

# Health Research Authority

## Business Plan

2016 – 17



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## 1.0 Introduction

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

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

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

An invaluable contribution is made by the 1,000 or so volunteers who serve on the RECs, the National Research Ethics Advisors' Panel (NREAP), the Public and Patient Involvement Panel and CAG who give their time freely to support the HRA.

The HRA is responsible for a budget of £13.1M and currently has 199 (*Jan 2016*) full time equivalent (fte) staff and offices based in London, Bristol, Jarrow, Manchester and Nottingham.

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

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

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

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

## 2.0 Strategic Direction

The HRA's overall strategic goal is to make the UK a global leader for health and social care research.

We 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

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

To exercise its Care Act remits of:

### 1. Protecting the Interests of the Public;

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

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

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

### 2. Streamlining Research;

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

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

As you will see in the following pages, we have set out and have made good steps in delivering an ambitious programme of work to improve the framework and processes for the approval and management of research in the NHS with many of our projects involving collaboration with partners, some of which are led by them. These partners include NIHR (National Institute for Health Research), MHRA (Medicines and Healthcare Products

Regulatory Agency) and the Devolved Administrations to provide a UK wide system for research that is proportionate and effective for approving research.

### 3. Promoting Transparency;

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

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

We publish a summary of health research projects conducted in the UK that require ethical approval through the UK wide service.

### 4. Working in Collaboration;

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

### 1. Introduction

As a NDPB the HRA lays its Annual Report and Accounts before Parliament and robust public and Parliamentary accountability arrangements are in place between the Department of Health (DH) and the HRA to ensure good communication and effective collaborative working as the DH, on behalf of Parliament, is required to assure itself of the HRA's delivery of its objectives.

### 2. The Board

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

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

Director  
Director

Tom Smith  
Janet Messer

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

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

The HRA's senior executive management structure is provided at **Annex A**.

## 4.0 Highlights of 2015 - 2016

### **HRA Approval Programme and Collaborative Projects**

During 2015/16 we laid the foundations and have delivered HRA Approval as a radical new system to simplify the regulatory system for health research. Building on the creation of the programme team, governance structure and plans in 2014/15, we moved to implementation of HRA Approval starting roll out by study type in May 2015. An iterative approach has allowed careful internal management of the new system, with opportunity for feedback and learning. Extensive change management activity with stakeholders, particularly the NHS, has been crucial to delivery. A new team within the HRA has been recruited and trained to deliver the new assessment and Approval service, guidance has been developed and published, and training to external stakeholders has been delivered in collaboration with industry and non-commercial partners.

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

In the first 10 months we have approved 89 studies through the new process, involving every NHS (Foundation) Trust and every primary care research support function in England. The median time from application to HRA Approval for these studies is 19 days (range 2-94), noting that the majority of studies so far have not required REC review. We have issued guidance for a clear and consistent system for setting up studies at NHS sites that is proportionate to the impact of the research on NHS organisations, and allows for site set-up to be conducted in parallel to HRA Approval. This simpler site set-up process enables research support staff to focus on ensuring the necessary arrangements are put in place for research.

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

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

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

Alongside the HRA Approval Programme, we have continued to work collaboratively with a range of partners. Particular examples include:

- Working with DH and funders to support the effective implementation of the guidelines for Attributing Costs of Research & Development (AcoRD) across the grant and study set-up timeline
- Supporting Public Health England with the development of processes to support public health research through local authorities
- Publication of protocol templates for qualitative research and clinical trials
- Working with the UKCRC accredited clinical trials units to identify opportunities for more efficient clinical trials
- Advising Genomics England on the arrangements for working with the NHS.

## Service Improvements

### 1. Confidentiality Advisory Group

This year has seen the establishment of a second Confidentiality Advisory Group in recognition of the new functions for the HRA.

The number of new applications reviewed was 53; 30 precedent-set applications and 93 annual reviews. The timelines for review continue to be improved with applications being reviewed in an average of 36 days.

CAG is an advisory group of volunteer members appointed by the HRA, which provides expert and independent advice to the HRA on access to confidential patient information for medical research purposes under Section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 in line with the HRA Directions 2013. In line with the additional responsibilities outlined above, the CAG has recruited seven new members to primarily provide the advice to HSCIC whilst also sharing the review of research applications. This now means that the CAG will meet twice per month in London and Manchester and will provide more flexibility for those applicants submitting applications for medical research which require S251 support.

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

There has been a review and streamlining of existing application guidance to further support applicants and provide greater clarity of process. It has been a year of continuing change in the overarching information policy frameworks within which the CAG operates however it continues to be well-placed to engage with key bodies as legal and policy changes within information governance develop. It has worked closely with the HSCIC at all levels to provide clarity of process to applicants, and to seek to reduce duplication, and has engaged with national bodies to maintain awareness of key changes so that its recommendations remain fully informed.

CAG continues to provide internal training support at inductions and bespoke events and has trialled a bespoke training session at University College London that focused on the legal framework and practical implications when submitting an application. It has also contributed to other external guidance such as NHS England development of guidance to

support 'Pioneer' applications and MRC broader guidance to support applicants seeking data from the HSCIC

The CAG, via its advice team, continues to provide credible advice on information related issues to internal functions, steering groups, and policy initiatives.

## 2. Research Ethics Service

RECs provide an ethical review of applications submitted to the HRA for research which involve patients and the public, the use of their tissue and data. They are comprised of a maximum of 18 volunteer members. The HRA has 68 RECs, including the Social Care REC which transferred into the HRA in 2015-2016

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

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

We recognise the benefit of greater understanding of the remit and expectations of RECs. Our staff have visited a number of NHS organisations and Universities to deliver "the only way is Ethics" presentation about applying to a REC.

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

## Public Involvement

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

We have an interactive, co-produced and co-delivered session on public involvement in the induction programme for new staff which continues to play an important part in embedding public involvement into the core business of the HRA as well as emphasising how important the work of all our staff is to patients and the public.

We have developed and introduced new policies and procedures on our overall approach for the involvement of the public in HRA work, involvement in staff recruitment and paying public contributors.



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

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

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

The re-procurement of the supplier for IRAS and HARP during 2014 allowed a significant series of developments during the course of 2015/16. These were delivered to time and budget and were all successfully released to live.

Although many of the developments were to support the implementation of HRA Approval, there were also incremental improvements to HARP for Research Ethics Committees and the Confidentiality Advisory Group. Different secure portals into HARP now allow Research Ethics Committee members to review applications online and NHS organisations to confirm the Approval status of research projects.

IRAS developments have supported the UK partners. The creation of a combined form for ethics and R&D not only supported HRA Approval, but provided a mechanism to develop electronic submission of R&D applications for the devolved administrations. An electronic interface is being developed between IRAS and the NIHR Central Portfolio Management System.

Fundamental to the above successes with delivery has been the addition of a quality function within the Research Systems Team. This has added to the capability and capacity the team has for software testing, response to auditing and documentation of the systems.

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

### **Financial Balance and Budgeting**

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

- A published Financial Plan for 2015/16 and agreed budgets being in place;
- Submissions for the 4 year Spending Review which will form the basis for a strategic 5 year financial plan ;

- Financial reports within 4 working days and reporting to the EMT and the Board as agreed;
- Forecasts which are reviewed monthly through close finance to service partnering;
- Improved payment performance, not only meeting the Better Payment Practice Code of 95% of invoices paid within 30 days but achieving 98%, 61% of which were in 10 days.
- Continued improvements in early travel bookings (2 weeks or more ahead) to take advantage of discounted ticket rates; and
- Near 100% use of recycled copying paper (better value and 'environmentally friendly').

## Partnership Working

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

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

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

## Transparency

The HRA has long recognised that transparency within research is not only an important area for the UK but that this is a global issue, of interest to the public, research participants, patients and also the wider research community. The HRA's committed to taking a lead in research transparency through the introduction of pragmatic transparency measures, to ensure the UK remains as a competitive place in which to undertake research and critically, one where the public and patients have confidence in the research undertaken and resulting findings.

Over the past year we have;

- Continued to ensure the declaration within IRAS in relation to clinical trial registration is non-cumbersome and straightforward for Sponsors and that remains a simple route, where required, for a deferral to be sought, with 44 such request in year, all of which were agreed;
- Seen the publication of "Can UK NHS research ethics committees effectively monitor publication and outcome reporting bias?" by Rasheda Begum and Simon Kolstoe, supported by the HRA (<http://bmcmethics.biomedcentral.com/articles/10.1186/s12910-015-0042-8>); and

- Circa 6,000 of summaries of research added to the HRA website with links, where appropriate to clinical trial registries.

## **Organisational Development and Staff Learning**

We created a Technical Talent Programme to ensure that staff developed broader knowledge of the governance of research and roles that sit with our stakeholders. This included going to visit R and D departments. 40% of those on the programme achieved new job roles internally, including some in the new HRA Approval areas.

We implemented leadership development, to support leaders to manage high performance and ran a separate internal leadership talent programme, which included more senior potential leaders as well as staff on some lower grades where potential had been identified.

We introduced Civil Service Learning to allow all staff access to a wide range of personal and leadership development e-learning and resources, which ensured geographically spread staff could be developed in a cost effective way.

## **Staff Engagement**

Developing and maintaining a high level of staff engagement is a key factor in enabling the HRA to achieve our ambitions and business objectives. The 2015 Staff Survey achieved an excellent response rate of 74%. The findings show that 91% of respondents are committed to helping the HRA be successful and 93% agreed they are happy to go the “extra mile” at work when required. The employee engagement index has risen to 81% compared to 74% in 2014 and is significantly above the benchmark figure of 69%. These findings are set in the context of an organisation that has grown and changed significantly with the implementation of HRA Approval in 2015/16.

## **Communications**

Through 2015-16, the communications team have helped raise awareness and understanding amongst stakeholders of the HRA by, supporting and promoting its activities and initiatives. In particular:

- Communications support for the collaborative work of the Department of Health and its arm’s length for the Regulatory Advice Service for Regenerative Medicine.
- Delivering targeted communications in support of HRA Approval.

Ensuring wide-reaching cascade and awareness raising of the opportunity to provide feedback as part of the public consultation on the UK Policy Framework for the conduct and management of health and social care research

In addition the website has been undergoing a programme of review, with changes to content and the front page as well as work on a new patients and public section co-produced with public contributors and the HRA’s public involvement team. The website will be a continued focus for the forthcoming year.

## Operational Quality Assessments

The number of RECs which went through the QA Accreditation audit process during 2015/16 was 29. The outcome was 55% were given a full accreditation, 21% full accreditation with conditions and 24% provisional accreditation with an action plan. Observation of REC meetings by operational managers continue to be conducted on an annual basis.

We continued our well established Shared Ethical Debates (ShED) – covering the following areas clinical trials and complementary therapies, studies involving paediatrics and a qualitative study. This involves a previously reviewed application being reviewed by a number of RECs and analysing the decision making of each committee. This year in response to a request from two researchers we were able to extend this to a 'mystery shopper' where the same application was submitted to 12 RECs by the researchers, the results of which were presented to the HRA Board in January.

Overall their view of the service was very positive but with improvement actions to be considered and taken forward.

The work of the CAG and the RECs is hugely dependent upon the services provided by its voluntary members and their efforts and expertise are very much valued by the HRA. Internal audit has reviewed the TOPs and CAG functions in 2016.

## Quality Assurance

The Quality Assurance (QA) Department continues to hold ISO 9001:2008 certification and build upon well-established Quality Management System (QMS) principles.

Noteworthy achievements in this area over the last year include:

- In preparation for the extension in scope of ISO 9001 the QA Department worked with colleagues to ensure their processes were relevant, functional and documented. This work led to improved internal working in order to achieve greater consistency and quality of services provided by the HRA;
- The QA Department completed a programme of 42 internal QMS audits of HRA functions and services in addition to the 29 REC accreditation audits in order to provide assurance that the services/functions were being delivered to the standards expected; where non-compliances were identified action plans were issued;
- The QA department once again achieved ISO 9001:2008 certification, after external audit, with no observations / non-conformities being raised by British Standards Institute (BSI) who commented, "A very robust, neat and concise Quality Management Framework has been in place for a number of years. The Framework contains process maps at various levels which demonstrate the interaction of the core key elements. The Framework has been refined, revised and continuously improved based on this understanding of the customers and staff's needs and has proven to be very beneficial", affording a strong position for future developments; and
- The established user satisfaction function has been expanded to provide guidance and administrative support to HRA staff seeking ad hoc feedback from stakeholders in order to ensure an effective and consistent approach 15 feedback surveys have been undertaken, in addition to the routine quarterly reporting of user satisfaction.

## Guidance and Advice

Notable successes over the past year include:

- Deploying dedicated software to facilitate improving the HRA Queries Line services;
- Responded to over 2,400 enquiries through HRA Queries Line of which 94.3% were responded to within our target of 4 working days & 79.3% within 1 working day;
- Work with the Medical Research Council (MRC) Regulatory Support Centre to finalise and publish an online guidance tool for applicants, and potential applicants, to the Confidentiality Advisory Group (CAG) about reducing the disclosure of confidential patient information;
- Preparing and publishing guidance specifically for applicants for HRA Approval, which has been iteratively developed to complement the phased roll-out and also to respond to feedback;
- Continued work with Partners to ensure that we offer consistent and timely information and advice. For example through: continued partnership with MHRA, HTA and HFEA to deliver the regulatory advice service for regenerative medicine; and disseminating updates in respect of the future implementation of EU Clinical Trials Regulation.

## Learning to the REC and research community

Notable successes over the past year included:

- Facilitating 50+ learning events during 2015/16, with an average overall score of 97% satisfaction (up to December 2015);
- Actively collaborating with Partners and developing new opportunities to work together, maximising opportunities from limited resources, including shared events with the Institute of Clinical Research and a seminar series with the Medical Research Council; and
- Developing freely available e-learning modules for REC Member Induction, Equality and Diversity, Research Design of Clinical Trials, five 'Proportionate and Pragmatic' CSP modules and additional modules in preparation.

## The Over-volunteering Prevention System

The purpose of TOPS is to provide a simple, national, robust mechanism to ensure healthy volunteers do not over volunteer for clinical trials. The HRA launched a new TOPS database on 13<sup>th</sup> October 2014. The HRA implemented a number of improvements to TOPS as part of the new database and has worked closely with the Phase 1 community since the launch in order to provide further improvements. Improvements have been made to TOPS this year including functionality to specify where a volunteer took part in a study which involved Monoclonal Antibody and other practical improvements to the system.

## Estates

Considerable progress made towards our agreed HRA Estates Strategy:

- We aimed 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;

- We successfully submitted 3 lease exemption cases which meant we could plan for the longer term at Manchester, Bristol and Nottingham;
- We made changes in each of these offices, making good progress towards achieving the Cabinet Office target of 8sq metres per Whole Time Equivalent, whilst at the same time improving the look and feel of offices for staff;
- We aimed to adopt the industry standard of 8 desks to 10 staff ratio and to achieve this by March 2016 if not sooner we moved from a 1.06 ratio (of more desks to staff) and achieved 0.89 by March 2016 with continued progress planned;
- We successfully accommodated all staff within our 5 offices, closing our short term location of Standard Court in January 2016 thereby releasing planned savings;
- We introduced digital telephony into all offices across the organisation. The system allows staff to view availability and location of all HRA colleagues who are on-line, to instant message them, to phone them and collaborate through video conferencing or shared desktops. The system works at any location with an internet connection, although quality of connection can impact on the reliability of the system. This system will be a key element of being able to make continued efficiencies within our estate; and
- We successfully completed a “Proof of Concept” project to test home working from our Bristol Office.

## Procurement

We successfully awarded a tender for our main Research Information Systems following 3 months of good inter Directorate team and partner collaboration. We secured additional resource to advise us through this process. In addition to delivery to planned timescales we delivered 20% savings.

## Programme Management Office

- Portfolio Management concept introduced and maturing with senior management support and active participation;
- Project Management and Governance training developed and extensively delivered throughout the organisation;
- Development and piloting of processes and tools for project Start-up, initiation and management start gates;
- Selection and integration of the HRA Hub collaboration tool within the organisation; and
- Programme and Project Planning, critical path development and template development for Approval programme.

## 5.0 The Government’s Priorities

All Health, Health Related and Social Care bodies need to consider how their work contributes to the joint delivery of the DH’s priorities for health and social related research to ensure the system is aligned, consistent and works effectively through collaboration. These priorities as set out in the Shared Delivery Plan (SDP) are:

- Improving out of hospital care;
- Creating the safest, high quality healthcare service;

- Maintaining and improving performance against core standards while achieving financial balance;
- Improving efficiency and productivity;
- Preventing ill health and supporting people to live healthier lives;
- Supporting research, innovation and growth;
- Enabling people and communities to make decisions about their own health and care;
- Building and developing the workforce; and
- Creating a technologically and digitally enabled service.

Whilst the HRA's contribution to these will primarily be focussed on 'Supporting research, innovation and growth', broader contributions include:

- facilitating an improvement in the speed with which research is approved and delivered will improve the rate of understanding of disease and the development of effective treatments that will improve patient care and mortality rates;
- 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 resource limits thus ensuring that budgets are effectively managed throughout the organisation.

With regard to on 'Supporting research, innovation and growth', the HRA's specific contributions include:

- 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 by ensuring that researchers using the 200 Human Tissue Authority licensed tissue banks benefit from a streamlined process where RECs give generic approval for tissue collection, storage and release arrangements; and
- 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;

## 6.0 The Golden Thread

The HRA has adopted the Golden Thread planning methodology as a coherent framework to co-ordinate both long and medium term planning and as an effective internal and external communication medium. Key benefits of the methodology are:

- Helps staff perform effectively and focus efforts on activities that matter;
- Helps everyone understand how personal contribution helps deliver strategic goals;
- Helps everyone understand their contribution to the achievement of the organisations vision and mission; and
- Connects the Board to front line staff.

<b>VISION</b>	The HRA promotes and protects the interests of patients in health research and seeks to streamline the regulation of research. It aims, with partners, to make the UK a great place to do health research, to build confidence and participation in health research, and so improve the nation's health.
<b>CORE VALUES</b>	<p><b>Inspiring leadership:</b> Enabling people and teams to develop and deliver dynamic, innovative and transformative services and systems.</p> <p><b>Integrity:</b> Being fair, ethical and honest in everything we do.</p> <p><b>Trusted:</b> Being respected for delivering to consistently high standards.</p> <p><b>Transparent:</b> Being accountable and open about all aspects of our work.</p> <p><b>Collaborative:</b> Listening to and working with others to identify and make improvements to the health research environment.</p> <p><b>Empowering:</b> Supporting independent thinking and decision-making.</p>
<b>STRATEGIC GOALS</b>	<p>Leading improvements that make it easier to conduct good quality research in the UK;</p> <p>Improving efficiency and effectiveness of systems, and of advice and guidance;</p> <p>Building and consolidating productive relationships with public and professional stakeholders;</p> <p>Having a skilled, dedicated and motivated workforce and HRA volunteer committee members; and</p> <p>Ensuring the HRA is managed and governed effectively, and provides value for money to the tax payer.</p>
<b>BUSINESS GOALS (CARE ACT 2014)</b>	<p>The HRA's main functions are:</p> <ul style="list-style-type: none"> <li>• Co-ordination and standardisation of practice relating to the regulation of health &amp; social care research;</li> <li>• Recognising and establishing Research Ethics Committees;</li> <li>• Being a member of UK Ethics Committee Authority (UKECA); and</li> <li>• Providing approvals for processing confidential information relating to patients.</li> </ul> <p>The main objectives in exercising these functions are to:</p> <p>Protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical; and</p> <p>Promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical - including promoting transparency in research.</p> <p>Transparency in research includes the registration of research, the publication and dissemination of research findings and conclusions, the provision of access to data on which research findings or conclusions are based, the provision of information at the end of research to participants in the research and the provision of access to tissue used in research, for use in future research</p>
<b>PRIORITY SERVICE PLANS</b>	See detail below in 7.
<b>FUNCTIONAL OBJECTIVES</b>	See detail below in 8.
<b>INDIVIDUAL OBJECTIVES</b>	Detailed in Appraisals and set annually to reflect Business and Directorate Objectives.



The overarching approach for 2016 – 17 is to align the Business Plan far more closely to this Golden Thread methodology so that the Service Plans and Directorate Objectives combine to achieve the Strategic and Business Goals thus comprising this Business Plan. In addition and importantly, this business planning approach aims to align business processes far more closely to the HRA Programme Management approach that ensures consistent and co-ordinated resource management, programme and project delivery and benefit realisation.

## 7.0 Key HRA Developments 2016 -17

From the beginning of Q3 2015 the organisation has been developing what has been termed the 'HRA Portfolio'. These are activities that, it is considered, would enhance the service offered by the HRA and therefore contribute to the overall improvement of Health Research in the UK. These activities fall into one of two categories i.e. suggestions for improving existing services or new developments linked to the emerging role of the HRA. This 'bottom up' process led to the identification of around 150 activities which ranged in scale and size from high level objectives of 'embedding the HRA Approval Programme' to more specific items to 'improving minute and letter writing guidance'. A high level assessment was then made as to their level of importance in contributing to the HRA's strategic objectives.

As a result of this planning work the following programme themes which will underpin the delivery of our strategic ambitions to; streamline research, protect the interests of the public, promote transparency and working in collaboration were identified.

- Proportionality/Consistency
- Public confidence, including transparency
- Equipping ourselves to deliver our best
- The researcher journey and experience
- Statutory corporate requirements

In considering these themes the following major project / programme areas were then identified to be of a high priority for 2016/17 as if effectively delivered will significantly contribute to our strategic ambition.

Suggested Priority Programme Areas	Description
<b>HRA Approval</b>	Further consideration of UK-wide compatibility and potential for further simplification of process for researchers between REC, assessment and other approvals. Evaluation and identification of benefit to promote uptake and full benefit realization. Considering broader scope for HRA Approval (non NHS and social care)
<b>IRAS Development</b>	To enable IRAS to support researchers in navigating the research approvals process by simplifying forms, enabling information to be used once for multiple purposes, and improving information exchange between sponsors, researchers, regulatory bodies and sites.
<b>Consistency in decision making</b>	To reduce level of provisional opinion rates to strengthen confidence in the expected timelines for decisions, minimising duplication of review and to ensure consistency in decision making by HRA including REC and Approval

<b>Policy Development and Policy Guidance</b>	Development and implementation of policy and legislation. Including known priorities driven by legislation and regulation and developing further policy guidance in identified priority areas for the HRA to further improve the policy platform for research in the UK.
<b>Social Care Research</b>	Scoping Social Care Research in order to understand the implications of social care research for the HRA.
<b>Guidance and Advice</b>	Development, review and revision of guidance in response to new policy development or amendment. Review and revise guidance (HRA site and IRAS) in light of finalised Policy Framework
<b>Public Involvement in research and the role of the HRA</b>	To develop practical standards for researchers and funders and to support and promote further public and patient involvement. Revise the questions on IRAS and consider better ways to evidence and improve standards for involvement through the assessment and REC review processes.
<b>Web Development</b>	This will enable users to understand the role of the HRA and the services we offer, meet user needs, making it easy to use and navigate. It will also guide researchers through the approval process from start to finish. It will further strengthen the HRA's reputation as being a source of trusted and vital guidance.
<b>Proportionality</b>	Reviewing the opportunities for more proportionate approaches within guidance (e.g. consent) and operating procedures (criteria for proportionate review)
<b>HRA Strategic 5 year Plan</b>	The HRA's Board has the stated ambition of developing a 5-year Strategic Plan by September 2016. This will be developed through a collaborative approach with key stakeholders to ensure that resources and activity can be focussed on those areas that will realise the most benefit to the Health Research landscape
<b>Organisational Change</b>	To ensure the organisation makes best use of its capacity and capability to deliver its strategic objectives.
<b>Ways of Working/Efficiency initiatives</b>	To implement an efficiency programme that enables us to reduce costs whilst maintaining high quality services. These will include more effective use of estates, reduction in travel and utilising enhanced IT capability to manage existing processes and procedures more effectively
<b>Shared Interest Agenda</b>	Explore working more collaboratively together with other ALB's in areas where there is an opportunity to save operating costs and or deliver a more effective service

These priority areas will be shaped into programmes of work that will be characterised by applying strong programme management disciplines, including the development of the necessary programme 'products' e.g. programme initiation document, business case, delivery plan, (including defined benefits) and a robust and accountable governance and management structure.

It should be noted that these activities do not intend to represent the sum total of the work of the HRA and much of the work contained in the overall HRA portfolio will also be developed and started in 2016/17 however the intention is to ensure that the priorities remain a strong focus for the HRA's available capacity, capability and resource. The list should be considered alongside those activities within in key functional areas which are outlined in the following section.

## 8.0 Plans for our functions

### 8.1 HRA Approval

Following the controlled roll out of HRA Approval by study type during 2015/16, 2016/17 will see an increasing volume of studies being processed through HRA Approval. Through on going oversight of study volumes and review of internal and external processes we will ensure efficient processing of this increasing volume. We will continue to monitor the timelines for both end to end processes and individual components to identify elements requiring attention. The quality management system we have implemented will ensure that lessons are learnt so both applicants and NHS organisations are confidently able to accept assurances from HRA Approval. We will continue to develop the interfaces with other internal and external systems to support applicants in navigating processes. We will also consider opportunities to extend the benefits of HRA Approval to other research settings, such as third-sector care settings and social care.

Our goal is to:

- Embed HRA Approval during the course of 2016/17 for the NHS to simplify the research approval process in England
- Increase consistency of arrangements for study set-up for the NHS in England
- Identify opportunities to streamline arrangements for research across health and social care boundaries

Which we will seek to achieve by:

- Continuing to manage interfaces with internal and external systems;
- Continuing to ensure that staff are appropriately trained to deliver continuous improvement to internal systems;
- Continuing to implement change management, communication and engagement plans;
- Continuing to develop and implement the necessary Information Systems (including HARP and IRAS) to support relevant interfaces with partner systems;
- Completing the roll-out of pharmacy and radiation technical assurances;
- Continuing to review feedback from users and staff to refine the system;
- Continuing to standardise systems (e.g. for information governance for research in the NHS) and templates (e.g. through updating model agreements); and
- Scoping the potential to offer aspects of HRA Approval for studies across a wider range of health and care sectors.

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.

### 8.2 Research Ethics Service

Our goal is to:

Continue to provide an efficient, responsive, proportionate, effective and robust Research Ethics Committee operation working with colleagues in the devolved administrations to continue to deliver a UK-wide research ethics service and HRA assessment team to align processes to deliver HRA approval.

Which we will seek to achieve by:

- Maintaining and improving timelines for review of applications to RECs;
- Improving the quality and consistency of ethical review and administrative processes, including SOP review; minutes and letters review; and shared ethical debate development;
- Roll out the extended administrative validation and quality review for all non-NHS studies;
- Developing and delivering training for staff and contributing to development of training initiatives for the research community;
- Reviewing staffing establishment in each office as a result of implementation of new developments;
- Exploring the use of technologies: extending the use of member electronic review of applications; use of video capability for attendance at meetings; use of hybrid mail system;
- Developing a procedure for RECs to be flagged and reviewing the system of flagging of RECs;
- Explore the increased use of staff in reviewing PR applications;
- Development of a trainee REC manager programme linked to the national apprenticeship scheme;
- Development of a recruitment procedure for REC members to maintain the diversity of REC membership and reconsider terms and conditions of service in relation to time limits on appointments;
- Undertake an options appraisal to ensure number of RECs is sufficient to review applications and to include the review of applications for social care research;
- Consideration of development of a process for the review of generic applications encompassing a programme of research
- Consideration of a process for review of long term studies to ensure that research remains up to date in terms of ethical standards and legislation;

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.

The Directorate will work with the policy team and with the members of NREAP and external stakeholders to consider the issues of relevance to ethical review including the topic within the mystery shopper exercise this year of “opt out” consent.

### 8.3 Confidentiality Advisory Group

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;
- Extending the use of HARP for e-submission and management of applications;
- Maintaining provision of early advice to stakeholders to improve the quality of applications;
- Development of mechanism to produce detailed granular statistics on CAG operations;

- 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 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);
- Development of the CAG Register to ensure that information on approved projects is available to the public;
- Establishment of searchable Precedents database on CAG advice; and
- Reviewing the implementation of CAG providing advice to HSCIC under the new framework.

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.

## 8.4 Policy

### Policy Framework

Our goal is to:

Lead improvements that make it easier to conduct good quality research in the UK

Which we will seek to achieve by:

Publishing the revised Policy Framework and associated guidance which will support researchers in the conduct of their work; including:

- guidance on proportionate consent including electronic consent
- guidance on the identification and recruitment of potential participants in research and
- guidance on conducting health and social care research in prison

So that:

The HRA can encourage a proportionate approach, reduce the burden placed on researchers and clarify areas of uncertainty.

### Identifying Policy Issues

Our goal is to:

Work strategically with the research community and other stakeholder groups to proactively identify and develop policy issues

Which we will seek to achieve by:

Developing a more systematic process to the identification and prioritization of policy issues and reviewing the way in which we work with advisors and academia and engage with the research community

So that we:

Raise the profile of the HRA as a leading authority on the debate and development of policy in the health and social care arena.

## Engagement

Our goal is to:

Continue to engage in public dialogue with patients and the public

Which we will seek to achieve by:

Collaborating with partners to engage with the public using a deliberative approach to understand their views on complex policy issues of interest to both parties

So that:

The HRA builds public confidence in health and social care research and in the wider research community.

## Preparing for Implementation of the EU Clinical Trials Regulations with the Medicines and Healthcare Products Regulatory Agency (MHRA)

Our goal is to:

Continue to prepare for the successful implementation of the EU Directive on Clinical Trials

Which we will seek to achieve by:

Working with the MHRA and the devolved administrations to design and develop the required processes and information system changes.

So that:

- The HRA promotes the coordination and standardisation of practice in relation to the regulation of health and social care research giving it a leading role in removing duplication and streamlining the regulation of health and social care research across the regulatory system; and
- The UK is recognised as being a leader globally in clinical research.

## Social Care

Our goal is to:

Scope social care research in England

Which we will seek to achieve by:

Understanding the scale and nature of social care research approved by University RECs and explore the decision making process undertaken by researchers in social care when they decide on approval route.

So that:

The HRA can support the future integration of social care research alongside health research.

## 8.5 Public involvement

Our goals are to:

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

Which we will seek to achieve by:

- Supporting our colleagues across all areas of our work to identify where public involvement would add value and can be promoted as part of our influencing work with research communities;
- Further developing our processes and procedures to integrate public involvement into the core business of the HRA;
- Promoting and supporting an increase in the amount and quality of public involvement in health and social care 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;
- 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 its work, and uses its influence on others to support an increase in the amount of effective public involvement in health and social care research

## 8.6 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:

- Evaluating the uptake and impact of published templates and guidance on protocols; and identifying potential opportunities to minimise the number of times and places where researchers need to provide information about their study;
- Collaborating with other regulators to identify and implement streamlined arrangements (e.g. Administration of Radioactive Substances Advisory Committee);
- Collaborate with other bodies to support the preparation for implementation of new legislation (e.g. EU Data Protection Regulation);
- Collaborating with sponsors to support the sharing of good practice and delivery of training and tools to support responsible sponsorship; 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.

## 8.7 Research Systems

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

IRAS 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.

HARP is an application delivered through a password protected web interface. It was originally 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 was subsequently developed to support the Confidentiality Advice Group (CAG) and HRA Approval.

Our goals are to:

- Ensure continued availability of IRAS and HARP for HRA, devolved administrations and partners;
- Undertake significant developments to IRAS to simplify the approvals system for the research community, in response to user feedback reducing the number of separate forms and making it easier for researchers to provide information once for multiple purposes.;
- Deploy a series of upgrades to HARP to meet the requirements of all four nations for integrated work between REC and R&D functions to streamline the research environment;
- Deliver developments to IRAS and its interfaces with other systems, to allow information and documents to be appropriately and securely shared across relevant parties to reduce duplication for researchers; and
- Support the planning for implementation of the EU Portal for clinical trials in 2018.

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;
- Undertaking regular meetings with MHRA and the European Medicines Agency (EMA) to contribute to planning for the EU Portal;
- Delivering a planned programme of upgrades to time and budget for HRA and the devolved administrations;
- 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; and
- Secure a permanent quality function within the Research Systems Team rather than the current reliance on contractors, to provide effective software testing, quality systems and procedures, and robust oversight, and achieve continued delivery on time and on budget.

So that:

IRAS and HARP continue to be provided 24-7 and meet the needs of researchers and partners UK-wide 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.



## 8.8 Standards

### Preparing for Implementation of the EU Clinical Trials Regulations with the Medicines and Healthcare Products Regulatory Agency (MHRA)

Our goal is to:

Ensure successful preparation for the implementation of the EU Clinical Trials Regulation.

Which we will seek to achieve by:

Working with the MHRA and the devolved administrations to design and develop the required processes and information system changes.

So that:

The UK is recognised as being a leader globally in clinical research.

### 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.

### Transparency

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;
- Further raise awareness and support for the HRA's transparency agenda, the responsibilities of wider research community within research transparency and report on findings; and
- Continue to support and ensure dissemination of proportionate transparency initiatives led by partner agencies, appreciating that transparency is the responsibility of all, including researchers and sponsors and that UK research is part of a global environment.

Which we will achieve by;

- Continuing to monitor compliance of registration for clinical trials in order to inform further developments /make recommendations for future measures /pragmatic steps;
- After cohort 4 of HRA Approval (which sees the majority of Approvals for research in the NHS in England provided by the HRA) has been completed and evaluated we will look to add the additional assessment on research registration for all research studies submitted to the HRA; This will therefore bring in an initial advisory function through the assessment and, subject to consultation, capture as requirements through the REC opinion;
- Offering further consideration in connection with reporting /publication of research;
- Considering options for managing transparency breaches;
- Continuing to work with others to promote transparency, where others are the more appropriate lead, recognising the effectiveness of collaboration; and
- Working collaboratively across stakeholders to ensure successful implementation of the EU Clinical Trials regulations.

So that:

The UK continues to have proportionate and pragmatic measures in place to maintain UK competitiveness within Health Research and critically continue to inspire public confidence in research.

## 8.9 Quality, Guidance and Learning

### Quality Assurance

Our goals are to:

- Develop assurance systems in order to increase public and patient confidence in health research;
- Continue to build of the culture of quality and continual improvement within the HRA, in order to support development of functions and services; and
- To secure and maintain ISO9001:2015 certification for the HRA.

Which we will seek to achieve by:

- Conducting audits and feedback surveys to inform HRA services that directly impact public and patients e.g. the implementation of the revised information sheet guidance, monitoring of trial registration for clinical trials;
- Considering ways in which the HRA can work collaboratively with regulatory bodies in order to support and contribute to their role as research regulators;
- Working with the BSI in order to achieve ISO 9001:2015 certification of HRA functions and services and to continue to undertake internal QMS audits therefore maintaining the certification of the QMS;
- Agreeing and establishing, with HRA colleagues, the auditable standards associated with the HRA approval programme and setting up quality systems in order to monitor compliance to the agreed standards; and
- Continue to improve established HRA QA systems so that they remain fit for purpose and provide assurance to both internal and external stakeholders.

So that:

There is an assurance that the services we deliver, to support the UK research environment, are of a high quality and compliant with statutory/regulatory requirements, in order to build confidence in the HRA and wider in the health and social care research in the UK.

## 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 Line email services.

Which we will seek to achieve by:

- Reviewing and updating our guidance to support changes in the regulatory and governance environment, such as the publication the UK Policy Framework and completion of the roll out of HRA Approval;
- Ensuring that the advice given by our email Queries Line services in relation to enquiries is timely and of high quality;
- Using our dedicated software for Queries Line services to monitor overall performance and identify trends in enquiries;
- Using data from our Queries Line services, user feedback and work with others, including Quality Assurance, Learning and Operations as well as external colleagues to develop and improve our portfolio of guidance, advice and learning. Key themes of this activity will be consideration of appropriate mechanism and format of delivery as well as content and ensuring effective signposting of other information to reduce unnecessary duplication.

So that:

The advice and guidance provided by the HRA is relevant, accurate and accessible to support the continual improvement of research and research applications across the UK.

## Learning to the research Community

Our goal is:

To develop and deliver a blended learning system, which is better able to meet the diverse needs of our Committee Members, staff and wider research communities.

Which we will seek to achieve by:

- Continuing to deliver high quality, needs-led face-to-face training events which provide opportunities for REC members and the wider research community to learn and network;
- Designing, developing and piloting a blended learning programme for Research Ethic Committee (REC) Members and the wider research community to support and gradually replace elements of the face-to-face programme;
- Develop and pilot a range of delivery options including: e-learning, webinars, podcasts, video and other online resources;
- Building collaborations with partners to develop effective solutions to providing learning to wider research communities, utilising existing networks and new technologies.

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.

## 8.10 Finance, Procurement and Estates

### 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.

### Estates Efficiency

Our goal is to:

- Continue to 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;
- Consideration of achieving 7 desks to 10 staff; and
- Maintain the current five geographic offices.

Which we will seek to achieve by:

Continued to review 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.

### Financial balance & 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; and
- Ensure that there are no surprises during the year and that financial activity is visible and reported across the organisation.

Which we will seek to achieve by having:

- Published a Financial Plan for 2016 -17 and agreed budgets in place by the 1<sup>st</sup> April 2016;
- A Strategic 5 year financial plan published and agreed by the summer alongside agreement of the revised organisational strategy;
- 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;
- Forecasts produced from September at the latest and reviewed monthly thereafter with close partnering between the finance partner and the service lead.

- Training for all budget managers, with particular focus on the importance of accurate forecasting and their role in this regard;
- Financial information published which complies with the HM Treasury Guidance by the 15th working day of the month; and
- 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 identified in the Spending Review work are delivered and further opportunities maximised to enable investment 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:

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:

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

Which we will seek to achieve by:

Reviewing our Procurement Pipeline and ensuring best value is obtained for all new contract agreements, critically reviewing services that are required.

So that:

The HRA is continually reviewing and identifying opportunities to make efficiencies through our procurement choices in the same way as any tax payer would.

## 8.11 Corporate Services

### Organisational Development and Staff Learning

Our goal is to:

Ensure that the HRA is structured in a way which supports its mission and goals, and that its workforce is developed to effectively deliver the business agenda

Which we will seek to achieve by:

- Developing staff in:
  - The core skills to do their job;
  - More advanced technical skills to ensure they can contribute to our developing agenda and work with our partners;
  - Personal skills to support good team working and personal development; and
  - Leadership and management skills to ensure that our leaders support high performance throughout the organisation.
- Supporting the CEO and Directors in ensuring the organisation is fit for function by:
  - Ensuring we have the right organisational design; and
  - Working with team, functions and Directorates to ensure good cross team / function / directorate working.
- Working with HR to create a joint Workforce and OD plan

So that:

The organisation is fit to function both now and in the future and has an effective and engaged workforce

### Human Resources

Our goal is to:

Continue to provide an effective, professional and timely HR services based on best practice and current employment law to support the HRA in achieving its objectives

Which we will seek to achieve by:

- Supporting and providing specialist HR advice and interventions to identified projects;
- Continuing to work collaboratively with our HR shared services provider, NHS BSA, to ensure managers and staff have access to a customer focused, efficient, cost effective and helpful HR services; and
- Continuing through to completion the HR policy harmonisation and revision project to ensure all of our people management policies are fit for purpose and legally compliant.

So that:

We deliver quality HR services that satisfy our managers and staff

## Programme Management Office

Our Goals are to develop and support:

- The prioritisation and scheduling of Change Initiatives;
- The governance and oversight of programmes, projects and activities; and
- Good development and delivery practices, capabilities and maturity.

Which we will seek to achieve by:

- Definition and delivery of the HRA Portfolio of change initiatives and activities and a pipeline of future potential items;
- Developing, supporting and maintaining process for resource management and tracking;
- Integrating Benefits Management activities into the delivery lifecycle; and
- Defining processes and tools for programme, project and activity planning and collaboration including
  - Start-up and Initiation processes and start gates;
  - QA, assurance, tracking and reporting benefits, risks, interdependencies, constraints, status and progress;
  - training, mentoring and support for programme and project managers; and
  - templates for project and programme management products.

So that:

HRA will develop a clear line of sight and links from business and organisational Strategy to Benefits and to their related Initiatives, programmes, projects and activities  
More reliable information will be available to ensure better investments in change initiatives and allocation of funds and resources to ensure maximum value for money and productivity, transparency, and engagement by senior management.

## Corporate Business support

Our goal is to:

Ensure that the HRA is given effective corporate business support to be able to carry out its core functions and everyday business.

Which we will seek to achieve by:

- Continuing to collaborate with HRA Finance to align policy and practice;
- Continue to manage the client relationship with key suppliers for travel and accommodation services and Stationery;
- Strive to build into work plan Redfern booking training biannually;
- Continue to provide support to the Head office and Estates Strategy implementation at SKH;
- Continue to encourage use of 'Green catalogue' on Banner where there is opportunity;
- Continuing to monitor savings and efficiencies made in relation to the above; and
- Continue to provide high level administrative support to the HRA on the Approvals Programme Gateway Review work.

So that:

We provide an efficient corporate business infra-structure for HRA staff in the areas above

## Communications

Our goal is to:

Promote and support the HRA's vision, strategy, objectives and activities internally and externally, highlighting successes; keeping stakeholders informed; communicating openly and transparently

Which we will seek to achieve by:

- Ensuring communications activity continues to be focused in support of organisational objectives and priorities;
- Building our reputation on what we do and how we deliver. Demonstrating what we are doing, focussing on benefits and achievements as they become tangible;
- Delivering targeted communications integrated across digital and traditional channels;
- Supporting activity to engage people across the HRA's initiatives, including events, publications and partnerships;
- Continually improving existing communications channels and activities( with a particular focus in the coming year on our website) ; and
- Ensuring staff are fully informed to support them in their role.

So that:

All people with an interest in the HRA have the right level of understanding of our activities and initiatives and easy access to all information relevant to them

## 8.12 Corporate Secretariat

### 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; 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.

### 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.

## 9.0 Measuring our Success

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

In April 2016 the HRA Board will receive and publish a benefits realisation plan for the HRA. Recognising that benefit realisation whilst having key performance indicators at the heart of success, will need to go further to ensure that success is translated into real and tangible benefit for stakeholders including those who use our services and a measure of our overall contribution to UK wide competitiveness for health and social care research.

This suite of indicators is under continual development with active input from the Board. For 2016/17, a new performance dashboard has been approved and is included below.

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.

The HRA Board and Executive Management Team (EMT) formally review progress against delivery quarterly, though naturally performance management is an integral and ongoing business process at all levels of the organisation.

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

## Performance Dashboard 2016/17

The Performance Indicators for 2015/16 were reviewed by the board and the following approach was agreed for 2016/17 which re-categorised previous measures into three specific areas

KPI's – Collected monthly and reported to the board quarterly. These are considered to be the measures which will be of greatest interest to the board as they reflect the impact that the HRA has on the wider health research economy/environment. They would also be able to meet the following principles

- **Performance of HRA can be clearly identified** - even when part of wider system with other stakeholders
- **Has an agreed target and/or benchmark** – it is important that the level of performance can be compared either with a statutory target or a HRA established one
- **Measure outputs rather than inputs** – to move away from routine reporting to the board what could be considered management information e.g. HR, Training, Finance data to focus on KPI's that will clearly measure the operational impact of the HRA
- **Data is readily available and can be collected monthly** – unless the data can be regularly and efficiently collected, analysed and presented on a regular cycle then its value is diminished
- **Performance can be compared over time** – The ability to identify trends is vital to ensure that we make timely interventions to address any issues of failing performance as well as celebrate improving or continuing good performance.

KPI's to Board (collected monthly reported to board quarterly)
Description
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
Increase in number of applications that have clearly involved patients, service users and the public in their development from 15/16 baseline
Reducing the number of Provisional Opinions at first review (baseline to be set)
Reducing the number of queries raised as a result of REC review (to be further developed)
Reducing the number of amendments being processed before a study recruits their first patient (to be further developed)
HRA Approval KPI's (please see additional notes)
Non-REC studies: Approved studies (non-REC) are approved in median 15 days from date of application to HRA to date of Approval (amber=15-25, red=25+)
REC-PR studies: Approved studies (REC-PR) are approved in median 10 days from date of additional REC conditions being met to date of Approval (amber=10-20, red=20+)
Full-REC Non-Commercial studies (NC Full REC): Approval studies are approved in median 25 days from date of final REC decision to date of Approval (amber=25-35, red=35+)
Full-REC Commercial studies (C Full REC): Approval studies are approved in median 10 days from date of final REC decision to date of Approval (amber=10-20, red=20+)

The Board will regularly consider the effectiveness of key performance indicators and may from time to time adjust to ensure relevance and value

Management Information (MI) – Collected monthly and considered by EMT. Important data that generally reflects internal service measures with ‘triggers’ i.e. points at which a level of performance that is below an acceptable level would be reported to the Board

<b>MI collected monthly and reported to EMT. Trigger points set to escalate to board</b>
<b>Description</b>
All operational complaints are reviewed and pursued for learning
100% of final Research Ethics Committees audit action plans submitted and accepted by QA within agreed timeframes
100% of final audit action plans <b>other than Research Ethics Committees</b> across all functions submitted and accepted by QA within timescales
50% of Research Ethics Committees to receive full accreditation at first audit
Publish 100% of REC opinions and CAG advice
Report on the number of requests of deferral of the full HRA record on the website alongside the opinions
Report on the number of requests for deferral of clinical trial registration
99% availability of systems - IRAS, HARP, WEB, INTRANET, TOPS, ATOS
90% of all queries completed within in 4 working days
75% of all queries completed within 1 working day (stretch target)
website user satisfaction (to be measured by bounce rate - target 50%)
85% of available training places are taken up
To achieve at least 85% satisfaction for each training course. If not achieved investigation completed to ensure improvements can be made
100% of planned training (staff/member/researcher) events are delivered
Responding to complaints within 25 working days or if longer, by keeping the complainant fully informed.
100% of all FOI requests (valid and invalid) acknowledged and additional clarification sought within 10 working days
100% of valid FOI requests to receive final response within 20 working days of receipt (where qualified exemption does not apply)
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
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)
Improve % of payments made within 5 days using 14/15 as a baseline
Financial reports produced within 4 working days and overall financial position reported to the EMT on a monthly basis and Board bi monthly
65% (or more) rail journey's are booked 7 days or more in advance (longer time booked in advance, greater level of savings)
10% (or less) rail bookings are made 2 days or less from date of travel
Avg cost of hotel/night in London is the same or less than £115
Avg cost of hotel/night outside London is the same or less than £75
Short term sickness absence rates do not exceed 1%
Long term sickness absence rates do not exceed 3%
Monthly staff turnover remains within -1% - +1% of NHS Average of 0.9% (Health & Social Care Information Centre, National Workforce Statistics for period Apr/May 2015)

Further Evidence – Considered at agreed periods during the year, in most cases this would be on an annual reporting basis generated by a particular scheduled activity to gather that evidence.

## Further evidence used to inform performance

### Description

Audit clinical trial applications to access registration compliance against HRA policy
The new research policy framework is adopted UK Wide
Stakeholder feedback supports the new framework as meeting HRA objectives to make it easier to do good quality research and maintain public confidence in health research.
HRA News delivered to plan (%) and effectiveness judged through staff survey
Stakeholder newsletters delivered to planned timescales, quality judged through perception and satisfaction audits
All consultations are noted as closed when the deadline is reached
Maintain proportion of lay members on committees
Publish all necessary Finance and HR data in accordance with data transparency
Financial forecasts are produced from September 2015 at the latest and reviewed monthly thereafter
Financial plan 2015/16 published and agreed budgets in place by May 2015.
Strategic 5 year financial plan published and agreed
Demonstrate reduction in spend in the following areas across all functions:- Travel and Accommodation per head count; Office Supplies per head count Office Accommodation per head count.
All services continue to deliver savings year on year on a like for like basis
To report on results of VfM test derived from new procurements in year
Staff Engagement levels - remain at or above 2015 staff survey results
Improvement in targeted areas of staff survey identified in action plan
User Feedback Surveys (gauging quality of service from researcher perspective)
Production and consideration of audit reports published by HRA Internal Audit Team and the DH Health Group Internal Audit Team

## Proposed KPIs for HRA Approval

For 2016/17 the Board have agreed metrics for HRA Approval. As the Approval process has only recently been fully implemented the following points are important to note to understand the context of their development.

- Proposed metrics are based on early information and will therefore be open to review and revision with further experience.
- No overall single measure for application to Approval – metrics must reflect different study types and be proportionate
- Measuring from the point of REC favourable opinion to HRA Approval is relevant to stakeholders and avoids double-counting the Approval and REC metrics.
- We need to measure studies with full and PR REC separately as the shorter timeline for PR review reduces the potential to address all issues prior to REC opinion
- Clinical trials are of particular interest because of the benchmarks – we need to measure commercial and non-commercial separately though as industry generally respond quicker and we want to be able to show data to industry that reflects the part they are playing to improve performance.
- Propose using medians rather than percentage achieving a target. This better reflects the reality of different studies having different complexities and use of medians resonates better with applicants and industry

### The KPIs:

1. Non-REC studies: Approved studies (non-REC) are approved in median 15 days from date of application to HRA to date of Approval (amber=15-25, red=25+)
2. REC-PR studies: Approved studies (REC-PR) are approved in median 10 days from date of additional REC conditions being met to date of Approval (amber=10-20, red=20+)
3. Full-REC Non-Commercial studies (NC Full REC): Approval studies are approved in median 25 days from date of final REC decision to date of Approval (amber=25-35, red=35+)
4. Full-REC Commercial studies (C Full REC): Approval studies are approved in median 10 days from date of final REC decision to date of Approval (amber=10-20, red=20+)

All above figures to be *calendar* days without clock stops.

We will separately undertake some work to start predicting how long it will take to get a study approved, and then collect data on whether it is possible to accurately predict the approval timelines for different studies. The outcome for this may be a paper that sets out the factors identifiable in an application on receipt that make it easy to predict, or that increase the chances of it getting Approved quickly, or the features of projects that make them 'complex' from the perspective of getting through Approval.

## 10.0 Financial Plans

### Revenue

The HRA is required to plan for a balanced income and expenditure position. Further detail can be found in Appendix B.

The table below sets out our planned costs for 2016/17 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 (£12.6M), with the balance (£200k - *current estimate*) coming from undertaking activities by agreement with the Devolved Administrations alongside a non-cash revenue resource limit of £270k). The table below also highlights how that income is deployed.

### Prioritised Business plan 2016/17

		Cost analysis 2016/17		
Functions provided - all core business and captured in the care bill	Note	Statutory function (£'000)	Other commitment (£'000)	Ministerial priority (£'000)
RECs, Ethical review	1	6,416		
Approvals for processing confidential information relating to patients	1	454		
IRAS and systems to support ethical review	2	1911		
Training, guidance and advice	3		843	
Quality Assurance to support ethical review	4		268	
HRA Approval - Co-ordination and standardisation of practice relating to regulation of health and social care research.	5			2,483
Policy - including research governance, engagement and public involvement		905		
<b>Gross costs</b>		<b>9,686</b>	<b>1,111</b>	<b>2,483</b>
				<b>13,280</b>
<b>Notes</b>				
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				
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 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.				

### Main Cash releasing savings and efficiencies plan accounted for in the plan

	2016/17
Description	Plan
	£000s
Vacancy factor	237,214
Estates strategy	111,000
Digital technology e.g. member portal	
Training delivery models	20,250
Efficiency review	64,846
<b>Total savings and efficiencies made</b>	<b>433,310</b>
<b>% of 15/16 GIA</b>	<b>3.23%</b>
Excludes reductions linked to year 3 of HRA A funding	
Further work required on the digital technology project	

### Capital Plans

	2016/17	2017/18
Description of investment	Plan	Initial plans
	£000s	£000s
Research Information System developments	910	810
<b>Total capital investment plan</b>	<b>910</b>	<b>810</b>



## 11.0 Annex

### A. Senior Management Structure

Operations		Finance, Procurement and Estates
Director: Joan Kirkbride		Director: Debbie Corrigan
REC Operations	Confidentiality Advice	
Research Ethics Committees (REC); REC: Improvement & Quality Assurance and Control; REC Standing Operating Procedures; The Over Volunteering Protection System (TOPs) management.	Confidentiality Advisory Group including Confidentiality Advice Team (CAT) support CAG: Improvement & Quality CAG Standing Operating Procedures	Financial governance Incl. Standing Financial Instructions and scheme of financial delegations Financial management information Financial accounts and statutory annual accounts Budget setting and monitoring Payroll, Capital planning, Internal audit, Estates, Counter Fraud, Procurement
Corporate Services		Quality, Guidance and Learning
Director: Ian Cook		Director : Tom Smith
Human Resources Organisational Development Training & Development Internal communications External communications incl. Public Relations Information Technology (The Open Service IT Platform, Video Conferencing, Infrastructure) Public and Patient Involvement, Business Intelligence, Programme Office		Quality assurance ISO 9001 Advice and Guidance Transparency
Research Systems, Standards and HRA Approval		Corporate Secretary
Director: Janet Messer		Corporate Secretary: Stephen Robinson
HRA Approval Programme Research Systems (IRAS, HARP) Collaboration & Development (C&D) programme management Quality, Standards & Information also sits within this Directorate		Business planning Policy Development Board support, Standing Orders / Scheme of Delegation Corporate and Information Governance Risk management, Health & Safety, Business Continuity Planning, Equality & Diversity, Freedom of Information / Complaints Appointing authority RECs, CAG and NREAP

## B. Financial Plan Detail

<b>Health Research Authority Financial plan detail 2016 - 17 Business plan by cost category</b>			
<b>Revenue costs (classed as Admin revenue departmental expenditure limit DEL excl depreciation)</b>			
		<b>2015/16</b>	<b>2016/17</b>
		<b>Plan</b>	<b>Plan</b>
		<b>£000s</b>	<b>£000s</b>
<b>Admin Expenditure</b>			
Pay		9,509	8,719
Temporary Staff/Contract Services		250	250
Consultancy Services		0	0
Other e.g. stationery, travel etc.		3,773	3,788
Audit Fees		73	73
<b>Total Admin Expenditure</b>		<b>13,605</b>	<b>12,830</b>
<b>Admin Income</b>			
<i>Devolved Administration*</i>			
Scotland		(132)	(103)
Wales		(81)	(61)
Northern Ireland		(45)	(36)
<i>Total Income from Devolved Administration</i>		<i>(258)</i>	<i>(200)</i>
Admin Income from outside NHS/DH/ALBs		0	0
<b>Total Admin Income</b>		<b>(258)</b>	<b>(200)</b>
<b>TOTAL ADMIN NET OUTTURN and GIA</b>		<b>13,347</b>	<b>12,630</b>
<b>Other Revenue costs (classed as Admin ring fenced DEL)</b>			
		<b>2015/16</b>	<b>2016/17</b>
<b>Description</b>		<b>Plan</b>	<b>Plan</b>
		<b>£000s</b>	<b>£000s</b>
Depreciation and Amortisation		270	450
Impairments		0	
<b>Total Admin Ring Fence DEL</b>		<b>270</b>	<b>450</b>





REVIEW NEEDED APRIL 2017 TO MARCH 2018							2015/16	2016/17					2017/18				2017/18 or later
Name of successful tender	Description of Service	Apprx Cost per annum (£000s)	Estimated end date	Start Date for procurement activity ( for open ended 3 years from start date)	Remarks	Extension option on contract (start and end of period)	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
The Danwood Group Limited	Provision of Printing services at HRA Nottingham REC centre	?	26/11/2017	30/05/2017	Add to ATOS?	-											
SBS	Provision of external financial services	178	01/04/2018	05/07/2017		Clause 15.2: May request an extension for a period of 12 months, by giving written notice not less than 12 months before the end of the initial term											
Edge Wear Properties Limited	Lease for Manchester office	67	13/06/2018	16/09/2017		-											
Watercoolers Direct	Quarterly service visits for maintenance of bottle cooler at HRA Jarrow	0.1	13/01/2018	15/10/2017		N/A											
Vodafone	Provision of mobile phones and data packages		Until terminated	30/11/2017	No details	-											

## Key to Procurement Pipeline

Action needed urgently

Procurement or review started

Info outstanding

Action to be started

New contract start

No further action - contract to terminate at end date

#### D. Estates Footprint and Premises Related Costs

Office Location	Approximate Size (m2)	Staff Numbers (Headcount) *	Lease Cost (p.a.) (£)	Cost per Head p.a. (£)
HRA HQ & London REC Centres Ground Floor (Old Library), Skipton House, 80 London Road	476	70	212,896	3,041
Nottingham Centre. The Old Chapel, Royal Standard Place.	207	36	28,200	783
Manchester Centre. 3rd Floor, Barlow House, 4 Minshull Street	522	38	58,392	1,537
Jarrow Centre. TEDCO Business Centre, Viking Industrial Park, Rolling Mill Road	168	23	28,760	1,250
Bristol Centre. Whitefriars, Lewins Mead	287	32	41,540	1,298

\* 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	New Document 21/1/16	First draft
V0.2	26/01/16	Addition of Corporate Services Info
V0.3	28/01/16	Draft to DH
V0.4	09/02/16	Draft to HRA Board
V0.5	23/03/16	Updating financial tables
V0.6	05/04/16	Updating Key HRA Developments
V0.7	11/04/16	Updating Operational end of year data
V0.8	18/04/16	IC adding Performance Information
V 1.0 Final	18/04/16	Final Published Version

## 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	V0.1 Draft
I Cook	Dir. Corp Services	V0.2 Draft
J Wisely	Chief Executive	V0.3 Draft