Health Research Authority

Business Plan

2017 – 18

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Contents

1. 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. The HRA has a vital health and social care research system leadership role and iin 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 66 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 on research applications 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 plans to have 221 full time equivalent (fte) staff in 2017/18 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.

2. 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 a 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 requires 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 IRAS Partners, including the Devolved Administrations.

3. 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
Acting Chief Executive	Teresa Allen (from November 2016)
Executive Director	Ian Cook
Executive Director	Debbie Corrigan (to September 2016)
Executive Director	Karen Williams (from Jan 2017)
Director	Joan Kirkbride
Director	Tom Smith
Director	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 Board has an Audit and Risk Management Committee, which meets quarterly to provides assurance that the HRA is meeting its statutory and regulatory requirements by scrutinising audit services and programmes, risk management, the annual governance statement, statutory annual accounts and corporate governance arrangements.

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

4. Our highlights from 2016 - 2017

The launch of the new HRA Approval Service

One of the most significant achievements of 2016 was the roll out of the new HRA Approval Service. This is now the single route for new applications and amendments for studies involving the NHS in England.

HRA Approval has been embedded during 2016-17, with NHS organisations adopting new arrangements focussed on supporting site set-up. We have learned a lot from this implementation. When we went live in April, a significant volume of additional work was submitted which could not be captured in the models used to forecast workload for this change. A significant number of researchers who had previously submitted studies to REC but not to R&D over a period of months and years prior to March 2016 sent in requests for HRA Approval immediately after the roll out. Additionally a high number of amendments had been submitted for REC review but not for R&D review prior to March and therefore had to be processed through HRA Approval arrangements along with new amendments, creating an unexpected surge in volumes. We recognised that this caused significant inconvenience to some researchers and we rapidly implemented a number of measures to bring the volumes under control and we are pleased to report that the service is functioning efficiently again.

We have also developed a UK-wide system of technical assurances for pharmacy and radiation, and are collaborating on revisions to model agreements.

The Research Ethics arm of the Approval Service has continued to deliver excellent performance achieving statutory timelines and Key Performance Indicators, despite a significant turnover of staff, many of whom were able to take advantage of career progression opportunities within the HRA. New processes were put in place to help streamline the categorisation of amendments and a pilot has led to the adoption of a more efficient process. Excellent ratings from user satisfaction surveys recognise the help and support provided by both the REC staff and members.

We have worked collaboratively with the National Institute of Health Research (NIHR) Clinical Research Network, the devolved administrations, industry bodies, charity funders, and professional membership bodies, and other regulators in developing and refining HRA Approval and related activities. We were pleased to gain agreement from NIHR on changes to its funding timeline, which means that applicants can receive initial funding to support the preparation of study documents and processes in advance on submission for HRA Approval.

New guidance was developed to support the implementation of HRA Approval. In the second half of the year we sought to streamline and simplify our content in response to applicant feedback.

Collaboration & Partnering

We worked with the Medical Research Council (MRC) Regulatory Support Centre on our online guidance and tools. This collaboration resulted in the publication of a revised version of the e-learning module for IRAS and further iterative improvements to our online consent guidance. We also worked with colleagues in all UK nations to develop guidance for researchers seeking to make amendments to studies conducted in the NHS/HSC. These revisions clarify the processes that are relevant to this sector and have provided a consistent UK-wide approach.

We have 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.

The panel of National Research Ethics Advisors has been revised to become a larger, virtual panel representing a much wider range of expertise, including experts in social care research.

Patient & Public Engagement & Involvement

Teams across the HRA have worked to increase the level of patient and public engagement activity to inform or support a number of changes as follows:

- Patient and public engagement was conducted to inform the Confidentiality Advisory Group (CAG) in its new advisory role to NHS Digital in relation to commercial scenarios to identify scenarios that might impact on public confidence.
- During the course of the year the HRA published joint HRA and INVOLVE evidence and guidance statements on involving the public in health and social care research and the relevance of public involvement to the role of RECs. The aim of the two documents is to raise awareness of public involvement when researchers are in the early stages of designing a study.
- New patient and public pages were launched on the website that were developed by the HRA working alongside a patient and public group who helped to write the content, design the layout and feature in the videos we made with them.
- A programme of work focused on public involvement in ethical review has also progressed further during the year, increasing the depth of understanding for the approach to the revision of IRAS questions in relation to public involvement.

Transparency

Summaries of all health research projects conducted in the UK that require ethical approval through the UK wide REC service have been published on the HRA website, with 100% requests received for a deferral all of which were agreed,

With the EQUATOR Network, we undertook a call-for-comment on the IRAS question A51 (intentions to report and publish research results) with the resulting recommendations from EQUATOR being presented to the HRA in March ’17.

The HRA led a cross European taskforce of patients, industry and others to develop new EU Guidelines on Lay Summaries of Clinical Trial results. The taskforce was chaired by Sir Nick Partridge and the new guidelines were adopted by the European Commission in January 2017.

Supporting the Research Community & our Volunteer Members through Training & Development

During 2016, with the aim of increasing open access to HRA learning tools, we have uploaded 5 new eLearning modules to the HRA Learning Management System (LMS) which have received in excess of 1,300 visits. We also joined with the Institute of Clinical Research to provide training on HRA Approval, including commercial sponsors and collaborated with the Medical Research Council Regulatory Support Centre and the R&D Network to deliver a one-day workshop for 100 non-commercial sponsors.

Meeting our Financial Objectives

The HRA remained within agreed revenue, capital cash and resource limit for 2016/17 and our financial reporting targets were met throughout the year. New initiatives included the roll out of improved monthly reforecasting from September 2016 and budget manager training which has seen a significant improvement in our forecasting accuracy and strategic allocation of resources. Other initiatives to improve efficiency and reduce costs include:

- Investment in technology and smart working which has yielded 10% reduction in travel and accommodation costs and 45% reduction in mobile phone costs.
- An office refresh programme across our 5 regional offices. This programme supports our aim of achieving the industry benchmark of 8sqm / FTE across our estate portfolio. At the end of the year we are pleased to have achieved this benchmark.

5. Our Priorities for 2017/18

Strategic Planning

We recently completed some work which describes what we believe the HRA will look like from the perspective of our users by 2022 which we plan to publish by the end of the summer within our new strategic plan. One of our aspirations is to ensure that we have made our processes for protecting people participating in research so easy to use that we can refocus our resources on the promotion of high quality research. We want patients and the public to feel safe, ready and able to participate in research. To achieve this we want to be active collaborators, working with others on a daily basis helping to accelerate the sharing of high quality research outcomes for the benefit of patients and society.

Service Improvement

One of the main priorities for the HRA during 2017/18 will be the delivery of our Service Improvement Programme to further enhance the user experience of the HRA approval changes introduced during 2016. This is a significant change programme which will build on the foundations already established which transferred a number of governance activities into the HRA to provide assurance to the research community, patients and the public.

Our ambition is to collaborate with researchers who use our service to deliver the most efficient, proportionate operating model which directs their studies down different routes depending on the nature of the study. We know that the provision of a rapid turnaround time for study approval allows researchers to focus on site set up and the recruitment of participants. Our change programme includes a number pieces of work aimed at the improvement of processes, enhancement of functionality within our IT systems and training and development to support our staff to adapt to new ways of working. We also plan to develop an information management system for use across the HRA which pulls data out of our systems and allows our teams to prioritise their work effectively. Managers will be able to track performance and monitor the effectiveness of interventions in a more timely manner. These changes will require the HRA to develop or secure new skills. We believe we already have a highly skilled, adaptable and knowledgeable workforce who will rise to the challenge and help us deliver more integrated systems and processes. The resource released from these changes will offer us the opportunity to spend

more time with patients, the public and the research community so that we can further enhance our guidance and advisory services. The effective co-production of solutions and communication of any changes to service users and staff will require the development of pro-active communication and engagement plan with a range of stakeholders throughout the duration of the programme.

The full Service Improvement programme is intended to deliver all of the necessary activities which will enable HRA to achieve the following aims and objectives over the next two years:

- to build on the changes implemented to the new approval service rolled out in April 2016 by improving the customer experience and journey through HRA services (guidance , amendments, pre-approval advice, ethics assessment, confidentiality advisory services , expert opinion);
- to streamline and reduce service costs through the removal of non-value added processes and duplication and the creation of a more integrated staffing structure;
- to release expertise and capacity to support a significantly increased remit around adult social care and promotion of research;
- to develop and test / pilot any scoped enhancements / changes to processes and the existing IT systems HARP and IRAS by the end of 2018 / 19;
- to accommodate and factor in new regulatory measures e.g. new E.U. Clinical Trials regulations;
- to develop and pilot new processes which will allow us to safely test out changes with selected user groups prior to implementation at scale;
- To develop an effective and efficient corporate support function that offers the HRA a model of service that secures the best value 'mix' of in-house, third party and shared arrangements with other Arms Lengths Bodies (ALB's) reflecting the capacity and capabilities needed to deliver an excellent service that meets the current and future needs of the organisation;
- to activate accounts on training and live environments for research users during evaluation phases;
- to deliver a more automated management information solution facilitating strategic and operational decision making; and
- to identify opportunities for HRA to work more collaboratively with the wider research "system" to co-produce ITC solutions which are better aligned to user requirements and NHS digital strategy.

The expectation is that this programme will take up to 2 years to deliver

Website Development

Visitors to the HRA website and our own staff have highlighted a number of areas which need improving on our public facing website. We have recently secured expertise and agreement to start the work to improve the content and navigation of the site and items which provide guidance related to the submission of research study applications will be updated and transferred onto the IRAS portal. It is anticipated that these improvements will be completed by the end of the summer following a discovery phase to ensure that user needs have all been considered.

6. Additional Plans

The priority plans detailed in Section 5 either enable us to deliver on our strategic aims directly or, as in the case of the strategic planning work, by helping reshape our strategic direction itself. But they are not our only plans so these additional ones are detailed below, categorised under each strategic aim. By their very nature these plans can facilitate the delivery of a number of strategic aims, but we have nevertheless grouped them under the aims that they significantly support. Additionally, many of these plans will develop into and be integral to the overarching Service Improvement Programme.

Further, and for the sake of clarity, we have categorised them as either organisational; those plans that directly support the delivery of our strategic aims or infrastructural; those that provide essential background support to the organisation thus in turn helping deliver the strategic aims.

6.1 Organisational Plans

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

UK-wide NHS / HSC Compatibility

The UK nations are committed to providing compatible systems for the set-up of research across the NHS/HSC. A programme was initiated in December 2016 to deliver improved consistency for sponsors in processes for site set-up and amendments. During 2017 we have a number of initiatives to align activities throughout the UK.

Preparing for Implementation of the EU Clinical Trials Regulations (EUCTR), the General Data Protection Regulations (GDPR) and the Medical Devices Regulation (MDR).

We will, by working with the MHRA, other key stakeholders and the devolved administrations, design and develop the required processes and information system changes to prepare for the successful implementation of the EUCTR, GDPR and MDR. These should help the coordination and standardisation of practice in the regulation of health and social care research helping us to achieve the ambition of the UK being recognised as a global leader in clinical research.

With the expertise of CAG we will also continue to work in partnership with NHS Digital and other bodies to help applicants to navigate the systems and standards for use of health and social care data for research. We will clarify how these systems, standards and safeguards will align with the requirements of the EU General Data Protection Regulation and any future arrangements post-Brexit.

Transparency

Appreciating that transparency is the responsibility of all, we continue to support and ensure dissemination of proportionate transparency initiatives including where led by partner agencies, including researchers and sponsors.

To help ensure that UK research is part of a global environment promoting research transparency, we will take proportionate and pragmatic measures to improve and measure transparency in the UK and to increase public confidence and involvement. We will achieve our part by continuing to monitor compliance of registration for clinical trials, undertaking a further review of compliance with clinical trial registration, liaising with Sponsors/ CRO organisations where appropriate and;

- Building upon the IRAS question A51 call-for-comment, consider recommendations from EQUATOR and how these might add to proportionate research transparency without adding to researcher burden;
- Follow-up with CROs/Sponsors where clinical trial registration cannot be sourced;
- Consider options for managing transparency breaches; and
- Monitor Research Tissue Banks to ensure registration on the UKCRC database.

Proportionality

We continue to further develop a proportionate approach to our work and in particular to the ethical review and assessment of low risk research. This means that we need to refine our proportionate review process to differentiate further between research methodologies across both ethical review and HRA assessment. It is hoped this will reduce the burden on both researchers and the HRA in a risk proportionate way.

HRA National Operational Roles

To ensure a UK wide operational framework and delivery within the appropriate legislation, policy and operational standards we will;

- Chair the UK operations group, through which HRA standard operating procedures are monitored and maintained;
- Chair and provide secretariat support to the UK Ethics Committee Authority;
- Chair and provide secretariat support for the Four Nations meetings; and
- Consider the impact of and responding to the implementation of the EU Clinical Trials Regulation.

Improving efficiency and effectiveness of systems and of advice and guidance.

HRA Approval

We will continuously improve our HRA Approval Service (Research Ethics Service, Confidentiality Advice Service, Assessment and Technical Assurances) for the benefit of applicants by streamlining our workflow, integrating our internal processes and systems, reducing internal duplication, integrating our communication with applicants, and reducing waste in our processes so that we make it quicker and easier to do good research. Our

new processes will be aligned with the requirements of the EU Clinical Trials Regulation, allowing a seamless transition period.

Further, we will underpin the Approval Service by providing a responsive, supportive and robust UK- wide Research Ethics response by:

- Continuing to actively seek and act upon feedback from the research community, volunteer members and colleagues;
- Rolling out the extended administrative validation and quality review for Phase I clinical trial applications;
- Exploring the expansion of focus groups set up to support researchers with novel research or areas with particularly difficult ethical issues;
- Further developing the shared ethical debate process for Research Ethics Committees; and
- Rolling out the Research Ethics Committee Chairs development programme.

Social Care

During 2017, we aim to develop a policy for providing both ethical review and research governance to social care research in England by setting up a cross-HRA working group to develop proposals for the delivery of ethical review and research governance for social care research in England, working closely with expert stakeholders in the area and building on the scoping work undertaken so far. This will include looking at how we can bring both health and social care research in care homes in scope and facilitate the demand for research in this area.

Real World Data Research

This is research using data collected during normal clinical activity, rather than the additional collection of information from patients. Working with a range of stakeholders including patients and public together with other bodies such as Wellcome, MRC, MHRA and NICE we plan to look at the need for guidance in the area of real world research. Development of guidance in the area of real world data would help bring clarity to researchers whilst at the same time maintaining public confidence in how their personal data is used.

Endorsement of 'consent to be contacted' models / recruitment registries

We have already started working with stakeholders to develop support principles and guidance which will facilitate the establishment of a new panel to provide endorsement of "consent to be contacted" models so that where HRA endorsement exists, research ethics committees will no longer need to scrutinise the recruitment aspects of individual studies using the model.

Guidance on Health Research in Prisons

We aim to replace out of date guidance by developing, in conjunction with academics and key stakeholders in prison research, new HRA guidance on health research in prisons

Guidance and Advice for the Research Community

We will, by working with the research community and other regulators, continue to develop, review and revise our guidance for the research community so that it becomes easier for the research community to readily access clear and relevant guidance.

We aim to provide timely advice to enquirers to the HRA Queries Line by responding to 90% of queries within 4 working days and through making service improvements identified through monitoring and user feedback to ensure that the research community has a clear route for accessing timely support and advice.

Learning

Our goals include development of further online learning opportunities and increased collaboration, in particular:

- Six new eLearning modules will be launched in April/May 2017 aimed at HRA staff, researchers, R&D managers and industry, to include: Human Tissue Act, Adults Lacking Capacity, Radiation, Information Governance, Medical Devices and Schedule of Events;
- A further two modules developed in early summer will support pharmacy and radiation technical assurance processes;
- The rollout of short online seminars (on a series of different topics) and webinars;
- A shared approach to learning through the collaboration of a network including NIHR CRN, MRC, R&D Forum and the HRA; and
- The continued delivery of a needs-led, face to face training programme for Members and researchers, supported by online seminars.

Building and consolidating productive relationships with public and professional stakeholders.

Partnership Working & Collaboration

Working with users, colleagues and stakeholders we will make continuous developments and improvements to our system and processes by:

- Embedding the knowledge acquired from the 2016-17 consistency improvement programme and increasing awareness of the resulting guidance and changes;
- Developing and communicating advice and guidance to support the research community;
- Building on the outcomes and learning gained from internal audits and quality assessments;
- Exploring opportunities to share and develop learning materials and events with stakeholders; and

Collaboration with the Human Tissue Authority (HTA) on public trust and confidence in collection and sharing of tissue and data leading to future guidance

To understand the issues which impact on public confidence in linking their patient data with tissue for research, we will identify points of concern and the reassurances required to maintain public confidence in broad consent and ongoing dynamic consent in

deliberative workshops with the general public and clinical research experts, so that the HRA and HTA can produce joint guidance to inform researchers and tissue banks how best to seek consent for the use of tissue and patient data.

We aim to enable researchers to make better use of tissue and data collected for research by working with relevant parties to ensure that there are effective national systems and standards for bioresources and projects using them.

6.2 Infrastructure Plans

Improving efficiency and effectiveness of systems and of advice and guidance.

IRAS and HARP

Our goal is to further develop IRAS from both the technological and user perspectives to ensure it continues to provide a world-leading integrated research application system, and to develop HARP to provide an efficient and flexible system to support our operational services for applicants. We will also work with MHRA to ensure that relevant information systems developments are undertaken to prepare for the implementation of the EU Clinical Trials Regulation in 2018/19.

We will also undertake developments to make it easier to publish information about studies that we have approved, so that patients and the public can more easily access information about research.

Finally, we will begin to take forward a programme for delivery of a future iteration of IRAS. It is likely that this programme will span several years and will deliver improvements in terms of functionality, performance, stability, ease of maintenance and cost savings.

Building and consolidating productive relationships with public and professional stakeholders.

Public Involvement

We will continue to develop the HRA into an effective 'involving' organisation, further embedding public involvement into the core of the HRA business. We will further develop the role of the HRA with partners to increase the amount and quality of public involvement in health and social care research.

Communications

We will promote and support the HRA's vision, strategy, objectives and priorities, building our reputation on what we do and how we deliver; communicating openly and transparently across both traditional and digital channels, redeveloping our website to keep stakeholders and our people informed.

Having a skilled, dedicated and motivated workforce and HRA volunteer committee members.

Organisational Development and Staff Learning

To ensure that the HRA is structured in a way which supports its mission and goals and its workforce is developed to effectively deliver the business agenda, we will continue to develop staff in core and advanced technical skills, personal skills to support good team working and personal development, leadership and management skills to ensure that our leaders support high performance throughout the organisation.

Human Resources

We will continue to provide an effective, professional and timely HR services based on best practice and current employment law by providing specialist HR advice and interventions to identified projects and 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 service.

Ensuring the HRA is managed and governed effectively and provides value for money to the tax payer.

Financial Strategy and Management

We will ensure our resources are effectively and efficiently allocated to meet our strategic and operational aims and that we remain within agreed revenue and capital resource limits. We plan to publish a three year strategic financial plan, roll out a new business partnering framework, develop improved management information and meet all internal and external reporting requirements.

Best Value, Efficiency and Savings

We will ensure that the HRA achieves best value in procurement, contract management and shared services, achieving spending review savings targets whilst delivering on strategic and operational aims for the year. We will do this by working collaboratively with our shared service providers, DH and the health arms-length bodies (ALBs) as well as colleagues at the HRA to further improve our effectiveness and efficiency.

Programme Management Office

By developing and supporting the prioritisation, scheduling, governance and oversight of change Initiatives, programmes, projects and activities the HRA will develop a clear line of sight from business and organisational strategy to deliverable benefits and their related Initiatives, programmes, projects and activities as well as obtaining more reliable information to ensure better investments thus ensuring maximum value for money, productivity, transparency, and engagement.

Quality Assurance

We will develop our assurance systems supporting a culture of quality and continual improvement within the HRA to ensure our services are of the highest quality. This will include developing a corporate assurance map; conducting audits and feedback surveys; working collaboratively with regulatory bodies; and, continuing to improve established HRA QA systems so that they remain fit for purpose and provide assurance to both internal and external stakeholders.

Transparent Governance and Compliance

We will continue to promote organisational visibility and openness and operate within all statutory and regulatory requirements. We will do this by publishing all information unless legislative restrictions apply; ensuring compliance with the signed Public and Parliamentary Accountability protocol; operating within the required standards of information governance; and ensuring compliance with relevant legislation and guidance, including the Equality Act and Health & Safety.

Estates

We will deliver the HRA estates strategy that aims to provide effective office space and support smart working for our people whilst driving down estates costs. We will do this by achieving at least the industry benchmark of 8 sqm / FTE and where possible seek to achieve 8 desks to 10 FTE staff ratio.

7. Performance Monitoring

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.

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 2017/18

Following the introduction of the new approval service in 2016, the HRA board has agreed to the development of a new performance dashboard during 2017 which better reflects the end to end user experience of our service and is more closely aligned to our emerging strategic aims. The HRA leadership team will review and publish performance metrics for each of the service elements which contribute to the overall approval service, but these will only be reviewed by the board where there is an indication of an issue requiring board assurance. The table below highlights examples of the metrics that we aim to introduce during 2017 some of which were recommended by researchers supporting service improvement workshops. The delivery of these proposed metrics will require new data extracts from our HARP/IRAS systems.

The table below sets out the nature of proposed measures and the intended associated benefits. We also plan to develop further operational indicators that will enable the monitoring of performance at various stages from pre assessment to approval. These measures will be introduced once the 'improved' process is in place.

	Theme	Description	Suggested Measures	Benefits
1	User experience Service Delivery	Our ability to predict how long a particular type of application will take to process based on the quality of application and complexity of study (categories and timelines to be determined)	Percentage of studies approved within predicted timeline *New KPI baselines to be developed and tested during 2017/18* (methodology to be designed and tested in Q1 2017, new metrics to be piloted in Q2 2017)	Offers the applicant a more precise timetable to allow them to plan subsequent activity
2	User Experience Guidance & Advice	Our ability to increase the number of applications which are "right first time"	Reduction in the number of applications received by HRA with missing documentation /information from >30% to <10% (average all study types) *New KPI for development during 2017/18* New- 80% of users rate their experience of our online guidance as either 4 or 5 [percentage is calculated as a portion of those that expressed an opinion]	Increased turnaround of approval outcome Reduced cost of re-working applications Increased user satisfaction

	Theme	Description	Suggested Measures	Benefits
3	User Experience Service Delivery	The full elapsed time for a valid application to receive HRA approval from receipt date of original submission	Target based on 16/17 baseline minus 2 days *New KPI for development during 2017/18* HRA to consider how it can capture information using stop clocks during 2017/18	Improved speed of study set-up will improve potential for researchers to recruit to target and complete studies to schedule.
4	User Experience Satisfaction	Capturing customer feedback on a more regular basis for specific aspects of the service to establish their overall level of satisfaction with the Approval process Capturing positive customer feedback	New >75% of applicants scoring the overall service at 4 or 5 on a scale of 1-5 *New KPI for development during 2017/18* >90% of queries completed within 4 working days	High rates of satisfaction will potentially increase attractiveness of UK as place to carry out research and enhance reputation of HRA Sharing positive news enhances staff morale
5	HRA operating model Financial Performance	Reduction in the unit cost of processing each application – (baseline to be determined)	New >5% cost reduction on 16/17 baseline	A reduction in cost would enable a redeployment of our staff or savings to meet other business priorities
6	HRA operating model Forecasting	Enhancing the HRA forecasting tools to deliver a balanced I&E position	New Divisional forecasts to be within 4% range of forecast target	Improved assurance around active divisional financial management
7	HRA operating model Estates	Improving facilities utilisation and cost effectiveness	New Achieve 8sqm/desk industry benchmark Work towards achieving 8:10 ratio of desks /staff member	Efficient, cost effective and well managed estates facilities ensure resources are available to meet our business priorities
8	HRA operating model Transparency	Our ability to demonstrate publication of research findings	New The percentage of studies in which publication is notified to HRA *New KPI for development during 2017/18*	Improve visibility of research

	Theme	Description	Suggested Measures	Benefits
9	Our people Development	Our commitment to developing our people	New 100% of our eligible people have had at least one appraisal within a 12 month period (All staff to have objectives)	Our people have an opportunity to discuss their development needs and have clear objectives and feel more engaged
10	Our people Development	Our ability to respond to user needs	New >50% of our people have an opportunity to interact outside their direct HRA role with research community	Our people will understand user needs and feel more engaged
11	Our people Desktop Services	Our commitment to supporting our people with the IT tools that they need	New 10% improvement on 2017 staff survey response for IT service	Increased staff satisfaction Increased productivity
12	Our people	Level of Staff Engagement	>80% from annual survey	Strong evidence that high engagement level results in more productive organisation
13	Our people	Sickness absence	<2200 lost days per annum equivalent to **3%** (2016/17 = 3.5%). Figures based on establishment of 200FTE = 73,000 days	Lost days have an economic cost as well effect on staff morale. Therefore vital that a healthy working environment is created – both in terms of workload and workplace
14	Leadership HRA Strategic Stakeholder Engagement	Increased participation (by invitation) on strategic decision making groups across the research system	New - HRA executives spending at least 20% of their time engaging with key external stakeholder groups, managing relationships New – More people aware of HRA and what we do (Use Stakeholder perception survey to set baseline)	HRA becomes more visible with positive reputation and, is recognised as a key opinion leader

8. Financial Plans

Revenue

The HRA's total funding for 2017/18 is **£13,085k** (2016/17: £13,280k). We receive most of our funding directly from the Department of Health. This funding, known as grant-in-aid (GIA), has been confirmed at **£12,310k** for 2017/18. The balance comes from two other sources:

- **£205k** from the Devolved Administrations as part of cost sharing arrangements for ethical review and UK wide research governance developments; and,
- **£570k** non-cash revenue from the Department of Health to fund the HRA's depreciation costs.

To meet the requirements of the Comprehensive Spending Review, the HRA is well prepared to deliver on our increased remit with fewer resources. We have planned for a balanced income and expenditure position for 2017/18. This has been achieved by implementing an efficiency programme including tight control over recruitment and vacancy management, a revised estates strategy, smart working for our people and robust procurement to drive value in our purchasing. This strategy has provided savings to enable the HRA to invest in the continual improvement and delivery of our services and research systems.

The table over the page sets out our prioritised business plan and sources of funds for 2017/18. It also shows how these compare with our 2016/17 financial plan.

Prioritised business plan 2017/18

Services	2017/18 Pay £000	2017/18 Non-Pay £000	2017/18 Total £000	2016/17 Pay £000	2016/17 Non-Pay £000	2016/17 Total £000
HRA Approval						
- Assessment & Approval	2,367	371	**2,738**	2,164	332	**2,496**
- Ethical Review	2,925	1,104	**4,029**	3,040	1,157	**4,197**
- Confidentiality Advice Group	221	97	**318**	184	99	**283**
Service Improvement Programme	50	50	**100**	0	50	**50**
Research Systems (IRAS & HARP)	385	513	**898**	478	571	**1,049**
Guidance and Learning	401	180	**581**	356	242	**598**
Public Involvement & Engagement	74	24	**98**	79	28	**107**
Quality Assurance	103	17	**120**	151	27	**178**
	6,526	**2,356**	**8,882**	**6,452**	**2,506**	**8,958**
Chief Executive, Policy & Projects						
Chief Executive & Policy	659	127	**786**	597	137	**734**
Communications	127	70	**197**	154	49	**203**
Strategic and Operational Projects	75	37	**112**	150	149	**299**
	861	234	**1,095**	901	335	**1,236**
Corporate Services, Finance & Administration						
Governance, Legal & Administration	255	190	**445**	240	225	**465**
Corporate Services	504	391	**895**	487	456	**943**
HR & Training	201	175	**376**	270	153	**423**
Finance	530	292	**822**	490	315	**805**
	1,490	**1,048**	**2,538**	**1,487**	**1,149**	**2,636**
Total costs before depreciation	**8,877**	**3,638**	**12,515**	**8,840**	**3,990**	**12,830**
Depreciation	0	570	**570**	0	450	**450**
Total costs including depreciation	**8,877**	**4,208**	**13,085**	**8,840**	**4,440**	**13,280**
Funded by						
Grant in aid (confirmed)			**12,310**			**12,630**
Non cash revenue (depreciation funding)			**570**			**450**
Other income - devolved administrations			**205**			**200**
Total			**13,085**			**13,280**

Efficiencies and savings built into 2017/18 financial plan

The HRA is committed to maximising our impact by delivering on our statutory objectives, achieving the desired outcomes for the users of our services, patients and the public while minimising costs. Our drive is to deliver year-on-year improvements in effectiveness, efficiency and economy.

We want to continuously adapt, improve and advance what we do. Through investment in our service improvement programme we aim to streamline, speed up and simplify the way we work and deliver efficiencies. For 2017/18 we have planned to achieve 4% efficiencies and costs savings, whilst investing £100k in our service improvement programme and £75k in enhancing our online presence.

Efficiencies and Savings

	2017/18 £000
Vacancy factor	250
Procurement and contract management	100
E-review and technology	50
Operational efficiencies	50
Other cost savings	25
Total	**475**
% 2017/18 GIA	**4%**

Capital Plans

	2017/18	2018/19
Description of investment	**Plan**	**Initial Plans**
	£000s	**£000s**
Research Systems developments*	690	650
Investment in ICT infrastructure	25	25
Estates	85	75
Total capital investment plan	**800**	**750**

**based on current contractual arrangements*

9. Annex

A. Senior Management Structure

Operations	Finance, Procurement and Estates
Director: Joan Kirkbride	**Director: Karen Williams**
Research Ethics Committees (REC); REC: Improvement & Quality Assurance and Control; The Over Volunteering Protection System (TOPs) management.	Financial strategy and governance Financial management and reporting Statutory annual accounts and audit Best value, efficiency and cost reduction Capital planning and payroll Procurement Estates strategy
Corporate Services	**Guidance and Learning**
Director: Ian Cook	**Director : Tom Smith**
Human Resources Organisational Development Business planning Internal communications & External communications incl. Public Relations Information Technology (The Open Service IT Platform, Video Conferencing, Infrastructure) and Research Systems (IRAS, HARP) Public and Patient Involvement, Business Intelligence, Programme Office	Guidance and Advice External Learning & Staff Training Standard Operating Procedures Transparency
	Policy Development
	Joint Heads: Amanda Hunn / Bill Davidson
	Statutory policy-making function(s) Collaborative working – policies that affect us
Research Systems, Standards and HRA Approval (*Guidance and Learning also sits within this Directorate*)	**Corporate Secretary**
Director: Janet Messer	**Corporate Secretary: Stephen Robinson**
Research Systems Senior Responsible Owner HRA Approval Programme HRA Assessment and Assurance Collaboration & Development (C&D)	Confidentiality Advisory Group including Confidentiality Advice Team (CAT) support CAG: Improvement & Quality
	Appointing authority RECs, CAG and NREAP Quality Assurance Board support, Standing Orders / Scheme of Delegation Corporate and Information Governance Risk management, Health & Safety, Business Continuity Planning Equality & Diversity, Freedom of Information, Complaints

B. Financial Plan Detail

Health Research Authority Financial plan			
Revenue costs ***(classed as Admin revenue departmental expenditure limit DEL excl depreciation)***			
		2016/17	**2017/18**
		Plan	**Plan**
		£000s	**£000s**
Admin Expenditure			
Pay		8,368	8,655
Temporary Staff/Contract Services		250	*225*
Consultancy Services		0	0
Other e.g. stationery, travel etc.		4,139	3,565
Audit Fees		73	70
Total Admin Expenditure		**12,830**	**12,515**
Admin Income			
Devolved Administration			
Scotland		(103)	*(100)*
Wales		(61)	*(66)*
Northern Ireland		(36)	*(39)*
Total Income from Devolved Administration		(200)	*(205)*
Admin Income from outside NHS/DH/ALBs		0	0
Total Admin Income		**(200)**	**(205)**
Total Admin Net Outturn and GIA		**12,630**	**12,310**
Other Revenue costs **(classed as Admin ring fenced DEL)**		**2016/17**	**2017/18**
Description		**Plan**	**Plan**
		£000s	**£000s**
Depreciation and Amortisation		450	570
Impairments		0	0
Total Admin Ring Fence DEL		450	**570**

C. Estates Footprint and Premises Related Costs

Office Location	Approximate Size (m2)	Staff Numbers (FTE)	Lease Cost (p.a.) (£)	Cost per Head p.a. (£)
Overall	1,660	218	384,371	1,763
HRA HQ & London REC Centres Ground Floor (Old Library), Skipton House, 80 London Road	476	47	212,896	4,530
Nottingham Centre. The Old Chapel, Royal Standard Place.	207	30	27,183	906
Manchester Centre. 3rd Floor, Barlow House, 4 Minshull Street	522	43	67,404	1,568
Jarrow Centre. TEDCO Business Centre, Viking Industrial Park, Rolling Mill Road	168	24	35,438	1,477
Bristol Centre. Whitefriars, Lewins Mead	287	34	41,540	1,222

***** *Overall staff numbers include 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	21/12/2016	New Document / First draft
V 0.2	22/02/2017	Director Input / First draft to Board
V 0.3	27/02/2017	Changes to highlights section
V 0.4	13/03/2017	Changes to all sections following EMT & other comments
V 0.5	21.03.2017	KW Changes
V 0.6	21.03.2017	Leadership changes and Finances
V 0.7	28.03.2017	Changes to Section 6 SR
V 0.8	03.04.2017	KW Changes to finance sections
V 0.9	05.04.2017	TA changes to performance KPIs
V 1.0	10.04.2017	FINAL
V 1.1	20.06.2017	Minor amend to Staff Sickness KPI

Reviewers

Name	Position	Version Reviewed
EMT		V 0.1 – V 0.9
BOARD		V 1.0 FINAL

Distribution of Approved Version

Name of person or group	Position	Version Released