**HEALTH RESEARCH AUTHORITY
BOARD MEETING**

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 15 May 2019 at the London HRA Centre, Skipton House, 80 London Road, London, SE1 6LH

Present
HRA Non-Executive and Executive Directors

Graham Clarke (GC)	Non-Executive Director
Ian Cook (IC)	Director of Transformation & Corporate Services
Richard Cooper (RC)	Non-Executive Director
Professor Andrew George (AG)	Non-Executive Director
Professor Sir Jonathan Montgomery (JM)	Chair
Karen Williams (KW)	Director of Finance, Procurement and Estates

HRA Directors who attend the Board

Dr Janet Messer (JM)	Director of Approvals Service
Juliet Tizzard (JT)	Director of Policy

In attendance

Mary Cubitt	Programme Implementation Manager – HRA Approval
Katherine Guerin	Deputy Director, Corporate Services
Stephen Tebbutt	Head of Corporate Governance & Risk

Observers
Alison Barbuti, HRA
Sarah Hamerton, HRA *(in part items 1-12)*
Nicola Williams, Health and Care Research Wales *(in part items 1-9)* Bernie Pearson, Health and Social Care Research & Development, Northern Ireland *(in part items 1-9)*

Item	Item details	Action
1.	**Apologies** Teresa Allen, Chief Executive Dr Nicole Mather, Non-Executive Director *(written comments received prior to meeting).*	
2.	**Conflicts of interest** None to note. The Board noted JMo had now been appointed as Chair of Oxford University Hospitals NHS Foundation Trust.	

3.	**Minutes of last meeting** The Board agreed the minutes of the last meeting were a true and accurate representation of the matters discussed without amendment.	
4.	**Matters arising** Staff Survey 2019 The Board noted the report had been shared with the Non-Executive Directors and was on the agenda today. Service Improvement Programme (SIP) The Board noted the SIP closedown report was on the agenda today. Transparency Forum & the Collaboration & Development Forum Terms of Reference The Board noted any final comments on the terms of reference should be sent to JT. Approvals Workforce Programme Lessons Learned document The Board noted this document had not been finalised as yet but would be shared with the Board once ready.	
5.	**Update from Chair** R & D forum The Board noted the R & D Forum had been successfully held in Brighton earlier this week. JMo advised he had received largely positive feedback regarding the HRA and the forum had been a good opportunity to showcase recent work undertaken by the HRA. JMo expressed his thanks to Nicola Williams who had managed the development of the programme with the HRA involved in helping set the content. The Board agreed the HRA should commit to providing similar support to future forum programmes. HRA Chair recruitment The Board noted the advert for a new Chair had now been published with interviews anticipated early in July 2019. Annual report and accounts delegated authority The Board agreed to delegate authority to JMo to approve the Annual Report and Accounts for 2018/19 following HRA Audit & Risk Committee review on 30 May. The Board noted this would ensure the Annual Report and Accounts are signed and laid before Parliament in accordance with the Government timetable. National Genomics Healthcare Strategy JMo advised he is due to attend a workshop to discuss the strategy, with a focus on regulation and governance, on Friday.	
6.	**Update from Chief Executive**	

The Board noted the following update from TA which had been received prior to the meeting.

1) We have recently submitted the HRA Business Plan for publication. Due to budget pressures we have prioritised activity which will deliver benefits or outcomes which are fully aligned to our 5 strategic aims. A number of activities will be a continuation therefore of work started in 2018/19 rather than a number of new initiatives.

2) We are currently finalising our annual report which shows a significant amount of activity during 2018/19 and many of the benefits will become more apparent over the coming months. Many of the actions were associated with streamlining and integrating our services to speed up the approvals service and assist faster recruitment into studies.

   Our own timelines have improved further with a focus in recent months on Clinical Trials of Investigational Medicinal Products (CTIMPs) and non-REC studies. This includes our Combined Ways or Working pilots with MHRA which has reduced total timelines to a median of 43 days. Evidence suggests that to improve the timelines further still, additional work is required outside of the HRA to complement our work.

3) Brexit activity has slowed post the Easter break but we will now contribute to a lesson learned process.

4) The new Approvals restructure is bedding-in however workload remains an issue. Management has actively responded by implementing some immediate changes to release pressure on staff and are actively encouraging feedback. It is essential that we give staff and managers as much support as possible but there is a risk that timelines will increase slightly while staff get used to their new roles.

5) Policy restructure – the Head of Policy post has been appointed to and remaining posts will follow over the summer. This leaves the team quite light, but work is being actively moved around and prioritised while the new posts are being recruited.

6) The Research Systems restructure is ongoing. Research Systems staff have moved through organisational change and are transitioning into new roles.

7) New IRAS - We are at a critical stage in the transition from Pega experts to HRA sourced secondees and resources procured under a Pega partnership. To mitigate risks we have retained a small number of business critical Pega resources until the end of June. We have also increased the communication with MHRA to try to align resources better in both organisations for the next stage of the build.

8) We are therefore working through a period of intense issue and risk management and our SLT has increased the frequency of our own

		meetings to ensure that decisions can be taken rapidly. We recognise that through our governance structures that we need to devolve some of the risk mitigation down to a programme team level so that we maintain an agile approach.	
7.		**Directorate update**	

Approvals Directorate

HRA Approval

The new integrated structure and processes were implemented on schedule in April. This is a significant change to roles, work instructions, and team structures and it is therefore a testing time for the team. We held a two-day training session, followed by a further follow up day to ensure everyone understood new processes and had an opportunity to start getting to know their teams. Staff who have been used to being co-located with their line manager are getting used to seeking support from a new line manager, sometimes in a different location. We are trying to listen carefully to provide support where it is needed. Where we can take further action to adapt quickly based on experience, we are doing so. Although sickness absence is no worse than the previous year, new arrangements for cover mean that staff feel more concerned that the quality of service might slip. We are very grateful to all the team, who have been coping with uncertainty and a significant work volume during this transition period. We will continue to monitor the new arrangements carefully, responding as needed.

As well as supporting the transition, the new Approvals Support Division is rapidly reviewing and prioritising the workplan to address issues relating to volunteer members, particularly quoracy. The new structure is already deriving benefits in terms of visibility of issues and a coordinated, consistent response.

Technical Assurance

Although the take-up of the pharmacy technical assurance remains low, we have been pleased to receive very positive feedback.

Programme activities

Study amendments create a disproportionate amount of work for the HRA and for the NHS. A key part of the current process for handling amendments is that HRA (and colleagues in the devolved administrations) categorise amendments on behalf of sponsors to provide a single decision about the impact of each amendment on participating NHS organisations. This process is intended to reduce variation across NHS sites in implementing amendments. However, this requires considerable staff time and is a complex decision-making process. Determining what regulatory reviews any amendment requires is a further complex decision for researchers. In order to make the categorisation more consistent, and reduce the volume of work for the HRA, we have commenced early testing of an algorithm that allows sponsors to accurately categorise amendments themselves, and determine what reviews

are required. If successful there will be further stakeholder testing ahead of live piloting. It is intended that the tool both tests the logic to be built into IRAS and alleviates workload for the Approvals Operations Division in processing amendments.

The HR Good Practice Pack has been updated to ensure consistency with the requirements of the General Data Protection Regulation and is now hosted on the IRAS Help website.

The Life Sciences Sector Deal 2 includes a commitment to increase the use of Participant Identification Centres – NHS organisations that identify and refer potential participants to consider participation in studies hosted by other NHS organisations. This approach extends the reach of individual studies, providing wider opportunities for patients to take part in research. We have agreed a UK-wide definition of Participant Identification Centres and a consistent approach to contracting to make the process of setting them up more consistent.

We await feedback from DHSC on actions to resolve the issues we have raised about changes to the Master Indemnity Agreement for loaning equipment to sites.

Combined Ways of Working

The pilot continues successfully, with a small but steady trickle of applications that have allowed us to refine the processes and guidance in collaboration with MHRA and the devolved administrations. Timelines are promising, although the sample size is small. Detailed work with MHRA on the process is being finalised to support the completion of the technology that will support electronic submission through new IRAS, and an interface between HRA and MHRA case management systems.

Learning and Development

Having made significant progress on the new Learning Management System for both internal and external users last financial year, our focus at the start of this year is actions to support development of our staff. We have agreed a new policy for staff Learning & Development, including a new commitment to providing two days (or pro rata) protected study time for all staff, in addition to mandatory and job-specific training. We are also finalising a proposal for offering interest free loans for staff wishing to undertake courses of personal study/development which are beyond the remit of the HRA to provide.

Guidance and Advice

We published guidance and templates for the UK Local Information Pack on 15 April. The UK Local Information Pack brings consistent paperwork to site set up activities in the NHS across the UK and is due for implementation on 5 June. It is being supported by a wide range of change management activities, particularly in Scotland and Northern Ireland where its introduction will be a larger change from the use of Site-Specific Information Forms.

Directorate governance

Following the restructure new governance arrangements across all the teams and management are being implemented by the Deputy Director, to provide clear line of sight and support relevant cross-working across teams.

Janet Messer external meetings/visits

- MHRA/RES Joint CWOW project group and MHRA clinical trials programme board
- DHSC clinical trials steering group
- Four nations' policy meeting
- NHS Digital Research Advisory Group and streamlining working group
- NHS-HE Information Governance Working Group
- Meeting with IAoCR to discuss 'high throughput centre' proposals
- Meeting with Guys & St Thomas NHS Trust to discuss 'high throughput centre' proposals
- Regional REC Chairs meetings
- Meeting with NIHR CRN to discuss interoperability
- Meeting with Shaun Treweek to discuss interoperability
- Meeting with Imperial College Healthcare Partners to discuss innovation
- Presentation to Institute of Clinical Research Forum
- NIHR transparency workshop
- Meeting with NIHR Office for Clinical Research Infrastructure on CWOW and communicating with industry
- Facilitated at MRC workshop on use of data in research
- Industry Life Science Clinical Research Working Group
- Presentation at UseMyData workshop
- Chairing sessions at NHS R&D Forum conference

<u>**Policy**</u>

Research transparency

The Research Transparency Strategy Group has now met twice and is making great progress on drafting a strategy for consultation over the summer. Whilst the group is doing its work, Policy directorate staff are engaging with key stakeholders and possible future collaborators, taking speaking opportunities and planning for a new campaign to promote the strategy and to raise awareness of transparency benefits and requirements.

Policy and engagement team

The new Policy and Engagement team is now in place, with four out of the seven permanent staff in their new roles. We have also retained our seconded Data Policy Advisor for another year. Following a very competitive recruitment process, we recently offered the Head of Policy and Engagement role and will now recruit to the remaining two posts in the team. Capacity remains tight and the focus is largely on the research transparency project.

<u>**Finance**</u>

Year-end

Draft annual report and accounts have been prepared and shared with Audit and Risk Committee and our external auditors. The audit is due to start on 8th May with ARC meeting on 30th May to review the final accounts and audit report. The team have worked incredibly hard to meet the tight timelines and produce a high-quality report for discussion at ARC last week. Feedback from this discussion will be fed into further iterations of the report.

Chairs delegated authority to approve the accounts following ARC review will be required from the Board to ensure the Annual Report and Accounts are signed in accordance with government timetable.

Out-turn figures are well within our 4% target benchmark, as expected.

ESR and Electronic expenses

Electronic expenses have been rolled out to all staff from 1 April 2019. This new approach helps speed up and streamline the process, removes the need for email approval and helps ensure expenses are only claimed within policy.

We have also rolled out a simpler processing approach for member expenses to reduce administrative time and release capacity within HRA approvals member support team.
Manager self-service has been implemented in ESR from April 2019, providing automated tools for managers to support their people. This includes system-based workflows for annual leave approval and management. This functionality will provide better visibility to managers and staff of their annual leave management and will help all staff become more familiar with the functionality in ESR as part of a wider ESR programme to roll out.

Procurement

We have successfully procured Microsoft licencing for Office 365 and are now in the process of procuring facilities management services for three of our offices – Bristol, Manchester and Nottingham. In both procurements we have been supported by DHSC commercial teams.
RS phase 2 commercial activity is now also ramping up to provide the skills and capabilities required to deliver this second phase of the programme. Meetings have been held to agree how this will be managed and a number of key resource requirements are currently being procured. The detailed roadmap for the second phase of the development, once finalised, will be a core document to inform our commercial strategy for the next phase.

Estates

A revised head lease for our Manchester office has been signed by the Secretary of State extending our term to June 2023 (from June 2020) and providing for the ability to sub-let to government organisations. At the same time, we have agreed the sub-lease with HS2 to share one of our Manchester office meeting rooms and generate approximately £20k/annum in additional revenue. HS2 moved into their Manchester office at the end of April.

Regional office manuals have been drafted to provide all staff with the information they need to work well in each office. Once finalised these will form a key part of each new member of staff's induction.

Corporate secretariat

Administration review

Elements of the admin review are now being implemented including revised templates for meeting agendas, minutes and actions.

Information governance

Data sharing agreements have been signed or are about to be signed with all data sharing parties. This includes 11 organisations involved in research ethics review across the 4 Nations as well as MHRA.

A new reporting format has been agreed with ARC to ensure IG and Data Security is reported regularly to ARC.

Fraud, bribery and corruption

New functional standards have been produced by Cabinet Office for fraud, bribery and corruption. The HRA are being asked, as an ALB, to ensure we meet all mandatory fraud standards by September 2019. Work is underway to achieve this deadline with our approach being discussed by ARC at the end of the month.

RECs accredited by Quality Assurance Team

RECs accredited under 2016 Accreditation Scheme
-    South East Coast – Brighton & Sussex
RECs accredited under 2018 Accreditation Scheme
-    East of England – Cambridge South
-    East of England – Essex
-    South Central – Hampshire B
-    South West – Frenchay
-    East of Scotland 1
-    East of England – Cambridge East
-    North of Scotland 1
-    Wales REC 6
-    West of Scotland 3
-    West of Scotland 5

Research Systems

Work continues on CWOW in partnership with MHRA, necessitating changes on both the Pega platform and existing research systems to facilitate.

Pega Systems came to the end of their 11-month engagement and a final report was received week ending 10 May.

	Research Systems staff have moved through organisational change and are transitioning into new roles Phase 2 of the Research Systems Transformation Programme is current being defined and scoped. **Corporate Services** **CTM travel and accommodation** All is proceeding well since the sign-off of the new contract with CTM and the transition to the new booking platform via Digitis. There are some early signs of an increase in out of policy requests for accommodation as the summer season is approaching and hotels room will be in demand. **Recycled paper** Following a recent meeting with Banner it was noted the HRA does well in using predominantly recycled paper in comparison with some organisations in the NHS. Banner are looking at ways to offer more sustainable packages to organisations. It was recognised that some of the sustainable solutions may push costs up a little, but they are offset by saving elsewhere and especially by ordering recycled paper. **Disability Leave Policy** There has been some slippage in the timelines for this policy as other critical priorities have required attention. However, a significant level of input has gone into this and the various drafts have been commented on by SLT and the Disability Leave Working Group. We are in a position to take this to the next stage, and a meeting will take place this week to restart work on this.	
8.	**Transformation Programme: Service Improvement Programme closure report** The Board received and noted a presentation from KG regarding the SIP closure report. The Board recognised the considerable work undertaken as part of SIP and also the work of staff not directly involved in SIP but who continued to deliver the day to day workload during a period of change. The Board noted there had been good communication at the start of SIP however as it progressed and continued this communication could potentially have been improved to ensure staff remain engaged and up to date on progress. The Board recognised the development opportunity SIP gave to individuals such as being involved in projects and offering variety to the normal day to day role. The Board The Board discussed concerns that the new approval roles may not be appropriately resourced noting the low morale score from the recent staff survey. The Board noted the benefits offered by the development of the	

	Support division may take time to come to fruition and the new ways of working are still relatively unfamiliar. The Board discussed the governance structure for the programme and reflected on whether the links between the Transformation Board and the Workforce Board made the best use of resources and offered the most benefit. The Board agreed the SIP had delivered a considerable package of work and whilst it has placed pressure on staff the Board agreed this has been necessary to meet the savings required to continue to deliver our service.	
9.	**UK Wide Working update** The Board received and noted a presentation from MC regarding UK wide working. The Board was assured the working relationship between the four UK countries was good with close working and a good collaborative position held. The Board noted each country contributed to the Four Nations Compatibility Programme and was keen to continue to make the process as streamlined and seamless as possible for the researcher. The Board discussed the importance of the process being as simple and consistent as possible to help attract research to the UK. The Board agreed it would be beneficial to promote to investment partners globally regarding the improvements made and the benefits of undertaking research in the UK.	
10.	**Transparency strategy update** The Board received a presentation from AG and JT which provided an update on the development of the HRA's transparency strategy. The Board noted the consultation is intended to begin in June and run for 12 weeks until early September. Board approval of the strategy is subsequently anticipated to take place before the end of the calendar year. The Board was assured regarding the level of ongoing engagement and noted both staff and the HRA's volunteer members were being communicated with to make use of their valuable insight and experience. The Board noted the HRA had met with the Rt Hon Normal Lamb MP and recommended a further meeting take place in due course to keep the Select Committee updated on progress.	
11.	**HRA Staff survey: Management response to findings** The Board noted a seminar had been held this morning to discuss the findings from the staff survey with a presentation received from BMG research. The Board thanked the staff forum representatives for attending and agreed it had been a useful session. The Board noted the staff forum representatives had also had a session with only Non-Executive Directors present to discuss the findings further.	

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	The Board received and noted the management response to the staff survey. The Board agreed the proposal to monitor interventions being made by management and the impact of those interventions was a sensible proposal and should be regular reported to the Board. The Board noted staff forum representatives had already sought feedback from staff regarding progress since when the staff survey had been conducted and the Board agreed this should be fed through to the Board when appropriate. The Board was pleased to note a small improvement in the perception of IT reliability. The Board noted the staff forum representatives had highlighted the perception of staff sickness rates increasing as a result of the organisational change and low morale. The Board noted the staff sickness rates were comparable with last year however agreed it would be beneficial to keep an eye on staff sickness absence to see if there was any delayed impact. The Board noted the sickness absence rate could be added to the quarterly performance report. *Action: KW to add sickness absence rates to quarterly performance report*	**KW**
	The Board discussed the impact the recent organisational change may have had on the HRA's volunteer community, in particular those serving on RECs. The Board however noted there had been regular communication with REC chairs, in particular through regional meetings and this would continue. The Board noted the HRA, and its predecessor organisations, had been through change before, however the way change was managed in the past is different to the change process today. The Board noted the agile methodology may not be fully understood by staff and further understanding and learning regarding how the agile change process operates may be beneficial. The Board agreed an update on the staff survey next steps and the actions put in place by management should be brought to the next Board meeting in July. *Action: IC to provide an update on staff survey next steps at July meeting*	**IC**
12.	**Estates strategy update** The Board noted the latest position with regard to the HRA's Estates strategy. KW flagged a decision would be required at the July 2019 Board meeting regarding the future location of the London HRA centre. KW advised visits to each regional office is planned in the near future to discuss future plans. KW agreed to provide an update to the Board regarding any concerns staff may have in due course. *Action: KW to update Board with regard to visits to regional offices*	**KW**
13.	**HRA Performance Report (Quarter 4 2018/19)** - *Including Finance Report (March 2019)* The Board received and noted the Quarter 4 performance report. The Board recognised the possibility of a reduction in the number of applications being	

	reviewed within target timelines as the new Approvals process is embedded. The Board accepted this and recognised the need to support staff during this transition period. The Board recommended the performance report format be updated for the next quarter with a reduction in the number of indicators for the Approvals Service. The Board discussed the importance of predictability of timelines and also the quality of the REC review. The Board received and noted the finance report for March 2019.	
14.	**HRA Corporate Risk Register (Quarter 4 2018/19)** The Board noted the risk register for Quarter 4 2018/19.	
15.	**Out of session business conducted / External areas of interest since previous meeting** None to note	
16.	**Any other business** None to note	
17.	**Questions from the public** None to note	
18.	**Date of next meeting** 24 July 2019, Bristol HRA Centre	