NHS
Health Research Authority

Health Research Authority
Annual report and accounts
for the year to 31 March 2013

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1. Foreword

Thank you for reading our Annual Report and Accounts. In the first full year of operation we have aimed to establish a way of working with partners with a view to getting things done and making a difference – making concrete improvements now, as well as charting a course for the future.

We have a big agenda that is important for researchers, the NHS, industry and academia, for the health and wealth of our country, but above all for current and future patients. We cannot deliver it alone, but we can make a significant difference by working in collaboration.

The Health Research Authority (HRA) exists to protect and promote the interests of patients, participants and the public in health research. To do this, we need to understand their expectations. Our experience so far suggests that they want and expect a good research base for the care they receive, have an appetite for contributing to it, see the importance of openness and transparency, and value the oversight of Research Ethics Committees (RECs) in ensuring that their interests are protected, while avoiding unnecessary bureaucracy. It is already clear that there is a fundamental link between promoting and protecting their interests in health research and that these are complementary, rather than in conflict. Patients, participants and the public share a common interest with researchers and sponsors in good, ethical research being carried out, subject to proportionate regulation.

I am immensely grateful to Janet Wisely, her team and HRA committee members for creating such a solid foundation. Thanks also to all those who have helped to shape our vision that the UK should be a global leader for health research. The challenges for us are significant, but the prize is certainly worth the effort.

Professor Jonathan Montgomery
Chair

2. Introduction

The Health Research Authority (HRA) was established on 1 December 2011 as a Special Health Authority. This annual report is therefore the first full year report for the HRA and has been a year in which we have taken great strides in establishing the organisation and roles for the HRA, as well as continuing to provide and improve the National Research Ethics Service (NRES) at the HRA.

This year has seen my appointment as Chief Executive of the HRA, and appointments to the Board. I am delighted to have the opportunity to lead this new and ambitious organisation. At all levels in the country there is a collective determination to work collaboratively to address what have been well documented frustrations at the complexity and inefficiencies in setting up and managing research in the NHS. We are now in an excellent position to drive through the required improvements so we can make it easier to do good quality research in the UK.

The HRA has taken time this year to set out an agenda that is already making a difference and I am delighted to be able to report the excellent progress that has been made. The coming year will be pivotal for the HRA as we work to deliver tangible improvement. There is recognition of our good start and much is expected of us.

I would like to thank the Board, my senior team, staff and committee members at the HRA for their continued support and hard work. I would also like to thank colleagues in other organisations that give their time and commitment to the organisation, members of our Collaboration and Development Steering Group and others who recognise the need for us to work together for the benefit of researchers, industry, the NHS, patients and the public, and the health and wealth of the nation.

Dr Janet Wisely
Chief Executive

3. Our remit, principles and ambition

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 we provide the NRES. Our ambition is to make the UK a great place for research, where more money invested in research goes into carrying out relevant, good quality research.

Our purpose is to ensure that research involving members of the public is ethically reviewed and approved, that they are provided with the information they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the processes by which high quality research is assessed.

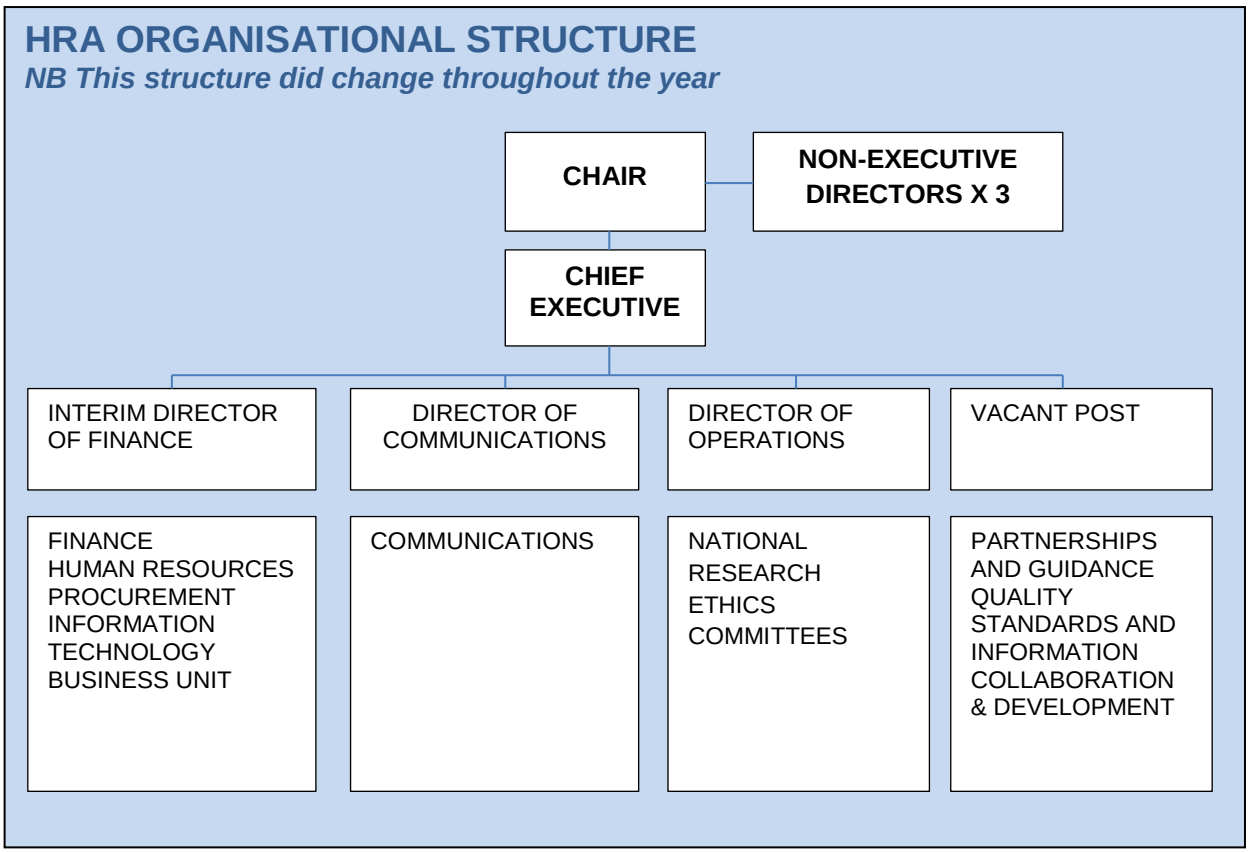
To achieve this, we will work with all relevant partners to help create an environment where:

- greater numbers of patients and the public can and do take part in health 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; and
- clinical trials are registered and research results get published.

4. The year at a glance

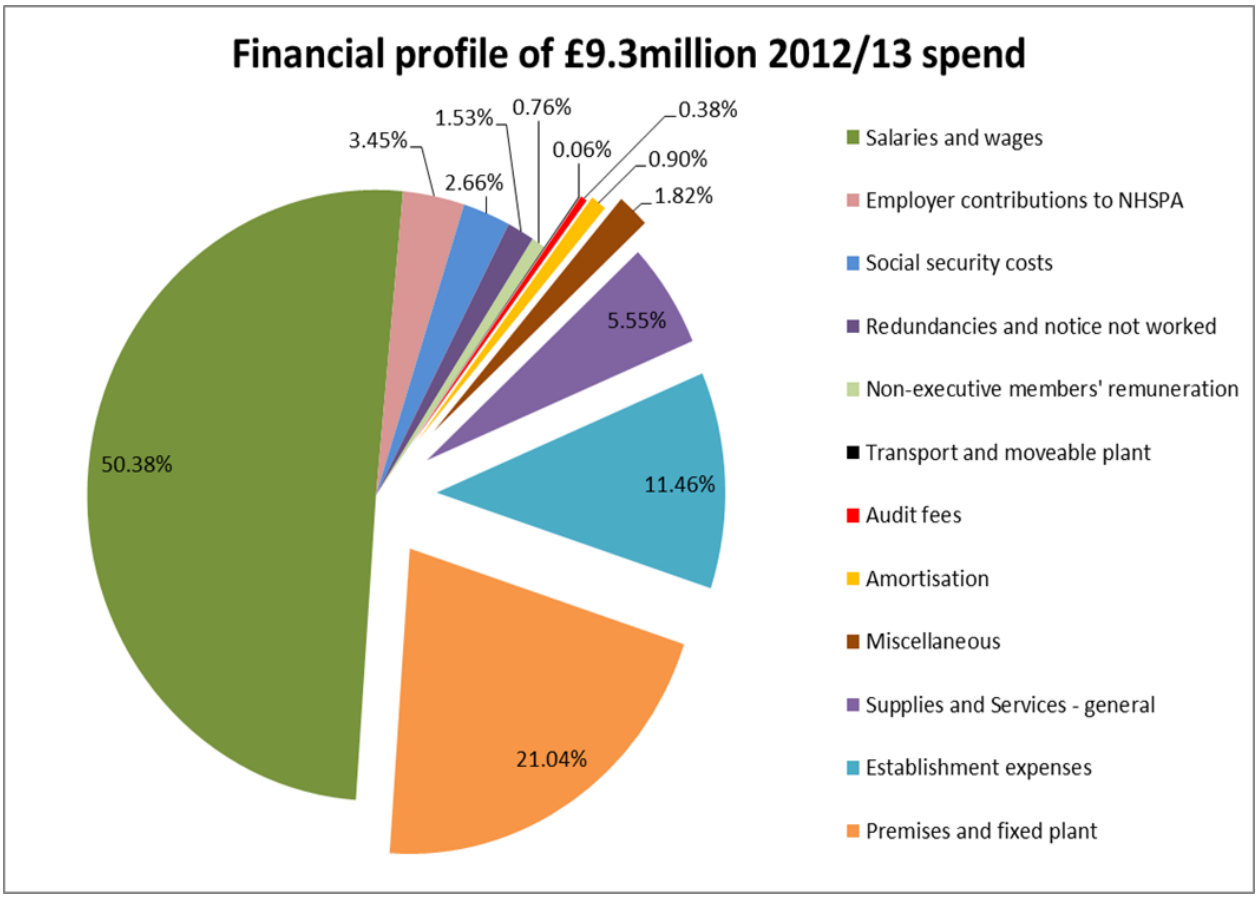
This year the organisation has achieved significant progress (see KPIs in ***Appendix 1***) in developing as a new organisation while also maintaining critical functions. Key highlights were:

- appointed a Chair and 3 Non-Executive Directors to the Board;
- appointed a Chief Executive and completed recruitment to other senior team vacancies;
- successfully transferred in NRES hosted staff to the HRA;
- set up a staff partnership forum, held the first all staff day and completed the first staff survey;
- established structures for managing work under the main areas of business: finance, corporate, improvement, collaboration and development, NRES Operations:

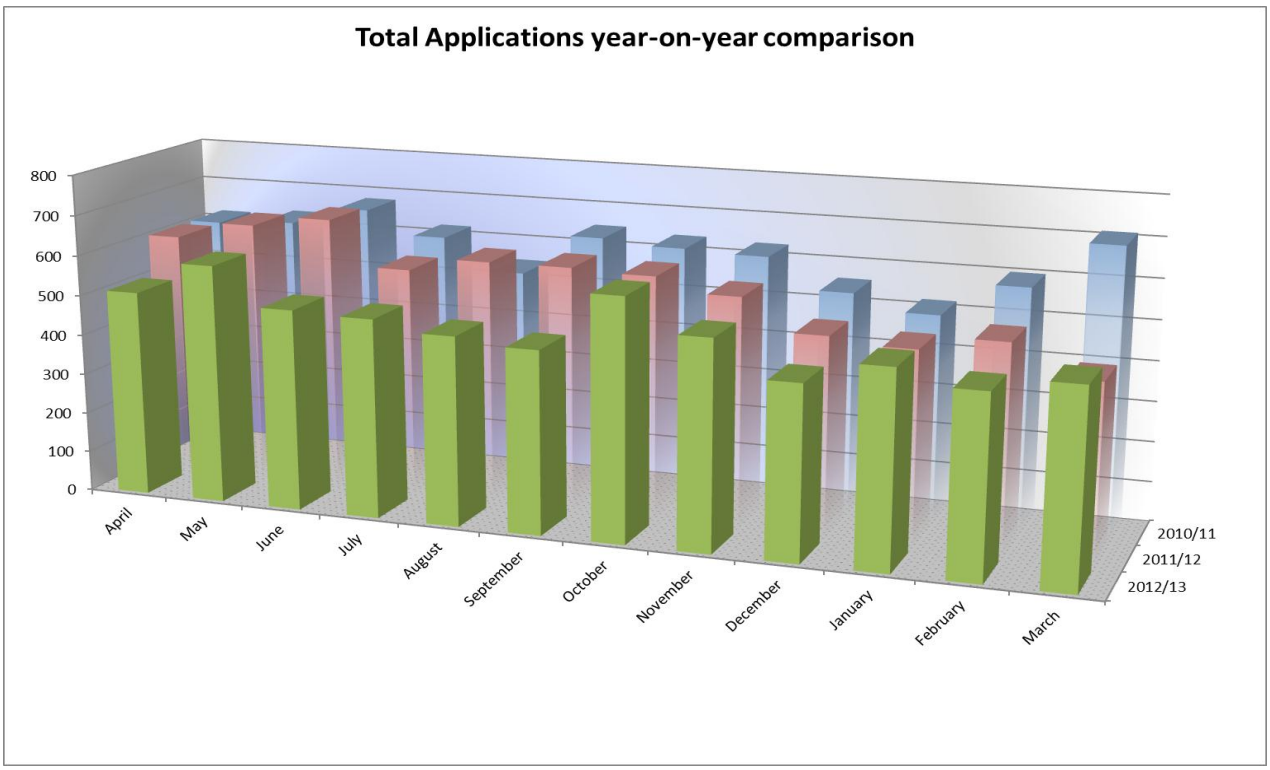


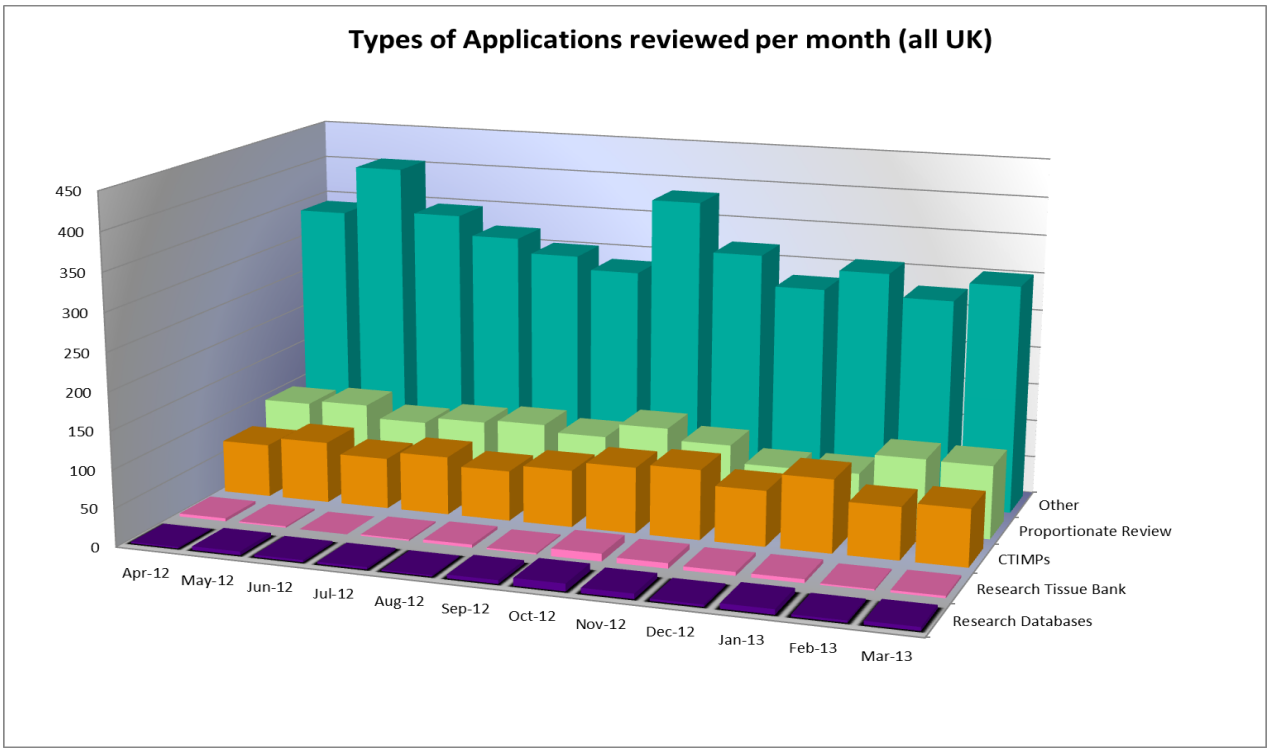
Total No: of staff	**Circa 123** (*116 whole time equivalent*) as at 31 March 2013				
Staff Profile	Female	Male	Disabled	Non-white British	Age Ranges
	78%	22%	>1%	31%	Evenly dispersed between 20 - 60
Turnover	6.5% (7% in NHS as a whole)				
Sickness Rates		Total	Short term sickness	Long term sickness	
	Whole Year	4.9%	1.48%	3.42%	
	March	2.64%			
	April	2.56%			
NB: Organisational changes throughout the year led to an overall decrease in total staff numbers and minor changes to profiles					

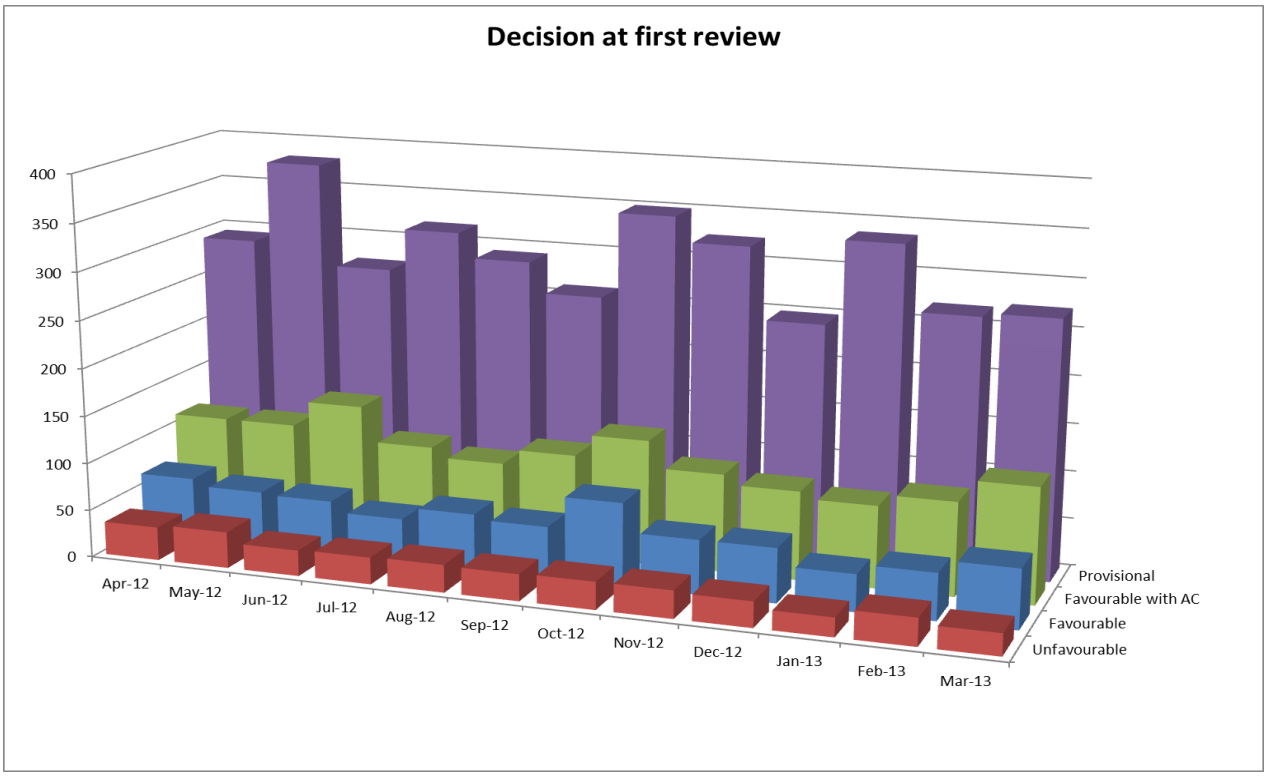
- continued to develop all required governance arrangements as the organisation matured and demonstrated this through internal and external audit;
- completed business within required budget envelope. £9.3 million was spent from an available budget of £9.7 million and an underspend in line with forecasts and expectations. The main reasons for the under spend were:
  a. reduction in developments to IRAS (Integrated Research Application System) as a result of the decision to proceed to procure a new system;
  b. reduced level of redundancies as a result of closing two HRA offices due to staff successfully securing alternative employment;
  c. project cost timing of actual expenditure later than originally planned; and
  d. finalisation of outstanding balances with Strategic Health Authorities not requiring deployment of operational reserves

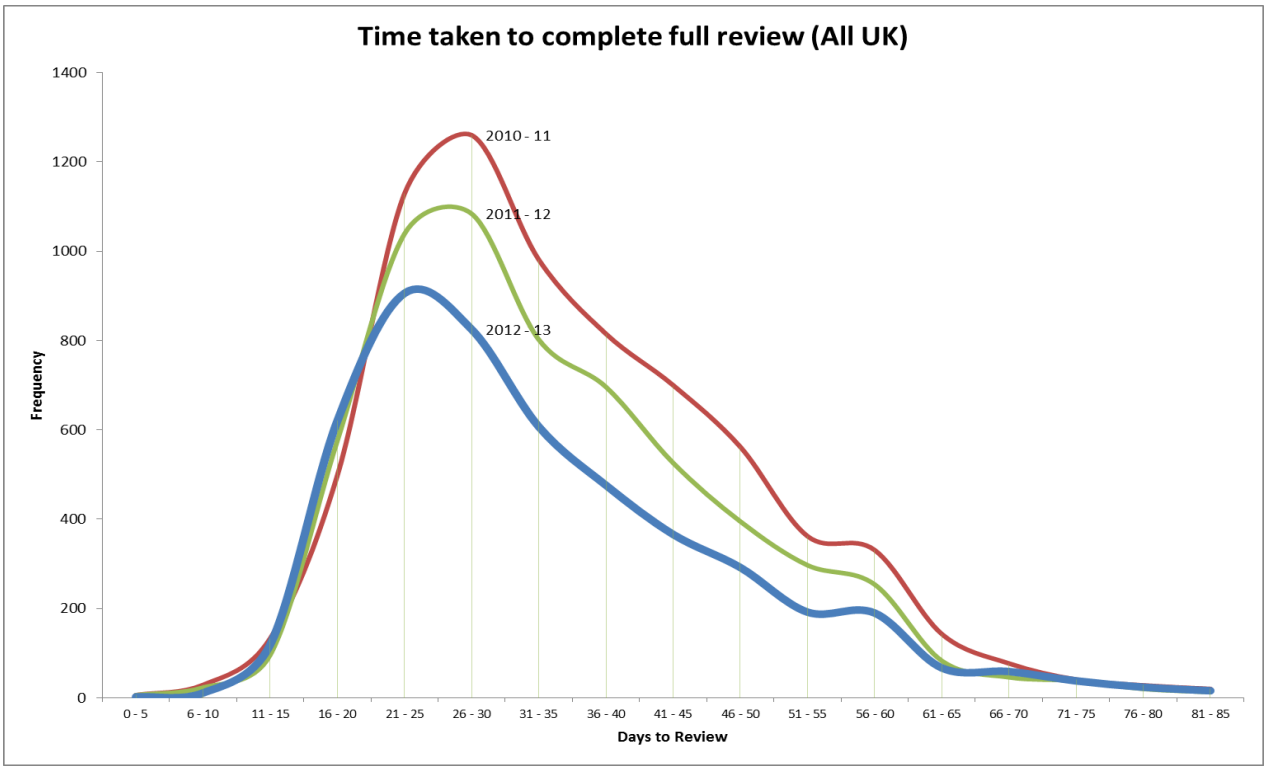


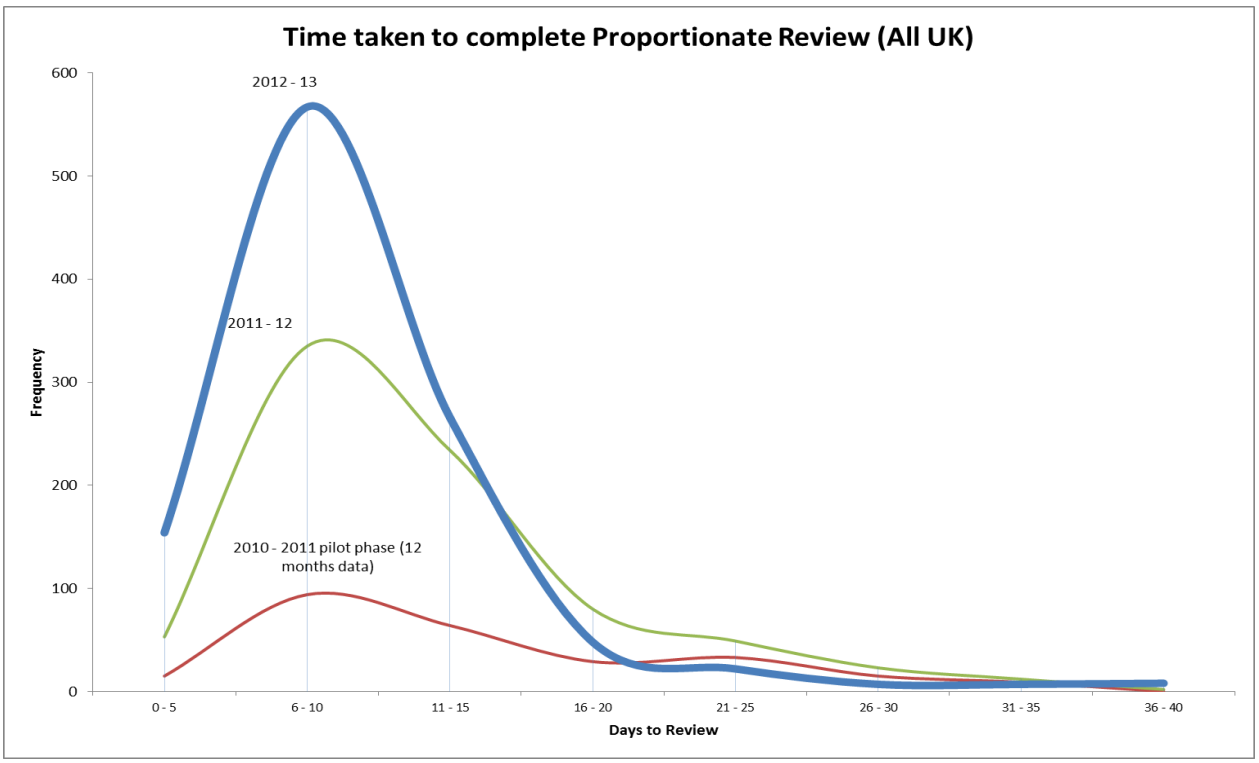
- achieved efficiencies to meet obligations set out in the comprehensive spending review. The organisation was required to make £1 million of savings during the year which had to fund the absorption of new functions as well as cash releasing savings. These were delivered alongside planning for further savings in 2013-14 required in the spending review;
- continued to provide NRES within operational targets and delivered improvement, including reduction in submission deadlines for early phase trials in response to Industry feedback;
  The charts overleaf highlight the operational achievements of NRES

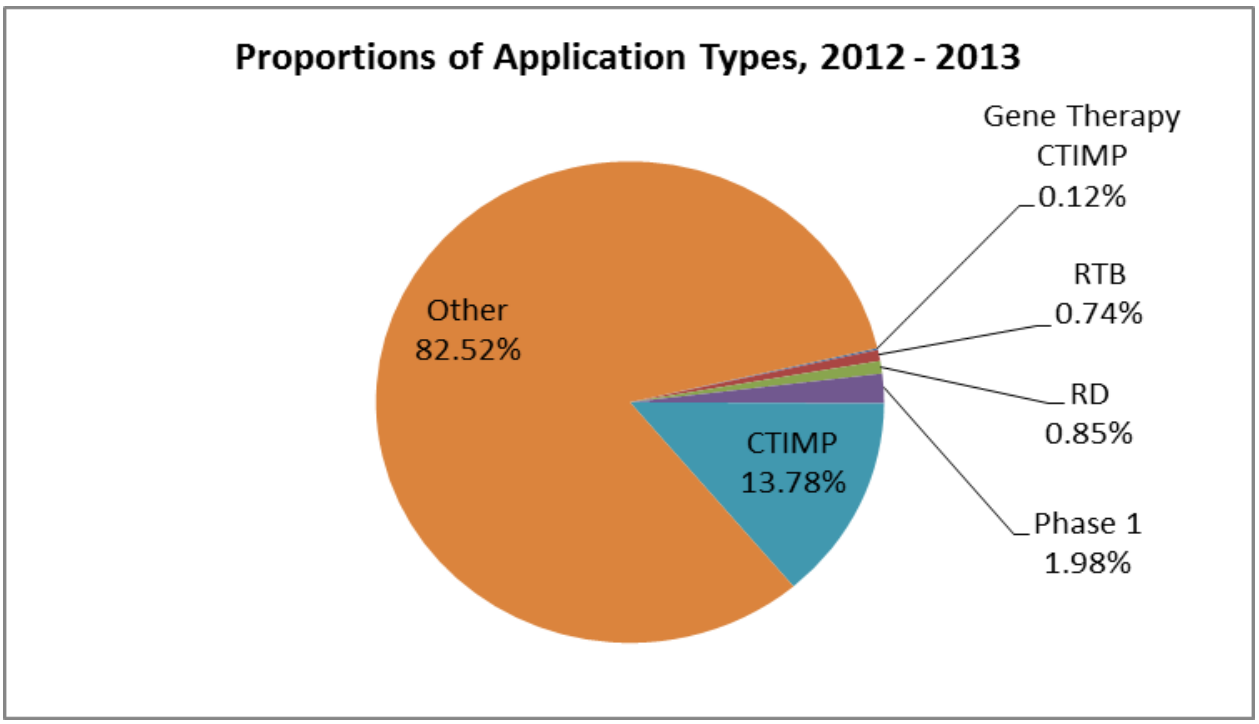

Total Applications year-on-year comparison
800
700
600
500
400
300
200
100
0
April
May
June
July
August
September
October
November
December
January
February
March
2010/11
2011/12
2012/13


Types of Applications reviewed per month (all UK)
450
400
350
300
250
200
150
100
50
0
Apr-12
May-12
Jun-12
Jul-12
Aug-12
Sep-12
Oct-12
Nov-12
Dec-12
Jan-13
Feb-13
Mar-13
Other
Proportionate Review
CTIMPs
Research Tissue Bank
Research Databases


Decision at first review
400
350
300
250
200
150
100
50
0
Apr-12
May-12
Jun-12
Jul-12
Aug-12
Sep-12
Oct-12
Nov-12
Dec-12
Jan-13
Feb-13
Mar-13
Provisional
Favourable with AC
Favourable
Unfavourable

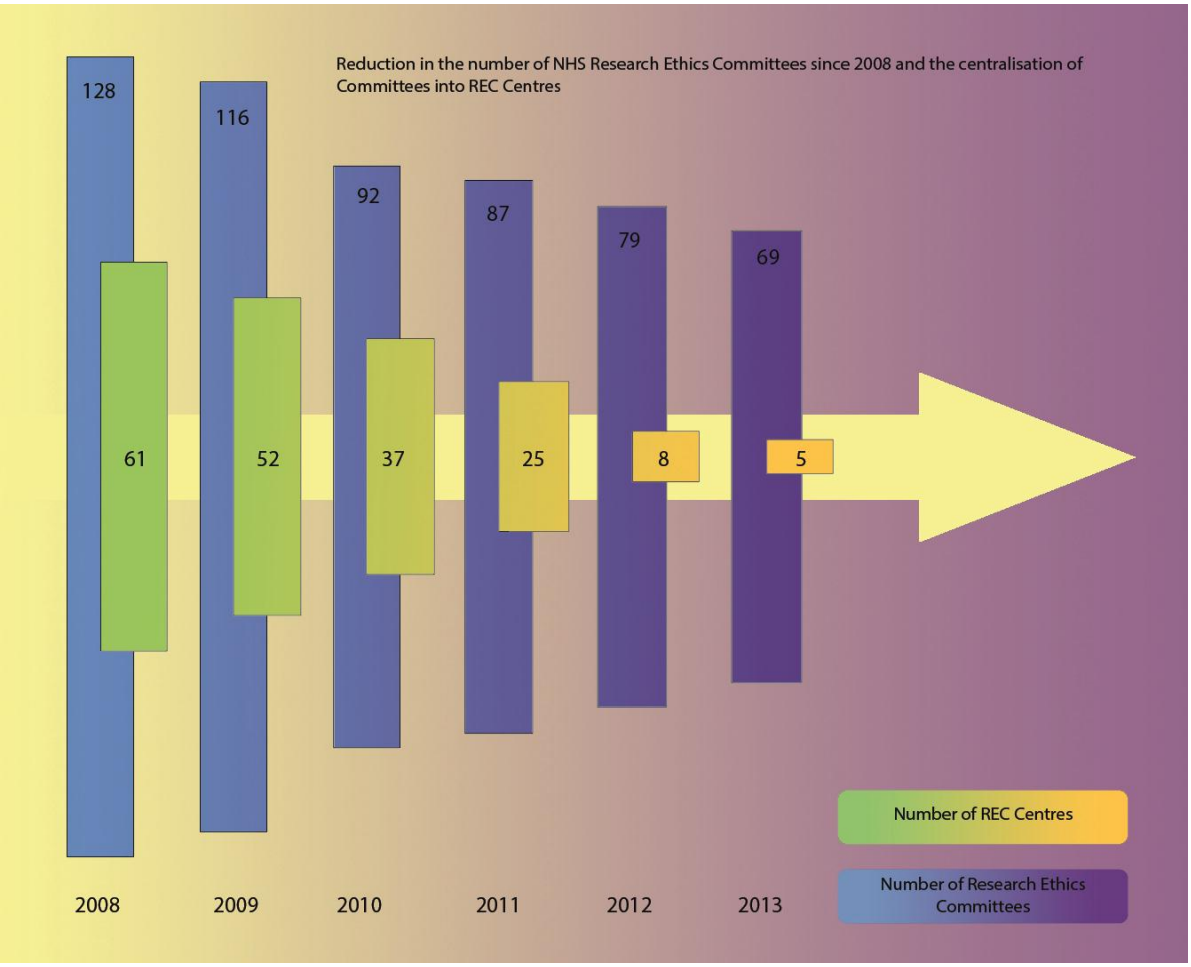

Time taken to complete full review (All UK)
1400
1200
1000
800
600
400
200
0
Frequency
2010 - 11
2011 - 12
2012 - 13
0 - 5
6 - 10
11 - 15
16 - 20
21 - 25
26 - 30
31 - 35
36 - 40
41 - 45
46 - 50
51 - 55
56 - 60
61 - 65
66 - 70
71 - 75
76 - 80
81 - 85
Days to Review



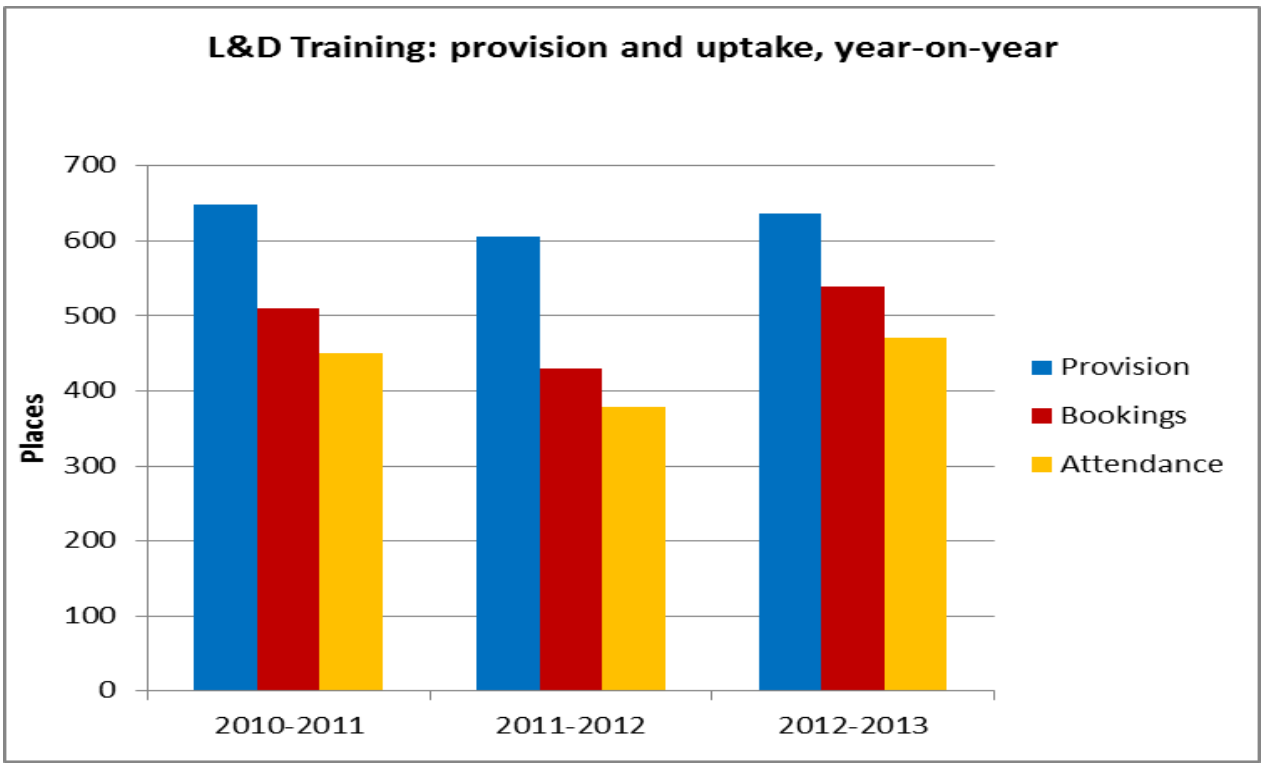


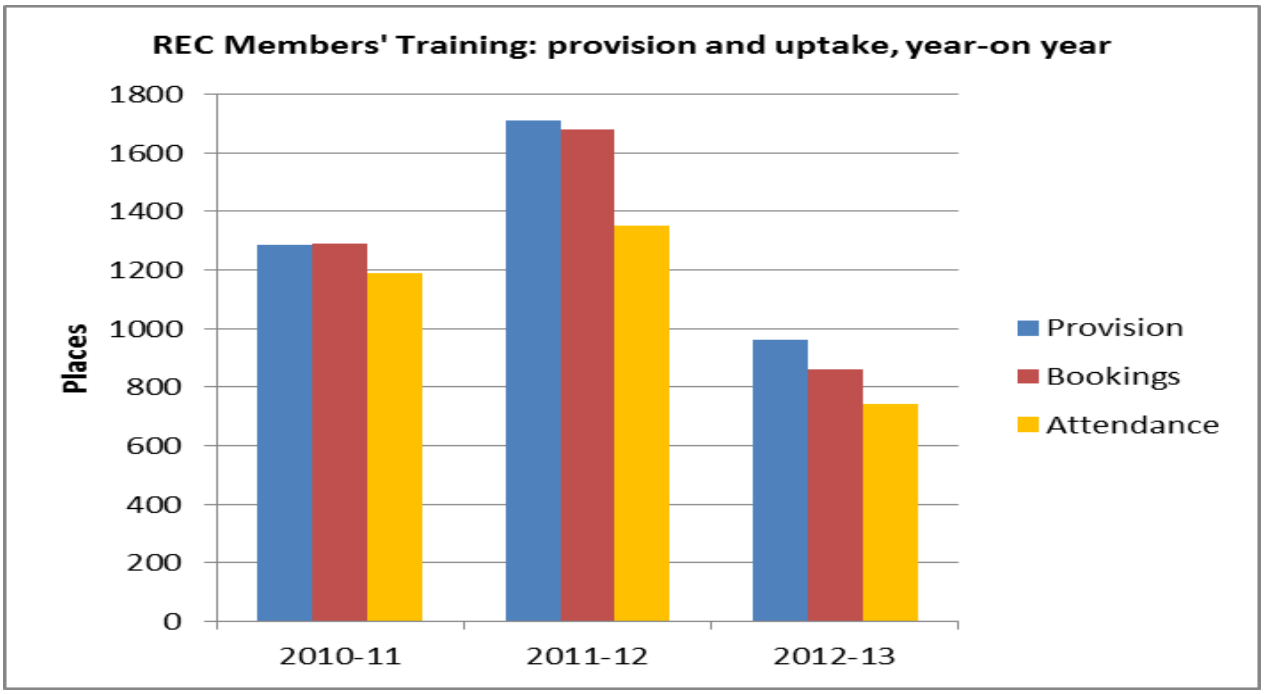
- taken responsibility for the Gene Therapy Advisory Committee (GTAC) and delivered immediate improvement to service provision for applicants;
- successfully managed the transfer from the National Information Governance Board (NIGB) of the advice and approval for access to confidential data service under section 251 of the NHS to commence from 1 April 2013;
- set up a Confidentiality Advisory Group (CAG);
- secured funding from ScienceWise to undertake a comprehensive public dialogue programme to inform policy and objectives;

- completed a project to scope current public involvement in health research to inform the development of a HRA public involvement strategy;
- continued to provide an email advice service and local support to applicants;
- completed the development of the first HRA decision tools;
- closed two HRA offices to consolidate staff onto five sites at London (Skipton House), Jarrow, Manchester, Bristol and Nottingham;
- completed a programme of Research Ethics Committees (REC) closures to reduce the number of RECs in England from 79 to 69 so that REC capacity continues to meet applicant demand, with RECs routinely reviewing 5-6 applications per meeting;



- assisted with the development of and supported the UK response to the EU consultation on the revision to the Clinical Trial Directive;
- maintained ISO9001 certification for the Quality Assurance directorate;
- delivered a comprehensive programme of training for staff, committee members, researchers, industry and those involved in research governance;





- put in place simple measures to improve the coordination of activity between NRES and NHS Research and Development (R&D) departments;
- developed proposals for a feasibility study of HRA assessment to support approval of research in the NHS, and progressed the proposals through to a pilot and test phase;
- set up a Collaboration and Development Steering Group for a programme of activity led by the HRA where implementation will require response by it and others;

- took forward early projects within the Steering Group to set out proportionate standards for researcher training, amendments in the NHS, approach to local agreements on site application forms and the use of an IRAS ID (project identifier);
- worked with EQUATOR to develop proposals for a structured study title for research in the UK;
- responded to consultations and calls for evidence, including data transparency in research and the Care and Support Bill (now the Care Bill 2013); and
- developed proposals and established a project to re-build the organisation website.

5. Directors' reports – delivering improvements

Performance against 2012-13 Objectives

5.1 Objective 1

To maintain and develop effective governance and leadership for the HRA

Previously an executive-only board upon establishment, the HRA has now appointed to the Chair and three Non-Executive Director (NED) positions. To ensure a staggered approach to Board renewal, two NEDs were appointed for three years and the other for two years. The Board operates according to the framework agreement with the Department of Health (DH) and a statutory instrument governs its functions. The Board meets on a quarterly basis in public, with additional Board seminars held throughout the year. Three full Board meetings were held in 2012-13.

The Board has established two sub-committees; the Audit and Risk Committee and the Pay and Remuneration Committee. The role of the Audit and Risk Committee is to advise the HRA's Accounting Officer and the Board on risk management, corporate governance and assurance arrangements in the HRA. The duties of the Remuneration Committee include advising the Board about appropriate remuneration and terms of service for the Chief Executive, other Executive Directors and those on Very Senior Manager Terms and Conditions of Service. A Health and Safety Committee has also been established.

A governance review was completed in May 2012 by DH Internal Audit and an action plan progressed. A further governance review was undertaken in March 2013. Overall assurance was reported as being amber/green with an opportunity for minor improvement to the control environment.

The transition programme for the HRA establishment has been a success with all staff now directly employed. Other moves to DH-provided shared services for Arm's Length Bodies (ALBs), such as the Business Services Authority and NHS Shared Business Services, have also taken place.

The HRA Staff Partnership Forum (SPF) has been established and is the main forum for consultation and staff involvement. It acts as an agreed forum that fulfils the statutory obligations to consult and discuss matters affecting the interests of staff. Culture and values development days for both staff and REC Chairs were also held in February 2013.

The HRA has a working draft involvement strategy and further work to consider patient and public involvement and stakeholder engagement will take place in 2013-14. A two day stakeholder event was held in February 2013.

5.2 Objective 2
To develop and maintain an effective communication strategy for the HRA

The first communications strategy was approved by the Board in July 2012 and revised in September. A part-time Director of Communications, seconded from the Human Tissue Authority (HTA) for two days a week, and a full time Head of Communications were appointed in November 2012 and January 2013, respectively. Implementation of the strategy is now underway after some delays in recruitment and negotiation through central procurement rules.

The HRA's first stakeholder forum, which took place in February, was attended by 150 delegates including researchers, people representing patients and the public and those involved in regulating health research. Delegates were brought up-to-date on our ambition to make it easier to do good quality research in the NHS and briefed on what we have delivered in our first year. They also learnt about the projects within the remit of the HRA Collaboration and Development Steering Group, and were given opportunities to get involved as we take forward our ambitious programme of work. As well as the HRA Chair, Chief Executive and Executive team, speakers included Sir Iain Chalmers of the James Lind Initiative and representatives of the Department of Health, the National Institute for Health Research and GlaxoSmithKline.

We worked with the Government Procurement Service to appoint agencies in March to deliver the new visual identify and fully functioning website, due in quarters 1 and 2 of the 2013-14 business year, respectively.

5.3 Objective 3
The provision of a platform for the unified approval process from IRAS

The Integrated Research Application System (IRAS) is a system provided by the HRA for all the IRAS partners, and is the system through which research regulatory and governance applications are made in the UK. The IRAS has been widely acknowledged as leading to considerable reduction of bureaucracy associated with generation of applications for regulatory and governance approvals in the UK.

During 2012-13 the organisation has:

- continued to provide the IRAS on behalf of the IRAS partners and has maintained the excellent record of system availability with IRAS available 24 hours a day, 7 days a week with less than 0.1% 'downtime' for system upgrades and maintenance;
- implemented the agreed early changes to deliver greater coordination of a unified approvals process from the system:
    - removal of NHS Site Specific Information (SSI) form question 23, which asks for signed confirmation on local agreements, eg pharmacy, and replacement with a confirmation by the investigator that they have discussed the study with local R&D;

  - making the IRAS project identifier available and visible on creation of the project in IRAS. This provides an additional universal reference number to complement those currently used by funders, sponsors, IRAS partners, trial registers and publishers. While the IRAS identifier will not be able to replace all other identifiers, the universal use of one identifier will address reported problems in identifying studies across the different systems and also support effective identification of funded and completed research; and
  - roll-out of full e-submission for all applications for NHS R&D permission processed via the National Institute of Health Research(NIHR) Coordinated System for gaining NHS Permission (NIHR CSP). Previously only recently created projects were able to make use of this functionality leaving forms created in older projects to use different, less streamlined processes. The roll-out of this functionality to all applications to NIHR CSP improves consistency and reduces confusion for applicants;
- made updates to IRAS to reflect the recent guidance that was issued on insurance and compensation arrangements in commercially sponsored Phase 1 trials in healthy volunteers; and
- remodelled the requirements for updates in IRAS to deliver the changes that the Administration of Radioactive Substances Advisory Committee (ARSAC) are making to move to a more integrated process with the NHS RECs.

During 2012, the Human Fertilisation and Embryology (HFEA) joined the IRAS partnership. A full list of current IRAS partners is contained at ***Appendix 2.***

The HRA had intended during 2012-13 to roll-out the full electronic submission functionality for applications to RECs and to the Medicines and Healthcare products Regulatory Agency (MHRA). However, in late summer 2012, the HRA announced that the delivery of this work was on hold pending a review of the functionality in the existing IRAS platform and in recognition of the possible significant process changes that are likely to come through from the HRA's Collaboration and Development programmes. It was the agreed late in 2012 that the most appropriate course of action was to maintain the existing system while a next generation system, which can deliver substantive future requirements, is procured and developed.

5.4 Objective 4
To improve and develop our advice and information services

During 2012-13, the HRA has continued to provide advice, support, information and guidance to RECs, researchers and others involved in supporting and managing research in the UK. It has achieved this through the information provided on the website, the email queries lines and expert advice provided through individual correspondence by staff and members of committees.

We have:

- continued to reply to requests for advice received through its queries lines and correspondence;
- responded to Freedom of Information requests;

- started development of decision tools to support researchers in determining whether their study is research and/or whether it requires REC approval and also to help decide which category of research best describes their study in filter question 2 of IRAS. These tools, which have been developed with the assistance of user groups, complement existing guidance and routes of support; the first of these tools will be published in quarter 1 of 2013-14;
- developed and issued guidance, including a statement issued about appropriate training for researchers; and
- developed proposals for integration of existing queries lines into a single consolidated queries line, which will be an integral part of an HRA advice service.

The National Research Ethics Advisors' Panel (NREAP)

The Panel was originally established in 2009 to help with the strategy, quality assurance and service development of RECs and improve the research environment in the UK. Since their inception they have released guidance and advised both NRES and its RECs on a number of important issues (see http://www.nres.nhs.uk/about-the-national-research-ethics-service/nrea/ for published guidance).

Following the establishment of the HRA, the NREAP conducted a thorough review of its membership and terms of reference. In October 2012 the NREAP re-launched with seven members and a new focus: to help RECs deliver robust, consistent and fair decisions. The Panel will achieve this through engagement and consultation with all stakeholders, including RECs, with an interest in health research in order to inform and deliver appropriate guidance and training to the REC community and researchers.

The Panel continued to meet and additionally held NREA-hosted meetings in each of the Centres where many ethical issues were raised and discussed. Chairs in the Centres have indicated how useful they find these meetings. Individual members of the Panel provided expertise to help resolve complex issues raised by RECs and researchers.

During 2012-13 the NREAP considered a range of topics, in the main suggested from the REC community. The minutes of the meetings are published on the website.

Formal advice was published on the following topics:

- What do potential research participants want to know?;
- The need to inform participants' GPs of their patients taking part in research; and
- Payments and incentives (including statements regarding their effect on benefit payments).

5.5 Objective 5
Maintain and build confidence in the HRA and health research in the UK

The HRA's role is to promote and protect the interests of patients and the public in health research. To fulfil this role it must have an effective public involvement strategy. The HRA set up a time limited project team to help inform what an effective public involvement strategy would look like and how we could measure the success of such a strategy.

From that initial project, two further pieces of work have been undertaken this year under the guidance of a steering group chaired by Simon Denegri, the NIHR National Director for Public Participation and Engagement in Research. Specifically, the HRA has recognised that it needs to understand current patient and public involvement work in the NHS for health research so it can set out roles that complement and build on this activity, not duplicate, and so learn from what has already been done by others.

A mapping project, specifically looking to inform recommendations to the HRA has been completed and has set out a series of recommendations which will be considered by the Board for delivery in 2013-14. The recommendations include early deliverables to set out a strategy for involvement that can be delivered by the HRA, such as establishing principles for good public involvement, considering for each activity and project what public involvement can contribute and setting up a public involvement panel to provide a resource for the public involvement. The recommendations also include areas where the HRA can influence and work with others, for example in providing best practice guidance for public involvement and simple tools to support this for researchers and others. The project report will be published on the HRA website.

The HRA also recognised that much current involvement activity in the NHS focusses on the patient involvement, and was keen to ensure it also involved the public more generally.

The HRA successfully secured funding from ScienceWise (http://www.sciencewise-erc.org.uk/) for a comprehensive programme of public dialogue. The aims were to inform current strategy and objectives and to gather views that will inform principles to underpin a more fundamental review of policy relating to health research in the UK. The dialogue and engagement part of the project has been completed this year, with the report being made available in due course. We will consider next steps in light of the findings from this project.

NRES had established national roles which at the HRA have been given greater authority and prominence. Through these and new roles, the organisation is gaining respect as a national leader and authority for health research. Specifically, the Chief Executive Chairs and the HRA provides secretariat to the UK Ethics Committee Authority and the Four Nations meetings. Through these the HRA takes a lead role in ensuring the UK delivers responsibilities for clinical trials as required in the UK Clinical Trial Regulations, and that a UK-wide system for research ethics is maintained.

A greater focus is a UK-wide approach for regulation and governance more broadly and the HRA is committed to working with colleagues in the devolved administrations to ensure that improvements delivered through the Collaboration and Development programme are coordinated UK-wide, even where they cannot all be implemented in the same way UK wide. The HRA is also represented on the MHRA steering group to provide the UK response to the consideration of the revision to the EU clinical trials directive and implementation of a new EU clinical trials regulation.

A key role for us is to help shape and inform policy and opinion on matters relating to health research in the UK. This year the HRA has given evidence to support select committee consideration on regenerative medicine and open clinical data, as well as the legislation in the Care and Support Bill (now the Care Bill 2013) to establish the HRA as a non-departmental public body (NDPB). It is essential that the organisation can continue to

speak with authority on such issues and demonstrate commitment to important principles such as transparency in research.

The HRA publishes the REC opinions on research applications and is rolling out a programme to also publish the applicant provided research summary. RECs are also asked to consider researcher plans for dissemination and publication of results, access to data and tissue and plans to tell research participants about the findings from the study. In recognition of the importance of transparency in research, the HRA has this year put in place mechanisms to explore how RECs consider these issues, how RECs may identify issues at the approval stage that need to be addressed early to ensure transparency later (for example potential conflicts of interest and handling strategies) and how the HRA may monitor compliance with approved plans within the REC opinion. The HRA set out a position paper and sought views from key stakeholders before setting out a programme of work for next year to take this agenda forward. We are also signed up to the All Trials campaign.

Essential to maintaining and building confidence is demonstrating quality in all that we do. The HRA has through its Quality Assurance directorate an ISO9001 certified programme of activity, including quality control and accreditation of the RECs.

5.6 Objective 6

Shaping an effective national role for the HRA – the unified approval process and promotion of proportionate standards for compliance and inspection

The Collaboration and Development Programme

A multi-agency project team completed a process review of the current health research environment in the UK in 2011-12 based on evidence from the research community and put forward recommendations for roles that the HRA could take forward. The Board agreed on an update to the Business Plan for setting out a range of activities where the organisation would lead improvements, or would have a role in influencing change by others.

A UK-wide Collaboration and Development Steering Group of stakeholders (***Appendix 3***) has been established to oversee the scoping, development and implementation of projects where the HRA will provide a platform for a wide range of organisations to work collectively to deliver change to the research environment. The HRA has adopted a co-production approach on the projects within this collaborative programme, using a range of methods to engage with stakeholders to create and test proposals together.

During the year, a priority area was a scoping exercise which led to agreement from the Department of Health to test the potential benefits of a simplified and streamlined HRA Assessment for all research in the NHS. The assessment would combine and replace aspects of the current review by NHS Research and Development (R&D) and RECs in order to improve both study set-up times and the quality and consistency of ethical review. The project was initiated through a range of task groups involving the REC and R&D community in developing detailed proposals. A range of approaches will be used in the spring of 2013 to test and refine the proposals, after which a decision will be made on whether to move to full implementation.

A key project, with potential to produce both immediate and long-term improvements, focusses on interactions between REC and R&D staff. For historical reasons, communication and interfaces between REC and R&D staff across the country are

variable. This project provides an opportunity to share good practice to provide a more seamless system for researchers. Shared induction and training will improve the quality of the approvals system while also paving the way for future potential developments, such as the HRA Assessment.

A stakeholder forum in February 2013 provided an opportunity to update the community on areas of work already underway and to explore projects in development. The adoption of the IRAS project number, as a unique identifier throughout the research pathway, is an example of a change where many partners need to be involved. The HRA now includes the IRAS identifier on correspondence from RECs alongside other identifiers, and has made the number visible as soon as a project is created in IRAS.

The NIHR CSP also routinely uses the IRAS identifier, so communication between the HRA and CSP about individual studies is now simpler. However, to achieve maximum benefit in communication and to support transparency from funding to publication many more organisations need to adopt this identifier alongside use of standardised formats for study titles. Feedback was obtained from stakeholders on a range of new projects, including development of a new IRAS, the handling of amendments, standards for sponsorship and researcher competency.

Arrangements have been put in place for a number of individuals from within and outside the organisation to dedicate time to working on these collaborative projects from April 2013.

5.7 Objective 7

To provide an efficient, responsive, proportionate, effective and robust National Research Ethics Service

The NRES has continued to operate to a high level of service delivery and maintained its reputation for the provision of an excellent service. During the year 2012-13, NRES Research Ethics Committees (RECs) in England reviewed 4,840 applications. Of these applications, 900 were processed through the proportionate review service. The proportionate review service is now operated through 63 RECs and is delivering a final opinion rate well within the 14-day timeline, with an average review time of 8 days. Additionally, 6,899 substantial amendments and 281 modified amendments were reviewed by RECs in England.

NRES took on responsibility for the former Independent Ethics Committees at Reading and Welwyn which now operate as NRES RECs. The Welwyn REC has recently merged with the Hertfordshire REC to form the Hatfield REC and Reading operates as Berkshire B. Both committees now review a wide range of applications.

All NRES staff transferred from their host organisations to the HRA by 1 September 2012. As part of the cost efficiency programme, two REC Centres (in Cambridge and Leeds) closed on 31 March 2013 and the administrative support transferred to other REC Centres. We would like to record our thanks to our staff who worked in those Centres for all their hard work during their time with us and for their professionalism, dedication and commitment to ensuring that they continued to deliver high quality services up until the closure. We wish those who left well for the future.

The number of RECs was also reduced from 79 to 69 through merger and closure of committees and there remains a good geographical spread of committees and availability of agenda slots.

These initiatives achieved savings in excess of £300,000, which the HRA will be able to utilise to fund new developments in taking forward its programme of work to improve the research environment in the UK.

November 2012 saw the closure of the GTAC (Gene Therapy Advisory Committee) and a revision of service provision for gene and stem cell therapy applications. Applicants now have the choice of review by four RECs with an increase in the number of meetings available from 6 to 44 per year and improved review times, with the first ever application being reviewed in under 60 days. The improved timelines and arrangements are welcomed by the research community.

The NRES has also introduced flagging for qualitative research studies. RECs were flagged based on the expertise of their members and the committee's experience of reviewing such studies. Researchers can be confident that these RECs will fully understand the methodologies used in qualitative research projects.

Communication to REC members was reviewed and information is now badged to indicate its source: HRA; NREAP; NRES. Within each communication, information is given a traffic light rating to highlight its importance and NRES information is signposted for dissemination to chairs and members.

Future Plans

The NRES will improve the timelines and processes for the review of Phase 1 research in the UK with RECs accepting submissions with a 7-day deadline.

We will continue to improve the timelines for submissions to the West London REC and GTAC and will review all within the legal timeline of 90 days and aim to review all within the standard approval time of 60 days. We will also work with the gene and stem cell therapy research community to see what further improvements can be made.

NRES Operations has undertaken an initial scoping exercise to look at the skill mix of staff working within REC Centres. We will take this work forward to ensure that we are utilising the skills and experience of our staff.

The categories of studies which can be processed through the proportionate review service will be expanded to enable more researchers to use the service which delivers a rapid review time.

A single booking line for proportionate review studies has been implemented so that applicants can obtain the first available agenda slot in the UK and this will be further expanded for all studies to make it easier for researchers to book their studies to a REC meeting.

There is a great deal of interest at the current time about the publication of research results and data. NRES will establish a register to follow up on applicants' stated intentions to publish.

UK Ethics Committee Authority

The UK Ethics Committee Authority (UKECA), established as required by the Clinical Trials Regulations, is chaired by the Chief Executive by agreement with the Department of Health

and the Devolved Administrations. The secretariat for UKECA is also provided by the HRA. Between April 2012 and March 2013, a total of seven meetings were held.

5.8 Objective 8
To test and evaluate further improvement to the National Research Ethics Service

Two pilots to look at further improvement to NRES were started between April 2012 and March 2013 and are still in progress with findings anticipated by autumn 2013.

The Proportionate Documentation for Proportionate Review (PD4PR) pilot, taking place in the North West, began in October 2012. The aim of the pilot is to test and evaluate whether applications with a reduced data set, ie fewer questions, can effectively be used by a Proportionate Review Sub-Committee to issue an ethical opinion for proportionate review service applications. Results from the pilot are expected by September 2013.

The Ethics Officer pilot, taking place in the North East and East Midlands began in November 2012. The objectives are to evaluate the role of an ethics officer function to see if it is possible to:

- increase the proportion of favourable opinions at first review, thus reducing the proportion of provisional opinions;
- improve the timelines of ethical review; and
- reduce the administrative burden on RECs and researchers.

The ethics officers, for the purpose of the evaluation, are experienced REC chairs and the function they provide will include giving an early assessment of the application form and associated documents, offering advice and support to the researcher, flagging any guidance or legal requirements the REC should consider and recording what advice the researcher received prior to submission.

The HRA has appointed an NRES Improvement Manager who will take forward a range of pilots and implementations to continue to improve the effectiveness and efficiency of NRES.

5.9 Objective 9
Standards and quality improvement

Maintained and developed the shared ethical debate programme

During the reporting period, four exercises have been reviewed: a single issue debate on inducements; a MCA (Mental Capacity Act) study; a Proportionate Review (PR) study looking at approval decisions (this was reviewed by both main and PR committees); and a qualitative study. In addition to the four scheduled exercises, an additional single issue debate was circulated to all UK RECs on the publication and dissemination of research and results. After each exercise a presentation was circulated to the RECs involved in order to deliver the results of the exercise and key findings. The results of the Shared Ethical Debate (ShED) relating to the review of an MCA application led the NRES Operational team to reintroduce the mandatory MCA flagging for RECs, in order to ensure that such studies are reviewed to the expected standards required by NRES Operations.

After receiving feedback from the RECs involved in the scheme, it has been agreed to amend the process to provide individual feedback to the RECs on their review compared to the others RECs and further develop guidance for use by stakeholders using the service.

The Programme has also continued with the following topics and applications reviewed:

- inducements (single issue debate);
- Phase 1; Mental Capacity; and
- A qualitative application looking at research on the internet.

Views have been extensively sought for improvements to the programme. A presentation for REC members was developed to supplement feedback delivered at facilitated workshops.

Maintained the audit and accreditation programme for the RECs and REC Centres

During the reporting period, the Quality Assurance department completed 24 audits with a welcome increase in the number of full accreditations, with and without conditions being awarded (42%) from the previous year (34%). Two Centre audits have been completed, Bristol and Manchester, both of which achieved full accreditation.

The Quality Control (QC) checklist was updated during the audit period in order to include new operational standards and in order to streamline the process further. QC training was delivered to NRES operational staff at three events during the year.

Further-developed user satisfaction reporting

The user satisfaction report was further developed during the reporting period in order to include an interim three-monthly report to the management teams on user feedback. This will enable the management teams to react promptly to any issues. A greater analysis of appeals data is now included in the report with observations and issues being made, which the HRA considers. Reports from the management teams are included to communicate changes made in response to feedback received through user satisfaction, from users of the service and HRA members and the appeals analysis.

Maintained ISO certification for the quality assurance programme

The Quality Assurance department maintained their ISO 9001 certification for their quality assurance programme and in 2013-14 is looking to expand HRA QA to include Section 251 and The Over-volunteering Protection System (TOPs) scheme.

Participant guidance

Work has been completed to revise the participant information sheet guidance and a range of multi-stakeholder workshops, including members of the public, have been held throughout the UK. This new guidance is currently being prepared on an interactive platform for both RECs and researchers.

Development of guidance is on-going in relation to recruitment for time-critical research and revision of the guidance on the use of ionising radiation in research has been progressed for completion in 2013.

6. Management commentary

6.1 Developing an organisation

The government announced the intention to establish a Health Research Authority in March 2011. The Authority was established rapidly with an executive-only Board on 1 December 2011. The work to establish the HRA was managed through a steering group chaired by Candy Morris, the Senior Responsible Owner for the establishment at the Department of Health. While the DH has led the policy and legislative aspects required to establish the HRA as a Special Health Authority and to prepare it to become a Non-Departmental Public Body, it has been responsible itself for all the practical aspects of the establishment. The organisation has negotiated core functions through shared services, including HR, Finance and Accounting, IT and payroll, and actively managed the transfer of all hosted staff into the HRA during 2012. The organisational development work required to ensure the organisation has been able to maintain services, as well as developing further extensive functions to improve the environment for research in the UK and preparing to be ready to receive new functions from the NIGB, has been considerable.

6.2 Information Governance

The HRA does not handle identifiable personal data other than that of its staff, members and researchers. Nevertheless, its position is that it must apply high standards of information governance to all records regardless. To maintain the highest standards of Information Governance in accordance with best practice and legal requirement the following governance structure was maintained throughout the year:

- the Chief Executive is the Board level Senior Information Risk Owner (SIRO);
- Dr Hugh Davies, HRA Ethics Advisor is the Caldicott Guardian (formally appointed, approved as substantive by the Board on 22 January 2013);
- the Information Governance lead is the Director of Corporate Services; and
- Directors, REC Centre managers and Heads of Department are Information Asset Owners (IAOs), as appropriate.

An annual Information Governance Report providing assurance that the HRA is meeting its Information Governance commitments was submitted to and accepted by the DH. The key points contained in the report were:

- all HRA staff participated in mandatory annual Information Governance (IG) training; and
- all information assets and associated systems are identified and included in an Information Asset Register and are subject to annual information asset assessments.

The principal information assets managed by the HRA comprise:

- IRAS: a web-based utility for researchers to make applications;
- RED: an application that supports the administration of Research Ethics Committees;
- Business Services Authority (BSA) Human Resources (HR) division use the NHS Electronic Staff Records (ESR) system to store staff records;

- Shared Business Services (SBS) finance and payroll also make use of the NHS Electronic Staff Records (ESR) system;
- electronic business information is stored on shared drives provided under the Department of Health's Open Services contract with ATOS;
- the HRA website;
- the training management system;
- paper-based applications and associated documentation submitted for ethical review; and
- paper-based staff records.

The HRA has an established Incident Reporting Procedure that dictates all security information incidents must be reported. No significant information incidents have occurred throughout 2012-13 resulting in a submission to the Information Commissioner. There have been six minor breaches during the year which have all been investigated with appropriate actions taken.

To ensure that the handling of personal data conforms to statute, guidance and best practice the HRA has in place a comprehensive suite of policies and procedures.

Finally, the organisation undertook regular QC checks (ISO 9001 accredited) whereby each REC Centre's Committees are subjected to six-monthly assessments. Information governance is an integral part of the accreditation programme and no significant issues emerged during 2012-13.

6.3 Health and Safety

During the year, the HRA began to plan for taking over the health and safety responsibilities from REC Centre host organisations from 1 April 2013. The inaugural Health and Safety (H&S) Committee, reporting to the Corporate Management Group (CMG), was held in December 2012 and oversaw an audit programme whereby each of the REC Centres was assessed to understand the associated risks. The Committee was pleased to learn that there was good adherence to best H&S practice, risks were effectively mitigated and no serious issues emerged.

Considerations to note, however, were:

- there was no organisation-wide incident reporting policy. This was not surprising as REC Centres worked to host organisations' policies, but a unified process would need to be instituted. A policy has now been drafted and is undergoing review; and
- the new leasing agreements with landlords need to take into account H&S requirements, such as fire safety equipment, fire alarms tests, fire drills, premises security, fire warden and first aider training. Discussions were progressed with landlords to ensure provision was built into contracts.

The committee also began to consider the following issues:

- lone working where staff sometimes have to travel to remote locations for REC meetings. To address the situation, a Lone Worker Policy has been drafted and is undergoing review;

- lifting and moving of boxes, especially where closed REC Centre files needed to be relocated. It was agreed that, where there is local need, REC Centre managers have the authority to organise local training or any other necessary interventions; and
- a recruitment programme for local H&S representatives to ensure health and safety is widely embedded throughout the organisation.

A programme of H&S Training for Managers was completed during the year and a Work Station Self- Assessment process agreed and communicated to all staff.

6.4 Equality and Diversity

As a new organisation, the HRA is committed to providing a service that promotes human rights, equality and diversity and does not discriminate against any staff, potential staff, members, partners, service users or anyone that deals with the HRA in any way.

To ensure that this is the case, the Equality and Diversity Policy was reviewed to ensure that all practices within the organisation are carried out in a fair, reasonable and consistent manner. The policy is at the heart of enabling us to deliver its core values and through its implementation, the HRA will ensure that a commitment to fairness and equality is evident at every level throughout the organisation and that everyone is treated fairly, reasonably and consistently regardless of background or personal characteristics. This is supported by Equality Impact Assessments.

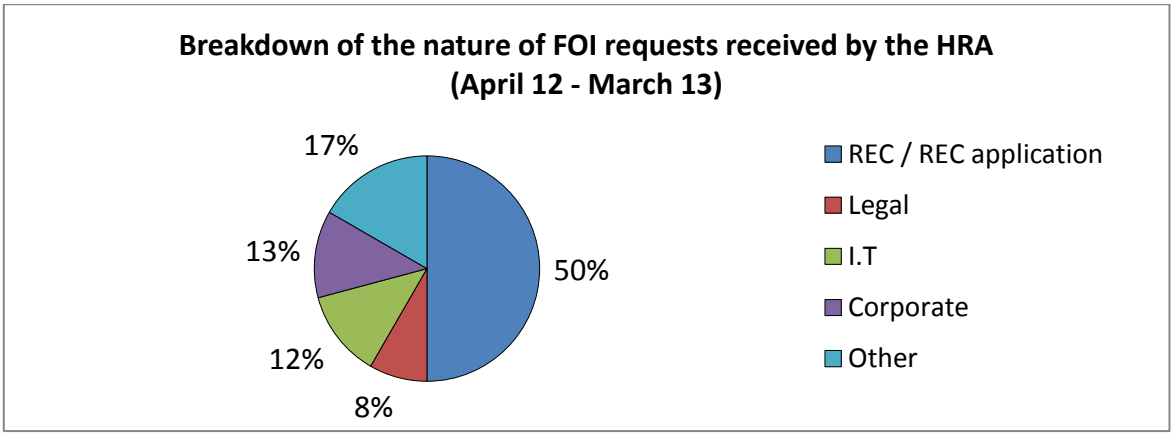
During the year, a very well-received E&D training programme was provided for all staff.

6.5 Freedom of information

From April 2012 to March 2013, the HRA received 24 Freedom of Information (FOI) requests. Of these, five were ambiguous regarding the nature of the request and further information was requested but not received; two were requests for information which was already publicly available, three were requests for information not held by us and the remaining 14 were valid FOI requests.

The average time for review of the valid FOI requests was 14.5 days, with two FOI requests exceeding the 20 working day timeframe as defined by the FOI Act.

The breakdown of requests received was as follows:



6.6 Complaints

6.6.1 Corporate Business

Four complaints were received during the reporting period 2012-13. Of these four, one related specifically to operational matters and correlates to one of the NRES complaints summarised below. Two complaints were made informally. One related to the Queries Line service but was not upheld as due process had been followed and no preventative action was required. The other concerned an applicant who had been experiencing difficulties in obtaining appropriate support and guidance to assist him to secure the necessary, relevant approvals. Although not directly pertinent to the HRA, help and guidance was provided. Following a thorough investigation, the final complaint was not upheld and no preventative action was required. The complaint was acknowledged within 4 working days, with a final response given within 14 working days.

6.6.2 National Research Ethics Service (NRES)

During the reporting period 2012-13, 37 formal complaints were received. All but three were acknowledged within three working days in line with the policy. 26 complaints were upheld, four not upheld, and seven partially upheld.

Of the complaints upheld, 22 related specifically to delays in the processing of study applications and amendments and most were specific to one REC Centre. Additional training was provided, including complaint handing training and since the delivery of this training, complaints relating to delays in processing have decreased. No other trends in the nature of the complaints received were identified.

Information received through the complaints process is used proactively to improve the service; improvements and changes made as a result of complaints include improved communications processes when closing REC Centres, the expansion of the use of generic committee email addresses across all RECs, changes to the delivery of the GTAC, the introduction of a mechanism to alert the HRA when studies which may prove controversial or of interest to the wider public are reviewed / approved, improvements to planning and making arrangements when researchers wish to attend meetings by teleconference.

6.7 Shared Services

6.7.1 HR

The organisation has continued to use the NHS Business Services Authority (BSA) for its transactional HR services and this arrangement will continue into 2013-14. Overall, the service has been good and strong working relationships have been developed between BSA and HRA staff. The strength of this relationship was particularly important during the staff transition period (between April to August 2012) which resulted in the successful transfer of the HRA's staff from 14 separate host employers. Regular contract review meetings take place between the HRA and NHSBSA to ensure that a high quality service is maintained.

A relatively small professional HR support capability (0.6 FTE) has been maintained in-house.

In terms of efficiency the HRA performs well against set government benchmarks for directly employed HR capacity, for the organisation it equates to 1:193 compared to a government target of 1:100.

6.7.2 Payroll / Finance

From 1 April 2012, the HRA has used NHS Shared Business Services (SBS) to deliver both a payroll service and finance and accounting services and systems.

Usage of the payroll service grew throughout the year as staff transferred into the authority from host employers. Additionally, at the end of the year the payment of allowances for REC Chairs was also processed through the payroll in response to an HMRC inspection which required the HRA to treat REC Chairs as office holders. Over the year, payroll numbers increased from 31 staff in April 2012 to a total of 176 (123 staff and 53 office holders) in March 2013.

The SBS Finance and Accounting Services were implemented from the beginning of the year and have been successfully used to produce all the Authority's internal and external financial reporting, to order goods and services and to pay suppliers. The improved performance in paying suppliers set out in paragraph 8.1 *Better Payment Practice Code* is a demonstration of the benefits delivered by the implementation.

6.7.3 IT

Transition to the interim DH IT service was completed for the HRA staff based in the London office, including the remote worker staff, in April 2012. A further migration to the new DH Open Service system took place by the end of March 2013 for all offices except Bristol.

The programme to migrate staff posed significant challenges for the organisation and continues to do so with the potential impact on our operational services remaining a constant theme through the financial year 2012-13 and into 2013-14. The HRA would like to record its thanks to all the previous host organisations for their help and support with the migrations and previous IT service provided and, in particular, to the University Hospitals Bristol NHS Foundation Trust for the continuing provision of IT services to support our Bristol office.

7. Our people

7.1 Organisational development

2012-13 has seen the organisation build on its interim structure set up during its establishment in December 2011. Its full Board (including the Chair) were appointed in June 2012, all staff were successfully transferred from 14 previous host employers, and a number of key appointments were made to the management team in order to meet the demands of its operational and change agendas.

The year also saw the planning to transfer the section 251 function (to commence with the HRA from 1 April 2013) and staff from the National Information Governance Board (NIGB) and the associated appointment of 16 members to the Confidentiality Advisory Group who have taken over the role from the Ethics and Confidentiality Committee in advising on

decisions relating to research and non-research applications on the use of confidential patient data.

7.2 Our staff

The most important asset to our organisation is our people and it is important to acknowledge their contribution to the development of the HRA during 2012-13 in the face of significant organisational change.

This contribution was reflected in the result from the staff survey that indicated 83% of staff were willing to go the 'extra mile'. The survey also showed very positive responses in other areas, eg the vast majority of staff understanding the need for change and the training and development opportunities that are made available, as well as positive views of line managers, but there were also areas where improvements could be made, eg more regular recognition of good work.

The HRA has endeavoured to engage with staff at all levels to develop both its vision and values and to build an organisation that people are proud of and committed to. To support this engagement, a staff forum has been set up, which comprises representatives from across the organisation, and a full staff conference has already taken place. The outputs from these and the staff survey will significantly contribute to the development of an organisation that intends to deliver on its key objectives and to be a great place to work.

Our volunteers

RECs are made up of volunteer members who give generously of their time, experience and expertise. Each committee consists of between seven and eighteen members of which at least one third must be 'lay', with the remainder of the committee being expert members. A typical committee includes members of the public, nurses, GPs, hospital doctors, statisticians, pharmacists and academics, as well as people with specific ethical expertise gained through a legal, philosophical or theological background. Currently the service has around 1,100 members.

During the period of recent change, which has seen the number of RECs reduce to 69 through a series of closures and mergers, our volunteer members have continued to support our service with many members choosing and being able to transfer to other committees. Sadly, however, we have had to say goodbye to a small number of members whose work and personal circumstances meant they were unable to join a new REC. During the year, members have attended a wide range of training events as delegates and some have also delivered and facilitated training on our behalf. As well as providing ethical review at main REC meetings and Proportionate Review sub-committees, and undertaking other sub-committee work, REC members and officers have supported the service in other ways, including involvement in pilot projects such as the Ethics Officer pilot, as interview panel members for recruitment and selection of new members and officers and input to collaboration and development projects.

We are grateful for the continued support and dedication of all our members.

7.3 Facts and figures

By March 2013, the HRA had 123 staff (116 whole time equivalents) on its establishment of whom 78% were female. 31% identified themselves as non-white British and just under

1% of staff declared themselves as disabled. The age range of staff is evenly dispersed between the ages of 20 and 60.

Turnover for staff during this period has been around 6.5% (compared to 7% within the NHS). Short-term sickness absence has been running at 1.48% for 2012-13 and long-term at 3.42%, which gives a combined total of 4.9% (compared to 4.5% within the NHS). However, the absence reports for March and April 2013 show a marked improvement (2.64% and 2.56%, respectively).

7.4 Learning and Development

The HRA is committed to providing good quality, timely and relevant training for all its staff, volunteer members, researchers and stakeholders via a robust training strategy. This strategy is developed and overseen by the Training and Development Group, chaired by the HRA Training and Development Manager.

Achievements and developments

Induction development for HRA staff and members has been a key feature of training work in 2012-13. The team produced bespoke induction manuals and organised a programme of REC Centre visits for the newly-appointed Chair and Non-Executive Directors of the HRA Board. It is seeking the views of REC members to ensure that they receive proportionate and relevant induction material, and the staff induction programme was also developed to offer induction specific for staff roles at the HRA.

2012-13 saw the transfer to HRA employment of staff from all REC Centres, heightening the responsibilities as an employer. The mandatory training provision was reviewed in December 2012 and staff now benefit from a more comprehensive programme of generic mandatory training, with face-to-face Equality and Diversity training provided for all staff in March 2013, together with Health and Safety training for managers. The Leeds and Cambridge REC Centres closed on 31 March 2013 and staff affected were offered training in interview techniques, job applications and other skills to help individuals secure alternative employment.

The need to procure external trainers has been limited by increasing the pool of experts on the Trainers' Register and another six members of staff have attended a 'Train the Trainer' course. An HRA Trainers' day was also held. This was a workshop designed for trainers to understand the training support services, have an input into the training programme and to meet our training team and other trainers. We continue to strive for value-for-money by using our own premises for training wherever possible, which are near mainline stations providing easy access for members, staff and other stakeholders.

This success in ensuring value-for-money across delivery of all training, having reduced expenditure by approximately 52% for staff training and 66% for members' training, has continued since the 2009-10 learning year. (Training was managed through NRES in 2009-10 until the establishment of the HRA in December 2011.)

The challenges within the training team in 2012-13 have been implementing a new training booking system which gives all stakeholders the opportunity to access bookings online.

Collaboration

The team has built on the work started in 2011-12 to promote and encourage collaboration in training, and our members' training days are now routinely available to the wider research community. Advertising via a broader circulation of our monthly training updates and a note added to all REC validation, final decision and amendment letters reminds the wider research community that they are welcome to attend HRA training days. This year the team has also actively collaborated with the NIHR and the DH Research Support Champions workgroup. We are seeking input from others, in particular NHS R&D staff, to contribute to delivering training to multi-stakeholder audiences, with consequent sharing of expertise.

Training for REC members and the wider research community

Two national training days for members that included a number of interactive workshops relevant to REC business were held, as well as providing an opportunity for delegates to network with HRA staff and colleagues from other committees. There was also a range of dedicated training days on topics including the Mental Capacity Act, the use of personal data, medical devices, clinical trials and children's research, all of which are open to members and the wider research community.

New for this year were advanced courses on the research aspects of the Human Tissue Act and Mental Capacity Act to meet the needs of our long-standing experienced REC members. Prison Research training was also introduced at the Manchester Centre in February 2013. The evaluation was positive.

Staff training

As well as a comprehensive programme, including management and leadership training, a new course on Ethics for REC Coordinators was held in February 2013 focusing on ethical principles and their influence on decision making in committee. The evaluation was positive and the course will be repeated in our 2013-14 programme. Operational staff are welcome to attend members' training days to broaden their understanding of ethical issues.

HRA Learning and Development Framework

This was updated in 2012 to include a section on succession planning to help identify, harness and develop talent within its staff, with the aim of encouraging retention and promotion of staff within the organisation. This Framework will inform a number of HRA training policies and procedures.

8. Our organisation – public interest

8.1 Better Payment Practice Code

The HRA seeks to comply with the Better Payment Practice Code by paying 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 shown in the table below. This shows that the organisation met the target set during 2012-13 and improved its performance compared to 2011-12. We are also working to further improve the speed of paying our suppliers and have achieved a rate of 41% for paying suppliers within 10 days.

Performance against the Better Payment Practice Code:

	2012-13	2011-12
Non NHS invoices		
Invoices paid in the year	**2,750**	3,591
Invoices paid within target of 30 days	**2,729**	3,506
Percentage of trade invoices paid within target	**99.2%**	97.6%
NHS invoices		
Total invoices in the year	**188**	156
Total invoices paid within target of 30 days	**183**	141
Percentage of trade invoices paid within target	**97.3%**	90.4%

8.2 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 £35,000. The audit certificate can be found on page 44.

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

8.3 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 Board agenda and members are expected to declare any interests on any agenda item before discussion commences.

8.4 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.

9. Remuneration report

9.1 Sub-Committees

There are two sub-committees of the HRA Board: Audit Committee and Pay and Remuneration Committee.

9.2 Pay and remuneration

The Chairman and Non-Executive Board members are remunerated in line with DH guidance that applies to all NHS bodies. Details of the 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 Executives 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	**2012-13**		**2011-12**	
	Salary (bands of £5,000)	**Other Remuneration**	**Salary (bands of £5,000)**	**Other Remuneration**
	£000	**£000**	**£000**	**£000**
Non-Executive Directors				
Jonathan Montgomery, Chairman (Appointed 12 June 2012) *See Note 1*	35-40	0	N/A	N/A
Sally Cheshire, Non-Executive Director and Audit Chair (Appointed 2 July 2012) *See Note 2*	5-10	0	N/A	N/A
Allison Jeynes-Ellis, Non-Executive Director (Appointed 2 July 2012) *See Note 2*	5-10	0	N/A	N/A
Julie Stone, Non-Executive Director (Appointed 2 July 2012) *See Note 2*	5-10	0	N/A	N/A
Directors				
Janet Wisely, Chief Executive. *See Note 3*	115-120	0-5	30-35	0
Deborah Corrigan, Interim Director of Finance (Executive Director) *See Note 3*	80-85	0	25-30	0
Joan Kirkbride, Director of Operations (Appointed 1 August 2012)	55-60	0	N/A	N/A
Shaun Griffin, Director of Communications (Appointed 1 November 2012) *See Note 4*	See note 2	0	N/A	N/A
Tom Smith, Director of Quality, Standards and Information (Appointed 4 March 2013) *See Note 5*	0-5	0	N/A	N/A
Band of Highest paid Director's Total Remuneration (£000s) (annualised)	115-120	0-5	100-105	N/A
Median Total (£)	27,901		38,851	
Remuneration Ratio	4.30		2.69	

Note 1: Jonathan Montgomery, Chairman, is seconded from the University of Southampton and is remunerated for his role as Chair in line with Department of Health (DH) guidance that applies to all NHS bodies. The 2012-13 figures above are the amounts earned in year. The full year equivalent band is £40k to £45k.

Note 2: The 2012-13 figures above are the amounts earned in period. The full year equivalent bands are as follows: Sally Cheshire £10k-15k; Allison Jeynes-Ellis and Julie Stone both at £5k-£10k *Note 3*: The 2011-12 figures above are amounts earned in the period. The full year equivalent bands were as follows; Janet Wisely £100k-£105k; Deborah Corrigan £75k to £80k *Note 4*: Shaun Griffin, Director of Communications, is seconded to the Health Research Authority for two days a week. He is employed by the Human Tissue Authority who re-charge the HRA for his services. In 2012-13, the HRA has paid the Human Tissue Authority £11,570.25 and accrued a further charge of £7,713.5 in respect of his services. Details of his remuneration are included in the Annual Report of the Human Tissue Authority. *Note 5*: The 2012-13 figure above is the amount earned in period. The full year equivalent band is £55k to £60k
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 remuneration of the highest paid Director in the HRA in the period April 2012 to March 2013 was £120,074. This was 4.3 times the median remuneration of the directly-employed workforce, which was £27,901. The ratio has increased compared to 2011-12 due to the completion of the transfers of staff from NHS hosts, which has resulted in a wider spread of salaries across the HRA compared to the position in 2011-12.

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, non-consolidated performance related bonus and severance payments. 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 2013 (bands of £5,000)**	**Lump sum at age 60 related to accrued pension at 31 March 2013 (bands of £5,000)**
	£000	**£000**	**£000**	**£000**
Janet Wisely, Chief Executive	2.5-5	7.5-10	20-25	70-75
Deborah Corrigan, Interim Director of Finance	2.5-5	10-12.5	10-15	40-45
Joan Kirkbride, Director of Operations	2.5-5	10-12.5	30-35	95-100
Tom Smith, Director of Quality, Standards and Information	0-2.5	2.5-5	5-10	20-25
Shaun Griffin, Director of Communications	See note 1	See note 1	See note 1	See note 1

Pension Benefits (continued)				
Name and title	**Cash Equivalent Transfer Value at 31 March 2013**	**Cash Equivalent Transfer Value at 31 March 2012**	**Real increase in Cash Equivalent Transfer Value**	**Employer's contribution to stakeholder pension**
	£000	**£000**	**£000**	**£000**
Janet Wisely, Chief Executive	400	326	65	0
Deborah Corrigan, Interim Director of Finance	239	167	67	0
Joan Kirkbride, Director of Operations	646	535	95	0
Tom Smith, Director of Quality, Standards and Information	116	93	20	0
Note 1 Shaun Griffin, Director of Communications, is seconded to the Health Research Authority for two days a week. He is employed by the Human Tissue Authority, who re-charge the HRA for his services. Details of his pension entitlements are included in the Annual Report of the Human Tissue Authority.				
The information above has been subject to audit.				

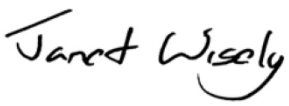
9.3 Cash Equivalent Transfer Values

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
24 June 2013



10. Sustainability report 2012-13

As the HRA was in its first year of operation in 2012-13, there was no benchmark with which to report comparative achievement. It is nevertheless wholeheartedly committed to adhering to the principles of the NHS Sustainability Framework and in particular to contribute to the target of reducing its carbon footprint by 10% by 2015 and subsequently further reductions of 34% by 2020 and 50% by 2025.

During the first quarter of 2013-14, it will be developing its own Sustainable Development Management Plan (SDMP) which will include clear targets to reduce carbon emissions from an agreed 2012-13 baseline.

There are likely to be four main areas of focus in the plan:

- Reducing travel :
  - introducing video conferencing;
  - developing a travel and accommodation policy that supports the reduction of CO_2;
  - consider how flexible working arrangements can reduce travel; and
  - work is already well underway and implementation of each is expected by end of Quarter 1 2013-14.
- Reducing energy use:
  - more effective procurement of energy;
  - reduction of heating and lighting use; and
  - more energy efficient photocopiers (with a view towards moving to a paperless office).
- Reducing waste:
  - improved recycling (closed loop).
- Organisational Development and Culture Change:
  - ensuring that the programme has clear leadership; and
  - engaging and involving staff and REC members in delivering the SDMP.

11. Statement of Accounting Officer's responsibilities

Under the National Health Service Act 2006, Section 232 (Schedule 15, paragraph 3) the Secretary of State has directed the HRA to prepare a financial statement of accounts for each year in the form and on the basis set out in the Accounts Direction.

The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the HRA and of its net resource outturn, 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 HRA. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the HRA's assets, are set out in Managing Public Money published by the HM Treasury.

12. Governance statement

12.1 Introduction

This Governance Statement sets out the framework utilised by the Health Research Authority (HRA) to regulate its activities and to ensure delivery of its functions and objectives. In addition to setting out the governance structure, it outlines the way in which performance is managed and reviewed; the risk management processes; and the process for setting Directors Remuneration. The Authority complies with the requirements of the Corporate Governance in Central Government Departments: Code of Good Practice (2011) insofar as they relate to public bodies.

A review of governance was undertaken by Department of Health Internal Audit during March 2013 to provide support and assurance to management and the Board on the on-going governance arrangements and more permanent structures, as well as capacity and capability during this period of transition.

12.2 Governance structure

12.2.1 Responsibilities of Accounting Officer

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

I have been the Accounting Officer for the period reported in this Annual Report and Accounts, 01 April 2012 to 31 March 2013. I am accountable for the discharge of my functions to the Authority's Board and appropriate arrangements are in place for the appropriate discharge of all statutory functions attached to the HRA. The HRA is aware of the findings from the Harris Report and will ensure it has the capacity and capability to comply with the statutory functions.

I am also accountable to the Minister of State at the Department of Health. This line of accountability is managed through a Framework Agreement between the Department of Health and the Health Research Authority, 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.

12.2.2 The Board

For the first three months of this annual report, the HRA operated with an interim executive Board whilst the recruitment process for the Chair and Non-Executive Director (NED) positions was undertaken. The Chair and three NEDs were appointed in June 2012 with the first full and public Board meeting taking place in July 2012. The Board is composed of four NEDs (including the Chair) and two executive directors (including the Chief Executive) and therefore conforms to the recommendations set out in the Corporate Governance in Central Government Departments: Code of Good Practice (2011) .

The Board has operated within the framework agreement as agreed with the Department of Health, and a statutory instrument governs its functions. Work to support the effectiveness and development of this new board commenced in February 2013 and an assessment of the Board's effectiveness and performance will be carried out in the reporting period April 2013 to March 2014.

Three public HRA Board meetings have been held between 01 April 2012 and 31 March 2013. Information regarding Board membership, meeting dates and attendance is shown below:

Position	Name	Meeting		
		30/07/2012	25/10/2012	22/01/2013
Chair	Professor Jonathan Montgomery	Present	Present	Present
NED	Sally Cheshire	Apologies	Present	Present
NED	Dr Allison Jeynes-Ellis	Present	Present	Present
NED	Julie Stone	Present	Present	Present
Chief Executive	Dr Janet Wisely	Present	Present	Present
Executive Director	Debbie Corrigan	Present	Present	Present
Director (non-voting)	Dr Shaun Griffin	Not in post	Present	Present
Director (non-voting)	Joan Kirkbride	Present as observer	Present	Present
Director (non-voting)	Tom Smith	Not in post	Not in post	Not in post

At each meeting there are clear agendas and papers, which are circulated to the Board and published on the HRA website a week before the meeting. Minutes are also published on the HRA website. HRA Board meetings are held in public and a week prior to the Board meeting a notification is added to the HRA website advising of the time and location and inviting members of the public to attend.

The HRA has developed an initial performance dashboard based on readily available information. At each meeting, the Board receives updates on current issues and receives reports on progress against the HRA's business and financial plans through this performance dashboard with key performance indicators listed. Work is underway to refine

and strengthen the performance dashboard, including setting some strategic indicators such that the information reported leads to continue performance improvement. Corporate level risks and their mitigation and management are considered via the HRA Board risk register at each meeting.

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

12.2.3 Sub-Committees

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

Audit and Risk Committee

The Audit and Risk 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.

The role of the HRA 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 Audit & Risk Committee met once as an Interim Board (prior to the appointment of the Non-Executive Directors) on 15 June 2012.

The full board met on 25 October 2012 and 22 January 2013.

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

Sally Cheshire (Chair), HRA Non-Executive Director
Julie Stone, HRA Non-Executive Director
Alison Jeynes-Ellis, HRA Non-Executive Director
Shelley Dolan, Chief Nurse, The Royal Marsden NHS Foundation Trust *(Interim Chair)*
David May, Assistant Director of Finance, NHS South West

The following people normally also attend meetings:

Solomon Ako-Otchere, Audit Manager, Department of Health Internal Audit (Substantive Head of Internal Audit for HRA)
Adrian Brook, Partner, Moore Stephens (External audit)
Kate Mathers, Director, National Audit Office (External audit)
Paul Holland, Audit Manager, National Audit Office (External audit)
Debbie Corrigan, Interim Director of Finance, Health Research Authority
Eric Read, Interim Senior Finance Officer, Health Research Authority

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. An annual schedule for the work of the Audit and Risk Committee is due to be taken to its meeting in June 2013 for sign off.

Attendance at the Audit and Risk Committee

The attendance by members of the committee for 2012-13 is shown on the composite table below. 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
Sally Cheshire, Chair and HRA Non-Executive Director	2/2
Julie Stone, HRA Non-Executive Director	2/2
Alison Jeynes-Ellis, HRA Non-Executive Director	2/2
Solomon Ako-Otchere, Audit Manager, Department of Health Internal Audit	2/3
Adrian Brook, Partner, Moore Stephens	3/3
Debbie Corrigan, Interim Deputy Chief Executive and Acting Director of Finance	3/3
Shelley Dolan, Chief Nurse, The Royal Marsden NHS Foundation Trust *(Interim Chair)*	2/3
Paul Holland, Audit Manager, National Audit Office	2/3
Michael Fox, Chair, Barnet, Enfield and Haringey Mental Health NHS Trust (final meeting in June 2012)	1/1
Kate Mathers, Audit Director, National Audit Office	1/3
David May, Assistant Director of Finance, NHS South West	2/3
Eric Read, Interim Senior Finance Officer, Health Research Authority	1/1
Richard Tiner, President of the Faculty of Pharmaceutical Medicine (final meeting in June 2012)	1/1

Pay and Remuneration Committee

The Pay and Remuneration Committee was established and constituted in October 2012. Its duties are outlined below (taken from its agreed Terms of Reference).

The duties of the Remuneration Committee include:

- to advise the Board about appropriate remuneration and terms of service for the Chief Executive, other Executive Directors and those on Very Senior Manager Terms and Conditions of Service including:
  i. all aspects of salary (including any performance-related elements/bonuses);
  ii. provisions for other benefits, including pensions and cars;
  iii. arrangements for termination of employment and other contractual terms;
- Standing Orders and Standing Financial Instructions;
- make recommendations to the Board on the remuneration and terms of service of the Chief Executive, other Executive Directors and those on Very Senior Manages Terms and Conditions of Service to ensure they are fairly rewarded for their individual contribution to the Authority – having proper regard to the Authority's circumstances and performance and to the provisions of any national arrangements for such staff;
- proper calculation and scrutiny of termination payments taking account of such national guidance as is appropriate, advise on and oversee appropriate contractual arrangements for such staff; and
- the Committee shall report in writing to the Board the basis for its recommendations.

The committee met in October 2012 and on 5 April 2013.

12.2.4 HRA Collaboration and Development Steering Group

The HRA has established a Collaboration and Development Steering Group that will enable the implementation of a unified approval process and will support the HRA in promoting proportionate standards for compliance and inspection; specifically where implementation will be required not just by the HRA but by others as well to improve the research journey in the UK.

The steering group will:

- advise the HRA on issues that need to be addressed and that should be considered within HRA business planning to improve the research journey in the UK;
- comment on HRA priorities to improve the research journey in the UK;
- discuss and agree key principles that would need wider adoption to enable the implementation of HRA driven solutions;
- endorse the principle of common formats and solutions for the HRA to implement; and
- actively support and promote the work of the HRA in improving the research journey in the UK.

The steering group is made up of a wide range of stakeholders, meets quarterly and is chaired by the HRA Chief Executive. The work is managed by HRA or other established groups, which report to the Collaboration and Development Programme Management Group.

12.3 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.

12.3.1 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 Audit and Risk Committee is the Board's sub-committee that reviews risk and ensures that the systems are in place to ensure effective risk management. The 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.

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

As agreed in the Business Plan, senior managers lead on the objectives of the Authority and, as such, they are responsible for managing risk at the project delivery and day-to-day operational level, as well as relating to transition planning. Each HRA management group (Corporate Management Group (CMG), National Research Ethics Service Management

Group (NMG) and Improvement Management Group (IMG)) holds its own risk register. The risk registers report the escalated risks and risk scores, risk owners, mitigating actions and due dates, as well as residual risk and assurances.

Any risks rated over 12 by the management group are raised to the Executive Management Team (EMT). The EMT will review each individual risk, and if appropriate, add it to the HRA Overall risk register. This is reported to the Board, Audit and Risk Committee and DH Sponsor on a quarterly basis.

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

The table below highlights a number of risks which were considered and managed by the Board over the past year. Risks over 12 from each departmental risk register are considered by the EMT before agreement is made regarding which risks should be added to the overall HRA risk register. The majority of the risks raised at the start of the year have now been closed, or have reduced sufficiently to be removed from the overall risk register due to the fact that they related to concerns associated with the establishment of the HRA and transitional arrangements.

Risk	Initial rating	End of year rating	Comments
Risk: Some stakeholders unclear about impact of HRA role as a NDPB on their interests Cause: The rapid establishment and on-going work to further develop the functions for HRA as a NDPB Effect: Added pressure and uncertainty on stakeholders	12	Closed or removed from overall risk register	Draft legislation published
Risk: Concern from REC members regarding change leading to reputational damage and inconsistent messaging to REC members Cause: REC members resistance and concern about change or expected change is raised by them outside of the organisation Effect: Inconsistent messaging and potential reputational damage	12	Closed or removed from overall risk register	Director and Head of Communication now appointed
Risk: IT services unavailable for HRA staff Cause: IMS3 not ready in time for proposed transfer of staff from closing organisations Effect: Business as usual affected for staff as IT provision not available after transfer from current hosts	20	Closed or removed from overall risk register	All but one REC centre now transferred to open service. Interim measures agreed for remaining REC centre with transfer date agreed
Risk: Non delivery of business as usual activity to support HRA Cause: Additional work pressures on the establishment of the HRA and transition Effect: Lack of financial control and advice to support developments	20	Closed / removed from overall risk register	Additional resource recruited and transition completed
Risk: Unable to make necessary developments to IRAS Cause: Insufficient resources of the supplier	20	Closed / removed from overall	IRAS contract moved to maintenance only and procurement

Effect: Unable to address issues and unable to provide updates to the system with the HRA's reputation potentially affected		risk register	procedure for new system begun

12.3.2 Information Governance

The HRA has an established Information Governance structure:

- I am the Authority's designated Senior Responsible Information Officer (SIRO) with responsibility for the system of safeguarding and protecting personal identifiable, confidential and sensitive data;
- the Information Governance Lead is the Director of Corporate Services;
- Dr Hugh Davies, HRA Ethics Advisor is the Caldicott Guardian (Appointed on an interim basis from 01 December 2011 until formally approved by the Board on 22 January 2013); and
- Directors, REC Centre managers and Heads of Department are Information Asset Owners (IAOs) as appropriate.

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

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

All information assets and associated systems are identified and included in an Information Asset Register and are subject to annual information asset assessments. These assessments inform the Corporate and Information Risk Registers and an associated Action Plan.

There have been no significant data breaches resulting in a submission to the Information Commissioner. There have been six minor breaches which have all been investigated with appropriate actions taken.

I, in my capacity as Chief Executive and SIRO for the Health Research Authority, confirm that the Information Assurance Annual Report has been completed and submitted to the Department of Health.

12.3.3 The system of internal control

As Accounting Officer, I have responsibility, for reviewing the effectiveness of the system of internal control, which has been in place in the HRA for the period April 2012 to March 2013 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

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 a governance review carried out in March 2013, his opinion was that the HRA's control environment and the governance arrangements are adequate and effective.

Following the March 2012 governance review, a governance assurance action plan was put into place to address the recommendations made in the report. This has been reviewed regularly by the HRA's management groups and the Audit and Risk Committee and good progress has been made and these will be subject to testing through the delivery of a full year's audit plan and further strengthened by recommendations made following the March 2013 review.

The EMT, led by myself, reviews and monitors progress with action plans and the CMG, IMG and the NMG provide focal points for operating divisions and teams to raise local risk management issues.

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

A Business Plan for 2013-14 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 not aware of any significant internal control issues.

12.3.4 Capacity to handle risk

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

- agreeing the Risk Management Policy;
- assigning a Responsible Senior Manager with oversight of Risk Management and who is responsible for championing risk management at HRA;
- ensuring risk management is embedded into all processes;
- reviewing the strategic risks identified in the Corporate Assurance Framework (CAF) bi-annually;

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

Currently responsibilities are as follows:

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

The HRA is committed to the shared service programme being driven by the Department of Health. A significant change programme has been undertaken over the last year and systems and processes were established to ensure that the transition of these services was undertaken in an efficient and effective manner.

12.3.5 Director's remuneration

The detail of the remuneration during the year is shown in the remuneration report at Section 9 above.

12.3.6 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.

12.4 Summary

The HRA has delivered a substantive programme of work this year, maintaining core services within key performance indicators and working in collaboration with others to set out an agenda that will further improve the environment for research in the UK, for the benefit of the health and wealth of the nation. The HRA is able to demonstrate delivery and effective governance, with all key corporate governance functions being executed effectively, robustly and efficiently and verified to be doing so by internal audit.

Janet Wisely
Chief Executive, Health Research Authority
24 June 2013

13. The Certificate and Report of the Comptroller and Audit General to the Houses of Parliament

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 year ended 31 March 2013 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 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 2013 and of its net expenditure for the year 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 Health Research Authority Foreword Management Commentary and Sustainability Report included within the Annual Report, for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

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

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

Date

14. The Accounts of the Health Research Authority 2012-13

Statement of Comprehensive Net Expenditure for the year ended 31 March 2013

	Notes	**2012-13**	2011-12* 1 Dec – 31 March
		£000	£000
Administration			
Expenditure			
Staff Costs	3	**5,471**	2,020
Amortisation	4	**84**	48
Other Expenditure	4	**3,752**	1,488
		9,307	3,556
Income			
Income from Activities	6	**270**	111
		270	111
Net Expenditure and Resource Outturn		**9,037**	3,445

The notes on pages 50 to 66 form part of these accounts

*The Health Research Authority was established on 1 December 2011 and the 2011-12 comparative figures are for a four-month period.

Statement of Financial Position as at 31 March 2013

	Notes	31 March 2013 £000	31 March 2012 £000
Non Current Assets			
Property, Plant & Equipment	7.1	**69**	0
Intangible Assets	7.2	**128**	212
Total non-current assets		**197**	212
Current assets			
Trade and other receivables	8	**156**	96
Cash and cash equivalents	9	**2,279**	3,574
Total current assets		**2,435**	3,670
Total Assets		**2,632**	3,882
Current Liabilities			
Trade and other payables	10	**1,176**	2,877
Other liabilities	10	**28**	0
Total current liabilities		**1,204**	2,877
Non-current assets plus net current assets		**1,428**	1,005
Assets less liabilities		**1,428**	1,005
Taxpayers' Equity			
General Fund		**1,428**	1,005
Total Taxpayers' Equity		**1,428**	1,005

The notes on pages 50 to 66 form part of these accounts

The financial statements on pages 46 to 49 were signed on behalf of the Health Research Authority by:

Chief Executive :
24 June 2013

Statement of Cash Flows for the year ended 31 March 2013

	Notes	2012-13	2011-12 1 Dec – 31 March
		£000	£000
Cash flows from operating activities			
Net expenditure for the year after interest		**(9,037)**	(3,445)
Adjustments amortisation	4	**84**	48
(Increase)/Decrease in trade and other receivables	8	**(60)**	(96)
Increase/(Decrease) in trade payables and other current liabilities	10	**(1,673)**	2,877
Less: liabilities assumed not passing through Statement of Comprehensive Net Expenditure		**0**	(2,882)
Net cash (outflow) from operating activities		**(10,686)**	(3,498)
Cash flows from investing activities			
Purchase of plant, property and equipment	7.1	**(69)**	0
Net cash inflow/(outflow) from investing activities		**(69)**	0
Cash flows from financing activities			
Net Parliamentary funding		**9,460**	7,072
Net financing		**9,460**	7,072
Net increase/(decrease) in cash and cash equivalents		**(1,295)**	3,574
Cash and cash equivalents at the beginning of the period		**3,574**	0
Cash and cash equivalents at the end of the	9	**2,279**	3,574

The notes on pages 50 to 66 form part of these accounts

Statement of Changes in Taxpayers' Equity
For the year ended 31 March 2013

	General Fund
	£000
Balance at 1 December 2011	**0**
Net assets transferred from NPSA	260
Liabilities assumed from the Department of Health	(2,882)
Net liabilities upon transfer	**(2,622)**
Net expenditure 1 Dec to 31 March 2012	(3,445)
Total recognised income and expenditure for the period	**(3,445)**
Parliamentary Funding for resources 11/12	4,190
Parliamentary Funding for liabilities to NHS hosts	2,882
Total Parliamentary Funding from Department of Health	**7,072**
Balance at 31 March 2012	**1,005**
Net expenditure 12/13	(9,037)
Total recognised income and expenditure for	**(9,037)**
Parliamentary Funding for resources	**9,460**
Total Parliamentary Funding from Department of Health	**9,460**
Balance as at 31 March 2013	**1,428**

The notes on pages 50 to 66 form part of these accounts

15. Notes to the Accounts

1. Accounting Policies

These financial statements have been prepared in accordance with the Government Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be most appropriate to the particular circumstances of the Health Research Authority has been selected for the purpose of giving a true and fair view. The particular policies adopted by the Health Research Authority are described below. They have been applied consistently in dealing with items considered material in relation to the accounts.

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 and non 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 and equipment

(a) Capitalisation

Property, plant and equipment which 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 cost net of depreciation and impairment, or at depreciated replacement cost where materially different.

(c) Depreciation

Equipment and IT Assets are depreciated evenly over the expected useful life:

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

1.5 Intangible Assets

(a) Capitalisation

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

(b) Valuation

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

(c) Amortisation

Amortisation is charged on each individual component of non-current assets.

Assets under construction are not amortised.

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

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

	Years
Software Licences	3
Bespoke Software licence	7
Intangible Information Technology	5 to 7

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 operating cost statement on an accruals basis, including losses which would have been made good through insurance cover had the Authority not been bearing their own risks (with insurance premiums then being included as normal revenue expenditure). 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 Agency commits itself to the retirement, regardless of the method of payment.

1.10 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.

1.11 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 Operating Cost Statement.

1.12 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.

1.13 Financial Instruments

Financial assets

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

Loans and receivables are recognised initially at fair value, net of transaction costs, and are measured subsequently at amortised cost, using the effective interest method. The

effective interest rate is the rate that discounts exactly estimated future 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 Net Comprehensive Expenditure.

Financial liabilities

Financial liabilities are recognised on the Statement of Financial Position when the Authority becomes party to the contractual provisions of the financial instrument or, in the case of trade payables, when the goods or services have been received. Financial liabilities are derecognised when the liability has been discharged, that is, the liability has been paid or has expired. The Authority's financial liabilities comprise: NHS Payables, other payables and accruals.

Financial liabilities are initially recognised at fair value.

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.

1.14 IFRS disclosure

Early adoption of IFRS's, amendments or interpretations

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

IFRSs, amendments and interpretations in issue but not yet effective or adopted

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

IAS 19 Post-Employment Benefits (Pensions)
IFRS 9 Financial Instruments
IFRS 13 Fair Value Measurement.

2. Analysis of net expenditure by segment

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

3. Staff numbers and related costs

	Total 2012-13 £000	Permanently employed £000	Other £000	Total 2011-12 £000	Permanently employed £000	Other £000
Salaries and wages	**4,760**	3,020	1,740	**1,613**	355	1,258
Social security costs	**248**	248	0	**28**	28	0
Employer contributions to NHSPA	**321**	321	0	**47**	47	0
Redundancies/notice	**142**	142	**0**	**332**	0	**332**
Total	**5,471**	**3,731**	**1,740**	**2,020**	**430**	**1,590**

The average number of persons employed during the year was :

	Total Number	2012-13 Permanently employed Number	Other Number	Total Number	2011-12 Permanently employed Number	Other Number
Total	**131**	**91**	**40**	**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 Resource Authority. These are included within the 'Other' column. These figures include social security costs and employer contributions to the NHSPA.

The Health Research Authority managed a phased transfer of staff from NHS hosts to the HRA starting on 1 July 2012 and completing by 30 September 2012.

Expenditure on staff benefits

There was no expenditure made on staff benefits in the year to the 31 March 2013 (Period to 31 March 2012 - £0).

Retirements due to ill-health

This note discloses the number and additional pension costs for individuals who retired early on ill-health grounds during the year. There were no such retirements in the year to 31 March 2013 (Period to 31 March 2012 - £0). This information has been supplied by NHS Pensions.

3.1 Exit packages agreed during

£142k (2011-12 £322k) has been charged to the revenue account in respect of redundancies, exit packages and the cost of notice worked.

£42k has been charged to the revenue account in respect of one early retirement case (2011-12 £0).

Early retirements and redundancies

Exit package cost band	2012-13			2011-12		
	Number of compulsory redundancies	Number of Early Retirements	Total cost of Exit packages by cost band (£000s)	Number of compulsory redundancies	Number of Early Retirements	Total cost of Exit packages by cost band (£000s)
<£20,001	5		47	5		74
£20,001 - £40,000	2		62	2		60
£40,001 - £100,000		1	42	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 2012-13 (2011-12)	**7**	**1**	**151**	10	0	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 event that led to the redundancies was the management decision to close two REC Centres by 31 March 2013.

There are no redundancy payments that require to be disclosed as Special Payments in note 15 (1.8).

3.2 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. 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 dataset 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 AVCs 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. Other operating costs

The Health Research Authority costs all relate to Administration costs

	Note	2012-13	2011-12 1 Dec – 31 March
		£000	£000
Non-executive members' remuneration		**71**	0
Other salaries and wages	3	**5,258**	1,688
Redundancies and notice not worked		**142**	332
Total Staff Costs		**5,471**	2,020
Supplies and Services - general		**517**	29
Establishment expenses		**1,067**	343
Transport and moveable plant		**6**	3
Premises and fixed plant		**1,958**	706
Capital: Amortisation		**84**	48
Auditors' remuneration: (*) Audit fees		**35**	25
Miscellaneous		**169**	382
Total programme costs		**9,307**	3,556

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

5.1 Reconciliation of net operating cost to revenue resource limit

	2012-13	2011-12 1 Dec – 31 March
	£000	£000
Net operating costs for the financial year	**9,037**	3,445
Change in level of Provisions		
Charge Against Revenue Resource Limit	**9,037**	3,445
Revenue Resource Limit	**(9,460)**	(4,443)
(Underspend) against Revenue Resource Limit	**(423)**	(998)

5.2 Reconciliation of gross capital expenditure to capital resource limit

	2012-13	2011-12
	£000	£000
Gross Capital Expenditure	**69**	0
Less: Net Book Value of assets disposed of	**0**	0
Charge against the Capital Resource Limit	**69**	0
Capital Resource Limit	**(125)**	(95)
(Underspend) Against Capital Resource Limit	**(56)**	(95)

6. Operating revenue

	Appropriated in Aid £000	Not Appropriated in Aid £000	Total 2012-13 £000	Appropriated in Aid £000	Not Appropriated in Aid £000	Total 2011-12 £000
Administration						
Fees & charges to external customers	**8**	**0**	**8**	5	0	5
Income received from Scottish Parliament	**0**	**110**	**110**	0	55	55
Income received from National Assembly for Wales	**0**	**64**	**64**	0	32	32
Income received from Northern Ireland Assembly	**0**	**38**	**38**	0	19	19
Income received from other Departments	**0**	**50**	**50**	0	0	0
Total Administration revenue	**8**	**262**	**270**	5	106	111

7. Non-current assets

7.1 Property, plant and equipment

	Information technology £000	Total 2012-13 £000
Cost or Valuation at 1 April 2012	0	**0**
Additions - purchased	69	**69**
Gross cost at 31 March 2013	**69**	**69**
Depreciation		
Accumulated depreciation at 1 April 2012	0	**0**
Charged during the year	0	**0**
Disposals	0	**0**
Accumulated depreciation at 31 March 2013	**0**	**0**
Net book value at 31 March 2012	0	0
Net book value at 31 March 2013	**69**	**69**

The Health Research Authority did not own any property, plant and equipment assets as at the 31 March 2012.

7.2 Intangible assets

	31 March 2013	
	Information Technology £000	**Total £000**
Gross cost at 1 April 2012	982	**982**
Additions – purchased	0	**0**
Transfers	0	**0**
Disposals	0	**0**
Gross cost at 31 March 2013	982	**982**
Amortisation		
Accumulated amortisation at 1 April 2012	770	**770**
Charged during the year	84	**84**
Disposals	0	**0**
Accumulated amortisation at 31 March 2013	854	**854**
Net book value at 31 March 2013	128	**128**
Net book value at 31 March 2012	212	212

	31 March 2012	
	Information Technology £000	Total £000
Gross cost at 1 December 2011	0	0
Assets transferred in from NRES	982	982
Additions – purchased	0	0
Transfers	0	0
Disposals	0	0
Gross cost at 31 March 2012	**982**	**982**
Amortisation		
Accumulated amortisation at 1 December 2011	0	0
Amortisation (for assets transferred in)	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

7.3 Profit / (loss) on disposal of fixed assets

The Health Research Authority did not make any disposals of non-current assets during the period up to the 31 March 2013.

8. Trade receivables and amounts falling due within one year

	31 March 2013	31 March 2012
	£000	£000
Trade Receivables	**69**	0
Other receivables	**80**	81
Accrued income and prepayments	**7**	15
Trade and other receivables	**156**	96

9. Cash and cash equivalents

	2012-13	2011-12
	£000	£000
Opening balance	**3,574**	0
Net change in year	(1,295)	3,574
Closing balance	**2,279**	3,574
Comprising:		
Held with office of Government Banking Service	2,279	3,574
Commercial banks and cash in hand	0	0
Balance at 31st March 2013	**2,279**	3,574

10. Trade payables and other current liabilities falling due within one year

	31 March 2013	31 March 2012
	£000	£000
Trade payables	**75**	810
Accruals and deferred income	**1,101**	2,067
Trade and other payables	**1,176**	2,877
Other taxation and social security	**11**	0
Other Current Liabilities	**17**	0
Other Current Liabilities	**28**	0
Total Trade Payables and other current liabilities	**1,204**	2,877

11. Contingent liabilities

At 31 March 2013, there were no known contingent liabilities (2011-12: £nil).

12. Capital commitments

At 31 March 2013 the value of contracted capital commitments was £0 (2011-12 £0).

13. Commitments under leases

Operating leases

There is an implied lease between the HRA and the DH for the Authority's occupation of Skipton House. There is no formal agreement relating to the lease but there is a Civil Estate Occupancy Agreement with the authority/memorandum of term of occupation for use between crown bodies.

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

		2012-13		Re-stated 2011-12
		£'000		£'000
Obligations under operating leases comprise:				
Buildings				
Not later than one year		189		187
Later than one year and not later than five years		520		709
Later than five years		0		0
		709	*	**896**
Other Leases				
Not later than one year		0		0
Later than one year and not later than five years		0		0
		0		**0**

***** The 2011-12 comparative figure for obligations later than one year but not later than five years has been increased by £189,000 to take into account an extra year.

14. Other financial commitments

The Health Research Authority entered on 1 April 2012 into a one year contract relating to the provision of financial and accounting and payroll services. The contract has been extended for a further year and is due to terminate on 31 March 2014. The annual cost of the contract is £170,000.

	2012-13	2011-12
	£000	£000
Not later than one year	**170**	170
	170	170

15. Losses and special payments

The authority made one fruitless payment of £10,137 to a supplier in respect of development work which was not accepted.

There were no Losses and Special Payments in 2011-12.

16. Related party transactions

The Health Research Authority is a body corporate established by order of the Secretary of State for Health. All transactions in the year were on an arm's length basis.

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 payables and receivables balances (£50k) and income and expenditure balances (£100k).

	Receivables @ 31.03.13	Payables @ 31.03.13	Income in year 2012-13	Expenditure in Year 2012-13
	£000	£000	£000	£000
Department of Health	0	19	0	533
East of England Strategic Health Authority	0	43	0	377
Guys & St Thomas NHS Trust	0	0	0	130
Imperial College Healthcare NHS Trust	0	11	0	119
Leeds & York Partnership NHS Foundation Trust	0	49	0	319
NHS North West	0	37	0	154
Nottingham County PCT	0	5	0	348
Stockton on tees Teaching PCT	0	43	0	167
Stockport PCT	0	8	0	338
University Hospitals of Bristol NHS Foundation Trust	0	60	0	686

No Board member or key manager, except as disclosed below, has undertaken any material transactions with the Health Research Authority during the year:

HRA Audit Committee Chair and Non-Executive Member, Sally Cheshire, was Chair of NHS NW until 31 March 2013. There were, however, no conflicts of interest in relation to the contractual and financial arrangements with the HRA.

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 Agency is undertaking its activities.

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

Foreign currency risk

The Health Research Authority 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. Provisions against receivables are calculated based on the type of receivable, ageing or the outstanding debt and knowledge of specific queries on the balances.

Trade Receivables are disclosed in Note 8. The Health Resource Authority had no trade receivables requiring provision at the 31st March 2013.

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 payables at the reporting date was:

	£000
Not past due	1,200
Past due 0-30 days	5
Past due 31-120 days	(1)
More than 121 days	0

Fair values

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

19. Intra-government balances

	Current receivables £000s	Non-current receivables £000s	Current payables £000s	Non-current payables £000s
Balances with Department of Health	0	0	19	0
Balances with other central government bodies	69	0	0	0
Balances with local authorities	0	0	0	0
Balances with Strategic Health Authorities	0	0	80	0
Balances with Special Health Authorities	0	0	96	0
Balances with Primary Care Trusts	0	0	56	0
Balances with NHS Trusts	0	0	50	0
Balances with Foundation Trusts	0	0	170	0
Balances with HMRC	18	0	11	0
Balances with public corporations and trading funds	0	0	0	0
	87	**0**	**482**	**0**
Balances with bodies external to government	69	0	722	0
At 31 March 2013	**156**	**0**	**1,204**	**0**

Health Research Authority
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Email: contact.HRA@nhs.net

16. Glossary

BSA	NHS Business Services Authority
CAG	Confidentiality Advisory Group
Clinical Trials Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004
CMG	Corporate Management Group
CSO	Civil Society Organisation
DH	Department of Health
EMT	Executive Management Team
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	Governance Arrangements for Research Ethics Committees: *A harmonised edition* (April 2011)
GIA	Grant in Aid
GTAC	Gene Therapy Advisory Committee
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)
ITT	Invitation to Tender
IAOs	Information Asset Owners
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
MoU	Memorandum of Understanding
NDPB	Non-Departmental Public Body

NIGB	National Information Governance Board for Health and Social Care
NIHR	National Institute for Health Research
NREAP	National Research Ethics Advisors' Panel
NRES	National Research Ethics Service
PCoE	Procurement Centre of Expertise
REC	A Research Ethics Committee established in any part of the UK in accordance with GAfREC and/or recognised by the under the Clinical Trials Regulations
ShED	Shared Ethical Debate
SIRO	Senior Information Risk Owner
SMEs	Small and Medium Enterprises
SOPs	The Standard Operating Procedures for Research Ethics Committees
SPF	Staff Partnership Forum
Sponsor	The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study
TOPS	The Over-volunteering Protection System
UKECA	United Kingdom Ethics Committee Authority

17. Appendix 1

Key Performance Indicators

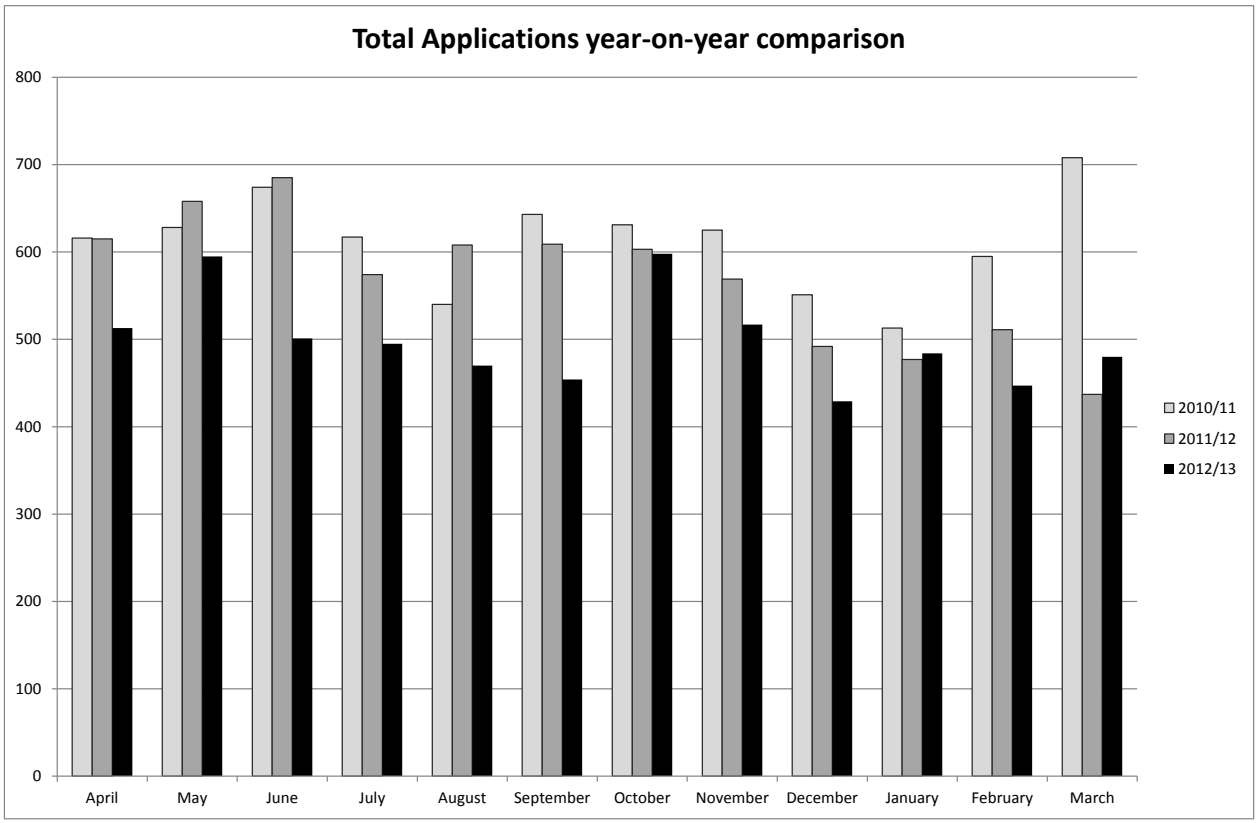
	KPI	Actual achievement	R/A/G
1	To consolidate the HRA Corporate and visual identity with a functioning, fit-for-purpose website and intranet	• Original plan to complete by March 2013 • January board meeting reported delays to recruitment and procurement, and large part would be delivered by March with final completion by July 2013 • Website survey of internal and external stakeholders completed • Values work progressed and linked to branding and design proposals • Web administrator recruited	**G**
2	To maintain IRAS as an available system 24 hours a day, 7 days per week (to 99%)	• Achieved	**G**
3	Provide processes for application and approval through IRAS	• Agreed January board, original KPI no longer relevant with move to replacement plans for a new system • Procurement discussions with DH progressing with a view to finalising procurement route in quarter 1 with intention of delivering new system late 2014 / early 2015	**G**

4	Create a common language and understanding within regulation and governance and use to underpin improvements to the research journey in the UK	• Collaboration and development steering group set up
		• A number of projects identified and leads assigned
		• Feasibility study approved by HRA Board
		  ○ testing commenced
		  ○ on track for HRA Board discussing findings from HRA Assessment Feasibility Study, testing, and next steps on 24 June 2013
			G

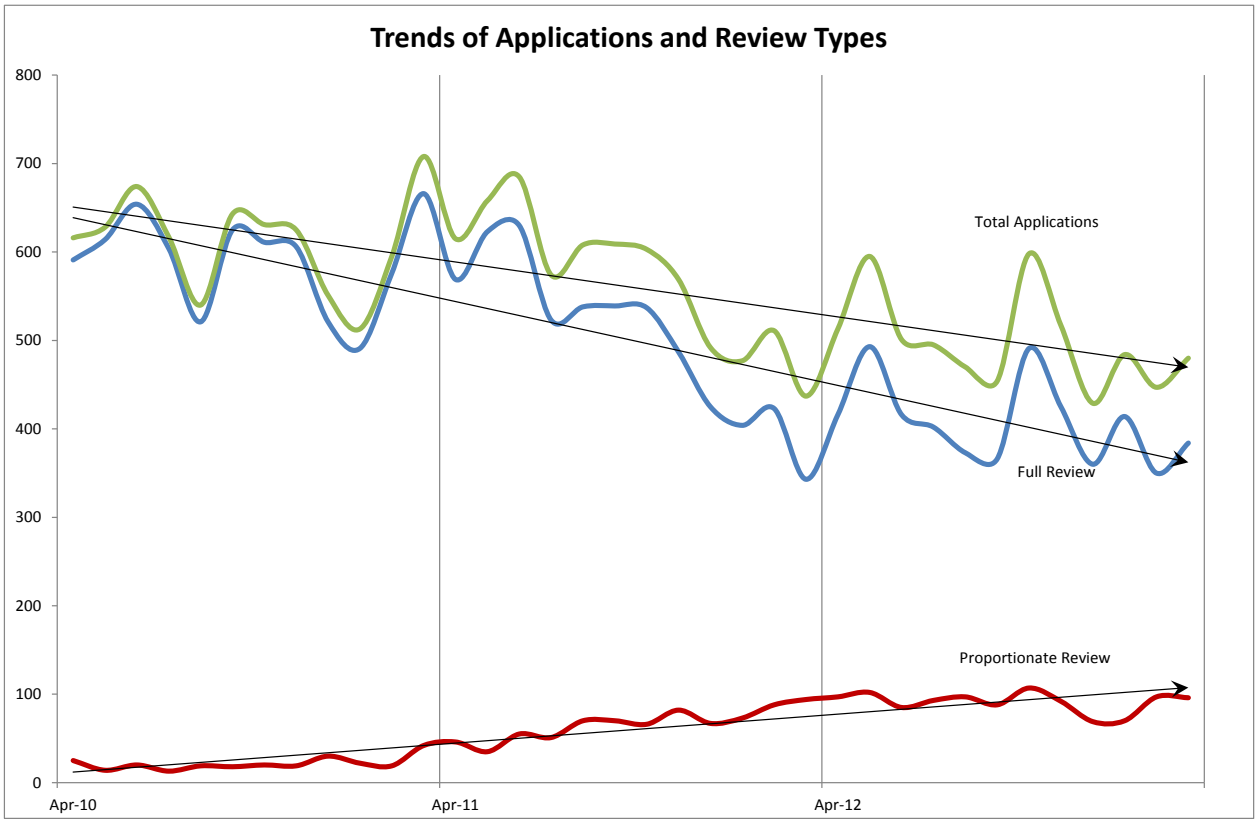
5	To maintain current 4 working day response times to requests for advice (90%)	• Overall achievement 96% April to March • Q1 achievement 96% • Q2 achievement 89% (100% July, August, 67% Sept) • Q3 achievement 100% • Q4 achievement 97%	**G**
6	95% applications to full committee to receive final decision within 40 calendar days	• 71% achievement overall April to March [71% December Board report] 75% in March Average time to review April to March - 35 days; 33 in March • 95% achievement of final decision within statutory 60 calendar days (only statutory for CTIMPS this reports for all studies) [93% December board report]	**A**

7	95% of applications to proportionate review service to receive decision within 14 calendar days	• 81% achievement April to March [76% December board report] • In final quarter, Manchester achieved 100% across each month in the quarter • Nottingham and Bristol both achieved 100% in the month of March	**A**
8	95% of amendments to receive decision within 20 working days	• 83% achievement April to March [82% December Board report] • Centre performance ranges from Nottingham 93% Manchester 90%, Bristol 87% to London 60% (was 40% first half of year) • 94% in 35 day requirement. Centre performance ranges from 100% Nottingham, 99% Jarrow, 97% Manchester/Leeds, 96% Bristol, 95% Cambridge, 72% London	**A**
9	100% of audit action plans to be completed within agreed timeframes	• 79% achievement April to March; 14 action plans [57% December board report] • January to March – 100% achieved; 7 action plans	**G**

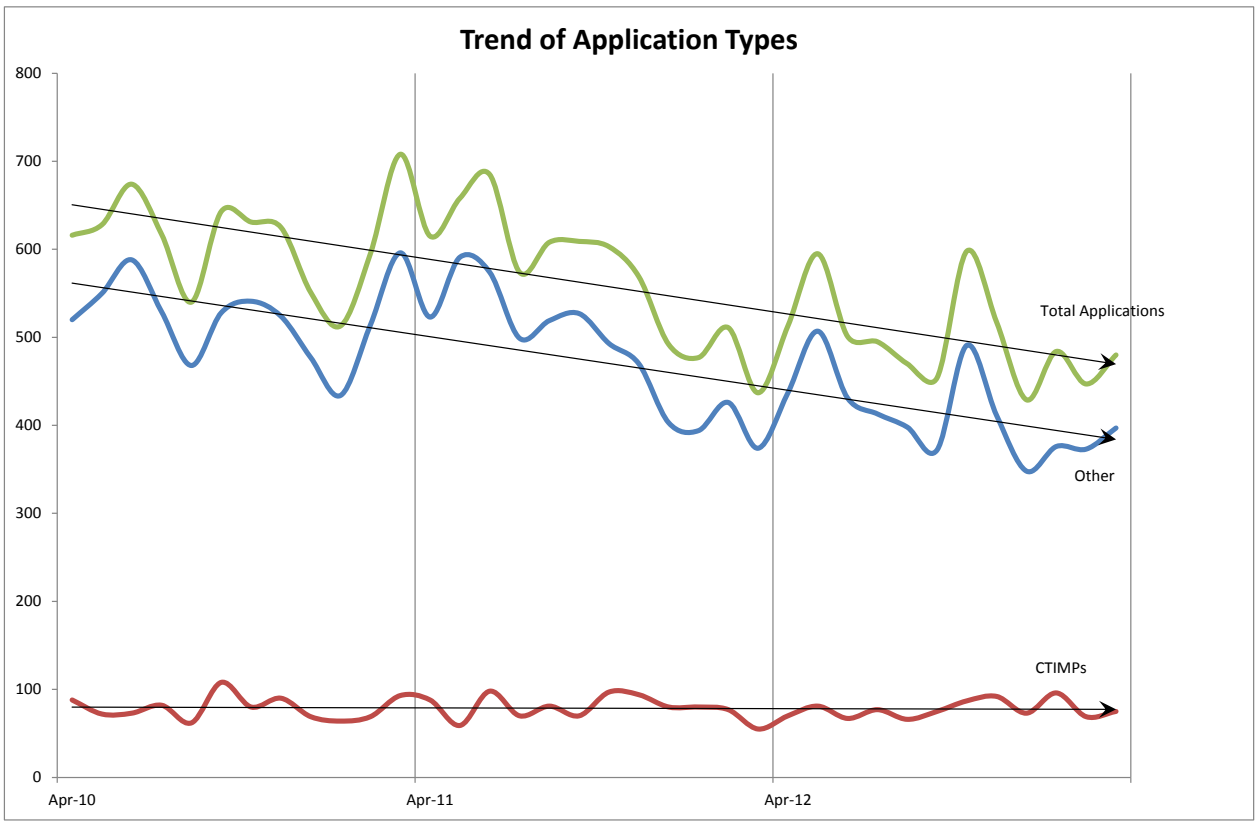
HRA NRES application data March 2013



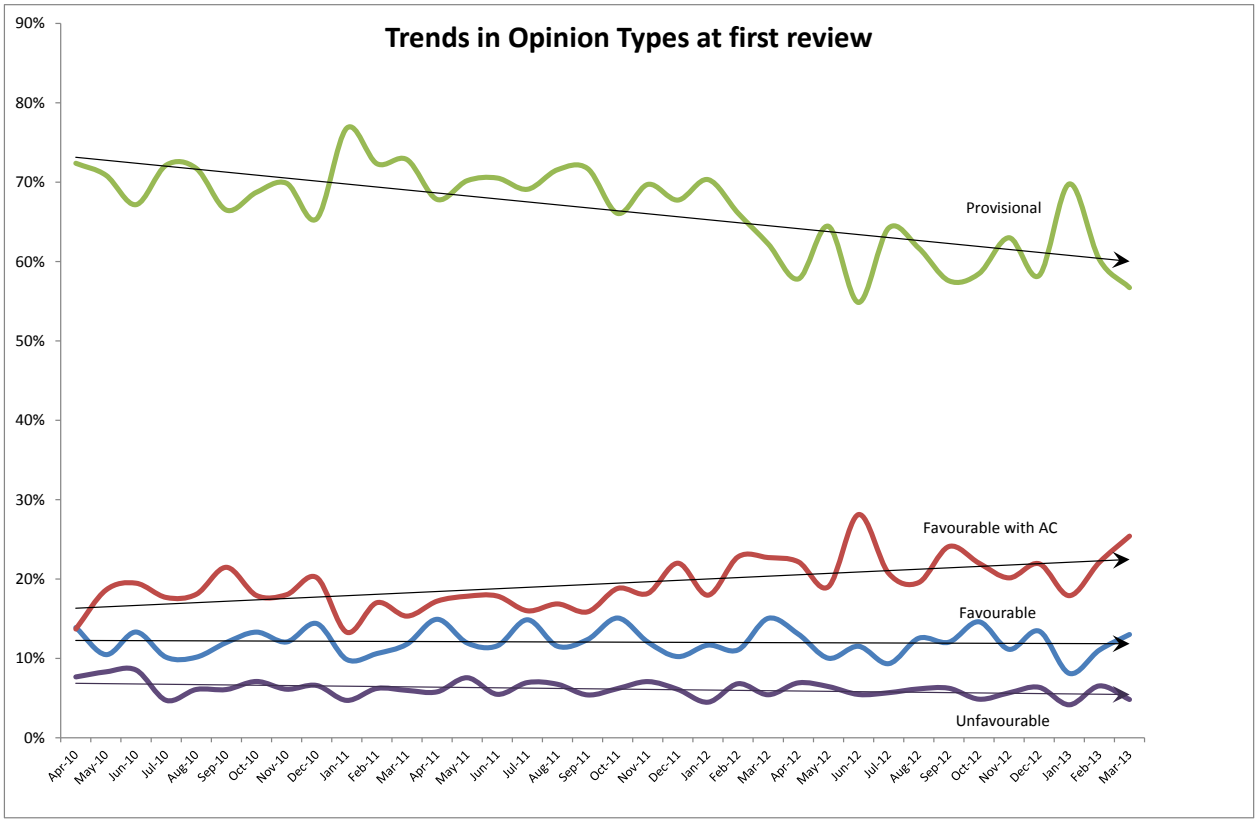
Total number of Applications (all types) – the reduction in 2012 is largely attributable to the removal of applications involving NHS staff and premises from the requirements for mandatory review



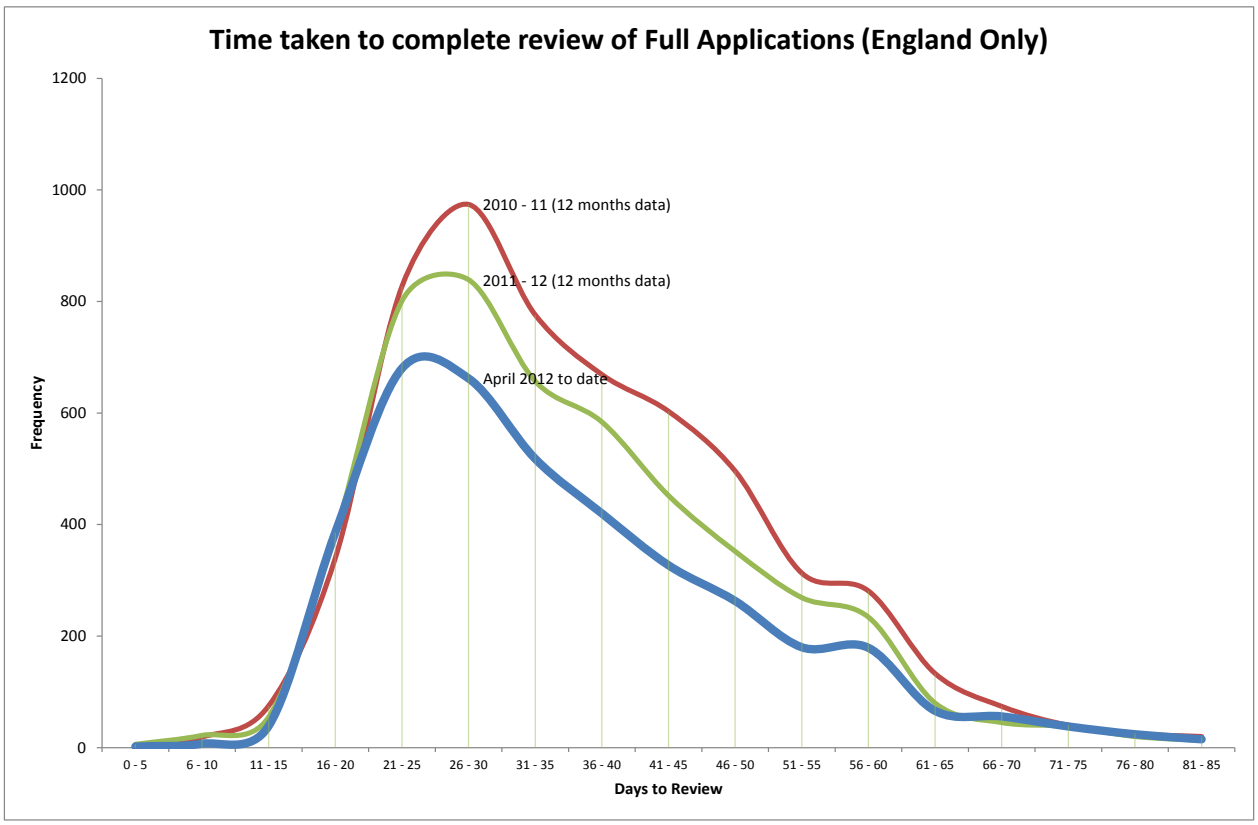
The above graph shows data April 2010 to March 2013. Total applications of all types also showing the number of Applications sent to Full Review and the number of Proportionate Reviews

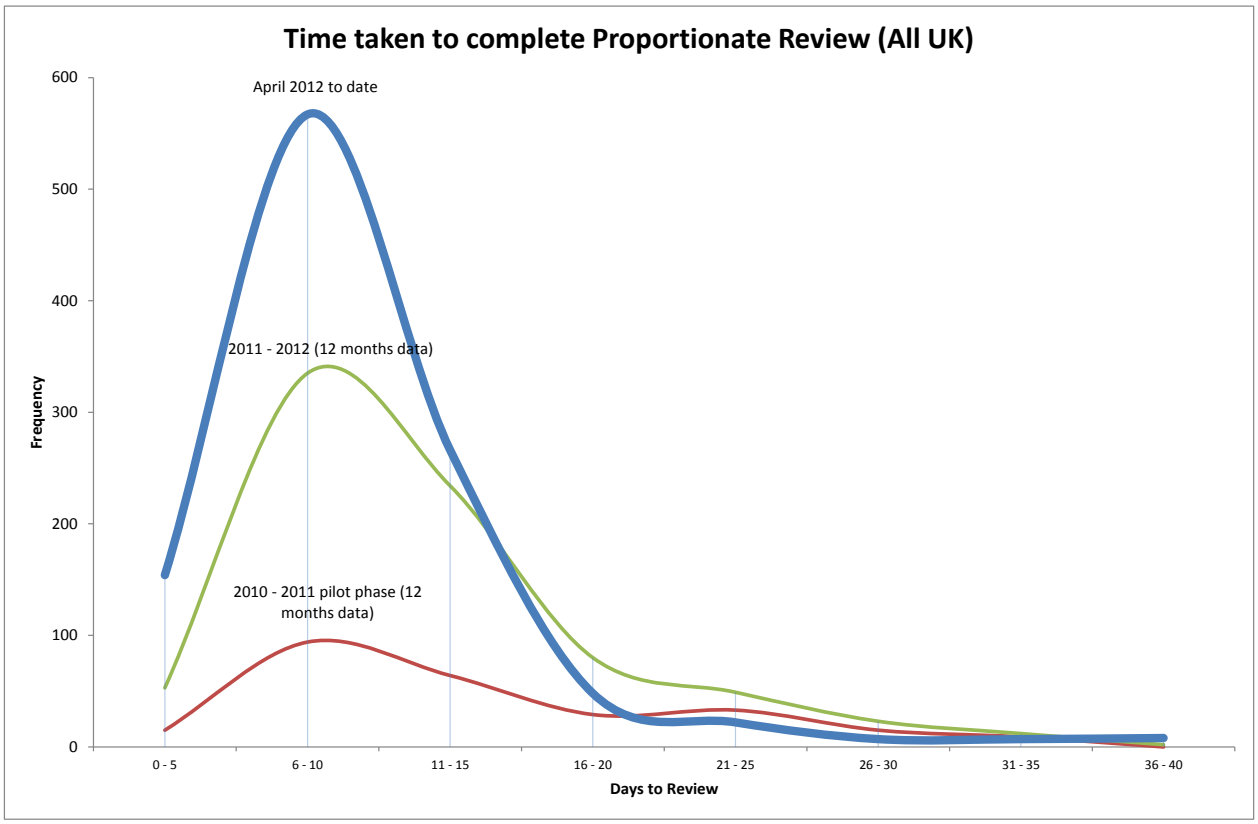


Shows data April 2010 to March 2013 - Total applications of all types also showing the number of CTIMPs and Non-CTIMPs (Databases/Tissue banks not included). Trend lines clearly show decrease in 'other' applications while CTIMPs remains stable.



The above chart shows data April 2010 to March 2013 - Total applications of all types also showing trends in proportion of decision types. A clear downward trend in Provisional opinions is evident.

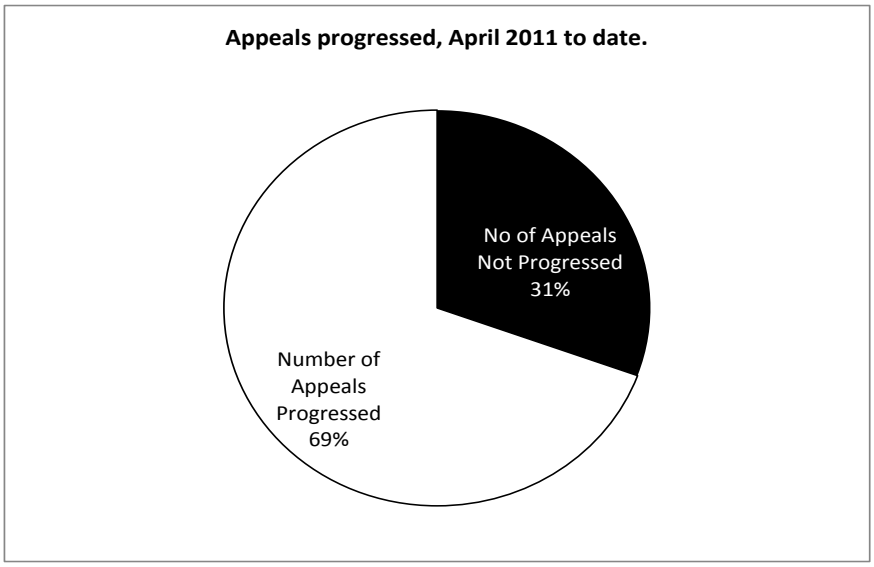

Time taken to complete review of Full Applications (England Only)
1200
1000
800
600
400
200
0
Frequency
2010 - 11 (12 months data)
2011 - 12 (12 months data)
April 2012 to date
0 - 5
6 - 10
11 - 15
16 - 20
21 - 25
26 - 30
31 - 35
36 - 40
41 - 45
46 - 50
51 - 55
56 - 60
61 - 65
66 - 70
71 - 75
76 - 80
81 - 85
Days to Review

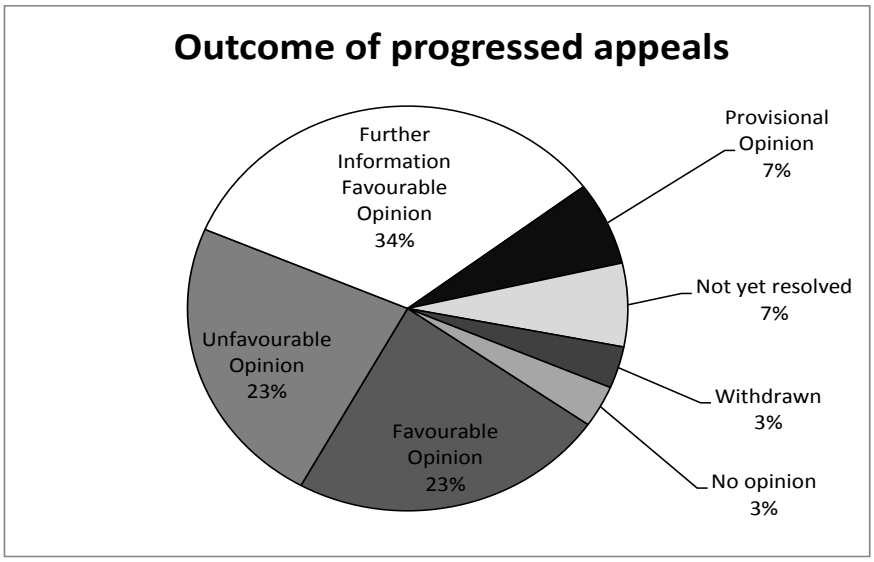

Time taken to complete Proportionate Review (All UK)
600
500
400
300
200
100
0
Frequency
April 2012 to date
2011 - 2012 (12 months data)
2010 - 2011 pilot phase (12 months data)
0 - 5
6 - 10
11 - 15
16 - 20
21 - 25
26 - 30
31 - 35
36 - 40
Days to Review

Appeals April 2012 to date (unchanged since end December 2012)

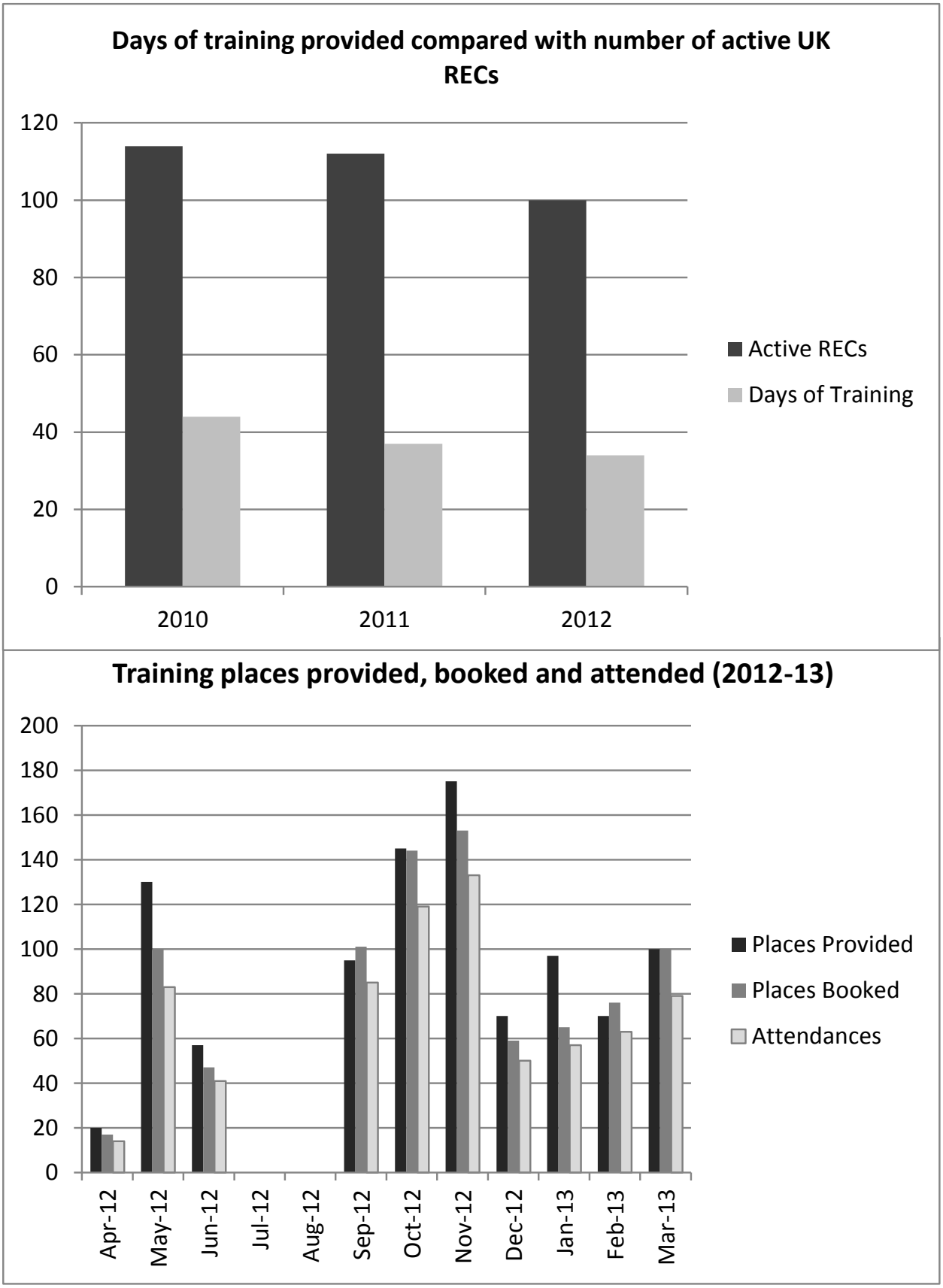
All Appeals, including Amendments	2011	2012 (to date)
Number of Appeals received	17	19
Number of Appeals progressed	14	11
No of Appeals not progressed – resubmissions	3	8

Note: The Appeals Register is sorted by the date on which the Appeal is granted, not the date of the Appeal Letter. However, it is possible for the letter and the day the Appeal is granted to fall within two different reporting periods. Appeals which are not progressed do not have a 'granted' date. For these reasons, this report is using the date of the Appeal Letter as the index date for non-progressed appeals but the granted date for progressed appeals. .



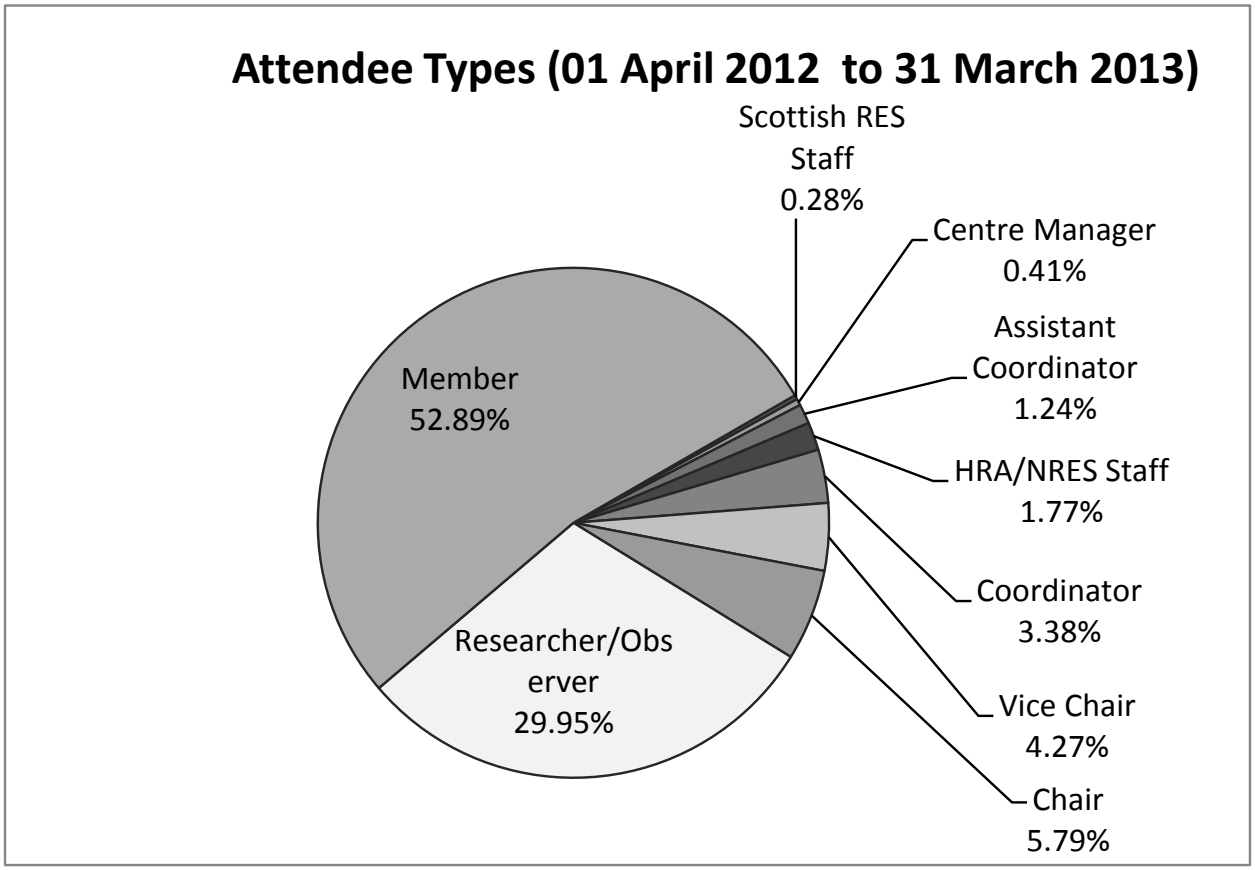


HRA Training for members – 2012-2013

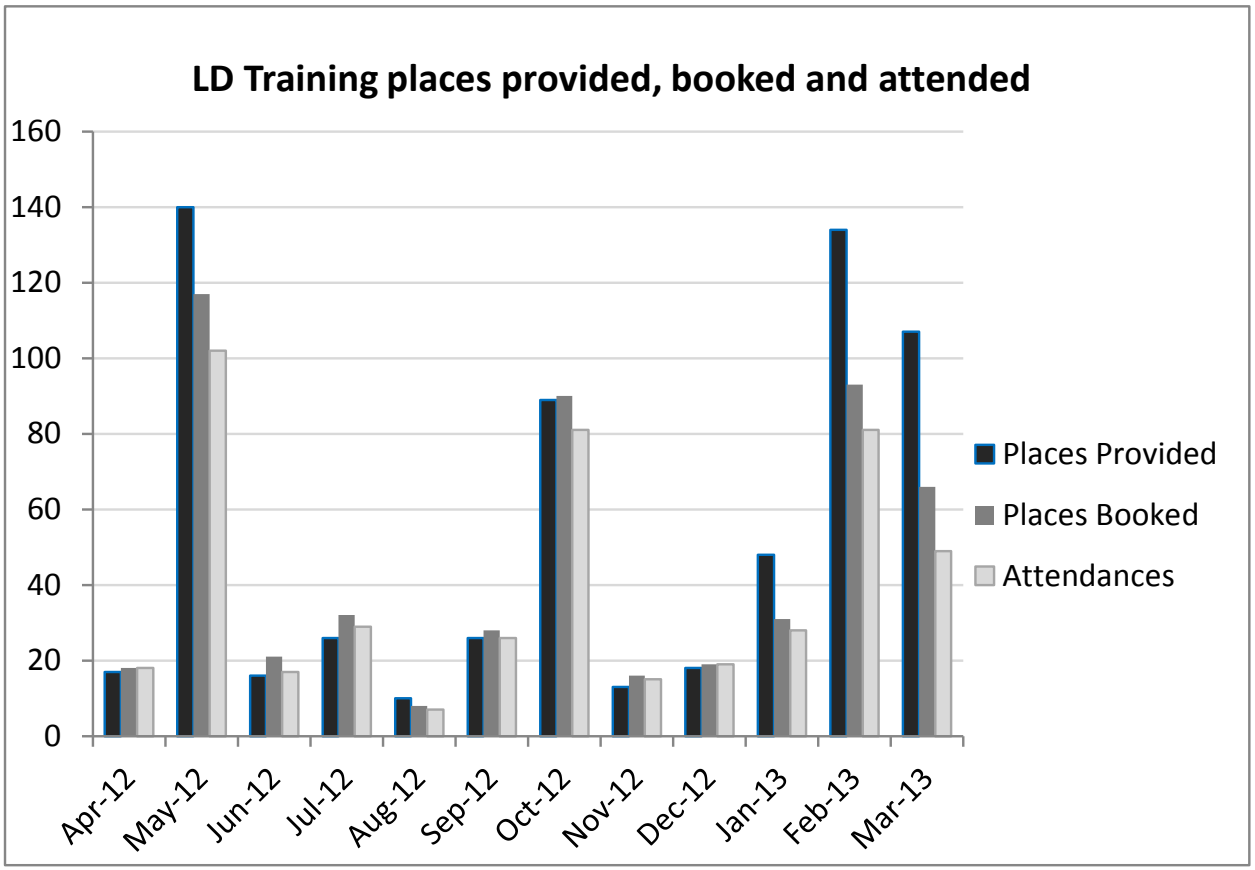


Uptake appears to be falling significantly short of provision in May, November and January. The events in question appear to be:

- **May:** Registered Trainers Workshop (London; booked 65%, attended 45%)
  NRES Committee Members' Induction (Dundee; booked 40%, attended 35% (estimated))
- **November**: Medical Devices (London; booked 55%, attended 50%)
- **January** : Researcher Training Day (London; booked 50%, attended 40%)

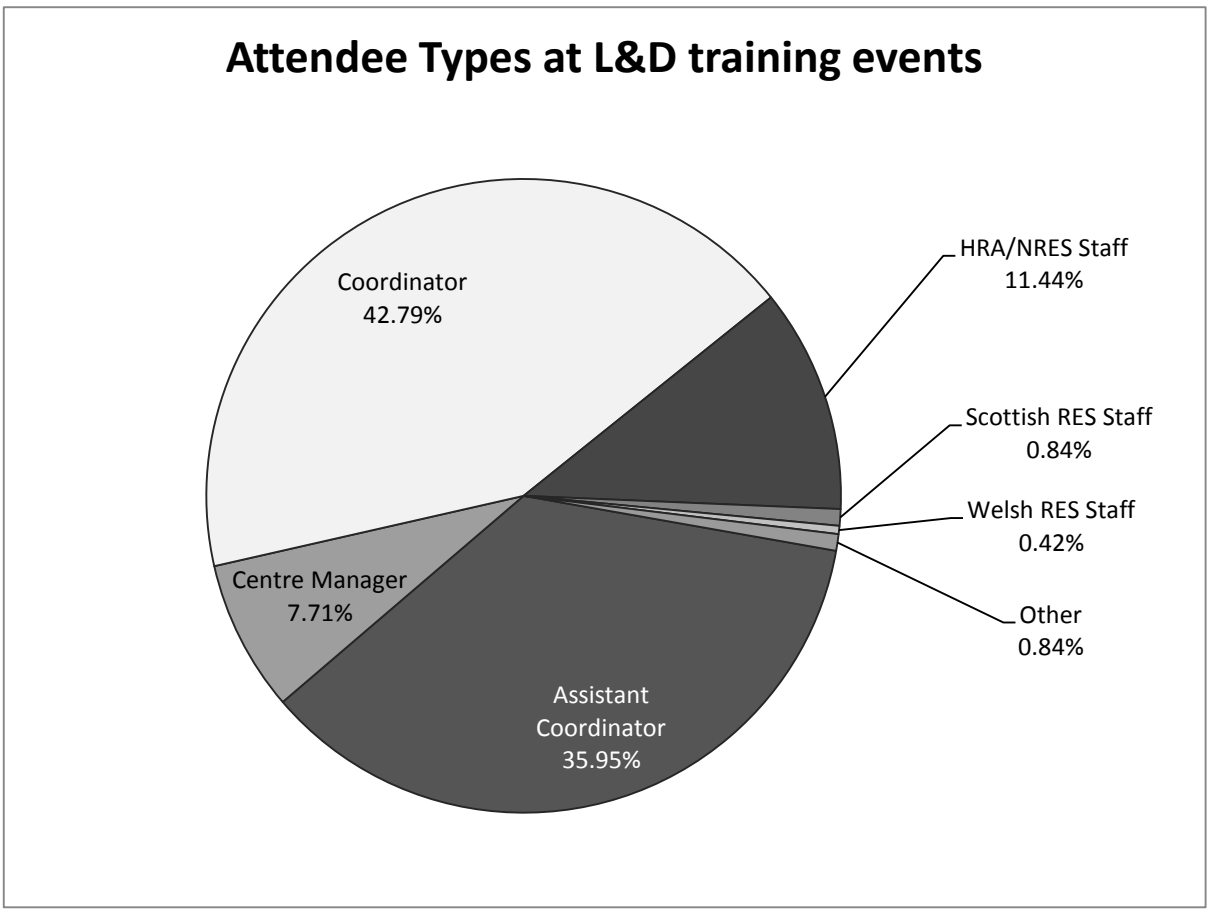


Learning & development training for staff – April 2012 - March 2013



Uptake appears to be falling significantly short of provision in May, January, February and March. The events in question appear to be:

- **May:** HRA Staff Induction (London; booked 45%, attended 30%)
- **January:** Essentials of Being a Co-ordinator Course B (London; booked 63%, attended 63%)
- **February:** Employment Law (Manchester; booked 35%, attended 30%) and NRES Staff Induction (London; booked 47%, attended 40%)
- **March:** H&S for Managers (Bristol; booked 41%, attendance as yet unverified). Overall uptake was poor.



In a small number of cases (4), sign-in sheets were not returned from training venues. Where this has occurred, attendance is assumed to be in line with the mean average attendance of all other events. The mean number of bookings which are known to be attended is 79%.

18. Appendix 2

List of IRAS Partners

1. Administration of Radioactive Substances Advisory Committee (ARSAC)
2. Chief Scientist Office, Scotland
3. Department of Health, England
4. Health & Social Care Research and Development (HSC R&D), Northern Ireland
5. Human Fertilisation and Embryology Authority (HFEA)
6. Medicines and Healthcare products Regulatory Agency (MHRA)
7. National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC), England
8. National Institute for Health Research Information Systems (NIHR IS), England
9. National Institute for Social Care and Health Research (NISCHR), Wales
10. National Offender Management Service (NOMS)
11. National Research Ethics Service (NRES)
12. National Social Care Research Ethics Committee

19. Appendix 3

List of Collaboration and Development Partners

1. Universities UK
2. Human Tissue Authority
3. University College London
4. ABPI
5. Department of Health
6. Administration of Radioactive Substances Advisory Committee
7. Ethical Medicines Industry Group
8. Medical Research Council
9. Newcastle upon Tyne Hospitals NHS Foundation Trust
10. Chief Scientist Office, Scotland
11. Cancer Research UK
12. Clinical Research Expert Network
13. ABPI
14. National Institute for Health Research
15. Association of Research Ethics Committees
16. Association of Medical Research Charities
17. Health and Social Care Northern Ireland
18. National Institute for Social Care & Health Research, Wales
19. Academy of Medical Sciences
20. The Committee on Publication Ethics
21. NIHR Clinical Research Network
22. Medicines and Healthcare products Regulatory Authority
23. Chief Scientist Office, Scotland
24. Library and Knowledge Services
25. University of Manchester
26. Wellcome Trust
27. Human Fertilisation and Embryology Authority
28. Great Ormond Street Hospital NHS Foundation Trust