Health Research Authority
Business Plan
2018 – 19

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CONTENTS

1. Background

The HRA's core purpose is to protect and promote the interests of patients and the public in health and social care research. In order to achieve this we:

- make sure research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services
- provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

We are one of a number of organisations that work together in the UK to regulate different aspects of health and social care research.

Most of our functions apply to research undertaken in England, but we also work closely with the other countries in the UK to provide a UK-wide system.

2. Introduction

The HRA was established in 2011 so five years on, during 2016 / 17, it was timely to revisit its strategic direction. The focus of this work was consideration of the HRA's role in a changing health and research landscape, looking at how the organisation can continue to provide an efficient and effective service in line with its established remit. Three key trends were central to this work:

The UK's relationship with the EU

The relationship with the European Union (EU) will be a significant influence for many years to come and there will be opportunities arising from changes that take place as a result of the Brexit referendum. The HRA needs to pursue opportunities to influence discussions around health and social care research and will work closely with other

ALBs and the wide variety of stakeholders within the research community, all of whom will have to adapt to the post-Brexit environment.

The HRA will need to be ready to influence legislation to help ensure the regulatory environment effectively supports high quality research. Dedicating resources to this could make the UK a more attractive place to conduct research. Future debates may include questions around what is defined as research, how different types of research activity are managed and regulated, and how research can be supported in a wider range of public and private settings. These types of questions may require a rethink of the legislative and regulatory environment.

Evolving uses of data

Data is changing the face of health and social care provision and is also a rich source for research where technology can be used to analyse large data sets in ways that weren't previously possible. The HRA will ensure it plays its role and, in carrying out its duties, contributes to public confidence in this growing area of research interest.

Changing technology

New and innovative technological platforms for collaboration and research are developing, but need to be balanced with security, control and public safety. The ethical implications of technological developments are an area that the HRA is focused on to ensure that the public are safeguarded and risks are mitigated. The HRA will adopt an innovative approach to regulation relating to new technology to continue to enable high quality research in this area.

Taking these three trends into account, the work crystalised into the following strategic aims for the HRA:

1.	Championing health and social care research
2.	Making it easier to conduct high quality research in the UK
3.	Developing a pro-active, strategically focused organisation
4.	Capitalising on technological developments
5.	Ensuring the HRA is governed effectively and provides value for the tax payer

These strategic aims, and the objectives that underpin them, form the detail of the business plan discussed in this document. Some of the activities described in this year's business plan will take up to two years to come to fruition and others will be delivered within the year, so we have set this out where we believe this will be the case.

3. Championing Health and Social Care Research

Health and social care research ultimately has a single aim: to bring benefits to the lives of patients and the broader public. The research sector is also a major contributor to the UK economy, underpinned by the unique situation of a National Health Service (NHS) working collaboratively with many sectors, including industry and a large number of charities. It is important that the UK retains its position as one of the best places in the world to do high quality research by attracting and retaining experts and innovators.

The HRA has a key role to play:

3.1. Being a champion for and implementing changes which drive transparency in research

We are proud of our track record in encouraging publication of research studies once they are completed and will continue to do so, but to have a real impact we want to make the dissemination of research findings the norm.

We will work with others to ensure that research findings are readily available and accessible, both to enhance research evidence and knowledge, and to avoid waste caused by duplication of work which has already been done.

We will continue our work in this area over the next two years:

- with partners in the Transparency Forum to promote research transparency and understand opportunities, obstacles and levers
- driving best practice around publication and dissemination (using the Integrated Research Application System)
- with the Devolved Administrations and others to explore a new requirement of study sponsors/chief investigators to publish or disseminate findings from all studies from a future date.

3.2. Effectively engaging and involving the public and research participants through evidence-based and collaborative strategies

Our Public Involvement in Ethical Review (PIER) programme uses the HRA's influence to promote and support patient and public involvement in research with the aim of increasing the amount and quality of public involvement by researchers before their application comes to the HRA. This helps researchers get a better understanding of real life experience to inform their study design, encourages discussions about risks and ethical issues, and helps improve study quality.

To help us achieve this over the next two years, we will:

- work with the wider research community to promote and support public involvement in research
- improve public involvement content, learning, guidance and resources to support research applicants
- publish public involvement case studies , evidence and evaluate the benefits of public involvement .

4. Making it easier to conduct high quality research in the UK

The main aim in establishing the HRA in 2011 was to improve the research regulation environment, creating a streamlined approval process to help researchers develop high quality, well prepared studies at lower cost. We have made great strides, notably with HRA Approval. By taking the principles behind those improvements and applying them to other aspects of our work we can make sure approval is proportionate, equitable and fair.

4.1. Streamlining processes for researchers

More than 6,000 research studies a year come through the HRA, including requests to the confidentiality advisory group. The HRA appoints and supports 67 research ethics committees. Over the last year we've made significant improvements with the HRA Approval service achieving stable timelines. The research ethics aspect of the approval service has continued to deliver excellent performance, achieving statutory timelines and key performance indicators. HRA Approval is now frequently being issued in a single communication with the final REC opinion.

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 Confidentiality Advisory Group and through Public and Patient Involvement. All give their time freely to support health and social care research and the HRA's work.

We are working on projects to further streamline approvals that will span the next two years. We will:

- work with stakeholders to deliver a single, integrated, proportionate HRA Approval and amendments process (fully integrating technical assurance), streamlining our processes for REC review and assessment to deliver a seamless service for applicants with a more proportionate approach to research approval
- work with the Devolved Administrations to deliver compatible and consistent approval processes across the UK for cross-nation studies involving the NHS/HSC
- implement revisions and mechanisms for ongoing updates to model clinical trials agreements for commercial studies and the model non-commercial agreement in 2018
- support the delivery by the National Institute for Health Research of proposals to simplify and streamline contract negotiation for multi-centre commercial studies
- continue to work with partners to address areas that cause delay to research such as research passports, amendments and excess treatment costs.

4.2. Supporting researchers through their applications, consolidating and improving advice and guidance to support simplified research and confidentiality applications, robust regulatory decision-making, and public confidence

During the last year we have invested in the development of a new website focussed around the needs of researchers as well as consolidating the UK-wide guidance that sits alongside the application process in the Integrated Research Application Service (IRAS). We will continue to build on this in the coming year.

In addition our external learning programme delivered over 50 learning events in the last year, which includes training for our volunteers as well as developing a portfolio of e-learning modules in key areas.

Supporting researchers through their applications is a central part of our work and we know that complexity for applicants wastes time and increases costs. We will extend our work in this area by:

- supporting applicants to prepare high quality complete applications with all the necessary information so that they are approved with fewer corrections required of the applicant, increasing the number of first time valid applications
- delivering a varied programme of learning opportunities across the year, including new e-learning modules and reviewing and updating our guidance where needed
- ensuring our volunteers, who play such an important role in health research regulation, are supported and provided with learning opportunities. We will continue to identify and deliver in areas which would benefit from improved support.

4.3. Developing innovative and clear policy to support UK-based research

Our UK-wide policy framework and governance arrangements for Research Ethics Committees provide a high-level framework for legal and ethical research in the UK. In 2018, we will publish revised Governance Arrangements for Research Ethics Committees (GAfREC) and develop policy that promotes high quality research, by:

- working with partners across the social care sector to develop guidance and support for researchers and ethics committees in this area of research
- working with expert researchers, artificial intelligence (AI) experts and other UK regulators to develop an understanding of the likely changes to research delivery arising from AI and analytics science, the benefits of this technology, and any regulatory implications
- continuing to issue new guidance to support the General Data Protection Regulations (GDPR) and support its implementation
- working with other stakeholders to address the issue of data confidence, and ensure our work supports the use of 'big data' in research. The HRA has a key role to play as the guardian of approvals for use of personal information where it is not always practical to obtain consent in research and non-research applications. Our remit to protect and promote the interests of patients and the public in health and social care research is a key part of this agenda. We will work closely with other stakeholders to ensure we contribute to public confidence in this growing area of research interest.

5. Develop a pro-active, strategically focussed organisation

The HRA is part of a wider system of organisations in the research landscape, and by working in collaboration with others we can do more collectively than we can each achieve on our own. The HRA has a breadth of relationships across the research system, with organisations including other regulators, ALBs, industry, charities, academia, NHS organisations, etc. Collaboration has been at the heart of our way of working, leading where we should and contributing and supporting others where we can add value. To increase our impact and effectiveness we want to further raise visibility of who we are.

The HRA has a key role to play as part of the overall UK health research landscape by:

5.1. Enhancing our strategic intelligence and engagement so that we can identify and respond to opportunities and work well with others to keep the UK's research system effective and attractive

By improving how strategic intelligence is shared across the organisation, and bringing a more strategic approach to how we respond to these insights, we can significantly enhance our impact. Creating the Director of Policy role is an important first step we have made towards this. Further work will include:

- further developing an engagement strategy, including evaluation metrics, to enhance the impact of our work externally and build key strategic alliances
- working with experts in the social care sector to develop a five year plan for social care research, which is proportionate to the risks and aligned to the anticipated increase in the number of studies arising from this critical part of the health and care sector
- increasing the HRA's knowledge about the changes in patient care pathways that are likely to drive changes to how and where research is conducted
- ensuring senior management are ambassadors for our engagement strategy and staff are encouraged to see engagement with external stakeholders as part of their work within the wider research community.

5.2. Increasing our visibility and external audience's understanding of who we are and how we work with others

We will continue to develop an understanding of who we are amongst external audiences based on our work. We will continue to present and attend relevant conferences, use digital channels, hold face to face meetings and build networks to profile and explain our work. In developing our website over the last year we engaged with the research community to better understand their needs, which enabled us to better present how we are able to support them and increase awareness of our role and work with others.

In the coming year we will:

- use new and existing networks to increase the profile and reach of our work, including work with patients and partners on key topics of interest
- ensure we continue to work with key partners and stakeholders to keep our role and ambition aligned to enable us to work effectively

- make sure the HRA is considered to be a key player when research system decisions are taken
- provide programme leadership for developments involving the four Nations and other key stakeholders.

6. Capitalising upon technological and data developments

The HRA delivers, maintains and develops two key systems that support researchers with their applications on behalf of the wider research system (the HRA Assessment and Review Portal (HARP) and the Integrated Research Application System (IRAS)). Digital advances continue to change how the health and social care research sector works and offer new opportunities, many of which relate to the innovative use of data and the benefits technology can bring to systems and process. It is essential that the HRA continues to be responsive, adaptive and relevant in this changing landscape to enable high quality research, simply and efficiently.

This year we will:

6.1. Continue work started in 2017/18 to engage with the National Institute of Health Research (NIHR) digital strategy and work with the MHRA on their systems strategy for Clinical Trials

We will work with the NIHR and MHRA to ensure we align across the research system with our technological developments and where possible take the opportunity to help improve the researcher experience.

6.2. Develop research systems.

The existing HRA research IT systems, IRAS and HARP, are essential components of the UK research governance ecosystem. These systems are used to perform regulatory assessment of all health and adult social care research in the UK and enable the HRA to fulfil its statutory role as the approval body for this research.

During 2017, the HRA commissioned an independent review of these systems to assess their ability to meet future requirements to support the wider UK research governance systems, which recommended changes to both systems. We will:

- deliver a new version of IRAS in 2019 that provides both coordinated applications and a unifying approvals process on behalf of IRAS partners. The new IRAS will be based around the needs of a range of users as well as fulfilling our regulatory remit. It will be aligned with the digital strategies of key stakeholders in the research community
- develop new guidance aligned to the changes we are making to IRAS.

7. Ensuring the HRA is governed effectively and provides value for the tax payer

7.1. We will develop our organisation so that we can deliver our strategic ambitions and put in place tools that help us better understand the impact we are having

In addition to further streamlining our application and approval processes, we will ensure that we are running our service as effectively and efficiently as we can. We will also seek to streamline our corporate and support processes. Throughout this service improvement programme we will maintain staff and volunteer engagement.

We will:

- ensure our corporate services are delivered with economy, efficiency and effectiveness
- refine our strategic planning and performance management to reflect our new strategic aims
- develop an operating model to meet the strategic needs of the organisation over the next five years that includes, people, technology and estates
- revise the REC accreditation scheme and Quality Control (QC) processes.

7.2. We will continue to develop a benefits realisation approach to demonstrating value to better understand the difference the HRA makes to the research community and ensure value in all that we do.

We will:
- monitor and report benefits together with strategic KPIs on a performance scorecard
- embed benefits processes throughout our work consistently ensuring there are benefits profiles for all projects and benefits realisation is factored into plans
- train staff on benefits analysis and its importance

8. Performance Scorecard 2018/19

Following the introduction of the new approval service in 2016 and new strategic aims in 2017 the HRA board is developing a performance scorecard which better reflects the end to end user experience of our service and is more closely aligned to our strategic aims. We are also developing our performance management and reporting systems to enhance these and ensure we drive our performance to meet our strategic aims and statutory requirements.

The table over the page sets out our performance scorecard and the associated benefits. We also report and monitor operational indicators as part of our day to day performance management.

Performance Scorecard 2018/19

	Strategic aims	Description	Measure	Benefits
	Championing health and social care research **Being a champion for and implementing changes which drive transparency in research**	Greater awareness of research registration and in turn, increased rates of registration for clinical trials.	Increase in awareness of the requirement to register clinical trails *KPI baseline and methodology to be developed in 2018/19.* Increase in registration rate for clinical trials *KPI baseline and methodology to be developed in 2018/19.*	Improved rate of research registration is important to enable other researchers to see that research is underway, avoid duplicating effort and know to expect findings to be reported.
2	**Championing health and social care research** **Effectively engaging and involving the public and research participants through evidence based and collaborative strategies**	Greater public involvement in research through increased applications for ethical review and increased participant numbers.	Increase in the number of applications reporting public involvement in applications for ethical review *KPI baseline and methodology to be developed in 2018/19.* Increase in the number of Applications which have clearly involved patients, service users and the public in their development. *KPI baseline and methodology to be developed in 2018/19.*	Increased numbers will benefit the needs of patients and helps ensure research is more likely to be understood by and accessible to patients and members of the public taking part.
3	**Making it easier to conduct high quality research in the UK** **Streamlining processes for researchers**	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 *KPI baselines determined in 2017/18. Methodology to be designed and tested in 2018.*	Offers the applicant a more precise timetable to allow them to plan subsequent activity

	Strategic aims	Description	Measure	Benefits
4	**Making it easier to conduct high quality research in the UK** **Streamlining processes for researchers**	The full elapsed time for a valid application to receive HRA approval from receipt date of original submission	Timelines within target range set. *KPI baselines determined in 2017/18. Target range and reporting in development.*	Improved speed of study set-up will improve potential for researchers to recruit to target and complete studies to schedule.
5	**Making it easier to conduct high quality research in the UK** **Supporting researchers through their applications, consolidating and improving advice and guidance to support simplified research and confidentiality applications, robust regulatory decision-making and public confidence**	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 >xx% to <xx% (average all study types) *KPI baselines determined in 2017/18. Target range and reporting in development.*	Increased turnaround of approval outcome Reduced cost of re-working applications
6	**Making it easier to conduct high quality research in the UK**	Capturing customer feedback on a more regular basis for specific aspects of the service to establish their overall level of satisfaction with the Approvals service. Capturing positive customer feedback	New >75% of applicants scoring the overall service at 7 or greater on a scale of 1-10 *KPI baselines determined in 2017/18. Reporting in place.*	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
7	**Develop a pro-active, strategically focussed organisation**	Ensuring senior management are ambassadors for our engagement strategy and staff are encouraged to see engagement with external stakeholders as part of their work	HRA executives spending at least 20% of their time engaging with key external stakeholder groups, managing relationships *KPI baselines determined in 2017/18 qtr4. Reporting*	HRA becomes more visible with positive reputation and, is recognised as a key opinion leader

	Strategic aims	Description	Measure	Benefits
		within the wider research community	*in place for 2018/19.* >50% of our people have an opportunity to interact outside their direct HRA role with research community *Measurement and reporting in place.*	Our people will understand user needs and feel more engaged
7	**Ensuring the HRA is governed effectively and provides value for the tax payer** **We will develop our organisations so that we can deliver our strategic ambitions and put in place tools that help us better understand the impact we are having**	Reduction in the unit cost of processing each application	>5% cost reduction on 16/17 baseline *KPI baseline and methodology to be developed in 2018/19.*	A reduction in cost would enable a redeployment of our staff or savings to meet other business priorities
		Enhancing the HRA forecasting tools to deliver a balanced I&E position	Divisional forecasts to be within 4% range of forecast target.	Improved assurance around active divisional financial management
		Improving facilities utilisation and cost effectiveness	Achieve 8sqm/desk industry benchmark and work towards achieving 8:10 ratio of desks /staff member *Measurement and reporting in place.*	Efficient, cost effective and well managed estates facilities ensure resources are available to meet our business priorities
		Our corporate services compare favourably with industry benchmarks	*Costs are equal to industry benchmarks.* *Measurement and reporting in development 2018/19.*	Efficient, effective and cost-effective corporate services enable resources to be directed to meet business priorities.
8	**Ensuring the HRA is governed effectively and provides value for the tax payer** **We will develop our organisations so that we can deliver our strategic**	Our commitment to developing our people	100% of our eligible people have had at least one appraisal within a 12 month period and	Our people have an opportunity to discuss their development needs and have clear objectives and feel more engaged.
		Our commitment to supporting our people with the IT tools that they need	10% improvement on 2018 staff survey response for IT service	Increased productivity Strong evidence that

Strategic aims	Description	Measure	Benefits
ambitions and put in place tools that help us better understand the impact we are having	Level of Staff Engagement	>80% from annual survey *Measurement and reporting in place.*	high engagement level results in more productive organisation

9. Financial Plan:

The HRA's total funding for **2018/19** is **£13,382k** (2017/18: £13,501k). We receive most of our funding directly from the Department of Health and Social Care. This funding, known as grant-in-aid (GIA), has been confirmed at **£12,110k** for 2018/19. The balance comes from three other sources:

♦ **£200k** from the Devolved Administrations as part of cost sharing arrangements for ethical review and UK wide research governance developments;

♦ **£72k** from NHS BSA as part of cost sharing arrangements for estates; and,

♦ **£1,000k** 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 preparing to deliver on our increased remit with fewer resources. We have planned for a balanced income and expenditure position for 2018/19 which includes £150k savings plan derived from economies and efficiencies throughout the HRA including sharing costs with other public sector organisations, increased automation, simplification and a proportionate approach to our internal processes. Planned investment in our research systems is also anticipated to create value for the sector to further support public sector economic drivers. The table over the page sets out our prioritised business plan and sources of funds for 2018/19. It also shows how these compare with our 2017/ 18 financial plan.

Prioritised Financial Plan 2018/19

	2018/19			2017/18		
	Non-			Non-		
	Pay	Pay	Total	Pay	Pay	Total
Services	**£000**	**£000**	**£000**	**£000**	**£000**	**£000**
HRA Approval						
- Assessment and Approval	2,694	369	**3,063**	2,448	371	**2,819**
- Ethical Review	2,937	1,050	**3,987**	3,166	1,104	**4,270**
- Confidentiality Advice Group	248	75	**323**	225	97	**322**
Service Improvement Programme	40	40	0	50	50	**100**
Research Systems	500	464	**964**	385	513	**898**
Guidance and Learning	330	176	**506**	409	180	**589**
Public Involvement and Engagement in Research	78	21	**99**	75	24	**99**
Quality Assurance	108	16	**124**	106	17	**123**
	6,935	**2,211**	**9,146**	**6,864**	**2,356**	**9,220**

Chief Executive, Policy and Projects

	Pay	Non-Pay	Total	Pay	Non-Pay	Total
Chief Executive and Policy	312	117	**429**	694	127	**821**
Policy (separated from CEX for 18/19)	380	88	**468**			
Communications	155	48	**203**	129	70	**199**
Strategic and operational projects (reserves)	282	26	**308**	75	298	**373**
	1,129	**279**	**1,408**	**898**	**495**	**1,393**

Corporate Services, Finance and Administration

	Pay	Non-Pay	Total	Pay	Non-Pay	Total
Governance, Legal and Administration	203	52	**255**	262	190	**452**
Corporate Services, ICT and Programme Office	515	350	**865**	512	391	**903**
HR and Training	194	198	**392**	210	175	**385**
Finance	455	261	**716**	541	292	**833**
	1,367	**861**	**2,228**	**1,525**	**1,048**	**2,573**

	Pay	Non-Pay	Total	Pay	Non-Pay	Total
Total before depreciation and Staff Vacancy Factor	**9,431**	**3,351**	**12,782**	**9,287**	**3,899**	**13,186**
Staff Vacancy Factor (to be allocated)	-250		**-250**	-250		**-250**
Efficiency Savings Factor		-150	**-150**			**0**
Total after SVF before depreciation	**9,181**	**3,201**	**12,382**	**9,037**	**3,899**	**12,936**

	Pay	Non-Pay	Total	Pay	Non-Pay	Total
Total before depreciation	**9,181**	**3,201**	**12,382**	**9,037**	**3,899**	**12,936**
Depreciation	0	1,000	**1,000**	0	565	**565**
Total after depreciation	**9,181**	**4,201**	**13,382**	**9,037**	**4,464**	**13,501**

Funded by

			Total			Total
Grant in aid (confirmed)			**12,110**			**12,731**
Non cash revenue (depreciation funding)			**1,000**			**565**
Other Income			**272**			**205**
Total			**13,382**			**13,501**

DOCUMENT CONTROL

CHANGE RECORD

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V 0.1	14/12/2017	New document / First Draft
V 0.2	19/12/2017	Amends after SLT Meeting
V 0.3	11.01.2018	Amends after Jan LT Meeting
V0.4	21/02/18	Further amends
V0.5	06/03/18	Proofing amends
V0.6	07/03/18	Preparation for leadership team
V0.7	15/03/2018	Preparation for Board
V0.8	22/03/2018	Removal of government priorities and addition of transparency KPIs agreed by The Board.
V0.9 Final	29/03/2018	Incorporate comments from DHSC

REVIEWERS

Name	Position	Version Reviewed
Senior Leadership Team		V0.4
Leadership team		V0.6
The Board		V0.7
DHSC		V0.9 Final

DISTRIBUTION OF APPROVED VERSION

Name of Group or Person	Position	Version Released
DHSC		V0.9 Final
HRA website		V0.9 Final