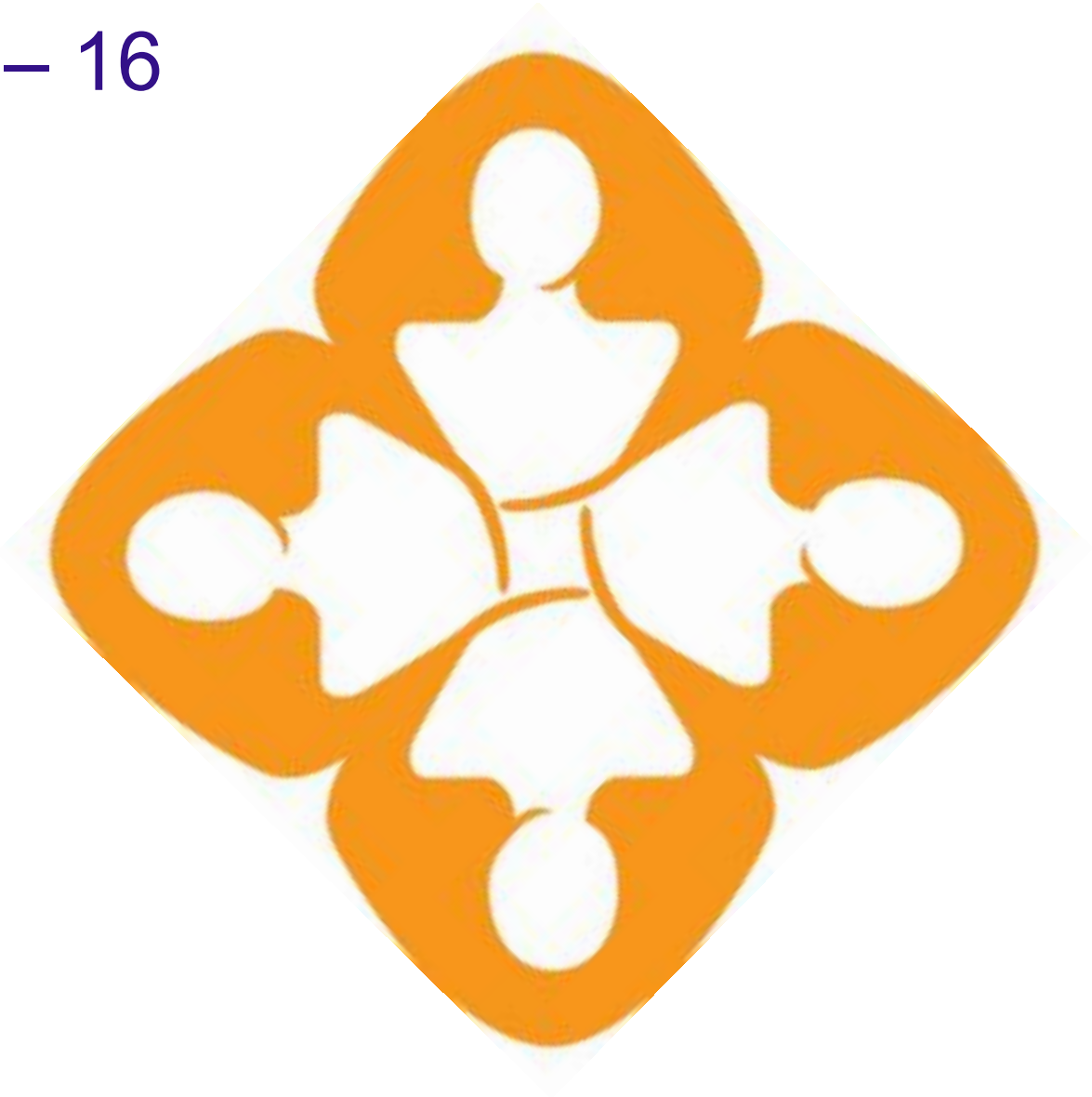
Health Research Authority

Business Plan

2015 – 16



Author: S. Robinson Date of Release: 21/05/2015
Version No. & Status: 1.0 Final Owner: J. Wisely Approved By: HRA Board
Supersedes Version: 0.7 Review Date: Jan 2016

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1.0 Introduction

The Health Research Authority (HRA) is now a Non Departmental Public Body established on 1st January 2015. Our main purpose continues to be to protect and promote the interests of patients and the public in health research in line with the Care Act, though our remit is now broadened to include social care. We do this by supporting and promoting a robust and efficient regulatory and governance framework in the UK.

Our vision and ambition is to develop a successful organisation that is:

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

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

- greater numbers of patients and the public can and do take part in health research and continue to feel safe when they do;
- applying to do research is simpler and getting a decision is quicker and more predictable;
- researchers find it easier to do high-quality, ethical research;
- commissioners and providers in the NHS appreciate 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 get registered and research results get published.

2.0 Strategic Objectives

2.1 Strategic Direction

Our overall strategic goal is to make the UK a global leader for health research.

We will work with a wide range of partners to help create an environment where more money invested in research goes into carrying out relevant, good quality research that is registered and published. To achieve this we will deliver the following strategic aims:

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

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

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

We have committed to a range of actions to improve transparency in health research. We require that clinical trials are registered as a condition of a favourable ethical opinion and we publish the summary of health research approved by the HRA in England. The HRA recognises that transparency of research is essential so that participants and patients are protected from unnecessary research and patients benefit from improved outcomes and care informed by high quality research.

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

The objectives and goals contained in this Business Plan provide the detail of actions we will be undertaking in the forthcoming year 2015/16, to support the delivery of these strategic objectives and build on the considerable progress made since the HRA was established in 2011, which in turn built on the widely recognised improvement to the management of research ethics delivered through the National Research Ethics Service.

2.2 How We Do This

Streamlining Research

We have a set out an ambitious programme of work to improve the framework and processes for the approval and management of health research in the NHS. Many of our projects involve collaboration with partners, and some are led by them. We work closely with other bodies, including the NIHR (National Institute for Health Research), MHRA (Medicines and Healthcare Products Regulatory Agency) and with colleagues in the Devolved Administrations to provide a UK wide system for research that is proportionate and effective for approving research. We also promote proportionate standards within a consistent national system of research governance. Regular updates on progress are available on our website and newsletter.

Transparency

Our plans to promote transparency in research will provide important reassurances to the public, and are part of our duty to support good quality, ethical research. These include the registration of clinical trials as a formal condition of Research Ethics Committee (REC) approval (from September 2013) using the sponsor declaration for a new study as a check point on compliance with transparency conditions of previous REC opinions, working with partners to understand what is meant by publication, and developing standards for publication to ensure findings are available for participants, patients and the public, researchers, clinicians and commissioners of health care.

We publish a summary of every health research project conducted in the UK that requires ethical approval through the UK wide service.

Given the overwhelming support for our transparency agenda, we expect that the vast majority of researchers, sponsors and funders will embrace the plans. In implementing our plans we have been mindful of our ambition to make it easier to do good quality research in the UK and have set out sensible and proportionate measures to increase transparency and increase confidence in UK-based research.

Protecting the Interests of the Public

The HRA has responsibility for the 68 NHS Research Ethics Committees (RECs) and the Social Care REC in England, and works with colleagues in the Devolved Administrations to provide a UK wide service working to HRA Standard Operating Procedures (SOPs). RECs meet regularly to consider UK wide applications for new research projects each year. The HRA is also responsible for the Gene Therapy Advisory Committee (GTAC), which reviews gene and stem cell therapy clinical trial applications from an ethical perspective.

The HRA, through its independent Confidentiality Advisory Group (CAG), provides advice about appropriate use of confidential patient information without consent in the NHS for research, and other purposes such as commissioning health services. The HRA is responsible for approving access in research and for advising the Secretary of State for purposes outside of research.

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

The phased implementation of HRA Approval during the course of 2015 will further protect the interests of the public by providing a transparent and efficient approval system.

Working with Devolved Administrations

Whilst the HRA's remit covers England, in accordance with the Care Act's duty on us to collaborate we work closely with the devolved administrations in Scotland, Wales and Northern Ireland to provide a UK wide ethics service and support UK-wide compatibility for the governance and management of research.

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

3.0 Governance

The HRA as a Special Health Authority (SpHA) was, in accordance with the new Care Act provisions of 2014, dissolved by Parliament and ceased to exist on 31st December 2014. The Commencement Order issued in October 2014 subsequently came into force on 1st January 2015 and established the HRA as a new, statutory Non Departmental Public Body (NDPB).

The primary role of the HRA will continue to be to protect and promote the interests of patients and the public in health research and to streamline the regulation of research, though this now includes a remit for Social Care. Additionally important new roles have been acquired to assume responsibility for the publishing of guidance on the good

management and conduct of research from the Department of Health (DH) and to promote transparency in research.

As an NDPB the HRA will continue to lay its Annual Report and Accounts before Parliament and robust public and Parliamentary accountability arrangements will be 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 will continue to be held which provide a mechanism for the DH, on behalf of Parliament, to assure itself of the HRA's delivery of its objectives.

The key benefits of being a statutory NDPB include increased independence from central government, a greater ability to maintain impartiality, continued transparency in its objectives and communications, and longer-term protection from dissolution (it would require statute to dissolve the NDPB). As a statutory body, the newly constituted HRA will not be required to act under direction of the Secretary of State for Health as it is directly accountable to Parliament. It will however still be 'managed' by the Department of Health.

This change to NDPB meant that whilst there were changes to the Board, all other contracts, arrangements and liabilities transferred by force of a Transfer of Staff, Property and Liabilities Order with no or very little change and all directly employed (permanent and fixed term) HRA staff transferred to the new HRA NDPB body. Importantly this Order ensures the protection of employees' contractual terms and conditions of employment.

The Board

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

Chair	Professor Jonathan Montgomery
Non-Executive Directors	Dr Allison Jeynes-Ellis, Prof. Deidre Kelly, Prof. Nalin Thakkar and Graham Clarke
Chief Executive	Dr Janet Wisely
Executive Director	Ian Cook
Executive Director	Debbie Corrigan
Director	Joan Kirkbride
Director	Tom Smith
Director	Janet Messer

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 A.

The HRA Board has established an Audit and Risk Management Committee, which will continue to meet quarterly to scrutinise audit services, risk management policy and activity, the annual governance statement, statutory annual accounts and corporate governance arrangements, providing assurance to the Board that the HRA is meeting its statutory and regulatory requirements.

The HRA is responsible for a budget of £13.8M and currently has 182 (*Nov 2014*) full time equivalent (fte) staff based in London, at the HRA office at Skipton House, and four offices in Bristol, Jarrow, Manchester and Nottingham.

An invaluable contribution to the HRA is made by the 1,000 committee members who voluntarily serve on the 68 national Research Ethics Committees (RECs) and the

National Research Ethics Advisors' Panel (NREAP), the members of our PPI Panel and the members of the Confidentiality Advisory Group (CAG) and who give their time freely to provide robust and independent ethical review of research proposals and advice to the HRA, research funders, research sponsors and those responsible for managing and conducting research in the UK .

4.0 Key Achievements of 2014 - 2015

HRA Approval Programme and Collaborative Projects

Funding for the HRA Approval Programme was announced at the end of 2013/14, following the successful submission of a business case in October 2013. After an initial phase of recruitment of programme resources, detailed work on the standards and processes for HRA Approval has been undertaken.

In collaboration with Cancer Research UK and the Experimental Cancer Medicine Centres, the standards and process for a single technical pharmacy assurance and ionising radiation assurance as part of HRA Approval has been implemented. The arrangements are being refined and evaluated to inform the subsequent roll-out, with early signs of reduction in duplication of review across sites.

Standards for template agreements and review of legal and practical considerations of studies have been agreed with relevant stakeholders. Detailed exploration of the issues relating to information governance has begun. The process of recruiting staff to HRA to undertake assessments and coordinate the technical assurance has commenced. Working with the NIHR Clinical Research Network and the devolved administrations, a UK-wide process to simplify and streamline the process for protocol amendments has been agreed. HRA has started coordinating the process for studies outside the NIHR portfolio in advance of the full implementation of HRA Approval for all studies.

Alongside the HRA Approval programme, the expectations of sponsorship of research have been explored extensively and work with non-commercial sponsors is developing toolkits and training to improve standards. With significant input from expert groups, including EQUATOR, the HRA has published for consultation-in-use the first of a suite of protocol templates to improve the standards of these important documents, with the potential in the longer term to reduce form-filling in applying for approvals. An application management service has supported researchers facing particular difficulties under current regulatory arrangements, improving the potential for successful completion of complex and novel research.

Research Ethics Committees

The HRA has 68 RECs and has continued to deliver an excellent service to researchers. The London REC office was rationalised with the administrative support for six RECs being moved to other HRA Centres. The change was implemented successfully with no disruption to service, and generated financial savings.

The timelines in England have continued to improve and the performance within statutory timelines is excellent with good efforts being made to achieve the stretched targets, particularly in relation to processing substantial amendments. Those efforts will continue in 2015. The number of applications reviewed by full committee was 3770 in England (4665 UK wide) and proportionate review applications (low risk applications through sub-committee) 1063 in England (1439 UK wide). The type of applications which can be

processed through the proportionate review service was further developed and the use of this service is increasing with applications being reviewed in an average of 10 days. All applications reviewed through the Gene Therapy Advisory Committee have been reviewed within the 60 day target.

The HRA has continued to work with the Phase 1 community to improve the review of Phase 1 studies. A new advanced training programme including presentations from Phase 1 CROs has been developed and implemented to the REC and wider research community.

A national booking service has been implemented so that researchers need only to dial a single number to book the first available agenda slot within the UK or a meeting of their choice.

Confidentiality Advisory Group

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

The CAG is now firmly established within the HRA. The CAG now meets more frequently, improving the service provision to applicants, and timelines for processing applications continue to improve. Application processes are becoming standardised through the development of standard operating procedures and improved streamlined links have been embedded with Research Ethics Committees. Training to RECs and researchers on the use of personal data in research and the role of the CAG and its processes has been provided throughout the year. All CAG advice and approval decisions continue to be made publicly available on the HRA website and the CAG has strongly supported moves towards improved transparency through its advice recommendations.

The HRA has had the opportunity to comment on the Health & Social Care Information Centre (HSCIC) Code of Practice on Confidential Information and the Department of Health '*Protecting Health and Care Information – A consultation on proposals to introduce new Regulations'*. The HRA is also working with the Department of Health on the development of new Regulations that will set out in statute criteria the CAG will take into account when providing advice so as to ensure greater public confidence in decisions taken by the approval bodies.

Public Involvement

The HRA has made significant progress with work to implement the HRA's public involvement strategy, which was approved by the Board in 2013/14. It has also established our Public Involvement Network, a panel of more than 70 people.

An interactive session on public involvement has been firmly established as the finale to the induction programme for new staff. As well as setting out the important part public involvement plays in health research and the work of the HRA this session also emphasises how important the work of all staff is to patients and the public. The session has been co-produced with Richard Stephens, one of our public contributors, and has been reviewed and improved with him between each induction course. Building on that we have run two interactive all-office video conference sessions on public involvement for staff who started at the HRA before the induction sessions and who wanted to learn more.

The HRA has also started to involve public contributors from our Public Involvement Network in the recruitment of new staff. In 2014/15 this has been done this for one director level post and two deputy director posts. This approach is being built into recruitment policy and processes for all staff where public involvement is relevant to the post. A project to develop the public involvement pages of the HRA's web site has also been initiated, working with members of the Public Involvement Network to co-design and co-produce new content, which is scheduled to be completed in June 2015.

The second joint project with INVOLVE to analyse the amount and nature of the public involvement reported in applications for ethical review in 2010 and 2012 has been completed. This showed an increase in the amount of public involvement reported for non-commercial funded studies and commercially funded studies. Work also started to improve the way public involvement is assessed as part of ethical review in order to try to increase the amount and quality of public involvement in health research more widely.

Financial Balance and Budgeting

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

- A published Financial Plan for 2014/15 and agreed budgets being in place;
- Preparations for a strategic 5 year financial plan during the course of the year;
- Financial reports within 4 working days and reporting to the EMT and the Board as agreed; and
- Forecasts which are reviewed monthly through close finance to service partnering.

Quality Assurance

The Quality Assurance Department holds ISO 9001:2008 Certification and has continued to build upon well-established quality principles over the last year. Noteworthy achievements in this area over the last year include:

- Successfully recruiting a small team of trained internal auditors;
- Introducing an electronic Document Management System to record, control, archive and version control HRA policies, procedures, SOPs, and other documents;
- Undertaking internal audits /gap analysis of HRA functions /departments on schedule and in consultation with managers; and
- Having a highly successful ISO 9001:2008 external audit with no observations / non-conformities being raised by BSI.

BSI commented (21/07/14): ‘”The organisation continues to demonstrate commitment to quality and improvements through transparent and comprehensive monitoring, analysis and reporting”.

In order to further improve the level of service offered by the HRA, the QA Department is widening the scope of auditing and seeking to further embed quality across the Authority.

Transparency

The HRA continues to recognise that the Transparency agenda is one which is global with a wide range of stakeholders. This is an agenda in to which however the HRA is committed to ensure that the UK is leading upon whilst remaining a great place in which to undertake research. Significant progress was made over the year in many areas including:

- Refreshing the HRA Research Summaries' web pages to create an improved service;
- Since September 2014 requiring the sponsor to declare that all clinical trials approved by a REC since September 2013 have been registered on a publicly accessible registry;
- Receiving almost 200 responses to our call for comment on improving transparency, the vast majority being greatly supportive; and
- Working with Phase 1 CROs in terms of the forthcoming EU Clinical Trial Regulations.

Over the last year, we have responded to consultations / initiatives others have led, such as the WHO consultation on publishing and have sought to ensure that the UK remains competitive for research to take place whilst ensuring that the commitment to Transparency continues. We have undertaken a small scale audit of publication rates, to be shared during 2015/'16 and have publically committed to the deferral option request for Phase1 studies to be registered continuing until the introduction of the EU Clinical Trial Directives, thus allowing research development whilst protecting the interests of participants.

Advice and Guidance

Notable successes of the past year include:

- Dedicated software to facilitate improving service to Queries Line has been procured;
- The HRA Queries Line has continued to see and assist increasing numbers of enquiries over the last year.1,287 enquiries were received in the period April – September 2014 (an increase of 38% year-on-year) and 4 out 5 were responded to on the same day as received;
- Put in place a panel to provide decisions on whether projects are managed as research and require NHS REC review; this panel complements the decision tools and provides additional support where decisions are not clear-cut;
- HRA has developed guidance for those working in regenerative medicine and has partnered with MHRA, HTA and HFEA to deliver a one stop shop for regulatory advice for regenerative medicine studies; and
- Launched the final, definitive version of the web-based guidance for consent and participant information sheets and worked with the NIHR, MRC and others to develop training to complement the online guidance.

Estates Strategy

A detailed review of the HRA estates footprint and space utilisation was undertaken and following consideration of a number of options a medium term estates strategy was agreed by the board as follows:

- To maintain the current 5 geographic office locations in the medium term (3 years) whilst focus is maintained on delivering HRA approval and its implementation and acceptance;
- HRA adopting the industry standard of 8 desks to 10 staff ratio; and
- To achieve this by March 2016 if not sooner.

HARP and IRAS

HARP (HRA Assessment & Review Portal) was launched to time and budget in spring 2014 to replace the technology for the system that supports the REC review process. This new platform will provide a foundation for the implementation of HRA Approval. During 2014 the procurement and contractual processes for further development of

HARP and IRAS were completed, ensuring that HRA is well-placed to implement a series of releases to these systems during 2015-16 that will streamline and simplify the research approvals process.

5.0 2015 – 2016 Objectives

5.1 Department of Health's Goals and Priorities

The HRA strategic objectives and operational plans are firmly aligned to the DH's priorities for health related research but on a broader note, the DH has set some clear priorities for delivery by the health and care system. All Health, Health Related and Social Care bodies therefore need to consider how their work contributes to the joint delivery of these priorities to ensure the system is aligned, consistent and works effectively through collaboration. These priorities are:

Living and ageing well
Helping people live healthier lives to make this country the best place in the world in which to grow old. Our priorities are preventing disease and poor health, improving care for people over 75, reforming social care, integrating health and care, and improving care for people with dementia;

Caring better
Raising standards in health and care, ensuring everyone is treated with compassion and respect. Our priorities are improving the quality of care and the use of technology, encouraging greater openness and taking significant steps towards parity of esteem between mental and physical health;

Preparing for the future
Making the right decisions today so that the health and care system can meet the needs of people in the future. Our priorities are ensuring the long-term sustainability of the system by maintaining quality, access and financial performance, working more efficiently and investing in research and innovation.

The HRA's contribution to these include:

- actively facilitating an improvement in the speed with which research is approved and delivered to improve the rate of understanding of disease and the development of effective treatments that will improve patient care and mortality rates;
- having an important and significant impact on improving standards of care by continuing to work with UK-wide partners across the research pathway to simplify research regulation and management, develop and disseminate agreed standards and systems to support good quality research and reduce duplication to improve efficiency for sites, sponsors and regulators;
- supporting biomedical research, including that involving the study of brains from the deceased, that contributes to improvements for those with dementia or who are likely to develop dementia. We continue to ensure that researchers using the 200 Human Tissue Authority licensed tissue banks benefit from a streamlined process where Research Ethics Committees give generic approval for tissue collection, storage and release arrangements;
- leading improvements that make it easier to conduct good quality research will contribute to the UK growing as an international centre for conducting health related

research which is able to attract significant additional investment that contributes to economic growth;

- embracing new technologies so that researchers making applications can take full advantage of recent advances; and
- maintaining a focus on efficiency and value for money by keeping within agreed revenue and capital cash and resource limits thus ensuring that budgets are effectively managed throughout the organisation.

5.2 Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research

HRA Approval

HRA Approval will provide a single system for all studies in England, replacing the current separate systems for ethical review and NHS permissions with an integrated process and single approval that provides assurance to researchers and to organisations hosting research. Following the award of funding at the beginning of 2014/15, the HRA has recruited resources, agreed standards and developed the detailed plans for the programme. Full implementation of HRA Approval will significantly reduce the complexity of the approvals process for academic and industry research.

The controlled roll out of HRA Approval by study type will take place during 2015. Each phase will be announced in time to allow others to prepare to adopt HRA Approval. Each phase is dependent on the success of the previous phase and will not be announced until the previous phase has been initially tested. Process flows will be tested to inform the required information system specification. This careful approach is essential to maintain confidence in the process and to avoid local preparation against dates that subsequently change. It will also ensure the information system specifications are driven by the informed testing of process flows so we create a system platform that maximizes the efficiency of the new Approval programme in the NHS. The initial shadow testing on old studies is in progress and the launch date for the first live implementation will be announced early in 2015. The ambition is to complete roll out for all study types by the end of 2015.

Our goal is to:

- implement HRA Approval during the course of 2015/16 in a phased and controlled way to simplify the system for research approvals in England

Which we will seek to achieve by:

- continuing to coordinate detailed planning, manage dependencies and implement the handover of approval systems, in collaboration with relevant stakeholders;
- undertaking recruitment of operational staff in accordance with plans;
- continuing to implement change management, communication and engagement plans;
- developing and implementing the necessary Information Systems (including HARP and IRAS) to support the different stages of implementation, ensuring relevant interfaces with partner systems are maintained; and
- implementing new functions, processes, tools and guidance in accordance with phased plans.

So that:

We remove unnecessary complexity and delay within the approvals pathway in the UK, making it quicker and easier to set up research studies.

Collaboration and Development Projects

The UK-wide Collaboration and Development group of stakeholders continues 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 together to deliver change within the research environment.

Our goals are to:

- continue working with UK-wide partners across the research pathway to streamline and simplify processes associated with research regulation and management;
- continue developing and disseminating agreed standards and standardised systems to support good quality ethical research, reduce duplication and improve efficiency for sites, sponsors and regulators; and
- evaluate the success of the measures taken to support good quality ethical research in improving confidence in UK health research.

We will seek to achieve this by:

- reviewing the operational implementation of the UK-wide process for protocol amendments;
- evaluating the uptake and impact of published templates and guidance on protocols; and developing, testing and implementing further versions for different study types to allow sponsors and researchers to reduce the number of questions that need to be completed in IRAS;
- continuing to collaborate with others in agreeing data standards and expectations for information shared across the research life cycle e.g. study identifiers and titles;
- collaborating with sponsors to support the sharing of good practice and delivery of training and tools to support responsible sponsorship;
- contributing to global developments on standards for competency of researchers; and
- collaborating with funders and review bodies to reduce duplication relating to progress reporting for researchers.

So that:

We support the improvement of the quality of research sponsorship and management of research and deliver further improvements within the approvals pathway that deliver efficiencies for researchers and reviewers.

Implementing the Amendment Co-ordination Process for non-CSP Studies in England

Our goals are to:

Contribute to achieving a streamlined UK-wide system for implementation of protocol amendments.

We will seek to achieve this by:

Appointing staff to coordinate the process for non-CSP studies in England, as part of the UK- wide system.

So that:

Researchers are able to implement protocol amendments at sites without unnecessary delay and duplication.

Transitioning HRA Assessment Process into 'Business as Usual'

Our goals are to:

Be ready to accept HRA assessment into standard business as usual operations to issue HRA approval including the independent ethical opinion.

We will seek to achieve by:

Undertaking the necessary preparations in the Operations & Approval team to accept the staff and processes to deliver HRA Approval.

So that:

HRA Approval is fully implemented and the full benefits to the research community are delivered.

Research Support and Governance Policy

Our goals are to:

- Develop a new UK wide policy for health and social care in the UK; and
- Develop guidance, advice, tools and training to implement the new policy framework.

Which we will seek to achieve by:

- Considering and consulting on principles to underpin the revision of the policy framework, including assessment of risks of research and risks to the successful delivery of research in the UK;
- Working in collaboration with the Devolved Administrations to ensure UK wide application of the policy, which identifies where the policy can be aligned and explains and manages where legislation or local requirements requires different but coordinated approaches; and
- Drafting and issuing for comment the revised policy framework to support research in the NHS, as the HRA becomes a NDPB and then formally consult later in 2015.

So that:

The UK has a policy framework that is proportionate and reflective of the risks in research, so as to provide a framework that supports good quality research in the UK and facilitates the NHS achieving the ambition in the NHS constitution to have all patients provided with the opportunity to participate in research.

Integrated Research Application System (IRAS)

IRAS (Integrated Research Application System) is a web-based application system through which researchers can input their information relating to their research projects only once so that multiple applications for approvals to the various regulatory bodies and IRAS partners can be submitted.

Our goals are to:

- ensure IRAS's continued availability for HRA and partners;
- deploy a series of upgrades to IRAS for the benefit of review bodies and applicants;

- deliver developments to IRAS and its interfaces with other systems to meet the requirements of HRA Approval, and related requirements for devolved administrations; and
- support the planning for implementation of the EU Portal for clinical trials in 2017.

Which we will seek to achieve by:

- undertaking regular meeting with IRAS Partners to oversee the development plan and delivery;
- reviewing the information required from sponsors and researchers through the Integrated Research Application System (IRAS) to make it easier to do good research;
- delivering, on behalf of IRAS Partners, a planned programme of upgrades to time and budget; and
- Undertaking regular meetings with MHRA and the European Medicines Agency (EMA) to contribute to planning for the EU Portal.

So that:

IRAS continues to be provided 24-7 and meets the needs of researchers and the IRAS partners by making it easier for applicants with good quality applications to seek approvals, and the UK is prepared for implementation of the EU clinical trials regulation.

HRA Assessment and Review Portal (HARP)

The HRA Assessment and Review Portal is an application delivered through a password protected web interface. It is designed to support the management and administration of the research ethics review by a Research Ethics Committee (REC) within the UK Health Departments Research Ethics Service and the Confidentiality Advice Group (CAG). It supports committee management and contains details about REC and CAG members. It was delivered on time and to budget during 2014.

Our goals are to:

- ensure continued availability of HARP for HRA and Devolved Administrations; and
- deploy a series of upgrades to HARP to meet the requirements of HRA Approval, and related requirements for devolved administrations.

Which we will seek to achieve by:

- delivering a planned programme of upgrades to time and budget for HRA and the devolved administrations; and
- working with colleagues at NIHR CRN to provide coordinated IS systems in England, and with colleagues in the Devolved Administrations to maintain UK wide compatibility.

So that:

HARP is available 24-7 and meets operational requirements UK wide.

Research Transparency

The HRA has a role to promote transparency in health research, and has already taken active pragmatic and proportionate steps to deliver in this role, including making registration of clinical trials a condition of the REC favourable opinion, since September 2013. This is a developing agenda where our goals are to:

- Continue to promote research transparency, taking proportionate and pragmatic measures to improve and measure transparency in the UK and to increase public confidence in health research;

- Continue to raise awareness and support for the HRA's transparency agenda and report on its effectiveness; and
- Continue to support and ensure dissemination of proportionate transparency initiatives led by partner agencies.

Which we will seek to achieve by:

- Further implementing registration requirements for studies approved by RECs;
- Implementing from April 2015, that all clinical trials in active recruitment in the UK should have been registered, including those that were approved before September 2013;
- Further monitoring of compliance, of mandated registration for clinical trials and offering consideration to potential sanctions for breach of requirements;
- Specifically leading on what is meant by reporting / publication, and for what purpose and audiences;
- Developing standards for reporting /publication, and considering how the HRA can implement and monitor compliance;
- Continuing to work with others to promote transparency, including access to data and tissue where others are the more appropriate lead; and
- Working collaboratively across stakeholders to ensure successful implementation of the EU Clinical Trials regulations; and
- Continuing to work with partners to widen the transparency of research within UK.

So that:

The UK has proportionate and pragmatic measures in place to ensure the registration and publication of research, which not only maintain UK competitiveness within Health Research but also inspire public confidence in research.

The Programme Management Office (PMO)

Our goals are:

- To provide independent QA, scrutiny and challenge to the HRA portfolio of programmes and projects
- To improve methods and tools for portfolio, programme and project (P3) prioritisation and management and integrate and support their use within HRA
- Build and maintain a centre of expertise and support for P3 prioritisation, planning and management.

Which we will seek to achieve by:

- Building and prioritising an HRA portfolio by collaboration with senior management
- Research best practice P3 management methods and tools and customise and tailor for HRA use
- Build expertise within the PMO, obtain performance feedback from stakeholders and define service KPIs
- Work closely with Quality Assurance function to support ISO9001 accreditation and adoption

So that:

We can enable the provision of quality services by maintaining a prioritised portfolio of programmes and projects with the correct balance between organisational change and business as usual with limited resources

5.3 Delivering Quality Services and Pursuing Continual Improvement

Implement Metrics to assess the delivery and impact of HRA Approval

Our goals are to:

- define and measure metrics for the operational performance of HRA Approval, including its components
- define and measure metrics for the wider approval pathway for research; and
- evaluate through a range of measures the impact of implementation of HRA Approval.

Which we will seek to achieve by:

- developing the mechanisms for collecting data for the relevant time points, both within and outside HRA, to analyse performance;
- exploring with others, including the MHRA, how components of approvals outside the HRA remit can be further coordinated to determine metrics for all regulatory approvals;
- working with others, including funders to compare data on timelines across the research pathway before and after implementation of HRA Approval; and
- continuing to look for measures to demonstrate efficiency not just in terms of timelines but also wider efficiencies as resources are released from current wasteful duplication of review and approval of research.

So that:

the benefits of implementation of HRA Approval are clearly articulated, significantly contributing to improved perceptions about the UK as an attractive place to do research.

HRA National Operational Roles

Our goal is to:

- Ensure a UK wide operational framework and delivery within the appropriate legislation, policy and operational standards.

Which we will seek to achieve by:

- Chairing the UK operations group, through which HRA standard operating procedures are monitored and maintained;
- Chairing and providing secretariat support to the UK Ethics Committee Authority;
- Chairing and providing secretariat support for the Four Nations meetings;
- Transitioning the Social Care REC into the HRA; and
- Considering the impact of and responding to the implementation of the EU Clinical Trials Regulation.

So that:

The UK continues to have an agreed framework for research that meets policy and legislative requirements.

Development of Quality Assurance Management Processes / ISO 9001

Our goal is to:

- Ensure all functions and services provided within and by the HRA are of a high quality, quality checked and continually improve in response to feedback;

Which we will seek to achieve by:

- Widening the Internal Quality Audit function during 2015 to be organisation wide, including to the emerging HRA Approval programme;
- Maintain HRA ISO9001 Certification (June ’15 external ISO audit) for the Quality Assurance Department; and
- Hold and maintain the document management system for HRA Policies and Procedures.

So that:

We can deliver quality services and demonstrate quality so as to build confidence in the HRA and health research in the UK.

Research Ethics Committee Operations

Our goal is to:

- Continue to provide an efficient, responsive, proportionate, effective and robust Research Ethics Committee operation.

Which we will seek to achieve by:

- Improving timelines for review of applications to RECs;
- Improving the quality and consistency of ethical review and administrative processes;
- Implementing the second stage pilot of early assessment and pre-committee review;
- Developing and delivering training;
- Managing the requirement for clinical trial registration, including requests for deferral;
- Reviewing staffing establishment as a result of implementation of new developments;
- Implementing electronic review of applications;
- Reviewing the system of flagging of RECs;
- Reducing the number of scheduled REC meetings from 11 to 10; and
- Rolling out proportionate information for the proportionate review.

So that:

Applicants continue to be satisfied with the service we provide and our commitment to continual improvement, and participants can take assurance from our role to protect their interests.

Confidentiality Advice Group (CAG)

Our goal is to:

- Continue providing independent, efficient, responsive, proportionate, effective and robust advice on access to patient identifiable data without consent for research and non-research purposes.

Which we will seek to achieve by:

- Improving timelines for studies using recognised methodologies;
- Implementing the use of HARP for recording CAG application data (research applications only);
- Maintaining provision of early advice to stakeholders to improve the quality of applications;
- Managing any relevant legal and policy changes impacting on CAG remit to ensure they are fully considered, implemented and communicated within processes and advice;
- Developing and implementing SOPs;

- Developing existing guidance and develop productive relationships with key collaborators in the information and research fields to ensure CAG advice remains accurate, responsive and credible;
- Proactively supporting, developing and maintaining effective communications with relevant external stakeholders to improve the quality of applications (this includes training activities we carry out); and
- Reviewing the feasibility of CAG providing advice on non s251 aspects in broader IG environments within HRA's work towards ISO accreditation.
- Consider the need for the establishment of CAG 2 to take on additional work to review HSCIC data releases.
- Develop a system for the endorsement of research registries to assist with recruitment of participants to clinical trials.

So that:

We continue to provide appropriate and relevant advice on access to confidential data that is in the interests of, and maintains the confidence of, patients and the public.

Working with our Partners

Our goal is to:

- Formally agree and document how we work with partner organisations.

Which we will seek to achieve by:

- Publishing tailored Memoranda of Understanding; and
- Explaining the relationship between the HRA and other organisations through the publications of joint statements and other communications as required.

So that:

Our partners, the research community and the public understand the basis on which we work together and collaborate to make the UK a better place to conduct research

Learning through Evaluation

Our goal is to:

- Ensure the HRA supports and maximizes the opportunities to research and evaluate how we manage research in the UK.

Which we will seek to achieve by:

- Continuing to support and provide expert contribution to identified projects, including statistical quality and protocol evaluation;
- Pilot and evaluation of service improvements to maximize effectiveness; and
- Continuing to monitor overseas developments.

So that:

We underpin improvement and development of our services by evaluation and understanding of their impact.

The Over-volunteering Prevention Systems (TOPS)

Our goal is to:

Protect healthy volunteers from the risks of over volunteering and Industry from the risks to research integrity from over volunteering which we will seek to achieve by:

- Continuing to manage healthy volunteers' participation in Phase 1 research;

- Supporting the management and improvement of the TOPs database; and
- Ensuring TOPs website accurately reflects the HRA brand.

So that:

The UK can ensure healthy volunteers entering in to Phase 1 studies are not putting themselves are risk through over volunteering.

The HRA Website

Our goals are to:

- Ensure the website is up-to-date, accurate, provides the public with the information they need; and
- Ensure website content reflects the breadth and depth of existing and new initiatives for which the HRA is responsible, or supports those of others.

Which we will seek to achieve by:

- Ensuring we manage website content accurately and in a timely way;
- Ensuring the website and newsletters regularly reflects progress of HRA plans and proposals so that shows demonstrable progress; and
- Continuing to monitor how people use the website and what they want from it.

So that:

The HRA website is seen as a comprehensive and accessible service which enhances the reputation and authority of the HRA.

Guidance and Advice

Our goals are to:

- Continue to update and develop advice and guidance provided by HRA in response to organisational policy, legislation and process changes, as required and in collaboration with others.
- Continue to provide and improve our Queries Lines email service review existing decision tools and other online resources to ensure the portfolio remains current:
- Review acceptance of the web-based version of consent and participant information sheet guidance

Which we will seek to achieve by:

- reviewing timelines and performance of advice provided by email; learning from these to improve standard operating processes and workflows for the handling of queries;
- Monitoring and responding to trends in queries by developing standard responses and using this information to improve guidance, systems, processes and learning and to inform projects;
- Surveying and seeking feedback from users of HRA guidance; and
- Working with others internally and externally to provide guidance that is consistent and up to date and which effectively signposts further information, reducing unnecessary duplication.

So that:

The advice and guidance provided by the HRA is relevant, accurate and accessible to support improvement in the quality of research, research applications and research review.

Training and Learning

Our goal is:

To support continual improvement in the quality of research, research applications and researchers skills to undertake high quality health research thereby improving research outcomes and improving public confidence.

Which we will seek to achieve by:

- Understanding the learning requirements of the research community, in terms of policy changes, ethical research and successful applications,
- Developing and maintaining a comprehensive learning and training programme for our volunteer Research Ethics Committee members;
- Providing learning /training to researchers and the wider research community;
- Reviewing and considering further future options for training courses for the wider researcher community; and
- Working with others where they are more appropriate to deliver learning and communicate the opportunities effectively to the research community.

So that:

The HRA maximizes the value from the investment in learning and training, by providing relevant and accessible training opportunities and sharing as appropriate learning opportunities and training material to be used by others and further improve public interest /confidence in health research.

Programme Management Office

Our goals are:

To support HRA portfolio, programme and project (P3) initiation, planning, governance, management, reporting, closure and learning.
To increase HRA P3 capability maturity

Which we will seek to achieve by:

Developing tools, techniques, templates, training and mentoring and integrating and supporting their use within the organisation
Developing approaches (consistent with best practices) to improve and extend HRA capabilities supporting effective and efficient programme and project delivery. These capabilities will include management control and governance and the management of benefits, finance, stakeholders, risk and resources.

So that:

We can increase HRA P3 capabilities to improve outcome speed and quality.

5.4 Leading in Partnership

Communications

Our goal is to:

- Ensure communications are effective to ensure we work together within our organisation and externally to support effective leadership.

Which we will seek to achieve by:

- Refining and refreshing our communications strategies and plans;

- Providing opportunities for engagement including the HRA stakeholder forum and other stakeholder event (s);
- Ensuring our approach to communicating change internally and externally reflects good practice and demonstrates we have acted on staff feedback;
- Effectively positioning CAG in a changing data landscape; and
- Surveying staff and stakeholders, and continually seeking and listening to feedback, to inform our strategic approach.

So that:

The communications from HRA are effective and professional to support the HRA leadership roles and enhance the reputation of HRA.

Working with the Human Tissue Authority (HTA)

Our goal is to:

Encourage sharing of tissue and to work with the HTA to improve reporting processes for research involving use of human tissue.

Which we will seek to achieve by:

Making it a condition of a favourable opinion that tissue holdings are registered on the MRC-funded database and to improve the annual reporting process on the use of human tissue.

So that:

Reporting processes and thereby transparency and the sharing of human tissue in the use of research is improved.

Public Involvement

Our goals are to:

- Further develop the HRA into an effective “involving” organisation;
- Embed public involvement into the core business of the HRA; and
- Develop the role of the HRA with its partners to increase in the amount and quality of public involvement in health research.

Which we will seek to achieve by:

- Developing capacity to support public involvement;
- Reviewing resource requirements needed to support involvement in our own work and the work we do to promote public involvement more widely;
- Reviewing business plans to identify all areas of work where public involvement would add value and can be promoted as part of influencing work with research communities;
- Promoting and supporting the spread of public involvement in health research with a view to this becoming the rule and not the exception. Also working with partners including the NIHR to exert our influence on those who conduct, fund and manage health research to understand the benefits of public involvement; and
- Ensuring action we take to promote public involvement will not increase the regulatory burden on the research community.

So that:

The HRA effectively and appropriately involves patients and the public in developing and implementing plans and proposals, and uses its influence on others to support effective public involvement in health research.

Stakeholder Management and Engagement

Our goals are to:

- Implement a stakeholder engagement strategic plan; and
- Ensure broad government and stakeholder support for the HRA's agenda.

Which we will seek to achieve by:

- Continuing to seek comment on plans and proposals to maintain engagement;
- Consulting as appropriate on changes to policies or processes; and
- Conducting and responding to a perception audit of key opinion leader stakeholders.

So that:

The HRA continues to be seen as an organisation that engages and listens so that the plans and proposals it develops are relevant and effective.

Supporting the UK's Position on Global Research

Our goal is to:

- Continue working with key stakeholders to gather evidence and promote the UK as a great place to do quality health research.

Which we will seek to achieve by:

- Working with key stakeholders to develop metrics that are comparable and understandable in a global setting; and
- Taking opportunities to promote the UK as a great place to do quality health research, providing information and examples to others as well as supporting and presenting at local and national events.

So that:

The UK is a great place to do quality health research, and the evidence is there to demonstrate it and build confidence in the proposition.

5.5 Strengthening Organisational Capability; Being Efficient and Effective

Organisational Development

Our goals are to:

- Develop and manage a programme of work to further embed organisational values and increase staff engagement;
- Ensure that the HRA's workforce has the necessary capacity, skills and knowledge to deliver the functions required of it;
- Support continued effectiveness of the Board and HRA Teams; and
- Manage change well.

We will achieve this by:

- Devising and implementing an Organisation Development strategy;
- Delivering bespoke facilitation and team building training;
- Undertaking successful recruitment to have staff with appropriate skills in place;

- Building strong teams;
- Maintaining an effective learning and development training plan;
- Developing a workforce plan and linked range of HR initiatives to ensure that the HRA has the appropriate workforce to deliver its objectives; and
- Ensuring through our HR initiatives that the workforce is managed in accordance with best practice and current employment law

So that:

The HRA is an organisation that has the people, structures and values that ensure it is able to deliver effectively, and command respect and authority in its leadership role for health research.

Shared Services

Our goal is to:

- Ensure the HRA continues to secure 'Best Value' in any shared service arrangement.

Which we will seek to achieve by:

- Working closely and collaboratively with our key shared service providers (DH/ATOS, NHS BSA and NHS SBS)
- Continuing to ensure we achieve best value from the relationships through strong contract management

So that:

The HRA works effectively within the Government provided framework for shared services.

Management Information

Our goal is to:

- Produce timely, accurate and relevant MI for a range of 'audiences' including our DH Sponsor, our Board and Executive Committees to reflect performance and trends in key operational and corporate activities.

Which we will seek to achieve by:

- Producing a quarterly high level KPI and Performance Assurance Report (a copy is included at Appendix C) from monthly returns which contains comprehensive and relevant performance information including key HR data such as staff turnover, and sickness; and
- Undertaking an assessment of the data (by relevant management teams) and agreeing to the mitigating actions required to address areas of concern as well as celebrating areas of good performance.

So that:

The HRA is able to make decisions and develop plans based on accurate management information, and to demonstrate delivery against objectives through relevant and transparent key performance indicators.

Estates Efficiency

Our goal is to:

- Further review the estates footprint to evaluate options to achieve the industry standard 8 desks to 10 staff alongside maximising the utilisation of the space available.
- Maintain the current five geographic offices.

Which we will seek to achieve by:

- Reviewing ways of working and operational policies to ensure that both are aligned to ensure the HRA meets on-going and future operational requirements as well as remaining affordable.

So that:

We meet our requirements as a public body to make best use of public funds.

Transparent Governance and Compliance

Our goals are to:

- Continue to promote organisational visibility and openness; and
- Operate within all statutory and regulatory requirements.

Which we will seek to achieve by:

- Publishing board agenda and papers on the HRA website;
- Operating to a policy of publishing all information unless legislative restrictions apply ;
- Scheduling and managing business effectively through the HRA Board and its committees;
- Ensuring compliance with the signed Public and Parliamentary Accountability protocol between the Department and HRA;
- Operating within the required standards of information governance ensuring that personal and business critical data is protected and is readily available for use when required, risks to information assets are appropriately managed with proportionate technical, procedural, physical and personal controls applied and that assurance is obtained by conducting regular risk assessments against known and emerging risks such as cyber security and changes in the legal and regulatory environment;
- Managing complaints according to HRA policies;
- Providing timely responses to requests under Freedom of Information;
- Ensuring compliance with equality and diversity legislation by publishing data on progress made and the results of our REC member equality survey; and
- Ensuring compliance with health and safety legislation.

So that:

We work in a fully transparent way at all times, in line with our organisational values and our expectations of others.

5.6 Delivering Best Value

Financial Balance and Budgeting

Our goals are to:

- Ensure that the HRA remains within agreed revenue, capital cash and resource limits, that finances are managed in a transparent way and to ensure that budgets are managed throughout the organisation.

Which we will seek to achieve by having:

- Published a Financial Plan for 2015 -16 and agreed budgets in place by the 1st April 2015;
- A Strategic 5 year financial plan published and agreed by the 1st April 2015;
- Financial reports produced within 4 working days and overall financial position prepared within 5 working days for reporting to the EMT on a monthly basis and Board bi monthly; and
- Forecasts produced from September at the latest and reviewed monthly thereafter with close partnering between the finance partner and the service lead.
- Financial information published which complies with the HM Treasury Guidance by the 15th working day of the month.
- Submitting the annual accounts and annual report to the deadlines set by the Department of Health (DH) and parliament

So that:

The HRA meets its requirements as a public body to making best use of public funds at all times.

Savings

Our goal is to:

- To ensure savings targets are identified for 2015 -16 and beyond to invest in further improvements, to maintain focus on efficiency and value for money and to offset any emerging cost pressures.

Which we will seek to achieve by:

- Identifying and agreeing savings targets included in the Financial Plan;
- Producing Monitoring Reports as part of the financial reporting cycle;
- Ensuring that all procurement of goods and services achieves best value for the tax payer, with the financial benefits from each procurement reported and monitored , whilst adhering to agreed efficiency controls; and
- Reviewing shared service arrangements for financial accounting in year to ensure that value for money is being achieved.

So that:

The HRA is able to use all resources to very best effect.

Productivity

Our goal is to:

- To critically review key areas of service delivery in order to generate efficiencies & more for less.

Which we will seek to achieve by:

- Linking with work on the estates strategy and critically reviewing processes in order to streamline, reduce duplication and waste, and maximise use of the estate and technology.

So that:

The HRA is continually reviewing and identifying opportunities to improve productivity so as to ensure all resources are used to best effect.

Procurement

Our goal is to:

- To critically review key areas of service delivery in order to generate efficiencies & more for less.

Which we will seek to achieve by:

- Linking with work on the estates strategy and critically reviewing processes in order to streamline, reduce duplication and waste, and maximise use of the estate and technology; and

So that:

The HRA is continually reviewing and identifying opportunities to improve productivity so as to ensure all resources are used to best effect.

6.0 Measuring our Success

The HRA Board reviews progress against delivery of objectives quarterly with the HRA Executive Management Team (EMT). To support these processes, a performance management framework has been developed to report progress against each objective. A separate performance report forms the basis of the formal HRA sponsor meetings with the DH.

The HRA has a set of operational measures that it monitors closely to determine and demonstrate progress against key objectives. Each director is responsible for managing and measuring performance against objectives and will have detailed metrics to inform the reports made through for scrutiny by the Executive Team and Board. The HRA recognises that these measures can form a core component on an overall indicator but that success in many areas is much more than a simple quantitative measure, success is that the HRA has delivered and that that delivery has led to tangible improvement that has been realised and valued by stakeholders including patients and the public, researchers, others involved in the regulation and management of research in the UK and other key stakeholders and opinion leaders. So we are truly making judgements about our ultimate ambition to make the UK a great place to do health research and to build patient confidence in health research.

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

This suite of indicators primarily constitute those that were used last year in order to offer continuity, however further thought has been given to those that are associated with the HRA Approval Programme. The set contained in the table describe measures that will be used to more specifically define the contribution the programme will have on the research process.

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

6.1 Performance Dashboard

The HRA's Key Performance Indicators are under continual review and refinement but the priority portfolio for 2015/16 currently consists of the following:

A	**Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research**			
	KPI		**Method of Measurement**	**Target or output**
1	Year on year improvement of HRA performance measures for operational functions including REC and CAG	a	Performance metrics collected from internal systems	• 95% of applications to full research ethics committee meetings to receive final decision within 60 calendar days (mandatory) • 95% of applications to full research ethics committee meetings to receive final decision within 40 calendar days (stretch target) • 95% of applications to research ethics proportionate review service to receive decision within 14 calendar days • 95% of amendments, on approved applications, submitted to research ethics committees to receive a decision within 28 calendar days (stretch target) • 95% of amendments, on approved applications, submitted to research ethics committees to receive a decision within 35 calendar days (mandatory) • 100% of GTAC applications to be receive a decision in 60 days • CAG/CAT – 75% of full applications to be completed in 60 days • CAG/CAT 75% of Precedent Set review applications to be completed in 30 days • CAG/CAT 75% of amendments to be completed in 30 days • Measure Improvements in performance against reported user satisfaction • Measure Improvements in REC/CAG performance against outputs from satisfaction audits
		b	Measure number of operational complaints pursued for learning	• Detail changes and improvements made as a result

A	Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research			
	KPI		**Method of Measurement**	**Target or output**
2	Year on year Improvement in transparency in health research	a	Publishing of research summaries, REC Decisions and Summary of Opinions	• Publish 100% of research summaries (except where deferral has been agreed) Publish 100% of REC decisions and make available summary of opinion on request
		b	Increasing number and visibility of HRA registers and audit tools that demonstrate the level of good conduct of research in the UK	• Monitoring of compliance with clinical trial registration requirements • Monitor publication rates from applications submitted to REC's • Monitor improvements in performance against satisfaction in public confidence and Industry confidence in UK competiveness for clinical trials
3	Year on year improvement on system provision and reputation	a	That key systems are available and accessible to levels as detailed in relevant SLA's	• IRAS HARP Web TOPS Open Service
		b	Deliver new systems and system improvements according to agreed project plans and ensuring value for money	• To demonstrate value for money Test improvements in performance against reported user feedback

B	Delivering Quality Services and Pursuing Continual Improvement			
	KPI		**Method of Measurement**	**Target or output**
1	HRA provides a high quality advice and guidance service in accessible format to its customers	a	Ongoing provision of effective tools and formal guidance and that agreed revisions and new tools are delivered within defined project timetable	• Tools and guidance offered is enhanced and welcomed by stakeholders and satisfaction is measured through the satisfaction audits and annual perception audits
		b	Response times to requests for advice	• 90% of requests for advice met in 4 working days (excluding complex /HRA Approval enquiries)

B	Delivering Quality Services and Pursuing Continual Improvement (Cont.)			
	KPI		**Method of Measurement**	**Target or output**
2	HRA continues to deliver and improve the high quality REC and CAG services	a	REC Audit action plans completed	• 100% of final audit action plans completed and submitted within timeframes and actions accepted by QA audit action plans from the accreditation of research ethics committees to be completed within agreed timeframes • 50% of committees to receive full accreditation at first audit
		b	Opportunities for further improvement are identified and delivered according to agreed and published timescales	• To demonstrate continued improvement in all services • This includes the collection of routine and targeted feedback from applicants to REC and CAG through the QA user survey
		c	All services are effective, efficient and represent good value for money	• The operational services continue to deliver savings year on year through continued improvement • Number of RECs (saving in term so Chairs allowance, meeting costs, staff costs) – 6 monthly reporting Catherine Blewett to report to JK/DC for review, • Meeting room cost savings - 6 monthly reporting • Sheila Oliver to report cost per REC to JK/DC for review, • Postage/Copying savings – through use of tablets – 6 monthly reporting – Catherine Blewett to report to JK/DC for review • Reducing meeting numbers from 11 to 10
3	Successful implementation of a UK wide policy framework for research which is recognised as supporting the HRA strategic objectives on making it easier to do good quality research and maintaining public confidence in research	a	Feedback on individual projects including public engagement, ahead of formal consultation to enable and ensure buy-in. Effective formal consultation process	• Delivery is welcomed by all key stakeholders and adopted UK wide

C	Leading in Partnership			
	KPI		**Method of Measurement**	**Target or output**
1	Successful implementation and delivery of HRA Approval	a	Monitor progress against plans	• Implement HRA Approval according to the agreed phasing and timelines in the detailed project plans
				• Implement protocol templates and guidance according to the agreed plans
				• Implement developments to IRAS and HARP according to the agreed plans
		b	Internal and external performance metrics	• Percentage studies achieving target timelines for HRA Approval, including elements within Approval
				• Reduction in overall timeline for the research approval process compared with baseline
				• Impact of implementation of HRA Approval on efficiency and cost of research process
2	The HRA will effectively communicate using a range of communication tools	a	The success of an annual stakeholder event which will comprise of key figures within the health research field	• Event evaluation reaches a satisfaction level of 80%
		b	Number of stakeholder newsletters issued	• Delivered to planned timescales, quality judged through perception and satisfaction audits
		c	Website audit to demonstrate improved website user satisfaction	• Website analytics - % website user satisfaction 70% of users find what they are looking for Website analytics show website used effectively %
		d	Positive coverage in media	• 70% media coverage positive or neutral about the HRA 100% of media enquiries answered in journalist deadline
3	The HRA effectively and appropriately involves patients and the public in developing and implementing plans and proposals, and uses its influence on others to support effective public involvement in health research.	a	Working with others to agree standards on public involvement in Health Research	• Reach agreement on standards and principles for effective involvement in the development of research design

C	Leading in Partnership (Cont.)			
	KPI		**Method of Measurement**	**Target or output**
3	The HRA effectively and appropriately involves patients and the public in developing and implementing plans and proposals, and uses its influence on others to support effective public involvement in health research. (Cont.)	b	Monitor current practice and % of involvement recorded in applications submitted through IRAS	• % increase in number of applications that have clearly involved patients and the public in their development. Repeating previous survey to identify levels and trends
		c	Value and support lay members on ethics committees and continue to offer access to induction, training and mentor support	• Maintain number of lay members on committees • Numbers attending Induction training, and feedback on relevance and value of the training • Numbers provided with additional individual support
		d	Ensuring patient and public involvement in HRA events and other work as appropriate	• Increase number of opportunities for public involvement in HRA Business
		b	Measure number of plans and proposals that went out for consultation	• Determine baseline for 14/15

D	Strengthening Organisational Capability, being Efficient and Effective			
	KPI		**Method of Measurement**	**Target or output**
1	The HRA continues to be an organisation that has structures and values that ensure it is able to deliver effectively, and command respect and authority in its leadership role for health research.	a	The delivery of OD and Workforce plan to maintain effectiveness against an expanding agenda	• Plan is delivered and meets requirements of organisations purpose and functions
		b	Structures and values are good value for money	• Cost of structure meets organisational requirements and is within agreed budget
2	The HRA is able to make decisions and develop plans based on accurate timely management information, and to demonstrate delivery against objectives through relevant and transparent key performance indicators.	a	The speed by which it can collect, collate, analyse and produce necessary performance reports	• Produce a quarterly KPI report (final version within 4 weeks from end of reporting period) for the board and monthly (within 7 working days from end of reporting period) for Executive Management Team (EMT)

D	Strengthening Organisational Capability, being Efficient and Effective (Cont.)			
	KPI		**Method of Measurement**	**Target or output**
3	The HRA maximizes the value from the investment in training by providing relevant and accessible training opportunities and sharing as appropriate training material to be used by others.	a	The take up of offered training places to HRA volunteers, researchers and staff	• 85% of available training places are taken up
		b	The evaluation score for each training course	• To achieve at least 80% satisfaction for each training course. If not achieved investigation completed to ensure improvements can be made
4	Staff are well motivated and are well supported to achieve their objectives	a	Responses from annual staff survey	• Year on year improvements (through results of staff survey) in staff engagement and 'support' indicators
5	We work in a fully transparent way at all times, in line with our organisational values and our expectations of others.	a	Time it takes to process FOI's and Complaints	• Responding to complaints within 25 working days • 100% of all FOI requests (valid and invalid) acknowledged and additional clarification sought within 10 working days (Quarterly report) • 100% of valid FOI requests to receive final response within 20 working days of receipt (where qualified exemption does not apply) (Quarterly report) • 100% of valid FOI requests where qualified exemption applies, and a public interest test may be required, to receive a final response within 40 working days of receipt
		b	Monitor REC membership and demonstrate greater diversity in REC member profile so there is greater alignment with that of the general population	• Profile data
		c	Data Transparency – 100% compliance with requirement to publish financial and procurement information complying with the HM Treasury Guidance and Cabinet Office by the 15th working day of the month	• 100% published on web

E	Delivering Best Value			
	KPI		**Method of Measurement**	**Target or output**
1	The HRA meets its requirements as a public body in making best use of public funds at all times.	a	Meeting formal reporting requirements	• 95% of all invoices to paid within 30 days (BPPC Target) • 95% of value of all invoices paid within 30 days • 60% of all invoices to be paid within 10 days (HRA Target) • 60% of value all invoices to be paid within 10 days (HRA Target) • Financial forecasts are produced from September 2014 at the latest and reviewed monthly thereafter • Financial reports produced within 4 working days and overall financial position prepared within 5 working days for reporting to the EMT on a monthly basis and Board bi monthly • Financial plan 2015/16 published and agreed budgets in place by the 1st April 2015.
		b	Reduction in key areas of non-staff spend	• Demonstrate reduction in spend in the following areas: - Travel and Accommodation per head count - Office Supplies per head count - Office Accommodation per head count
2	The HRA is able to use all resources to very best effect.	a	Meeting efficiency targets	• Cash releasing savings plans to be cover a minimum of 3 years plus achievement against these savings to be included in the report to the Board on a monthly basis with commentary and action plans where necessary
		b	Sickness absence rates	• Maintaining sickness rates for both long term and short term at 2.5% or below

7.0 Financial Plans

Revenue

The HRA is required to plan for a balanced income and expenditure position. A summary of the plan is provided in the table below. Further detail can be found in Appendix B.

Prioritised Business plan 2015/16

Planning Priorities	Note	Cost analysis 2015/16
		(£'000)
A. Improving & Streamlining Systems and Processes to support and improve confidence in health research		4,896
B. Delivering quality services and pursuing continual improvement		7,150
C. Leading in partnership		346
D. Strengthening organisational capability, being efficient and effective		998
E. Delivering best value		456
		13,848

Notes

All costs are stated as full cost and equivalent to GIA funding

All direct, indirect and overhead costs of support services have been aligned to each function

Devolved administration recharges are netted off, costs shown in separate table in appendix

The table below sets out our planned costs for 2015/16 by function. It is important to stress that health research for certain studies is not legal without ethics approval or approval from CAG as appropriate. Additionally, associated applications to undertake research in the UK cannot be made without IRAS and the application system we operate.

The HRA receives income from two main sources. The majority comes from grant in aid (GIA) provided via the DH (£13,848k), with the balance (£0.258k - *current estimate*) coming from undertaking activities by agreement with the Devolved Administrations. The table below also highlights how that income is deployed. In January 2015, the HRA became an NDPB and assumed responsibility for the policy framework underpinning the national research governance framework (previously DH Policy). The HRA also assumed responsibility for the Social Care REC from that date. The income and expenditure position therefore reflects new costs associated with the Social Care REC, year 2 of HRA Approval as set out in the DH approved business case alongside additional costs linked with implementing second and third Confidentiality Advisory Groups, and finally, costs associated with supporting a smooth transition between the current CSP co-ordinating centre and the final HRA Approval systems established.

Prioritised Business plan 2015/16

Functions provided - all core business and captured in the care bill	Note	Cost analysis 2015/16 Statutory function	Other commitment	Ministerial priority
		(£'000)	(£'000)	(£'000)
RECs, Ethical review	1	6,763		
Approvals for processing confidential information relating to patients	1	871		
IRAS and systems to support ethical review	2	856		
Training, guidance and advice	3		547	
Quality Assurance to support ethical review	4		360	
Co-ordination and standardisation of practice relating to regulation of health and social care research.	5			4,451
		8,490	**907**	**4,451**

13,848

Notes

All costs are stated as full cost and equivalent to GIA funding
All direct, indirect and overhead costs of support services have been aligned to each function
Devolved administration recharges have been netted off, costs are shown in separate table in appendix

1. Research is not legal without ethics approval or appropriate approvals from CAG. The costs presented here include national research ethics panel, as well as support service costs. They also include the costs of the Social Care REC and establishment of CAG 2 and CAG 3 to support increased applications for processing confidential information relating to patients.

2. Applications for health research cannot be made in the UK without IRAS and the applications system HARP.

3. Training supports our core business and includes training for volunteer REC members, researchers and patients and the public.

4. Quality assurance is part of our core business and part of the wider remit in the care bill to ensure quality and standards of both the review itself and the research governance and research processes.

5. HRA Approval related costs submitted to DH including year 2 increased costs and transition costs linked with systems supporting research and HRA Approval.

The income and expenditure position also includes planned efficiencies of £631k (equivalent to 4.7% of our current expenditure base), £468k are cash releasing savings largely as a result of investments made in 2013/14, the remainder are to ensure affordability of service delivery within the approved financial envelope and to fund cost pressures identified in the table below. Action is planned for the forthcoming year to further drive down costs associated with REC meeting frequency, efficient use of the estate and per head cost of premises, preliminary work to review options for further shared service efficiencies and to ensure further value is achieved through procurement contracts.

Cash releasing savings and efficiencies made

Description	2015/16 Plan
	£000s
Ethical review operational savings	25
Electronic review and associated savings	52.5
Estates strategy	300
E learning advice & guidance	50
Training materials	40
Cash releasing savings	**468**
Absorb pay awards of 1%	83
Absorb Ers pension increase and incremental drift	80
Total savings and efficiencies made	**631**
% of 14/15 GIA	**4.69%**
% of 15/16 GIA	**4.55%**

Capital

During 2015/16, the HRA is planning to build on the capital investment programmes initiated in 2013/14 and 2014/15. Further developments to the database application system (HARP) will be managed alongside developments to ensure that IRAS effectively captures all HRA Approval requirements. Details are being consolidated, however summarised plans are set out below for 2015/16 and 2016/17.

Capital plans

Description of investment	2015/16 Plan	2016/17 Initial plans
	£000s	£000s
HARP developments	100	75
IRAS	895	250
Video conferencing	5	5
Total capital investment plan	1,000	330

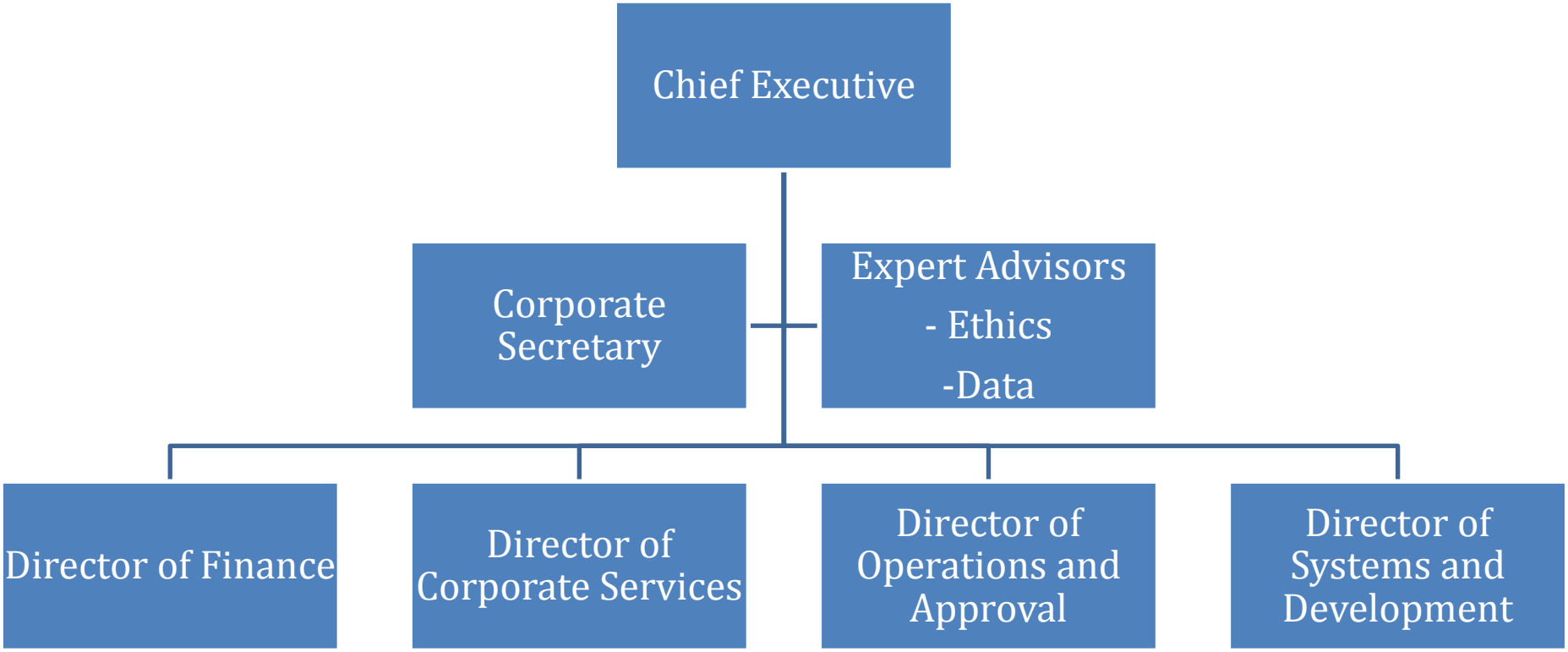
8.0 Glossary

ALB	Arm's Length Body of the Department of Health
BSA	NHS Business Services Authority
C&D	Collaboration and Development Programme and Projects
CAG	Confidentiality Advisory Group
Clinical Trials Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004
CSO	Civil Society Organisation
DH	Department of Health
EMT	Executive Management Team
EOP	Ethics Officer Pilot
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
GIA	Grant in Aid
GTAC	Gene Therapy Advisory Committee
HARP	HRA Assessment Review Portal – the replacement for RED
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
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
RED	Research Ethics Database used by REC staff to manage research applications
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
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

9.0 Appendix

A. Senior Management Structure



B. Financial Plan Detail

2014 - 15 Business plan by cost category

Revenue costs ***(classed as Admin revenue departmental expenditure limit DEL)***

	2014/15 Plan £000s	2015/16 Plan £000s
Admin Expenditure		
Pay	8,329	9,509
Temporary Staff/Contract Services	500	250
Consultancy Services	0	0
Other e.g. stationery, travel etc.	4,772	4,274
Audit Fees	50	73
Total Admin Expenditure	**13,651**	**14,106**
Admin Income		
Devolved Administration(current estimate)*		
Scotland	(108)	(132)
Wales	(62)	(81)
Northern Ireland	(37)	(45)
Total Income from Devolved Administration	(207)	(258)
Admin Income from outside NHS/DH/ALBs	0	0
Total Admin Income	**(207)**	**(258)**
TOTAL ADMIN NET OUTTURN and GIA	**13,444**	**13,848**

Other Revenue costs **(classed as Admin ring fenced DEL)**

Description	2014/15 Plan £000s	2015/16 Plan £000s
Depreciation and Amortisation	161	241
Impairments	0	
Total Admin Ring Fence DEL	161	**241**

C. HRA Procurement Pipeline 2014 – 15

GPS Catalogue area or Shared Service	Sub category	HRA Lead/s	HRA Current Suppliers	Estimated current value p.a.	HRA Contract Ref	Contract ends	Procurement Route	Date of Contract Award	Est. Contract Go live	Comments
IT	IRAS/HARP Hosting	Gaynor Collins-Punter	Rackspace	80,000.00	HRA005	31-Jul-15	Competitive tender via Framework	Q1	Q2	Assessment to be made as to value of tendering service against extending current arrangement
IT	IRAS/HARP Helpdesk services	Gaynor Collins-Punter	BGO Media	69,720.00	HRA052	04-May-15	Competitive tender via Framework	Q1	Q1	Assessment to be made as to value of tendering service against extending current arrangement
IT	IRAS/HARP Server Support	Gaynor Collins-Punter	BGO Media	25,000.00	HRA038	31-Mar-15	Competitive tender via Framework	Q1	Q1	Assessment to be made as to value of tendering service against extending current arrangement
IT	HARP Programme Development	Gaynor Collins-Punter	BGO Media	50,000.00	HRA033 & HRA044	30-Apr-15	Competitive tender via Framework	Q1	Q1	Assessment to be made as to value of tendering service against extending current arrangement

GPS Catalogue area or Shared Service	Sub category	HRA Lead/s	HRA Current Suppliers	Estimated current value p.a.	HRA Contract Ref	Contract ends	Procurement Route	Date of Contract Award	Est. Contract Go live	Comments
IT	Provide programming, test, deployment, configuration control and training services to support the effective implementation of IRAS	Gaynor Collins-Punter	BGO Media	300000+	HRA062	31-Jul-15	G Cloud	Q2	Q3	Assessment to be made as to value of tendering service against extending current arrangement
Office Solutions	Archiving	TBC	Various	10,000 - 12,000		TBC	Competitive tender via Framework	Qtr 2	Qtr 2	
Travel		Ian Cook	Redfern	300,000 (total cost of travel and accommodation)	HRA 016	31-May-15	Call off from main DH contract	Qtr 3	Qtr 4	Option to extend in line with DH Framework
Office Solutions	Photocopying (MFD)	Gill Habicht	Various	70,000.00		Various	Competitive tender via Framework	TBC	TBC	Discovery work to be carried out in 14/15 and future procurement strategy prepared based in business need

GPS Catalogue area or Shared Service	Sub category	HRA Lead/s	HRA Current Suppliers	Estimated current value p.a.	HRA Contract Ref	Contract ends	Procurement Route	Date of Contract Award	Est. Contract Go live	Comments
Professional Services	Learning and Development	TBC	Various	65,000 (Members) 45,000 (Staff)		Various dates	TBC	TBC	TBC	

Procurement pipeline: high level timeline

Ref	GPS Category	Sub category	HRA join contract	Value (all approximate)	Nov 14	Dec 14	Jan 15	Feb 15	Mar 15	Apr 15	May 15	Jun 15	July 15	Aug 15
1	Professional Services	Learning and Development	14/15 Q3 and Q4	60,000.00	Prep					Go Live				
2	Office Solutions	Photocopying (MFD)	14/15 Q4	70,000.00	Prep					Go Live				
3	Professional Services	Legal	14/15 Q4	20,000.00		Prep			Go Live					
4	Travel	Travel and Accommodation	14/15 Q4	300,000.00			Prep				Go Live			
5	IT	IRAS/HARP helpdesk	14/15 Q4	69,720.00			Prep				Go Live			
6	IT	IRAS/HARP server support	14/15 Q4	25,000.00			Prep			Go Live				
7	IT	IRAS/HARP hosting	15/16 Q1	80,000.00					Prep				Go Live	
8	IT	HARP Programme development	15/16 Q1	50,000.00			Prep				Go Live			
9	IT	Programming, training IRAS development	15/16 Q2	300000+						Prep				Go Live
10	Office Solutions	Archiving	15/16 Q2	15,000.00						Prep				Go Live

D. Estates Footprint and Premises Related Costs

Office Location	Approximate Size (m2)	Staff Numbers	Lease Cost (p.a.)	Cost per Head p.a.
HRA HQ & London REC Centres Ground Floor (Old Library) Skipton House	476m2	47	£339k	£7.2k
Nottingham Centre. The Old Chapel and Standard Court Nottingham.	325m2	21	£130k	£6.19k
Manchester Centre. 3rd Floor, Barlow House, Manchester.	522m2	28	£168k	£6k
Jarrow Centre. TEDCO Business Centre, Viking Industrial Park, Jarrow	155 m2	14	£35k	£2.5k
Bristol Centre. Whitefriars, Bristol	287m2	25	£113k	£4.52k

*Staff numbers exclude home based staff who are not linked to a particular HRA Centre due to the nature of their role.

Document Control

Change Record

Version Status	Date of Change	Reason for Change
V 0.1	N/A	First draft 12th December 2014 for DH
V 0.2	9.12.2014	Amends from EMT
V 0.3	11.12.2014	Final amends prior to DH Submission 12.12.2014
V 0.4	19.12.2014	Amends after DH Submission
v.0.5	13/01/2015	Minor update for Jan Board Meeting
V 0.6	05/02/2015	Updates after Board meeting
V 0.7	18/03/2015	Updates from DH review

Reviewers

Name	Position	Version Reviewed
EMT		V 0.1

Distribution of Approved Version

Name of person or group	Position	Version Released
S. Robinson	Corporate Secretary	V 0.1 for internal / DH review