscellaneous | | | **382** |
| **Total programme costs** | | | **3,556** |

*The Authority did not make any payments to Auditors for non-audit work.

## 4.3 Better Payment Practice Code - measure of compliance

| | 2011-12 Number |
|---|---|
| Total Non-NHS trade invoices paid in the period | **3,591** |
| Total Non-NHS trade invoices paid within target | **3,506** |
| Percentage of Non-NHS trade invoices paid within target | **97.6%** |
| Total NHS trade invoices in the period | **156** |
| Total NHS trade invoices paid within target | **141** |
| Percentage of NHS trade invoices paid within target | **90.4%** |

## 5.1 Reconciliation of net operating cost to net resource outturn

| | 2011-12 £000 |
|---|---|
| Charge Against Revenue Resource Limit | **3,445** |
| Revenue Resource Limit | **4,443** |
| **Underspend against Revenue Resource Limit** | **998** |

## 5.2 Reconciliation of gross capital expenditure to capital resource limit

| | 2011-12 £000 |
|---|---|
| Gross Capital Expenditure | **0** |
| Less: Net Book Value of assets disposed of | **0** |
| **Charge against the Capital Resource Limit** | **0** |
| Capital Resource Limit | **95** |
| **Underspend Against Capital Resource Limit** | **95** |

## 6 Operating Revenue Income

| | Appropriated in Aid | Not Appropriated in Aid | 2011-12 |
|---|---|---|---|
| | £000 | £000 | £000 |
| **Administration** | | | |
| Fees & charges to external customers | **5** | **0** | **5** |
| Income received from Scottish Parliament | **0** | **55** | **55** |
| Income received from National Assembly for Wales | **0** | **32** | **32** |
| Income received from Northern Ireland Assembly | **0** | **19** | **19** |
| **Total Administration revenue** | **5** | **106** | **111** |

### 7.1 Property, Plant and Equipment

The Health Research Authority did not hold any Property, Plant and Equipment assets as at the 31st March 2012.

### 7.2 Intangible assets

| | Information Technology | 31 March 2012 |
|---|---|---|
| | £000 | £000 |
| **Gross cost at 1 December 2011** | 0 | **0** |
| Assets transferred in from NRES (note 21) | 982 | **982** |
| **Gross cost at 31 March 2012** | **982** | **982** |
| **Amortisation** | | |
| Accumulated amortisation at 1 December 2011 | 0 | **0** |
| Amortisation (for assets transferred in) (note 21) | 722 | **722** |
| Charged during the year | 48 | **48** |
| Disposals | 0 | **0** |
| **Accumulated amortisation at 31 March 2012** | **770** | **770** |
| **Net book value at 31 March 2012** | **212** | **212** |
| **Net book value at 1 December 2011** | **0** | **0** |

The HRA was established on 1 December 2011. The NRES transferred to HRA on 1 December 2011

## 8 Trade Receivables

### 8.1 Amounts falling due within one year

| | 31 March 2012 £000 |
|---|---|
| Other receivables | **81** |
| Prepayments and accrued income | **15** |
| **Trade and other receivables** | **96** |

## 9 Cash and Cash Equivalents

| | As at 1 December 2011 £000 | Change in period £000 | As at 31 March 2012 £000 |
|---|---|---|---|
| GBS cash at bank | 0 | 3,574 | **3,574** |
| **Total** | **0** | **3,574** | **3,574** |

| | |
|---|---|
| **Comprising:** | |
| Held with Government Banking Service | **3,574** |
| **Balance at 31st March 2012** | **3,574** |

## 10 Trade Payables and Other Current Liabilities

### 10.1 Amounts falling due within one year

| | 31 March 2012 £000 |
|---|---|
| Trade payables | **810** |
| Accruals and deferred income | **2,067** |
| **Trade and other payables** | **2,877** |
| Other taxation and social security | **0** |
| **Other Current liabilities** | **0** |
| **Total trade payables and other current liabilities** | **2,877** |

## 11 Contingent Liabilities

At 31 March 2012, there were no known contingent liabilities.

## 12 Capital Commitments

At 31 March 2012 the value of contracted capital commitments was £0.

## 13 Commitments Under Leases

*Operating leases*

There is an implied lease between the HRA and the DH. 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. Total future minimum lease payments under this implied operating lease are given in the table below for each of the following periods.

| | 2011-12 £000 |
|---|---|
| Obligations under operating leases comprise: | |
| **Buildings** | |
| Not later than one year | 187 |
| Later than one year and not later than five years | 520 |
| Later than five years | 0 |
| | **707** |
| **Other Leases** | |
| Not later than one year | 0 |
| Later than one year and not later than five years | 0 |

| | 0 |
|---|---|

## 14 Other Financial Commitments

The Health Research Authority has entered into a contract relating to the provision of financial and accounting as well as payroll services commencing on the 1st April 2012 for 1 year. The total cost of the contract is £170,000

| | 2011-12 £000 |
|---|---|
| Not later than one year | 170 |
| | 170 |

## 15 Losses and Special Payments

There were no cases of losses or special payments during the year.

## 16 Related Party Transactions

The Health Research Authority is a body corporate 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.

The Heath 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).

| | Payments in Year 2011/12 | Receipts in year 2011/12 | Debtor @31.03.12 | Creditor @31.03.12 |
|---|---|---|---|---|
| | £000 | £000 | £000 | £000 |
| City & Hackney PCT | 0 | 0 | 0 | 92 |
| Department of Health | 111 | 0 | 0 | 0 |
| East Midlands Strategic Health Authority | 155 | 0 | 0 | 95 |
| East of England Strategic Health Authority | 307 | 0 | 0 | 216 |
| Guys & St Thomas NHS Trust | 0 | 0 | 0 | 110 |
| Imperial College Healthcare NHS Trust | 474 | 0 | 0 | 196 |
| Leeds Partnership NHS Foundation Trust | 115 | 0 | 0 | 91 |
| NHS London | 0 | 0 | 0 | 566 |
| NHS North West | 234 | 0 | 0 | 110 |
| North East Strategic Health Authority | 53 | 0 | 0 | 125 |
| Nottingham County PCT | 0 | 0 | 0 | 128 |
| North West London Healthcare Trust | 0 | 0 | 0 | 61 |
| St Georges NHS Trust | 0 | 0 | 0 | 65 |
| Stockton on tees Teaching PCT | 0 | 0 | 0 | 78 |
| South East Coast SHA | 114 | 0 | 0 | 0 |
| South West SHA | 314 | 0 | 0 | 0 |
| Stockport PCT | 254 | 0 | 0 | 0 |
| West Midlands Strategic Health Authority | 300 | 0 | 0 | 249 |
| University Hospitals of Bristol NHS Foundation Trust | 0 | 0 | 0 | 76 |
| Yorkshire and Humber SHA | 233 | 0 | 0 | 0 |

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

There are no events after the reporting period to report. 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 Authority in 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 takes measures to minimise all foreign currency risk. The Health Research Authority has no foreign currency risk.

### *Interest rate risk*

100% of the 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. Bad debt provisions are calculated based on the type of debtor, ageing or the outstanding debt and knowledge of specific queries on the balances.

The Health Resource Authority had no trade debtors as at 31 March 2012

### *Supplier Risk*

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

The ageing of NHS and Non NHS Trade creditors at the reporting date was:

| | £000 |
|---|---|
| Not past due | 417 |
| Past due 0-30 days | 5 |
| Past due 31-120 days | 3 |
| More than 121 days | 0 |

### *Fair values*

The Health Research Authority has no significant long-term debtors and creditors and therefore the book values are not different from the fair value.

## 19 Intra-government balances

| | Current receivables | Non-current receivables | Current payables | Non-current payables |
|---|---|---|---|---|
| | £000s | £000s | £000s | £000s |
| Balances with other central government bodies | 77 | 0 | 1,488 | 0 |
| Balances with NHS Trusts | 0 | 0 | 942 | 0 |
| | **77** | **0** | **2,430** | **0** |
| Balances with bodies external to government | 19 | 0 | 447 | 0 |
| **At 31 March 2012** | **96** | **0** | **2,877** | **0** |

## 20 IFRS Disclosure

### *Early adoption of IFRS's, amendments and 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*

*IAS 8, Accounting Policies, Changes in Accounting Estimates and Errors*, require disclosures in respect of new IFRS's, amendments and interpretations that are, or will be applicable after the accounting period. There are a number of IFRS's, amendments and interpretations issued by the International Accounting Standards Board that are effective for financial statements after this accounting period. The following have not been adopted early by the HRA:

- *IFRS 7 Financial Instruments: Disclosures* Amendment to allow for better comparisons between financial statements. The effective date is for accounting periods beginning on or after 1 January 2013. Also an amendment to improve the disclosure requirements in relation to transferred financial assets which is effective for accounting periods beginning on or after 1 July 2011.
- *IFRS 9 Financial Instruments* A new standard intended to replace IAS39. The effective date is for accounting periods beginning on, or after 1 January 2015.
- *IFRS 13 Fair Value Measurement* IFRS 13 applies when other IFRS's require or permit fair value measurements. The new requirements are effective for accounting periods beginning on, or after 1 January 2013.
- *IAS 1 Presentation of Financial Statements* Amendment to the existing standard to improve disclosures to users of the accounts. The effective date is for accounting periods beginning on, or after 1 June 2012.
- *IAS 19 Employee Benefits* The amendments will improve the recognition and disclosure requirements for defined benefit plans and modify the accounting for termination benefits. The new requirements are effective for accounting periods beginning on or after 1 January 2013.
- *IAS 32 Offsetting Financial Assets and Financial Liabilities* Amendments to clarify the application of offsetting requirements. The amendments are effective for accounting periods beginning on or after 1 January 2014.

None of these new or amended standards and interpretations are likely to be applicable or are anticipated to have future material impact on the financial statements of the HRA.

## 21 Transfer to the HRA of NRES and liabilities to NHS Hosts

### *NRES*

On 1 December 2011 the functions of NRES, its assets and liabilities, transferred from NPSA to HRA. The assets and liabilities acquired on that day were:

| | 1 December 2011 |
|---|---|
| | £000 |
| **Non-current assets** | |
| Intangible assets | 260 |
| **Total non-current assets** | **260** |
| **Current assets** | |
| Trade and other receivables | **152** |
| Cash and cash equivalents | **46** |
| **Total current assets** | **198** |
| **Total assets** | **458** |
| **Current liabilities** | |
| Trade and other payables | **198** |
| **Total current liabilities** | **198** |
| **Non-current assets plus net current assets** | **260** |
| **Assets less liabilities** | **260** |
| **Taxpayers' Equity** | |
| General fund | **260** |
| **Total Taxpayers' Equity** | **260** |

### *Liabilities to NHS Hosts*

On 1 December 2011 HRA became the appointing authority for Research Ethics Committees (RECs) in England and assumed the liabilities for NHS Hosts' RECs recharges. The liabilities of £2,882,000 received have been recognised as trade payables or accruals and a corresponding charge has been made to the general fund.

# HRA Contact Details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## Glossary

| | |
|---|---|
| **AMRC** | Association of Medical Research Charities |
| **Appointing Authority** | The body responsible for the appointment and indemnification of RECs |
| **ARSAC** | Administration of Radioactive Substances Advisory Committee |
| **CRN CC** | Clinical Research Network Co-ordinating Centre |
| **Clinical Trials Regulations** | The Medicines for Human Use (Clinical Trials) Regulations 2004 |
| **CTIMP** | Clinical trial of an investigational medicinal product (any other type of research is known as a non-CTIMP) |
| **DH** | Department of Health |
| **EU Directive** | Directive 2001/20 EC of the European Parliament and the Council of the European Union relating to the implementation of good clinical practice in the conduct of clinical trials of medicinal products for human use |
| **GAfREC** | The UK Health Departments' Governance Arrangements for Research Ethics Committees |
| **HFEA** | Human Fertilisation and Embryology Authority |
| **HRA** | Health Research Authority (Special Health Authority established from 1 December 2011) |
| **HTA** | Human Tissue Authority |
| **INVOLVE** | INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. INVOLVE is funded by and is part of the NIHR |
| **IRAS** | Integrated Research Application System, the online application system used to apply for most permissions and approvals for research in health and social care in the UK (www.myresearchproject.org.uk) |
| **MHRA** | Medicines and Healthcare products Regulatory Agency. MHRA (Medicines) is the competent authority for the UK in relation to the EU Directive and the Clinical Trials Regulations. MHRA (Devices) is the competent authority for the UK in relation to the Medical Devices Regulations 2002 |
| **NDPB** | Non-Departmental Public Body |
| **NIGB** | National Information Governance Board for Health and Social Care |

| | |
|---|---|
| **NIHR** | National Institute for Health Research |
| **NRES** | National Research Ethics Service |
| **NRES Director** | The senior manager with overall responsibility for management of the National Research Ethics Service |
| **REC** | A Research Ethics Committee established in any part of the UK in accordance with GAfREC and/or recognised by the UKECA under the Clinical Trials Regulations |
| **SCIE** | Social Care Institute for Excellence |
| **SOPs** | The Standard Operating Procedures for Research Ethics Committees |
| **SpHA** | Special Health Authority |
| **Sponsor** | The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study |
| **UKECA** | United Kingdom Ethics Committee Authority |


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ISBN 978-0-10-297756-1