



*Health Research Authority*

Health Research Authority  
Business Plan  
2013 - 2014

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*Protecting and promoting the interests of patients and the public  
in health research*

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## The purpose of the Health Research Authority

The Health Research Authority (HRA) is a NHS organisation established on 1 December 2011 as a Special Health Authority by the Secretary of State, pending its establishment as a Non-Departmental Public Body (NDPB).

The purpose of the HRA is to promote and protect the interests of patients and the public in order to support both their confidence and participation in health research, and improvements in the nation's health. It ensures 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 do this, the HRA will work with all the relevant partners to help create an environment where:

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

## Introduction

The HRA has set out an ambitious programme of work, and recognises that it needs to deliver tangible improvement, measure that success against agreed performance indicators and ensure that the success is relevant, recognised, appreciated and valued by all HRA stakeholders.

Objectives for this year will include establishing culture and values for the HRA through the Staff Partnership Forum (SPF) and the establishment of a REC member forum; implementation of the HRA communications strategy and further work within the HRA engagement strategy. New functions, such as the 'TOPS' scheme (The Over-volunteering Protection System), which protects over volunteering of healthy volunteers in clinical trials, and the advice functions on access to confidential patient data that have transferred from the National Information Governance Board (NIGB).

The HRA has established a Collaboration and Development Steering Group to oversee a set of projects to improve the environment for research in the UK. Recognising that the HRA has a lead role, it will need to work effectively with others to deliver improvement and unify processes for application and approval, so that tasks are worthwhile, proportionate and undertaken once by the most appropriate organisation to remove unnecessary activity and duplication, and the associated delays and inefficiencies.

## The HRA approach

The HRA is one of a number of bodies with responsibilities for the regulation and governance of research in the UK. However, it is in the unique position to consider the overall framework of both the regulation and governance of research, and linked key roles for those responsible for funding, sponsoring, hosting, publishing and responding to research. The HRA recognises that to deliver its ambition to make it easier to do good quality research in the UK it needs not only to work in collaboration with these other bodies but also influence and lead change with these other bodies. The work of the HRA is therefore set out to include what it will do, implement and be held directly to account for, as well as a set of projects under a UK Collaboration and Development Steering Group that will require change and implementation not just by the HRA but also by others.

The successful collaborations forged through the NRES and IRAS partnership have provided a foundation and framework for the collaborations that the HRA needs to deliver effectively.

The work identified is defined in terms of quick wins or medium-term objectives within existing policy and legislation, and long-term objectives to review the framework through which we regulate research in the UK. There are projects that the HRA will undertake now to inform these long-term ambitions, not least the work around public dialogue and engagement.

The HRA is also mindful of the Third Sector Compact, an agreement between the Government and its associated non-departmental public bodies that aims to ensure that Government and civil society organisations (CSOs), including voluntary sector organisations, work effectively in partnership to achieve common goals and outcomes for the benefit of communications and citizens in England. The HRA will follow the principles and standards around funding, transparency, information sharing, consultations, policy design and equal opportunities to help govern their relationship with the sector.

## The governance of the Health Research Authority

The Health Research Authority is an arm's length body of the Department of Health (DH), which operates within a framework agreement with DH and a Statutory Instrument governs its functions. The HRA lays its Annual Report and Accounts before Parliament, and robust public and Parliamentary accountability arrangements are in place between the DH and the HRA to ensure good communication and effective collaborative working between the two organisations. Monthly sponsorship and accountability meetings are held which provide a mechanism for the DH to assure itself of the HRA's delivery of its objectives. The DH is consulting on legislation within the Care and Support Bill, which will establish the HRA as a NDPB.

The HRA is governed by a Board that functions as a corporate decision-making body. The Board is composed of four non-executive directors (including the Chair) and two executive directors (including the Chief Executive). Four further directors attend the Board:

Chair:	Professor Jonathan Montgomery
Non-Executive Directors:	Sally Cheshire
	Dr Allison Jaynes-Ellis

	Julie Stone
Chief Executive:	Dr Janet Wisely
Executive Director:	Debbie Corrigan
Director:	Dr Shaun Griffin
Director:	Joan Kirkbride
Director:	Tom Smith
Director:	Rebecca Stanbrook

The HRA is committed to openness and transparency with Board meetings held in public and Board papers and minutes available on the HRA website. A copy of the HRA's senior management organisational structure is provided at [Appendix 1](#).

The HRA has established an Audit and Risk Management Committee, which meets quarterly to scrutinise audit services, risk management policy and activity, financial planning and management and reporting.

The HRA has an engagement strategy that includes a staff partnership forum and established formal feedback routes for the users of our services. The HRA has commissioned specific projects for patient and public involvement that will inform, ultimately, the HRA public and patient involvement strategy.

The HRA is responsible for a budget of £10m and currently has 119 staff increasing to 122 when the NIGB is incorporated, some 1,000 committee members who voluntarily serve on the 71 National Research Ethics Service committees (RECs), a National Research Ethics Advisors' Panel (NREAP) and a Confidentiality Advisory Group (CAG). Staff are based in London, at the HRA head office at Skipton House, and four offices in Bristol, Jarrow, Manchester and Nottingham.

An invaluable contribution to the HRA is made by the members who serve on NHS Research Ethics Committees, the National Research Ethics Advisors' Panel and the Confidentiality Advisory Group, and who give their time freely to provide robust and independent ethical review of research proposals and advice to the HRA.

## The functions of the Health Research Authority

- Corporate
- Appointing Authority for Research Ethics Committees in England
- Quality assurance
- HRA national roles and collaborations
- The National Research Ethics Service
- Communications
- Patient and public involvement
- Advice, guidance and training
- The Integrated Research Application System
- Access to confidential patient information under Section 251 of the NHS Act
- Transparency

- The Over-Volunteering Protection System (TOPS)

## Review of performance against 2012/13 Business Objectives

Many of the HRA objectives set out in plans in December 2011, April 2012 and May 2012 remain directly relevant to the current business of the HRA. A summary update against previous objectives is provided at **Appendix 2**. A more detailed review will be included in the HRA Annual Report.

## 2013/14 Objectives

Objectives for the HRA include on-going, short term, medium term and long term deliverables. Short term deliverables represent quick wins as well as early thinking to inform a longer term fundamental review of how we manage research in the NHS and a re-write of the research governance framework. The HRA is preparing now for when the HRA takes responsibility for this policy document in 2014 (legislation to establish the HRA as a Non Departmental Public Body includes assuming responsibility for this policy document that currently sits with DH).

### Corporate

#### *i. To maintain and develop effective governance and leadership for the HRA*

The HRA is responsible for delivering and leading the HRA business through effective and robust governance to:

- develop Board leadership and visibility;
- increase the profile and confidence in the HRA;
- schedule and manage business effectively through the HRA Board;
- demonstrate value-for-money;
- demonstrate delivery as required in the HRA-DH framework agreement, including finance, accounting and information governance;
- develop the organisation to consist of highly effective teams that have customer service and quality as central to their purpose;
- support and develop staff and committee members to build culture and values for the HRA;
- implement the HRA engagement strategy, including effective public involvement and stakeholder engagement;
- HRA already contracts for shared service provision for finance & accounting, payroll and HR transactional services. A set of projects will be initiated to migrate to the DH Shared Services Programme preferred suppliers, alongside work to change the financial coding in line with HM Treasury requirements.

*ii. To ensure the HRA operates within statutory and regulatory requirements*

As a Special Health Authority, the HRA must ensure it meets statutory and regulatory requirements, including information governance, complaints, freedom of information, equality and diversity, and health and safety, and will:

- operate within required standards of information governance;
- manage complaints according to HRA policies;
- provide timely responses to requests under Freedom of Information;
- ensure compliance with equality and diversity legislation;
- ensure compliance with health and safety legislation;
- prepare for implementation of the Health and Social Care Bill.

### **Timelines**

Many corporate objectives are on-going or are medium- to long-term deliverables. Short-term deliverables that will be completed this year are:

- Completion of the Board induction and early development programme quarter 2 (one year from appointments)
- Complete project to identify values for HRA (quarter 3, building on work started in 2012)
- Meeting DH shared service implementation targets in line with DH timescales

## **Appointing Authority for Research Ethics Committees in England**

*iii. As the Appointing Authority, the HRA will:*

- appoint members according to HRA policies;
- support members to ensure they are able to fulfil the requirement of membership, including training and provision of expenses;
- provide regular reports to the HRA Board;
- adopt and publish the REC annual reports.

### **Timelines**

These are established on-going objectives for the HRA as the appointing authority. The appointing authority report is a standing item on the HRA Board agenda.

## **Quality assurance**

*iv. Ensure all activity of the HRA is built on the principles of robust and effective quality*

The HRA has an established programme of quality assurance for RECs, including quality control, audit and accreditation within the NRES:

- maintain ISO9001 certification for the quality assurance of RECs;



- apply and expand these standards for new operational functions, including the Confidentiality Advice function and The Over-Volunteering Protection System;

In parallel, the HRA will:

- consider expanding certification to all functions;
- consider applying the Investors in People framework and work towards assessment.

### Timelines

The HRA will expand the ISO9001 certification to the new section 251 and TOPS functions in quarter 4. The HRA will determine by quarter 2 any further expansion of certification functions and agree implementation plans accordingly.

### **HRA national roles and collaborations – making it easier to do good quality ethical research in the UK**

The HRA has a national lead role and is committed to making it easier to do good quality research in the UK. The HRA has established a Collaboration and Development Steering Group to support UK implementation of projects, where the HRA will lead work that it and others will need to respond to, so together we achieve an ambition to make it easier to do good quality research in the UK. The HRA will:

- v. *Maintain UK-wide systems and ensure the UK can operate effectively within EU regulation:*
- work with colleagues in the Devolved Administrations to provide UK-wide systems and to provide support to the Social Care REC in England;
  - chair the UK Ethics Committee Authority (UKECA) and four nations meetings;
  - contribute to the development of EU-wide initiatives and respond to proposals for revision to the Clinical Trials Directive;
  - maintain and strengthen collaborations, including through the review and revision of existing formal agreements and Memorandum of Understanding documents;
  - promote a consensual and empirical foundation to our work.

### Timelines

Many of these are on-going programmes of work. The revision of the Clinical Trials Regulations is driven by the EU programme. The HRA expects to complete the update of current Memorandum of Understanding (MoU) by the end of quarter 3 and identify timescales for agreement of a new MoU within the IRAS partnership by the end of quarter 4.

- vi. *Lead and deliver the portfolio of projects within the Collaboration and Development Steering Group*
- Consider the feasibility of HRA assessment for research in the NHS:
    - conduct iterative testing of components of a proposed new process, and impact of the process on REC and R&D;

- develop tools and guidance for applicants and staff for HRA assessment;
- pilot proposed new processes to determine the opportunities for improvement;
- prepare a feasibility study to inform decision to proceed to implementation planning.
- Improve the researcher experience of REC & R&D interaction
- Rationalise requirements for amendments to NHS R&D and improve handling
- Look at opportunities to reduce the requests for additional information to approve research by identifying opportunities to take assurance from others, eg funders, or to use information in documentation required to do research, eg research protocol
- Implement UK-wide standards within a UK-wide framework, eg study titles, identifiers and terminology
- Review standards to promote a proportionate approach within a UK-wide framework
- Review expectations and systems for training and quality assurance of researchers
- Review, clarify and provide guidance on sponsor responsibilities
- Review reporting requirements to remove duplication and improve effectiveness
- Begin preparatory work to inform a comprehensive review of the research governance framework and development of a framework to support the effective management of research in the NHS, including:
  - consider, review and describe the nature of risk in research to participants, researchers and institutions;
  - explore current cultures in managing and responding to risks;
  - consider how the NHS can effectively support research in the NHS.

## Timelines

Many of these projects are at early planning stages with resources allocated from April 2013. The Collaboration and Development Steering Group will agree priorities and publish a high level summary plan in quarter 1. Projects with short-term deliverables include the HRA assessment for approval of research in the NHS which has task groups that will report in April 2013 and inform development of the feasibility study through testing and pilot before a decision on next steps is taken in quarter 2. Other projects that have already started include the REC-R&D interaction project, and study title projects and R&D amendment review, all of which will have early deliverables agreed and implemented in the first and second quarters of 2013/14.

The HRA expects to start a re-write of the Research Governance Framework in late 2014 and projects, such as the review of risks in research and how the NHS can effectively support research, are projects that will run initially from April to December 2013 to inform this work.

## National Research Ethics Service

### *vii. To provide an efficient, responsive, proportionate, effective and robust National Research Ethics Service (NRES)*

The RECs have worked to standard operating procedures since 2004 and the NRES has been widely recognised as having transformed the systems for ethical review in the UK. The NRES is a core service at the HRA in providing ethical review and opinion. The role of NRES is to protect the rights, safety, dignity and well-being of research participants and to facilitate ethical research. The NRES reviews around 6,000 applications per year (UK-wide figure) and 7,300 substantial amendments.

The NRES will undertake the following objectives:

- maintain and review standard operating procedures for RECs and ensure effective delivery against these standards against agreed targets;
- provide application-specific advice in a timely and effective manner;
- deliver improvements to application timelines reviewed through the GTAC (Gene Therapy Advisory Committee) service and work with the gene and stem cell therapy community to ensure an effective service is provided;
- reduce submission times for Phase 1 (early clinical trial) applications;
- ensure RECs are fit-for-purpose by carrying out quality control checklists on a six-monthly basis, observing meetings and increasing the percentage of RECs achieving full accreditation at first review;
- maintain capacity for REC review against application demand;
- carry out a review of the structure of the NRES directorate, including skill mix review within REC Centres;
- investigate the operation of a single national booking service for applications;
- manage reported potential breaches and misconduct register through agreed standard operating procedures, including consideration of sponsor or employee responses;
- publish NRES data: metrics on application review, including clock stopped and non-clock stopped data (following provisional opinion), appeals and complaints;
- establish a register to follow up on applicant's stated intention to publish research results and dissemination of outcomes;
- investigate ability to publish research outcomes linked to current research summary on the HRA website;
- build better collaboration between NHS R&D and NRES;
- establish a member forum to enable better communication with REC members;
- deliver within key performance indicators:
  - 95% of applications to full committee to receive final decision within 40 calendar days;

- 95% of applications to proportionate review service to receive decision within 14 calendar days;
- 95% of amendments to receive decision within 28 calendar days;
- 100% of GTAC applications to be reviewed within the legal timeframe of 90 days and a target of 80% to be reviewed within 60 days;
- 100% of audit actions plans to be completed within agreed timeframes.

### Timelines

Many of the NRES objectives are on-going maintenance and development of service. The short term deliverables for NRES include changes to SOPs to implement reduced phase 1 timelines (quarter 1 2013 – 2014).

#### *viii. To test and evaluate new ways of working within the National Research Ethics Service*

The NRES has an established history of learning and improvement. The NRES will:

- continue with the proportionate documentation for proportionate review pilot to test and evaluate the feasibility of further reducing the dataset required for proportionate review service applications;
- continue with the ethics officer pilot to test and evaluate the feasibility of improving the quality and consistency of ethical review, improving favourable opinion rates and reducing the timelines and the administrative burden on researchers and committees via the introduction of an ethics officer;
- support and implement projects within the HRA collaboration and development projects.

### Timelines

These are on-going improvement projects, implementation dates will depend on the outcome of linked projects within the collaboration and development programme, although ultimately a NRES-specific implementation plan may be adopted depending on the findings from the linked projects.

## Communications

#### *ix. To raise the profile and build the reputation of the HRA through effective strategic communications*

This will be implemented by:

- developing a corporate and visual identity for the HRA;
- communicating proactively and creatively through the right mix of digital and traditional channels;
- delivering a fully functioning fit-for-purpose website, which meets the expectations of users in line with the corporate identity;
- instigating a regular stakeholder newsletter;

- developing plans to communicate with HRA staff, stakeholders, patients and the public;
- developing a press office function;
- building a suite of resources to support communications, including a contacts database;
- measuring the effectiveness of communication channels.

## Public involvement

### *x. Develop and deliver an effective patient and public involvement strategy for the HRA*

The HRA's remit is to protect and promote the interests of patients and the public in health research. The HRA has identified projects to inform how the direct involvement with patients and the public may be implemented at the HRA:

- establish an effective patient involvement strategy for the HRA;
- complete, disseminate and consider findings from the Sciencewise funded public dialogue project;
- implement findings from the patient involvement scoping project;
- collaborate with others to capitalise on opportunities for effective public involvement.

## Timelines

The current project elements of the public involvement work are all scheduled to end in December 2013 with review points at the end of quarter 2 to inform further project work or agreement of plans to implement and resource the HRA public involvement strategy in light of findings from these early projects.

## Advice, guidance and training

### *xi. To improve and develop our advice and information services*

The HRA will continue to develop, improve and build upon its existing advice, support, information and guidance:

- develop and improve the advice provided at all levels of the organisation to ensure that advice is consistent and authoritative, including developing a single queries line;
- identify where new guidance is needed and/or existing guidance requires revision, where possible working with research regulators and other organisations providing guidance and advice to researchers to improve consistency of advice and reduce unnecessary duplication;
- provide the National Research Ethics Advisors' Panel and develop and support its remit to help RECs deliver robust, consistent and fair decisions;

- consult, and issue revised guidance, on participant information sheets and consent forms;
- develop a guide on the landscape for regulation, governance and inspection of research, including the organisations involved and links to advice;
- support wider implementation of the HRA decision tools on requirement for REC review, identify topics and develop further decision tools;
- further develop the HRA training programme, and increase our collaboration with other organisations, enabling development and delivery of joint training relevant to HRA business to multi-stakeholder audiences, with consequent sharing of expertise;
- continue to provide the Shared Ethical Debate programme (ShED) and provide improved feedback to participating RECs and learning to researchers.

### Timelines

Many of the objectives are on-going improvements to an established function. The first decision tools will be launched in quarter 1, and the revised participant information sheet guidance in quarter 2.

## The Integrated Research Application System

### *xii. Provision of the IRAS*

The Integrated Research Application System (IRAS), which is provided by the HRA on behalf of the IRAS partners, is a successful and established system launched in January 2008. The HRA has announced that in 2013 it will move to replace the system on a new platform to enable further development. This new system will be the Integrated Research Application and Approval System (IRAaS) signifying that it will include the integration of systems to support approval functions, as well as applications, and will therefore deliver the unified approval process. The IRAS branding will be maintained within IRAaS so we can keep the confidence and reputation of what is a familiar and successful system UK-wide.

The HRA will:

- continue to provide the current IRAS, on behalf of the IRAS partners, to maintain 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 maintenance;
- procure and develop a new generation of IRAaS, which will deliver:
  - electronic submission of information and supporting information to review bodies;
  - potential for single and application packages to multiple review bodies so that greater consistency and reduced duplication in processes is obtained;
  - provide a foundation for greater coordination and easy routes of communication between review bodies;

- functionality that can be more roles-based so that, for example, users that only interact with the system to review or authorise applications may access a simpler version of the system with only the functions they need;
- a system that is inter-operable with other systems so that, where required, data may be exchanged seamlessly;
- flexibility and adaptability so that the system can continue to evolve;
- develop and implement a transition plan to ensure that the processes for on-going projects are clearly communicated and as straightforward as possible;
- deliver these changes effectively, working closely with the IRAS (IRAaS) partners and wider stakeholders, including the research community.

### Timelines

The business case to proceed to procure a replacement system is approved and procurement is expected to be completed in quarter 2, with the start of the development of the new system in quarter 3. Implementation of the replacement system will depend on plans agreed with approved suppliers and will be announced later in the year. Implementation is anticipated to be in mid-2014.

### Access to confidential patient information

#### *xiii. Providing advice on access to confidential patient data and approval for the purpose of research*

The HRA took responsibility for the previous advice function within the National Information Governance Board (NIGB) for provision of advice on access to confidential patient information under Section 251 of the NHS act on 31 March 2013. The HRA also received additional functions to approve for research purposes from 31 March 2013.

The HRA will:

- ensure the effective working of the Confidentiality Advisory Group, at the HRA, in providing independent expert advice to the HRA;
- make decisions within robust and transparent standard operating procedures on access to confidential data for medical research;
- identify and implement opportunities for further efficiencies for the HRA and applicants with the move of the function to the HRA;
- provide expert advice to the Secretary of State through the nominated lead at the DH for access to confidential data without consent for purposes other than research;
- ensure the service responds to policy and service changes in England and Wales.

### Timelines:

The initial review to consider how the HRA can best provide this service and integrate it into other HRA services, such as advice, guidance and training, will report in quarter 2 2013/14.

## Transparency

*The HRA is fully committed to a transparency agenda:*

- HRA Board meetings are held in public and all papers are published on the HRA website;
- publish research summaries and summary of opinion for all applications;
- promote good research conduct, including the publication of results and access to data and tissue.

### Timelines

Objectives include established on-going provision of functions; further work to promote transparency will depend on the outcome of strategic events such as a workshop on 25 April 2013 to inform the development of further functions and responsibilities for the HRA.

## The Over-Volunteering Protection System (TOPS)

*xiv. To protect against over-volunteering of healthy volunteers in clinical trials*

The HRA, in taking responsibility for an established and simple scheme (TOPS), acknowledges the importance for the rigour of research and the protection of healthy volunteers to ensure they do not over participate in clinical trials. The HRA will:

- ensure the continued provision of TOPS;
- ensure implementation UK-wide and work with the MHRA to consider inclusion in the Phase 1 implementation scheme;
- consider opportunities for improvement and expansion, including EU approaches.

### Timelines

On-going objectives to deliver and improve the new function transferred to HRA.



## 2013/14 Objectives – Timeline Chart

Domain	Objective	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Corporate	Board induction and early development programme				
	Identify values for HRA				
	Shared service implementation targets in line with DH timescales				
Appointing Authority	Established objectives for the HRA	Standing item on HRA board agenda			
Quality assurance	Expand the ISO9001 certification to the new section 251 and TOPS functions				
	Determine further expansion of certification functions and agree implementation plans accordingly				
HRA national roles and collaboration	Maintain UK-wide systems and ensure the UK can operate effectively within EU regulation: update of current MoU				
	Maintain UK-wide systems and ensure the UK can operate effectively within EU regulation: identify timescales for agreement of new MoU within the IRAS partnership				
	Lead and deliver portfolio of projects: agree priorities and publish a high level summary plan				
	Lead and deliver portfolio of projects: decision on next steps				
	Lead and deliver portfolio of projects: R&D interaction project, and study title projects and R&D amendment review				
Communications	Launch of the new website				

Domain	Objective	Quarter 1	Quarter 2	Quarter 3	Quarter 4
<b>National Research Ethics Service (NRES)</b>	To provide an efficient, responsive, proportionate, effective and robust Service: On-going maintenance and development				
	To provide an efficient, responsive, proportionate, effective and robust Service: Changes to SOPs				
	To test and evaluate new ways of working: on-going improvement projects (implementation dates will depend on the outcome of linked projects within the C&D programme)				
<b>Public involvement</b>	Current project elements: Review points				
	Current project elements: Completion				
<b>Advice, guidance and training</b>	Deliver the first decision tools				
	Revise participant information sheet guidance				
<b>The Integrated Research Application System</b>	Procurement completed				
	Start of the development of the new system				
	Plans agreed with approved supplier(s)				
<b>Access to confidential patient information</b>	Completion of initial review				
<b>Transparency</b>	Workshop to inform the development of further functions and responsibilities for the HRA				
<b>The Over-Volunteering Protection System (TOPS)</b>	Deliver and improve the new function transferred to HRA				

## Performance and Assurance

The HRA will be working with the Board to develop a strategic plan that builds on the vision and ambition for the HRA.

The HRA Board reviews progress against delivery of each objective quarterly. The HRA Executive Management Team (EMT) reviews progress bi-monthly, and the directorate management groups monthly. A performance management framework is used to report progress against each objective, along with any notable performance and risks.

Each objective in this Plan is subject to risk evaluation and review and supporting work plans and actions, which manage performance and identify and mitigate risks. Risks are captured and reviewed by each Directorate and are escalated in line with the HRA Risk Management Policy for resolution via the strategic risk register and performance review process. The strategic risk register is reviewed quarterly and forms a key element of the HRA corporate assurance framework.

The performance report forms the basis of the formal HRA sponsor meetings with the DH.

## Measuring success

### Understanding success for the HRA

The HRA objectives include areas of work where the HRA will be directly accountable for identifying and implementing solutions for work where the HRA may lead the identification of common solutions but implementation will sit, at least in part, with others. For both, there will be work which will have measurable quantitative objectives as well as areas where success will largely be based on opinion and recognition of improvement from stakeholders which may have different perspectives of what success looks like. One challenge for the HRA will be to consider appropriately and understand fully what success will look like where there will be potentially competing or conflicting indicators. For example, will making it easier to do good quality research in the NHS necessarily mean the number of individual applications increases? Most likely not, as one reported challenge is the sheer volume of applications and addressing quality at an earlier stage may actually reduce the number of individual applications accepted for review. Similarly, there will potentially be conflicting messages if the quality bar is set higher and the risk that studies are double counted; for example, the NRES currently takes a supportive approach where applicants have incorrectly completed the IRAS filter and additional information is required to make an application valid, whereas NHS R&D require a new application. A common approach is required and any change in such fundamental approaches needs to be understood and considered in terms of how high level quantitative measures, such as application numbers, is understood.

The HRA is aware that previously published NRES metrics, which the NRES presented as showing improvement, were quite widely misunderstood. The NRES worked hard to ensure applications were only reviewed once, taking out extensive duplication with multi-centre applications, applications before and after funding which required new review because of the changes made to secure funding, and welcome initiatives such as

database and tissue bank approvals, which significantly reduced the number of individual applications. The published reduction of individual applications, with the introduction of standard procedures to implement these improvements, were interpreted by those frustrated with the regulation and governance of research as indicators that the volume of research in the UK had reduced. In truth, the extent to which this was a factor and the extent to which the improved efficiencies of administration of ethics approval was a factor were never fully understood or determined, as the consequences and implications of change on metrics was never fully thought through before the metrics were reported.

The HRA needs to take great care in setting metrics that can demonstrate the radical improvement it has the ambition to achieve. Looking at HRA service-based metrics, metrics that may provide the evidence that it is easier to do good quality research in the UK and metrics that consider not just the views of policy makers, funders and sponsors of research and researchers, but also potential participants so that confidence is maintained in research in the UK and greater numbers of people have the opportunity to take part in research and continue to feel safe to do so.

## Key performance indicators

### Building confidence in health research in the UK

These are a set of measures, quantitative and qualitative, which may be used to demonstrate a greater confidence from public, patients, researchers and those responsible for holding the HRA to account that it has made a significant contribution to making the UK a great place to do health research. This includes identifying measures that may demonstrate a greater confidence of patients and public in health research in the UK either using qualitative measures to gain insight or making agreed assumptions from measures, for example, to improve transparency of research in the UK.

1. To consolidate the HRA corporate and visual identity with a functioning, fit-for-purpose website and demonstrate improved website user satisfaction
2. Create a common language and understanding within regulation, governance and compliance of quality, risks and standards and seek researcher feedback on how this leads to improved understanding of the requirements for regulation and governance
3. Monitor REC membership and demonstrate greater diversity in REC member profile so there is greater alignment with that of the general population
4. Increase the number of applications with published research summaries from the current 15% (clinical trials of medicinal products) to 50% of applications receiving review at full committee
5. Publish all REC decisions
6. Publish advice from the Confidentiality Advisory Group and decisions made by the HRA on access to confidential data under Section 251 of the NHS act

## **Making it easier to do good quality research in the UK**

The HRA needs to develop a set of metrics to identify improvement from the system, process and behavioural changes identified by the HRA and implemented by the HRA and others to make it easier to do good quality research in the UK. The HRA needs to do further work over the coming months with stakeholders to identify what success will look like, feel like and measures that can be used to demonstrate it:

1. Work with funders and sponsors to determine a baseline timeline across the full integrated approval pathway to final approval, and set a target to reduce the timeline UK-wide
2. Determine a baseline and set a target to increase the number of applications made through IRAS
3. Publish, with explanation, trends on number of individual applications to IRAS and individual IRAS partners, including NRES

## **HRA service improvement indicators**

Simple quantitative metrics to demonstrate improvement on new HRA functions:

1. Reduce GTAC timelines in line with other HRA RECs
2. Reduce S251 approval timelines in line with other approvals within HRA

## **HRA service indicators**

These are a set of simple measures to demonstrate HRA service delivery against established functions, which will primarily of interest to those holding the service to account and researchers applying to the service:

1. To maintain IRAS as an available system 24 hours a day, 7 days per week (to 99%)
2. To maintain the current 4 working day response times to requests for advice (90%)
3. 95% of applications to full research ethics committee meetings to receive final decision within 40 calendar days
4. 95% of applications to research ethics proportionate review service to receive decision within 14 calendar days
5. 95% of amendments, on approved applications, submitted to research ethics committees to receive a decision within 28 calendar days
6. 100% of audit action plans from the accreditation of research ethics committees to be completed within agreed timeframes

## HRA Corporate Services indicators

The Corporate functions that lend themselves to meaningful KPIs (key performance indicators) are advice services, complaints and Freedom of Information (FOI) requests. The relevant performance targets are as follows:

1. To maintain a 4 working day response times to requests for advice (90%)
2. Responding to complaints within 25 working days
3. Responding to FOI requests:
  - a. 100% of all queries, including both valid and invalid FOI requests, to be acknowledged and any additional clarification sought, within 10 working days of receipt;
  - b. 100% of requests to be responded to within 20 working days of when the valid FOI request was received, where a qualified exemption does not apply;
  - c. for instances where a qualified exemption applies and a public interest test may be required, a final response will be issued within 40 working days of receipt of the valid FOI request.

## Financial plans

### Revenue

The HRA is required to plan for a balanced income and expenditure position. The HRA receives income from two main sources. The majority comes from grant in aid (GIA) provided via the DH, with the balance coming from undertaking activities by agreement with the Devolved Administrations.

The income received pays for a wide variety of activity associated with our statutory functions from the NRES, IRAS, advice, guidance and training, through to working with other bodies with responsibilities across the regulation and governance of research in the UK to collaborate to make it easier to do good quality research in the UK. From 2013, the HRA has taken over responsibility for the previous advice function within the NIGB for providing advice on access to confidential patient information under Section 251 of the NHS Act. The income and expenditure position reflects new costs of £450k for this function. It also includes efficiency savings of £850k offset by the costs of this new function with a resulting net decrease in funding of £400k.

We place great importance on ensuring our finances are managed efficiently and in a way that minimises risks. We will work hard to improve the quality of financial services provided alongside the financial information presented for decision-making.

### *HRA Budget requirement and funding*

2012/13 £ million	Subheading	2013/14 £ million	Movement £ million
<b>10.08</b>	<b>Opening Expenditure Position</b>	<b>10.32</b>	<b>0.24</b>

5.70	<b>National Research Ethics Service</b>	4.88	<span style="color: red;">(0.82)</span>
	<b>Strategy and Improvement</b>		
0.10		0.55	0.45
0.30		0.31	0.01
0.07		0.10	0.03
0.10		0.13	0.03
	<b>Chief Executive</b>		
0.33		0.33	0.00
0.16		0.23	0.07
0.09		0.21	0.12
	<b>Corporate services</b>		
0.27		0.31	0.05
0.73		0.54	<span style="color: red;">(0.19)</span>
2.23		2.09	<span style="color: red;">(0.14)</span>
<b>10.08</b>	<b>Net expenditure (reduction)/increase</b>	<b>9.68</b>	<span style="color: red;"><b>(0.40)</b></span>

<b>10.08</b>	<b>Estimated Total Expenditure</b>	<b>9.68</b>	<span style="color: red;"><b>(0.40)</b></span>
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\* Includes new function transferred from 1st April 2013 - Access to confidential information under Section 251 of the NHS Act – costs of £450k

*Assumptions regarding inflation within the above figures for 2012/13 are based on a forecast of 2.7% for 2013/14 for non-pay. Pay inflation has been set at a modest 1% pending clarification.*

*Transitional costs associated with the work to move to the next stage of ALB-wide shared services for HRA Finance, Payroll, HR and Occupational Health have not been included at this stage and will be the subject of a separate submission.*

## Capital

During 2013/14, the HRA is planning to deliver a major capital investment programme with the development of a new generation of IRaaS and finalisation of investments in video-conferencing.

### Summary of Capital investment plans

Plan initiative	2013/14 £ '000
New generation of IRaaS	1000.00
Video conferencing	50.00
<b>TOTAL</b>	<b>1050.00</b>

## Opportunity for Efficiencies

The HRA is required to meet efficiency savings along with all Arm's Length Bodies in the current comprehensive spending review period. Efficiencies are embedded within all the HRA objectives and its provided services, and to enable others to work more efficiently within a streamlined and improved overall framework for regulation and governance in the UK.

Woven through all our activities is the need to maintain and improve cost-effectiveness and quality by systematically reviewing systems, processes and procedures. Quality assurance for RECs is established with an ISO9001 certification. The HRA will be considering the expansion of this certification across functions. Equally, the HRA will use its unique position to consider the overall framework of the regulation and governance of research and to work closely with others to minimise duplication.

The electronic submission of information and supporting information to review bodies through IRaaS will provide opportunity for efficiencies in the application and submission process and a review of skill mix required to support this work. Further developments in advice and guidance and early assessment will support researchers to prepare better quality applications, with an improved understanding of the requirements for favourable ethical opinion. Working with other research regulators and other organisations who provide guidance and advice to researchers will improve the consistency of advice and reduction in unnecessary duplication.

Improved quality and consistency of review will also facilitate the approval process for researchers. The HRA will develop more opportunity for video-conferencing and teleconferences to enable remote access to REC meetings and the opportunity to save costs to researchers and sponsors in time and travel to REC meetings. Work will continue to pilot a reduced dataset for proportionate review applications, in order to reduce the time and effort in preparing applications for low-risk studies. This will be



alongside the continued ethics officer pilot to improve favourable opinion rates and reduce the administrative burden for researchers, reduce timelines and improve predictability of timelines, which we know is a key factor in improving the environment for research in the UK.

The HRA financial plans include savings of £850K in the next financial year. This will be a challenge for a small, emerging organisation working to consolidate and deliver the improvements planned within this Plan's objectives that deliver efficiency and improvement, whilst maintaining robust standards and services.

The HRA has delivered the following savings so far and made changes to make efficiency savings, which have supported new functions and new costs arising from DH-led decisions, as well as releasing cash back to the DH.

### **Summary of delivery against CSR efficiency target**

Year	£'000	% of 2011/12 budget
2012/13*	1079.00	11%
2013/14	850.00	8%
<b>TOTAL TO DATE</b>	<b>1929.00</b>	<b>19%</b>
TARGET	3000.00	30%
TO GO	1071.00	11%

\* enabled new functions to be absorbed and cash releasing savings

### **The Shared Services Programme**

The HRA is working with the Shared Services Programme (SSP) to devise a set of 'shared' services covering Occupational Health, Payroll, HR and Finance/Accounting that aim to deliver more cost effective, reliable services and deliver the Government's policy objective of concentrating on core service delivery. To deliver appropriate solutions, the HRA is working through Discovery, Design, Build, Implementation and Operation phases for each service with the SSP. The HRA will actively engage in each of these stages by responding to requests for information promptly, clearly identifying functional requirements and risk, participating in key design activities and testing programmes, enter into appropriate contracts with suppliers, agree detailed implementation plans, make necessary internal changes and participate in on-going user and change control groups. Finally, the HRA will actively contribute to the assessment of benefits realisation.

### **Procurement**

Procurement arrangements remain in the process of consolidation. Historically, much of the procurement of goods and services was carried out by the host organisations that employed NRES staff. Therefore, there was little consistency across the country in

suppliers of the same goods and services or the prices charged. This situation offers a further opportunity to reduce overall spend in 2013/14.

The HRA is mindful that the Government procures a wide range of goods and services, spending around £236 billion annually. It therefore wants to demonstrate leadership in sustainable procurement to ensure purchasing power is harnessed to procure only those goods, works and services that assure a sustainable future. The HRA is committed to supporting the Greening Government and Sustainability initiative led by DEFRA and will rationalise procurement processes to implement efficient purchasing choices.

By quarter 1 in 2013/14, the HRA will have produced a procurement strategy (which will take its lead from the Government's procurement reform agenda). This strategy will articulate how its business requirements will be met through a more efficient and consistent approach to procuring of goods and services, and the management and monitoring of on-going spend. The successful delivery of this strategy will be measured against a 2012/13 baseline and will contribute towards central government's three specific procurement targets:

1. Supporting the overall Government target that 25% of procurement spend, direct and through the supply chain, goes to Small and Medium Enterprises (SMEs)
2. All non-complex procurements are undertaken within 120 days and the principles of LEAN sourcing are implemented:

*The majority of HRA procurement will be through existing government frameworks and therefore it is unlikely that the 120-day target would present a problem.*

*Recent examples of non-complex procurement – using the GPS Frameworks, which were carried out in November and December 2012 – saw times from ITT (Invitation to Tender) to Award of under 5 weeks*

3. Supporting the centralisation of common goods and services across Government:

*The HRA expects all its common goods and service requirements to be procured through centralised contract solutions during 2013/14 (see procurement pipeline).*

The HRA has key suppliers who are SMEs. The HRA will develop data monitoring, together with NHS SBS, to monitor performance in this area and will improve on payment rate within 10 days, which will aid SMEs in particular.

In taking this strategy forward, the HRA will continue to work closely with colleagues from the DH Procurement Centre of Expertise (PCoE) in determining appropriate procurement approaches and ensuring that all procurements are managed within the parameters of the DH's efficiency controls.

**Appendix 7** contains the HRA's current procurement pipeline. The major procurement activity over the next 12 months will be the letting of a new contract to replace the HRA's critical business applications (IRAS and RED). Much of the remaining projected procurement activity for 2013/14 will be on-boarding to existing government frameworks.

## Organisational Development

### Human Resources (HR)

In September 2012, all staff had transferred to the HRA from previous host employers and during 2013/14 the HRA will complete the process of policy harmonisation. This will be a significant step towards creating an organisation with a clear and consistent identity, and in which its staff are treated fairly and equitably.

2013/14 will also see additional work being carried out to define the organisation's values and shape its culture, including:

- implementing action plan from the all staff survey;
- developing culture and values building on early work by the SPF and discussion at the all staff development day.

Now that all staff have been transferred, the HRA has a greater understanding of the nature of its workforce **Appendix 6** presents a number of HR-related data tables from which a number of key points can be drawn:

- the workforce has a significant level of ethnic diversity (31% declared as non-white British);
- sickness absence overall is higher than the NHS national average (5.15% compared to 4.02%) but, as a small organisation, the figures can be significantly affected by relatively few members of staff having long-term sickness;
- the ratio of HR staff to WTE and HR costs to salary bill is far better than DH published benchmarks – although this appears positive it does place a significant strain on the organisation to do anything more than deal with day-to-day HR issues. A response to this position is outlined below.

### Increasing HR Capacity

The HRA currently receives its HR Transactional Services from NHS BSA (Business Services Authority) and also directly employs a part-time HR Manager. During the last 12 months, HR capacity has been stretched due to the demands of the transition work. This demand is likely to remain high due to the on-going policy harmonisation work, developing the organisation's culture and values and addressing issues from the staff survey. It intends to develop an HR Resource Plan for 2013/14 that will identify how HR capacity can be developed and used to meet this continuing demand. The plan will cover the following:

- skilling up managers to effectively manage basic HR transactional requirements and to deal more effectively with performance management issues;
- ensuring that the HRA gets best value out of its relationship with the BSA and in any future shared service arrangement;
- increasing HR Strategic planning capability, eg workforce development, succession planning and talent management.

## Estates

The HRA has five centres around England. Our head office is based in London at Skipton House and we have four offices in Bristol, Jarrow, Manchester and Nottingham.

The HRA will develop an estates strategy that aligns with the needs of the organisation and its financial plans. The HRA will work closely with DH estates.

The HRA is conscious of the need to reduce the environmental impact of its activities. It is actively working to reduce travel by staff wherever possible and part of our capital plans during 2012/13 included development of video-conferencing capacity to assist in this objective. The HRA also encourages staff to recycle where possible.

## Information Services

For the first time in 2013, all HRA staff will be operating from a common IT platform. The migration to a single IT system will provide the HRA with an opportunity to:

- streamline and manage the storage of documents in one place, reducing the current requirement to email multiple documents to colleagues;
- develop a SharePoint area as a repository for corporate documents and ultimately provide a 'shared' area for REC members to access information;
- progress video-conferencing functionality within REC Centres to facilitate researchers' remote attendance at REC meetings, as well as enhance HRA meetings, reduce the need for staff travel and, in the longer term, provide desktop-to-desktop video-conferencing;
- create an intranet area for staff to improve morale and encourage further unification of all areas of the business.

## Information Governance

The HRA as an organisation does not directly handle identifiable personal data other than that of its staff, members and researchers. Nevertheless, its position is that it must apply the highest standards of information governance to all records regardless. It has therefore established a high-risk appetite and employs the following principles to manage information:

- striking an appropriate balance between openness and confidentiality in the management and use of information;
- fully acknowledging its public accountability, but equally placing an importance on the confidentiality of personal information and commercially sensitive information;
- recognising the need to share information with other organisations in a controlled manner consistent with the interests of research and, in some circumstances, the public interest.

To maintain the highest standards of Information Governance in accordance with best practice and legal requirement the Chief Executive is the Board level Senior Information Risk Owner (SIRO), the IG lead is the Director of Corporate Services and Information

Asset Owners (IAOs) are Directors or Heads of Department, as appropriate. Finally, the Board approved the appointment of Dr Hugh Davies, HRA Ethics Advisor, as Caldicott Guardian on 22 January 2013.

All information assets and associated systems are identified, and included, in an Information Asset Register and are subject to annual information asset assessments. The annual assessments of these assets was undertaken at the end of February 2013 and will inform the Information Risk Register and associated Action Plan for 2013/14 maintained by the Director of Corporate Services. Actions and objectives are reviewed and performance managed by the Corporate Management Group (CMG) which has delegated authority from the Executive Management Team to manage information risks. Risks are managed in accordance with the HRA's Risk Management Strategy.

The HRA has a comprehensive suite of policies and procedures to ensure that the handling of personal data conforms to statute, guidance and best practice. All staff participate in mandatory annual Information Governance training, and through its Quality Directorate and Audit Committee regular Quality Control (QC) checks are undertaken.

As the DH acknowledges that the HRA falls within SRMO risk category 3, it has agreed that a report to the HRA Board, externally verified through the Audit Committee, will be sufficient assurance that the HRA is meeting its Information Governance commitments. Risk category 3 is defined as follows:

#### **Having Minimal Risk Factors**

- Potential damage to national security:  
*No access to protectively marked information and limited handling of personal protected data*
- Potential reputational damage to the department:  
*Limited Ministerial oversight; information related incidents expected to be handled locally*
- Duty of care to staff:  
*General duty of care still applies, recruitment controls consistent with BPSS and local security controls aligned with appropriate industry standards and best practice.*
- Organisational / reporting requirements:  
*Do not have to demonstrate compliance with the SPF. No annual return required. Parent department provides proportionate security advice*

In preparation for reporting, a gap analysis against the mandatory information security standards established by the Cabinet Office will be undertaken to ensure the necessary requirements are established within which to manage information governance across the HRA, the essential elements of which are:

- Preventative measures, including policies
- Protective marking
- Information Assets management and reporting

- Information security
- Physical and personal security
- Access rights
- Assurance and audit
- Culture
- Training and awareness
- Corrective action
- Monitoring, avoidance of reoccurrence and improvement

Section 251 obligations in the Health and Social Care Act transferred to the HRA on 31 March 2013. Throughout the transfer process, the HRA will ensure transition planning explicitly addresses information transfer issues.

## **Equality and Diversity**

As a public sector organisation, the HRA recognise both its general and specific equality duty towards people with protected characteristics identified by the Equality Act 2010. Our public duty under the Act covers eliminating unlawful discrimination (both direct and indirect), harassment and victimisation, advancing equality of opportunity between different groups and fostering good relations between different groups. To meet these requirements the HRA has:

- developed an Equality Policy;
- collected and published appropriate equality data that informs policy and decision making;
- provided equality training as part of its mandatory training programme with a target that all staff will have received training by 31 March 2013;
- requires all Chairs and Vice Chairs of RECs to undertake equality training that is checked during the accreditation audit every three years;
- set an informal target that at least 80% of other REC members should also undertake equality training;
- increased awareness among staff and REC members;
- included equality in business planning and service development, particularly through the undertaking of equality impact assessments.

Further work planned includes the development and monitoring of relevant targets. The HRA acknowledges that it is essential to be open to the views of staff, members and interested groups when developing equality objectives but suggests that the following be considered, to:

- collect the extended data set suggested by the Equality and Human Rights Commission for staff;
- achieve a 70% return of equality monitoring data from REC Members;

- ensure 95% of staff and REC officers have completed equality training and 80% of members;
- ensure the HRA website is checked for accessibility;
- ensure all RECs have facilities to enable applicants to be available at REC meetings without having to be in attendance in person;
- ensure all HRA organised training is conducted in facilities that are accessible to REC members with a disability.

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## Glossary

<b>BSA</b>	NHS Business Services Authority
<b>CAG</b>	Confidentiality Advisory Group
<b>Clinical Trials Regulations</b>	The Medicines for Human Use (Clinical Trials) Regulations 2004
<b>CMG</b>	Corporate Management Group
<b>CSO</b>	Civil Society Organisation
<b>DH</b>	Department of Health
<b>EMT</b>	Executive Management Team
<b>EU Directive</b>	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
<b>GIA</b>	Grant in Aid
<b>GTAC</b>	Gene Therapy Advisory Committee
<b>HFEA</b>	Human Fertilisation and Embryology Authority
<b>HRA</b>	Health Research Authority (Special Health Authority established from 1 December 2011)
<b>HTA</b>	Human Tissue Authority
<b>INVOLVE</b>	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
<b>IRAS</b>	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 ( <a href="http://www.myresearchproject.org.uk">www.myresearchproject.org.uk</a> )
<b>IRaaS</b>	Integrated Research Application and approval System. The second generation system which will be delivered from 2014 to be used to apply for permissions and approvals for research in health and social care and further support integration of information and system requirements for approving bodies (and deliver therefore the government commitment to a unified approval process)
<b>ITT</b>	Invitation to Tender
<b>IAOs</b>	Information Asset Owners

<b>MHRA</b>	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
<b>MoU</b>	Memorandum of Understanding
<b>NDPB</b>	Non-Departmental Public Body
<b>NIGB</b>	National Information Governance Board for Health and Social Care
<b>NIHR</b>	National Institute for Health Research
<b>NREAP</b>	National Research Ethics Advisors' Panel
<b>NRES</b>	National Research Ethics Service
<b>PCoE</b>	Procurement Centre of Expertise
<b>REC</b>	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
<b>ShED</b>	Shared Ethical Debate
<b>SIRO</b>	Senior Information Risk Owner
<b>SMEs</b>	Small and Medium Enterprises
<b>SOPs</b>	The Standard Operating Procedures for Research Ethics Committees
<b>SPF</b>	Staff Partnership Forum
<b>Sponsor</b>	The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study
<b>TOPS</b>	The Over-Volunteering Protection System
<b>UKECA</b>	United Kingdom Ethics Committee Authority

## Document Control

### Change Record

Version Status	Date of Change	Reason for Change
Draft 6	25/01/2013	Final draft for submission to DH
Draft 6.1	04/02/2013	Incorporating suggested changes from DH
Draft 6.2	15/02/2013	Incorporating further changes from DH
Draft 6.3	18/02/2013	Finalise changes from DH
Draft 6.4	26/02/2013	Caldicott Guardian and Financial Section
Draft 7.0	14/03/2013	Changes requested after meeting with DH Sponsors
Draft 8.0	17/03/2013	Finalising/formatting changes as above
Draft 9.0	26/03/2013	Minor administrative changes/formatting
Final Version 1.0	05/04/2013	Approved by DH

### Reviewers

Name	Position	Version Reviewed

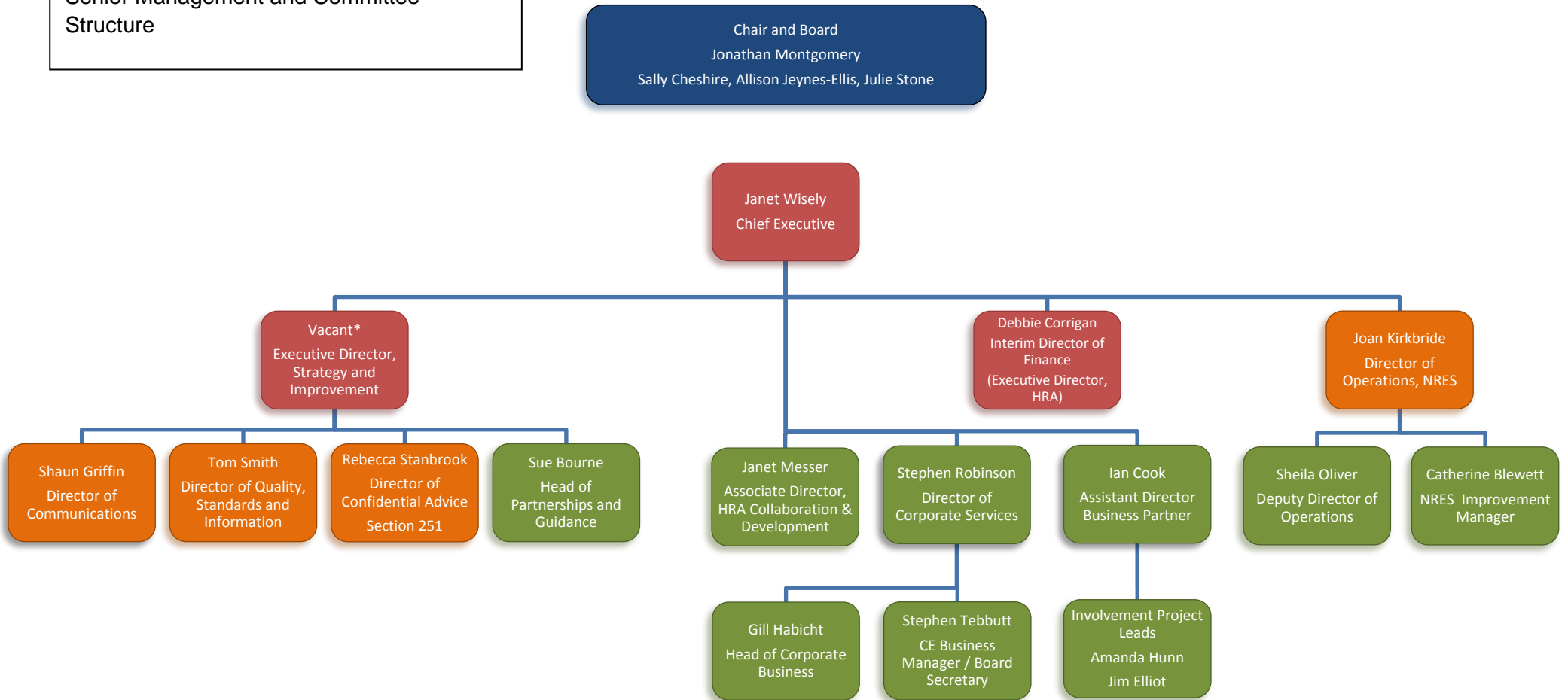
### Distribution of Approved Version

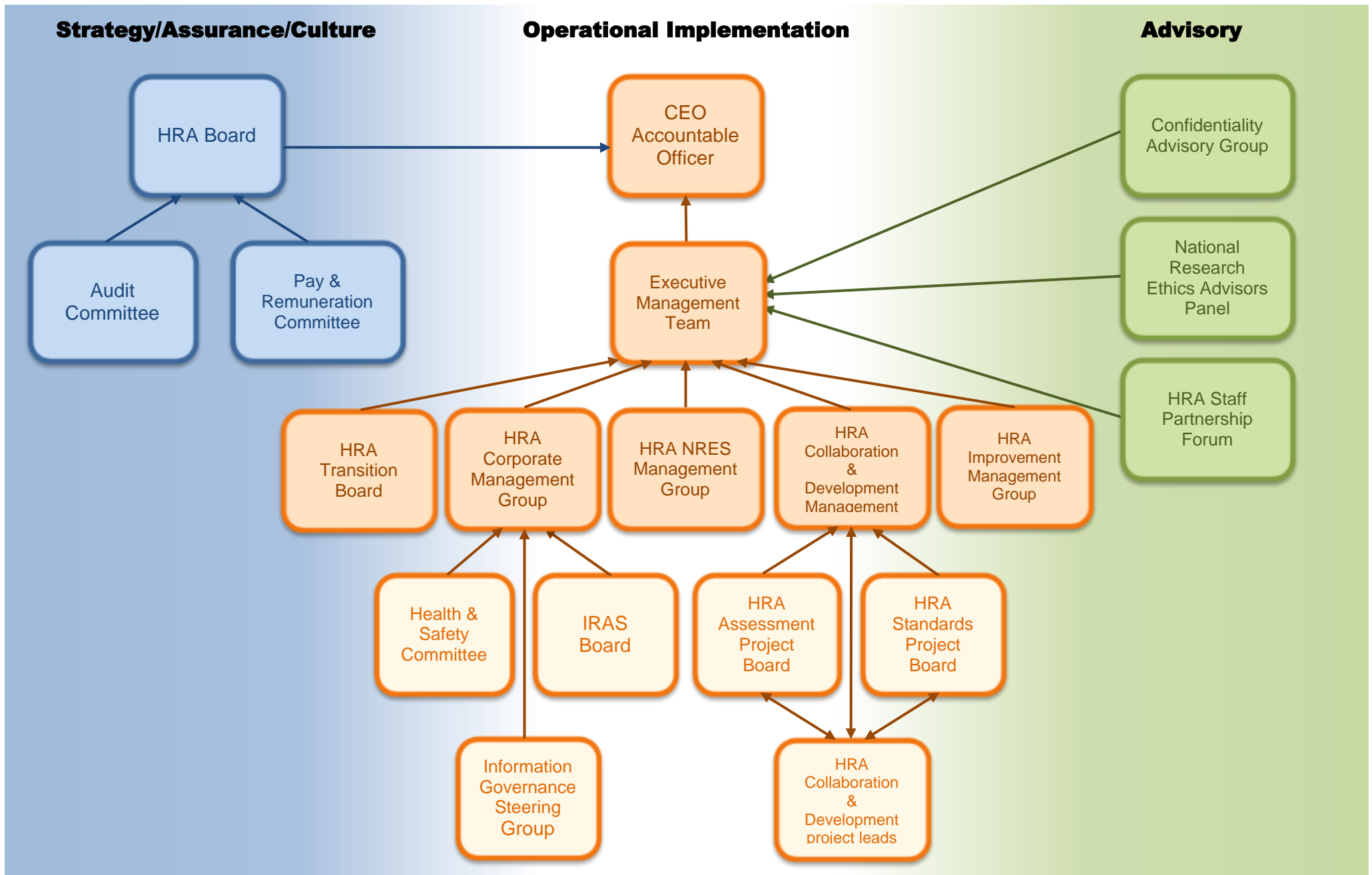
Name of person or group	Position	Version Released

# Health Research Authority

## Senior Management and Committee Structure

### Appendix 1





## **High level review of performance against 2012/13 Business Objectives**

### **Review of Business objective 1**

*To maintain and develop effective governance and leadership for the HRA*

Highlights:

- The HRA now has a fully appointed Board
- The HRA has the required governance committees, including audit and health and safety
- All staff have been transferred in to HRA
- Staff Partnership Forum established
- Governance review completed by Internal Audit and action plan progressed

### **Review of Business objective 2**

*To develop and maintain an effective communication strategy for the HRA*

Highlights:

- HRA's communications strategy approved by the Board in July 2012
- Delays in recruitment to key posts have delayed implementation of the strategy. Resources are now in place to enable its implementation, which will include the launch of the new website early in 2013

### **Review of Business objective 3**

*The provision of a platform for the unified approval process from IRAS*

Highlights:

- The IRAS has continued to be provided within target indicators, and is a stable and business critical system in the UK
- the Human Fertilisation and Embryology (HFEA) joined the IRAS partnership in June 2012
- Simple improvements have been delivered to the current system as described in business plans
- The more ambitious developments, such as electronic submission, have not been delivered in preference to investment in a new system that will also include the

developments needed to encompass the wider role agreed for the HRA in making it easier to do good quality research in the UK. Final specification is pending the outcome of the on-going feasibility study for the HRA assessment for approval of research in the NHS.

#### **Review of Business objective 4**

*To improve and develop our advice and information services*

Highlights:

- Continued to provide advice, support, information and guidance to RECs and researchers within agreed performance indicators
- Developed decision tools to support researchers in determining whether their study is research and/or whether it requires NHS Research Ethics Committee (REC) approval and also to help decide which category of research best describes their study
- Statement issued regarding the need for GCP training for researchers
- Developed and issued further guidance, including Guidance on insurance in Phase 1 trials
- Developed proposals for integration of existing queries lines into a single consolidated HRA queries line, which will be an integral part of an HRA advice service
- Reconstituted the National Research Ethics Advisors' Panel

#### **Review of Business objective 5**

*Maintain and build confidence in the HRA and health research in the UK*

Highlights:

- Set up a working group and stakeholder event to identify how the HRA should develop a patient and public involvement strategy
- Set up a further project as recommended by the working group to scope relevant activity within the NHS to inform the role for the HRA
- Obtained funding from Sciencewise for public engagement to inform HRA policy
- Presented a position for further dialogue on the HRA role on publication of results and data from research
- Contributed to the development of EU-wide initiatives and revisions to the Clinical Trials Directive
- Maintained the research summaries register for applications reviewed by a REC
- Maintained ISO9001 certification for the HRA quality assurance programme

## **Review of Business objective 6**

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

Highlights:

- Implemented structures to take forward the findings of the multi-agency project team
- Established a UK-wide collaboration and development steering group
- Presented early project findings, including governance amendments and study title guidance
- Hosted a stakeholder forum

## **Review of Business objective 7**

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

Highlights:

- NRES continued to operate to a high level of service delivery and maintained its reputation for delivery of an excellent service
- Reviewed 4,983 applications (England), of these applications 1,010 were processed through the proportionate review service
- Completed closures and mergers of RECs – no further programme is required in 2013 unless there is a change in demand
- Issued version 5.1 of the NRES Standard Operating Procedures
- Accepted Chairmanship of the United Kingdom Ethics Committee Authority and provision of secretariat
- Closed REC centres in Cambridge and Leeds, in line with agreed plans for efficiencies
- Took responsibility for the Gene Therapy Advisory Committee
- Continued to manage reported breaches and potential misconduct

## **Review of Business objective 8**

*To test and evaluate further improvement to the National Research Ethics Service*

Highlights:

- Initiated pilot of reduced dataset for low risk studies
- Initiated pilot of new ethics officer function to provide additional support to applicants and RECs
- Appointed a NRES improvement manager



## **Review of Business objective 9**

### *Standards and Quality Improvement*

#### Highlights:

- Delivered comprehensive training programme for staff and members
- Considered and issued advice on a range of topics
- Progressed work to revised the participant information sheet guidance, including a range of multi-stakeholder workshops, UK wide and involving patient representatives
- Maintained and developed the shared ethical debate programme
- Maintained the audit and accreditation programme for the RECs and REC Centres
- Further developed User Satisfaction reporting
- Maintained ISO certification for the quality assurance programme

## **Review of Milestones included in 2012/13 Business Plan update**

- Management information has been presented on NRES metrics for review of applications and amendments. Data without the clock stop for provisional opinion will be published in the 2013 annual report
- Plans put in place to follow up on applicant-declared intentions to register and publish trials
- NRES / R&D workshop held to identify areas where NRES and NHS R&D could better collaborate in areas of induction, training and communication

## **List of IRAS Partners**

1. National Institute for Social Care and Health Research (NISCHR), Wales
2. Chief Scientist Office, Scotland
3. Health & Social Care Research and Development (HSC R&D), Northern Ireland
4. National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC), England
5. National Institute for Health Research Information Systems (NIHR IS), England
6. Medicines and Healthcare products Regulatory Agency (MHRA)
7. National Offender Management Service (NOMS)
8. National Research Ethics Service
9. National Social Care REC
10. Department of Health, England
11. Administration of Radioactive Substances Advisory Committee (ARSAC)
12. Human Fertilisation and Embryology Authority (HFEA) (joined June 2012)

## The Shared Services Programme – Update and plans for 2013/14

The HRA is committed to the shared service programme being driven by the DH. The following table demonstrates our progress:

Shared service programme area	Progress
<b>Payroll</b>	Service is currently provided by NHS SBS; however, eventually the HRA will become part of the agreed DH Shared Services solution
<b>Finance and accounting</b>	As above
<b>HR</b>	Services are currently provided by NHS BSA; however, as with Payroll and Finance and Accounting, the HRA will become part of the agreed DH Shared Services solution
<b>Procurement</b>	The HRA will further develop its use of government frameworks to drive down costs and is working with the Procurement Centre of Expertise
<b>IT</b>	During 2013/14 all the HRA's IT services will be provided through the ATOS contract managed by DH
<b>Occupational Health Services</b>	Services are currently provided through the NHS BSA via a contract with Capita. During 2013/14, the HRA will move to arrange a direct contractual arrangement with the supplier when the new framework contract is awarded
<b>Internal audit services</b>	A service level agreement has been agreed with the DH internal audit service in line with the shared services programme. The HRA actively engaged in Group Audit Assurance Programme across the ALB sector
<b>Estates</b>	The HRA is working closely with the DH estates service to maximise savings from the use of premises across the HRA. Our plans in this area expect to release savings by 2013/14
<b>Legal</b>	A new cross government legal framework is currently in the process of being let. The HRA will use this for its legal requirements during 2013/14

## Government efficiency programme – controls assurance

Control measure	Assurance
<b>Recruitment</b>	<p>The HRA has maintained internal controls to comply with DH guidance which places a freeze on all external recruitment except where it is frontline or business critical.</p> <p>No HRA posts fall within the front line classification.</p> <p>Business critical posts – a local recruitment committee (RC) has been established in line with the delegated authority to recruit to business critical posts. The Executive Management Team acts as the RC. The HRA has established approval guidance and a vacancy control policy.</p> <p>A monthly report is provided to the DH Governance Assurance Committee on posts approved to proceed to the ALB internal recruitment pool or to recruitment.</p>
<b>Recruitment (contingent labour)</b>	<p>The recruitment control has been applied to all new appointments, including the use of temporary and agency staff. The status of the employment relationship is immaterial. The key is whether the post to be filled is frontline or business critical.</p> <p>The approval process described above applies whether the established post will be filled with a permanent recruit, a fixed-term appointment or a temporary/agency worker.</p> <p>For specialist or interim staff, recruited into roles that are not part of our established posts, these ‘appointments’ are covered by the rules controlling spending on professional services (below).</p>
<b>Communications, marketing and advertising</b>	<p>Cabinet Office approval is sought for all communications and marketing proposals greater than £100k.</p> <p>Expenditure over £20k requires that we work with the DH Communications Directorate to ensure it is consistent with Cabinet Office principles.</p> <p>The HRA has a delegated authority for spending of up to £40k in respect of recruitment marketing activity, subject to that spending being in line with centrally agreed contracting routes.</p>
<b>Professional services (inc consultancy)</b>	<p>DH departmental approval is required for all spend on services categorised as professional services</p> <p>Ministerial approval is required on:</p> <ul style="list-style-type: none"> <li>• expenditure over 100k defined as consultancy</li> <li>• expenditure over 200k for any professional service</li> </ul>

Control measure	Assurance
	Cabinet Office approval is required for: <ul style="list-style-type: none"> <li>• professional services contracts exceeding 9 months</li> <li>• extending existing professional services contracts beyond 9 months</li> <li>• procurement related consultancy over 20k</li> </ul>
<b>Information &amp; communications technology</b>	ICT contracts with a value greater than £5m, and <i>any</i> new spend greater than £1m on systems that support administration must be approved by Cabinet Office. The HRA works closely with DH IS on all ICT developments to ensure alignment with standards and development of common services. In this respect, the HRA will continue to notify DH IS of ICT related expenditure greater than £100K for review and advice. This includes change controls or new orders to modify or extend existing ICT or ICT-based services.
<b>Property</b>	No new property leases or lease extensions are to be granted without Treasury approval. This means that all new property 'events' will need to be approved by the DH Property Asset Management (PAM) Board. The HRA works closely with the DH Estates department.
<b>Procurement</b>	The HRA procures common goods and services from centrally approved contracts and frameworks. The HRA participates in the shared services programme and initiatives to maximise scope for savings.

**Note:**

Compliance as per document: *Departmental Efficiency Measures, Arm's Length Bodies – Operational Guidance, August 2011 and subsequent updates*

## Headcount movement 2012/13 – Figures to be confirmed

<i>Headcount position as at 31 March 2013</i>								
Description	Headcount	WTE						
Payroll HRA	123	116.32						
Non-payroll HRA temporary members of staff	11	5.49						
Secondees	17	6.2						
Non-payroll recharged permanent staff	0	0						
<b>TOTAL</b>	<b>151</b>	<b>128.01</b>						
<i>Headcount position by quarter 2013/14</i>								
Description	Q1 (Apr – Jun) projected		Q2 (Jul – Sep) projected		Q3 (Oct – Dec) projected		Q4 (Jan – Mar) projected	
	Headcount	WTE	Headcount	WTE	Headcount	WTE	Headcount	WTE
Payroll HRA	126	119.32	126	119.32	126	119.32	126	119.32
Non-payroll HRA temporary members of staff	11	8.49	11	8.49	11	8.49	11	5.49
Secondees	17	6.2	17	6.2	17	6.2	6	2.2
Non-payroll recharged staff	0	0	0	0	0	0	0	0
<b>TOTAL</b>	<b>154</b>	<b>134</b>	<b>154</b>	<b>134</b>	<b>154</b>	<b>134</b>	<b>143</b>	<b>127</b>

<b>Further staff analysis (as at January 2012)</b>								
2012/13 (as at 31/12/12)	Headcount	M	F	WTE	M	F	Ethnicity	Disability
On payroll	123	28	95	116.32	26.1 (22%)	90.22 (78%)	31% (Non-White British)	<1% declared

<b>Sickness absence</b>	
	2012/13 (period Sep - Dec 2012)
Short - term sickness absence	1.42%
Long- term absence	3.73%
Overall	5.15%

National comparator 's = 3.6% for SpHA'S and 4.02% for NHS overall

<b>Comparators requested by ALB Team</b>		
Description	Measure 2012/13	Target Benchmark
Ratio of VSM or SCS to WTE staff complement;	1:36	?
Number of staff earning more than £142,500 now and any projected change during the planning period	0 (no projected changes)	?
HR staff to WTE employee ratio	1:196*	1:100
<i>Cash ratio has been based on a staff salary cost of c4m p.a.</i>	£121/member staff	£468 (upper quartile)
<i>HR staff to WTE employee + REC member ratio (based on 1500 REC members each at 0.08 WTE)</i>	1:394	1:100
Training budget as a % of pay bill	2.4%	?

## **HRA procurement pipeline (current)**



20121105  
Procurement pipeline