# HEALTH RESEARCH AUTHORITY
# BOARD MEETING

## PART 1 – PUBLIC SESSION

## Minutes of the Health Research Authority (HRA) Board meeting, held on 24 September 2018 at etc. Venues, Avonmouth House, London

| Present | | Initials |
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| *HRA Non-Executive and Executive Directors* | | |
| Teresa Allen | Chief Executive | TA |
| Graham Clarke | Non-Executive Director | GC |
| Ian Cook | Director of Transformation and Corporate Services | IC |
| Allison Jeynes-Ellis | Non-Executive Director | AJE |
| Deirdre Kelly | Non-Executive Director | DK |
| Jonathan Montgomery | Chair | JMo |
| Karen Williams | Director of Finance, Procurement and Estates | KW |
| *HRA Directors who attend the Board* | | |
| Janet Messer | Director of Approvals Service | JMe |
| Juliet Tizzard | Director of Policy | JT |
| **In attendance** | | |
| Amanda Hunn | Joint Head of Policy (for items 1-9) | AH |
| Martin Stevens | Chair, Social Care REC (for items 1-9) | MS |
| John Woolham | Senior Research Fellow, Social Care Workforce Research Unit (for items 1-9) | JW |
| Penelope Gregory | PA to the Chair and Corporate Secretariat | PG |
| **Observers** | | |
| Katherine Guerin, HRA | | |

| Item | Item details | Action |
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| **1.** | **Apologies**<br><br>Nalin Thakker, Non-Executive Director | |
| **2.** | **Conflicts of interest**<br><br>None to note. | |
| **3.** | **Minutes of last meeting**<br><br>The Board agreed the minutes of the last meeting were a true and accurate representation of the matters discussed without amendment. | |

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| **4.** | **Matters arising**<br><br><u>Regulation of new technology</u><br>The Board noted an update would be provided in Part 2.<br><br><u>Timelines to first patient recruited performance update</u><br>The Board noted the timelines had been circulated out of session<br><br><u>Interoperability workshop principles with Board</u><br>The Board noted the Interoperability workshop principles had been shared out of session<br>***Action: TA to provide update in CE update with further discussion to take place at the November Board meeting***<br><br><u>Transformation programme</u><br>The Board noted an intended benefits paper would be provided for the November Board meeting.<br>***Action: IC to provide for the November Board meeting***<br><br><u>Research Systems Programme</u><br>The Board noted a discussion regarding the programme would take place in Part 2 – confidential session as this related to a commercially sensitive contract.<br><br><u>SIP Proportionality project timelines</u><br>The Board noted the project timelines had been circulated out of session.<br><br><u>Transparency forum update</u><br>The Board noted an update regarding the Research Transparency Project will be provided at the November Board meeting.<br>***Action: JT to add to the Directorate update for the November Board meeting***<br><br><u>Terms of Reference – Transparency and collaboration & development forums.</u><br>***Action: ST to add terms of reference to January 2019 Board meeting*** | **TA**<br><br>**IC**<br><br>**JT**<br><br>**ST** |
| **5.** | **Update from Chair**<br><br><u>NHS England Chair</u><br>Lord David Prior has been announced as the preferred candidate for the Chair of NHS England and supported after the pre-appointment hearing. It is anticipated that he will take up the post on 01 November. He has previously chaired NHS Trusts, the CQC and been a Conservative Health Minister.<br><br><u>NED Recruitment</u><br>The advert for NED directors has been cleared and is expected to go live this week, including in the Sunday Times, probably next weekend. It is planned that the advert will specify "senior experience in one or more of the following:<br>• digital technology transformation;<br>• senior health/social care research;<br>• pharmaceutical, biotech or other life science industry, with a track record in innovation."<br><br><u>Key Stakeholder Meetings</u> | |

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| | • Social Care Research round table 30/7 & associated follow up<br>• Meeting NIHR NETSCC Matt Westmore 31/7 to discuss the 'adding value in research' work.<br>• Meeting Martin Landray to understand better the HDR-UK work in improving clinical trials<br>• Meeting with the Academy of Medical Sciences: in connection with the forthcoming 'data driven technologies' policy report - including Sir Mike Rawlins from the MHRA.<br>• Streams workshop 11/9 | |
| **6.** | **Update from Chief Executive**<br><br>**Governance Arrangements for Research Ethics (GAfREC)**<br>The latest version of GAfREC was published on 17th September by the Health Research Authority and the UK health departments in Northern Ireland, Scotland and Wales. The majority of changes have been made to take account of legal, policy and operational developments since the previous version published in 2011.<br><br>Following public consultation led by the Human Tissue Authority, research involving human DNA extracted from acellular material, which previously did not require REC review, is now included in GAfREC for the first time.<br><br>**Brexit**<br>Most of the activity since our last board meeting has been around preparations for the possibility of a 'no deal' Brexit:<br><br>• In late August, the Government published a first batch of 'technical notices', advising businesses about what would happen in a 'no deal' scenario<br><br>• At the same time, the Secretary of State wrote to frontline staff about access to medicines, medical products and care in this scenario<br><br>• Some of the technical notices relate to medicines and clinical trials and we alerted our audiences to those as soon as they were published<br><br>Meanwhile, the negotiations with EU continue and the Government expects that a deal will be reached this autumn.<br><br>We continue to work with MHRA to prepare for the new Clinical Trials Regulation, which is due to be implemented during the transition period.<br><br>**HRA Digital Strategy**<br>Earlier this year we agreed that the HRA would participate in the Future Services Programme to replace our desktop Information Technology Services. The recently proposed changes to our Research Systems now require us to develop a longer term strategy for the application of digital services across the HRA at a corporate level to ensure that all systems and staff groups are considered. We have started this work and will be bringing forward proposals | |

to the HRA board over the coming months.

**IRAS development**

In line with our strategic ambition to use software as an enabler for our work, we are now several weeks into the development of the new IRAS platform with the HRA team adopting a new agile software development approach. This has represented a significant change to the way of working for many of our staff who have been co-located with the developers in HRA 1 at Skipton House. This new approach is different to the way that software has been developed previously as it creates solutions out of user stories instead of detailed specifications and development cycles are typically 2-3 weeks. A number of staff have undergone training and are adapting to this way of working which is running in parallel to the approach being used to develop HARP. We have also brought in some new resources and skills to complement the existing team.

The first phase of work prioritises the development associated with changes to the Clinical Trials Regulations and is being aligned directly to MHRA developments and supports our combined ways of working project.

**Transformation Programme**

The IRAS development work has been fully embedded into our wider transformation programme which identified a number of service improvements around process, technology and people.

Many of the early pieces of work in this programme to deliver new processes have been successfully piloted and a number have been implemented. The proposed changes over the next few months will bring the staffing structures into alignment with the process changes for a fully integrated service provision across the assessment and Research Ethics teams. We will be initiating this work via a staff consultation for the majority of staff in the approvals directorate at the beginning of October.

I recognise that this will represent a period of uncertainty for a large number of our staff over the next six months and we are taking advice from the staff themselves and the staff forum on the type of support needed and from the union on a best practise approach.

**Cross Agency Interoperability**

In July I provided an update on the outcome of a cross agency workshop to discuss data standards The workshop brought together stakeholders from the National Institute of Health Research (NIHR), the Health Research Authority (HRA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) as well as a number of subject matter experts and representation from the DHSC in order to discuss how interoperability and derived benefits could best be delivered at pace across UK research systems in use/under development by the 3 agencies.

Key outputs from the meeting were:

● Development of a draft consensus statement governing overarching inter-agency activities on interoperability.

● Requirement for an cross agency Interoperability Steering Group with appropriate Devolved Nation involvement together with DHSC sponsorship/oversight

● Identification of a number of key work packages within a data standards work-stream in order to deliver data standards across a subset of 'in common' data items.

Since then I have been working with Jo Burns the Programme Manager who has been provided by NIHR to establish the Cross Agency Steering group which I have agreed to chair. We have also been identifying the leads for 5 workstreams and establishing the terms of reference for each piece of work. Recognising that work was done historically to deliver solutions for the research system, the data standards workstream will include lessons learned from previous attempts to address this challenge. We also need to be able to clearly articulate the benefits of this work as a defined piece of work.

**Summaries of external engagement activities and outcomes**

| | Purpose | Outcome |
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| Meeting with Jacqueline Johnson North IAOCR President & Karen Ruthven, Global Head of Workforce Competencies | To discuss how HRA can support the principles of High Throughput Research Centres being proposed under the Life Sciences Strategy | Both TA and JM invited to attend the IAOCR meeting. HRA to receive invitations to talk at meetings and share information which will aim to improve application submissions |
| Meeting with Sarah Wilkinson CEO NHS Digital | Introductory meeting to discuss a number of items of shared interest | Agreed the approach to a more formal agreement between the two organisations as recommended |
| Meeting with James Mucklow PA consulting | To discuss PA input into Interoperability work | Agreed actions in support of Interoperability Worksteams |
| ALB CEO meeting with Matt Hancock. Secretary of State for Health | Introductory meeting, plus invitation to share thoughts on the wider H&C agenda | CEOs had the opportunity to meet Matt, hear about his key priorities and share thoughts on areas needing his consideration to address challenges |
| Visit to NIHR Leeds to meet with Jonathan Sheffield CEO & members of the team | To discuss the HRA response to the proposal for High Throughput Research centres and the interoperability workstream | Invitation to do a PODcast as part of NIHR series<br>Agreed a number of useful new contacts and introductions |
| Social Care Round | To progress our | An action plan as outlined on |

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| | Table event ADASS and other experts in Social Care Research | understanding of social care research to develop our strategy | HRA Board agenda Sept 18 | |
| | York Research Ethics Committee Meeting | To meet with committee members and explore how we can improve the support and service that we offer to them | Ideas and feedback are being being collated from all REC visits by Directors and will be shared and discussed with the REC chairs and built into a prioritised action plan at the REC chairs meeting in November | |

**7. HRA Directorate update**

**HRA Approval**

A new organisational structure for the new Approvals Operations and Approvals Support divisions has been developed that will provide an integrated Research Ethics and Assessment service. The structure and roles draw on the evidence developed through the service improvement programme. Following discussion with union and staff representatives, the consultation on the proposal will commence on 2 October. Further work is underway on the planning and sequencing of transition to new processes as workforce changes are taken forward. This includes preparation of new work instructions and developments in our internal workflow management system HARP.

Our timelines for commercial clinical trials have been through a dip due to the time it has taken working with sponsors on compliance with GDPR. Many companies have needed to take time to consult their legal advisors and get global agreement on their approach to GDPR. We are grateful to the Information Commissioner's Office who have advised us during this time so that we can ensure that studies that have HRA Approval are compliant with the new Data Protection Act.

**Technical Assurance**

We will be accepting studies through Pharmacy Assurance from Monday 15 October. This marks the culmination of extensive work with Cancer Research UK and the pharmacy community. Pharmacy Assurance is intended to reduce duplication by ensuring that technical elements relevant to local pharmacy set-up for clinical trials are undertaken once per study, rather than being duplicated at each site.

Following the success of our phase one roll-out of the Radiation Assurance to accept oncology studies taking place in the NHS, we will open phase two on Monday 12 November. Phase two will continue to accept oncology studies, with the addition of cardiology, neurology and rheumatology studies.

**NHS England actions relating to Excess Treatment Costs and commercial contract research**

We have been working in partnership with NHS England, the Department of

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| | Health and Social Care (DHSC), the National Institute for Health Research (NIHR), and NHS Improvement (NHSI) to take forward actions following the public consultation 'Supporting research in the NHS'. This work centres around the first two of the twelve actions from the joint statement by NHS England and the NIHR '12 actions to support and apply research in the NHS': better managing excess treatments costs in non-commercial research, and improving commercial clinical research set up and reporting.<br><br>*Better managing excess treatment costs*<br>To address the issues identified, the way in which excess treatment costs are met is changing and a trial period for the new arrangements will roll out from 1 October 2018, through to April 2019. This will establish a more rapid, standardised and consistent process for the management of excess treatment costs, managed by the NIHR Clinical Research Network, to avoid delays during study set up and to maximise patient recruitment.<br><br>To underpin the new arrangements, the HRA has developed a cost attribution tool based on our existing Schedule of Events template. This tool is designed to capture the different costs associated with clinical research and attribute them accordingly. The new template will be used across England and Wales.<br><br>*Eliminating delays and further improving commercial clinical research set up and reporting*<br>While commercial contract research has been continuing to grow steadily, and HRA Approval has been acknowledged to have improved regulatory processes, feedback from industry partners continues to highlight that costing and contracting issues are delaying set up times.<br><br>Revisions to the NHS Standard Contract will come into force on 1 October, with the requirements on providers set out in a National Directive, which has been jointly developed by NHS England, HRA and NIHR. The National Directive sets out the nation-wide approaches for commercial contract research set-up which:<br><br>• Mandates the use of an unmodified model site agreement, as developed by the HRA, from 1 October 2018<br>• Mandates the use of the standard costing methodology using an updated NIHR Industry Costing Template, as already requested for HRA Approval, from 1 October 2018<br>• Introduces the concept of a single contract review process which will be further developed for future implementation.<br><br>**Combined Way of Working with MHRA**<br><br>Our joint pilot testing a single application submission reviewed by the MHRA, REC and study-wide assessment continues positively, with further applications from our existing pool of sponsors and interest from new sponsors in joining the pilot.<br><br>Detailed work is underway with IRAS and our case management systems to support the new process.<br><br>**Confidentiality Advice Service** | |

Our team has provided advice to colleagues in Ireland.

**Learning and Development**

The team that come together to provide training for the HRA on research for children and young people are delivering a workshop at the Royal College of Paediatrics at their annual conference. Hugh Davies, Dr Bob Philips and Jenny Newman (from Generation R young people's advocacy group) deliver regular training to our volunteers and the wider research community.

Hugh Davies, one of our regular trainers, is also working with HIC-Vac, an international network of researchers who are developing human infection challenge (HIC) studies to accelerate the development of vaccines against pathogens of high global impact.

A new eLearning module for Technical Assurance has gone live. Pharmacy Assurance Reviewer Training provides the essential training for new Pharmacy reviewers.

**Guidance and Advice**

We have implemented key updates to the 'Do I need REC' decision tool to align with the revised 'Governance Arrangements for Research Ethics Committees' (GAfREC), and to
the online consent tool, to support the joint statement between MHRA and HRA on informing participants and seeking consent by electronic methods ('e-consent').

We are developing a new workstream in our service improvement programme around customer support. One element of this is a Customer Charter. Staff were surveyed on potential themes to include in HRA Customer Charter and this is now being developed into a charter that will provide a series of statements about what our customers can expect from us and what we expect of them in return.

**Collaboration & Development**
Our Collaboration & Development Forum met in August.

We shared information about our Public Involvement in Ethical Review (PIER) Programme. Members were asked to help raise awareness in the research community about our new guidance and to identify possible sources of "third party assurances" of the quality of public involvement in applications to the HRA.

Neelam Patel from MedCity described work on developing a standards framework for digital health innovations; a collaboration between Medcity, PHE, NHS England, NICE and Digitalhealth.London.
Currently there is increasing development and uptake of innovation in the NHS. Demonstrating the effectiveness of digital health tools with appropriate evidence is challenging as manufacturers are not clear what evidence they need to produce and commissioners are unclear what evidence they should be

looking for.

The project aims produce:

- A trusted and respected set of standards on what evidence to produce for different types of digital health technologies;
- For innovators: to understand the level of evidence they need to produce making evidence generation plans faster and more cost-effective for them,
- For the NHS: to commission, deploy and scale clinically and cost-effective digital health tools that meet demand.
- Related educational links and advice on how to produce evidence of effectiveness and economic impact.

Gaynor Dalton from NHS Digital gave an update on the Data Service Platform being developed, which is a single system collecting, holding and processing NHS Digital Data. It will allow remote access for analysis in a safe environment where data is de-identified but permits linkage.

**Janet Messer external meetings/visits**

- Presented at meeting in Boston, USA on implementation of GDPR for US academic and commercial sponsors
- Visited US Institutional Review Board (IRB) member, health organisation research office and IRB network organisation
- NHS Research Scotland Strategy Board to discuss the Combined Ways of Working programme
- MHRA/RES project group
- Four nations' policy meeting
- NHS Digital Research Advisory Group streamlining working group
- NHS England Excess Treatment Cost/ Commercial Clinical Research working group
- NIHR Interoperability – workstream co-chair

**Governance Arrangements for Research Ethics Committees**

We have implemented the new edition of GAfREC in collaboration with the devolved administrations.

The updated document replaced the 2011 version from 17 September 2018, and the majority of changes have been made to take account of legal, policy and operational developments in the intervening time.

In addition, following public consultation by the Human Tissue Authority, research involving human DNA extracted from acellular material, which previously did not require REC review, is now included in GAfREC for the first time.

**Accreditation status as at 06 September 2018**

| Name of REC | Accreditation status as at 06 September 2018 |
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| North West – | Full accreditation under 2016 scheme (after |

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| Liverpool East | completion of action plan) Note: accreditation awarded for interim period of 12 months with a re-audit to be undertaken in 6 months' time. |
| London – Queen Square | Full accreditation under 2016 scheme (after completion of action plan) |
| South West – Central Bristol | Full accreditation under 2016 scheme |
| HSC B | Full accreditation under 2016 scheme |
| West of Scotland REC 1 | Full accreditation under 2016 scheme |
| Wales REC 4 | Full accreditation under 2016 scheme |
| West Midlands – Edgbaston | Full accreditation under 2016 scheme |
| South West – Cornwall & Plymouth | Full accreditation under 2016 scheme |
| North West – GM South | Provisional (action plan pending completion) |

**Finance**

**Forecast**

We have taken advantage of enhanced functionality in Oracle, our accounting system provided by NHS SBS, so that we will be able to report by actual, budget and forecast in the ledger from October this year.

**Year-end preparations**

Our audit planning meeting for 2018/19 has been held with Mazars and NAO. We have a new audit manager and also a new NAO engagement partner for this year's audit. Key areas of judgement highlighted for this year include accounting treatment of research systems development and potential organisational change costs resulting from Approvals and Policy team restructures.

**Estates**

We are participating in the London Office Strategy Project led by NHS Property on behalf of all Health organisations based in London. The project's objectives aim to reduce the number of leasehold properties in London ensuring office space is good quality, fit for purpose, value for money and supports greater collaboration and flexible working now and in the future. This is particularly pertinent for HRA given Skipton House lease ends 2021.

We are still working with the government property agency and another government body to progress sharing space in our Manchester office. NHS Property are supporting us in re-gearing the lease to enable sub-letting and potentially an extension to the current lease term.

**Corporate secretariat**

**Quality assurance framework**

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| | Our developing process for a comprehensive quality assurance framework has been audited by our internal auditors. Recognising the process is developing, the report provides useful recommendations to help develop the framework further. These recommendations are now being built into our plans for full roll out in 2019.<br><br>**Information governance**<br><br>**General data protection regulations**<br><br>The GDPR preparedness internal audit review is complete and recommendations are being implemented.<br><br>**Health, Safety and Welfare**<br><br>Policies and procedures have been reviewed and updated to reflect the new corporate secretariat structure and responsibilities. | |
| **8.** | **Transformation Programme Update**<br><br>IC provided an update to the Board.<br><br>The Board noted the SIP Programme remained on schedule and that the formal consultation with affected staff will commence on the 02 October.<br><br>IC reported there were some technical challenges due to connectivity issues with respect to the Research Systems Programme but advised the Board he was confident these would be resolved.<br><br>The Board was supportive of the development of new bespoke training for sponsors, academic supervisors and students. The Board acknowledged that whilst the training could not be mandated, it would be both helpful and beneficial to those who did decide to undertake it. | |
| **9.** | **Supporting Social Care Research**<br><br>The Board welcomed AH, MS and JW to the meeting. AH provided a presentation to the Board, updating on the progress achieved so far supporting social care research. AH reported there were currently three research ethics committees who are able to review social care research including the SCREC inherited from SCIE. The Board discussed the outcomes from the recent Social Care Round Table event, acknowledging the challenges posed by the lack of research capacity and resources within this area.<br><br>AH summarised 'Table 1 – Actions we plan to take forward' to the Board. The Board discussed the content and confirmed it was happy to support the actions as detailed.<br><br>The Board discussed the proposals contained in 'Table 2 – Recommendations for Consideration by the Board' as follows:<br><br>• The Board discussed the suggestion of organising a forum for interested | |

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| | parties to work collaboratively in developing a research culture in social care and agreed this would be a good idea providing the forum has a strong focus and clear outputs. The Board acknowledged however that should a social care forum be initiated, it may not be apt for the HRA to lead once the forum has become established. The Board suggested one approach may be to look for an enthusiastic partner to help build up a proposal.<br><br>• The Board was supportive of the proposal to conduct an options appraisal of the HRA remit of ethical review of social care research, providing it will add value. The Board stressed however, the importance of ensuring risk is appropriately covered and the potential vulnerabilities of social care research participants recognised. The Board suggested that any extension to the existing remit should prioritise the highest risk groups/types of studies.<br><br>• The Board discussed the proposal to establish a unified, consistent process for research guidance across local authorities but queried who had the authority to undertake this. The Board suggested that it may be preferable to undertake this task in partnership with the collaborative forum. The Board acknowledged that it would be beneficial to have some simple, concise standards illustrating good practice which could aid in the establishment of a consistent process regarding social care research across the country. | |
| **10.** | **Annual Report Summary for RECs in England April 2017 to March 2018.**<br><br>The Board received and noted the Annual Report for RECs in England. The Board welcomed AT to the meeting. AT provided a brief summary of the report, highlighting that as had been requested by the Board, the data was now presented by region rather than by REC centre.<br><br>The Board was reassured by the work which had been undertaken and the improvements made in respect of member recruitment and expressed thanks to AT and those involved.<br><br>The Board noted, and was assured by, the impressive timelines in respect of Full REC Review applications and acknowledged the work planned to improve the timelines for Proportionate Review applications.<br><br>The Board noted the variation between regions and RECs with respect to opinion rates and suggested that it may be helpful to undertake some further work and analysis to better understand why this disparity occurs. | |
| **11.** | **HRA Performance Report (Quarter 1)** ***including Finance report (August 2018) 2018***<br><br>The Board received, noted and approved the HRA Performance Report and the latest finance report. | |
| **12.** | **HRA Corporate Risk Register Quarter 1 2018/19 (Part 1)** | |

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| | The Board received and noted the HRA Corporate Risk Register. The Board queried why risk HRA628 – GDPR guidance had been had been removed from the risk register. JMe advised there had been an issue in relation to GDPR but confirmed this had now been fully resolved. | |
| **13.** | **Summary of 01.08.2018 Audit and Risk Committee meeting.**<br><br>The Board received and noted the summary of the Audit and Risk Committee meeting held on 01 August 2018. | |
| **14.** | **Out of session business conducted / External areas of interest since previous meeting**<br><br>The Board noted the following out of session business / external areas of interest since the last meeting:<br><br>- Principles from Interoperability Workshop between MHRA, NIHR and HRA held on 18 June 2018 shared for information.<br>- Excerpts from the Digital Transformation of Health and Care draft plan for the next 10 years shared for information. | |
| **15.** | **Any other business**<br><br>None to note | |
| **16.** | **Questions from the public**<br><br>None to note | |
| **17.** | **Date of next meeting**<br><br>21 November 2018, Manchester HRA Centre. | |