HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 21 November 2018 at the Manchester HRA Centre, Barlow House, 4 Minshull Street, Manchester, M1 3DZ

Present		Initials
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
Nalin Thakker	Non-Executive Director	NT
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		
Bill Davidson	Joint Head of Policy	BD
Katherine Guerin	Deputy Director Corporate Services	KG
Eve Hart	Head of Communications	EH
Dave Murphy	Communications Manager *(in part items 11 – 17)*	DM
Stephen Tebbutt	Head of Corporate Governance & Risk	ST
Observers		
Christine Holmes, DHSC The Board also welcomed a number of staff from the Manchester HRA Centre.		

Item	Item details	Action
1.	**Apologies** None to note	
2.	**Conflicts of interest** None to note	
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** <u>Interoperability workshop principles with Board</u> TA provided an update in the Chief Executive update. <u>Transformation programme – Benefits Paper</u> The Board noted this was on the agenda today. <u>Transparency forum update</u> The Board noted this was on the agenda today. <u>Terms of Reference – Transparency and collaboration & development forums</u> The Board noted this would be added to the January Board agenda. ***Action: ST to add to January Board agenda***	**ST**
5.	**Update from Chair** <u>NED recruitment</u> Interviews for thirteen shortlisted candidates were held on 12 and 19 November. The names of those considered to be appointable are now being submitted for ministerial consideration with a view to appointments being made in time to commence in January. We had over 40 applications. We have been able to forward the names for each of the three portfolios (digitalisation, senior experience in H & SC research in NHS and Higher Education, industry needs and Life Sciences) for which we have advertised. Induction programme to follow. <u>Meetings</u> Much of my time in the past few weeks has been spent on (a) matters relating to NED recruitment including meetings and calls with a number of interested candidates as well as shortlisting and interviews, and (b) the response to the report of the Select Committee on Science and Technology. In hybrid HRA/academic work, I have: • presented on the ethics of AI and other aspects of digital at the UCLH 'Grand Round' including discussing the Streams project and the HRA's approach to securing clarity on regulatory requirements (24/10/18) and • Presented on the ethics and regulation of innovation in relation to paediatric clinical ethics support at a conference aiming to establish a network for Wessex (2/11/18) • Taken part in the Genomics England steering group for their public engagement work on a new social contract for genomics and innovation in the NHS. • Engaged with the Academy of Medical Sciences on their work on the proper approach to the use of patient data and data driven	

	technologies. Their report is anticipated later this month and we are preparing as HRA to respond when it is published. I have supplied a comment for publicity use welcoming the initiative. <u>Liaison meetings</u> Maria Palmer re: NHS R&D Forum 25/10/18 MHRA 31/10/18 EMIG Parliamentary Dinner 12/11/18	
6.	**Update from Chief Executive** **1. Select Committee Enquiry into Research Integrity** This recent report which had a focus on research transparency was published at the end of October. HRA issued an immediate press statement in which we acknowledged that there is still much to do in this area. The recommendations suggest a significant change in role for the HRA from one which promotes transparency to one which monitors and enforces compliance. Our next steps will be to discuss the recommended changes with our sponsor team in the DHSC before drafting our formal response over the next few weeks and we will need to seek legal advice where this is indicated. We have already made progress against a number of the recommendations and welcome the opportunity to work with others to progress this important aspect of our work. **2. Life Sciences Sector Deal** Over the last few weeks we have attended a number of events with the Industry colleagues who are proposing a number of ideas to ensure that the UK remains attractive. Whilst the number of clinical trials being run in the UK is currently fairly stable, it is vital that the whole research sector pulls together to maintain the number of clinical trials conducted across the UK and to attract new studies. We are all being encouraged to identify what we could to do differently to achieve this goal. Feedback for the HRA is that speed and guaranteed timelines in addition to quality are the key factors for our services and we should regard the United States turnaround times for research ethics as the current benchmark to match or beat to remain competitive. **3. HRA Research Systems** We have now submitted our business case for additional funding to complete the changes necessary for all Brexit scenarios with respect to clinical trials and to deliver systems which bring benefits to researchers, easier to use, proportionate and mapped to the different types of project. The business case aligns with our emerging Research Systems Strategy. We have also started phase 2 of the current build. There have been a number of issues agreeing a common data set across the different partners which has delayed the essential work on interfaces and urgent action is being taken to address this. **4. Brexit Preparedness** The combined ways of working restricted pilot project is progressing well and a number of clinical trial applications have been through the new integrated process combining the MHRA assessment and the REC via a single application to	

the REC. The early results are encouraging and this work has demonstrated that this approach does enable faster approvals decisions when researchers are prepared to deal with issues that arise with their application immediately. The next stage of this work is to increase the pilot pool and to scale up for wider implementation. The software build supporting this work is approximately 65% complete and we aim to have this completed by the end of February 2019.

5. Cross Sector Interoperability programme

We were pleased to note Matt Hancock's support for work around interoperability. We now have a number of live workstreams in our programme covering this work for the research community which is focussing specifically on data standards and interoperability for research and will be in a position to share some of the progress via a stakeholder engagement communication plan after the steering group meets at the end of November.

Strategic Stakeholder Meetings / Events

Meeting / Event	Purpose	Outcome – follow up actions
NIHR – Industry event	Conference at which Industry leaders discussed their requirements.	Following my talk, a number of members of the audience spoke to me and indicated that they would be willing to pay for a fast track service. HRA to consider how it might offer this to all sectors for clinical trials.
IAOCR	This group met to discuss how high throughput centres could be developed in England to support clinical trials.	HRA to discuss with REC members and DHSC how we might support this model as it emerges.
CRPD	Introductory meeting for TA.	TA to discuss with SLT how we can support the emerging data hubs and innovation exemplars
CEO and Board of St Marks Hospital	TA attended to deliver a presentation on Research Transparency and join the board members judging panel at the North West London University Hospital Research Excellence Awards.	
NIHR, Jonathan Sheffield & Matt Cooper	Monthly catch up meetings to discuss progress of ETC/Commissioning changes, the Interoperability Project and the Sector Deal.	
Aisling Burnard, AMRC	Quarterly catch up to discuss issues which impact on the Charitable sector including Brexit. The other main topic of discussion/potential concern regarding the Select Committee recommendations.	
Sam Roberts, NHSE	Sam and I met ahead of a meeting with Chris Whitty to discuss what we might respectively do to ensure that Research retains a high profile post Brexit. Research will feature in the 10 year forward plan	

	due to be released shortly.
MHRA, Mike Rawlins and Ian Hudson	Quarterly meeting to discuss ongoing collaborative work on clinical trials and interoperability.
EMIG Conference	Presented an opportunity to speak to SME Industry colleagues about some of their ideas & to hear their views on Brexit.
HTA Annual Conference	Opportunity to discuss what cross regulator support is required to make it easier for researchers. Specific challenges raised included research which crosses the boundaries between regenerative medicine, devices and data.
NIHR Programme Directors	I was offered the opportunity to give a brief overview of recent HRA initiatives but this was largely an opportunity for me to meet the directors to gain a better understanding of their challenges.
UKCRC Board	The group discussed a number of topical issues including vaccine trials, Brexit and Research development.
P1 advisory Group	Introductory visit.

I have also attended a number of Research Ethics Committees to hear feedback on ways that the HRA could better support their work.

- South Birmingham, Nottingham 2, Preston, London South East, Cambridge East.

I was invited to join a board meeting on the Executive Development Programme and to give a short overview of our work at the HRA to a group of Aspiring Directors.

7. **HRA Directorate update**

<u>Approvals Service</u>

HRA Approval

We have concluded the consultation with the Research Ethics and Assessment teams on a new structure to deliver an integrated service.

I am grateful to staff who have engaged constructively with the process. We have received some helpful feedback that will help us prioritise activity to support the implementation of the new service. We will now proceed with implementing the proposed structure and roles through a structured process of allocating staff to roles. Our ambition remains to implement the new structure from the beginning of April.

As planned we will include a number of requests for voluntary redundancy as part of the process. Based on the number of requests received we do not envisage any compulsory redundancies.
We continue planning the new Work Instructions and the transition planning. This will be a complex process that will need to factor in delivery of training, handover of tasks and continuity of service.

	I am particularly grateful to Jonathan Fennelly-Barnwell who has led this process with great care and concern for the staff affected. In relation to delivery of the service, we had noted a dip in performance in the summer, which we attributed to additional time taken for applicants to make changes to comply with the new General Data Protection Regulation. Our service has now been restored and we are pleased to have reached agreement with the many companies who had chosen to develop their own transparency wording through their global headquarters. More generally, the UK's approach to implementation of GDPR has been commended in a number of places and we have been asked to present at a range of fora. I am grateful to staff who have maintained excellent performance during the consultation process. We have made significant improvements to the percentage of applications where staff have been able to provide assessment assurances to the REC in advance of the meeting – reaching 83% of applications reviewed at full committee. **Combined Way of Working with MHRA** We continue to pilot the joint working with MHRA, testing a single application submission reviewed by the MHRA, REC and study-wide assessment. We are getting positive feedback from sponsors and have published some case studies along with more information about the pilot. We are continuing to refine the process through the pilot, working with applicants to achieve the challenging timelines proposed for the future clinical trials regulation. We are also testing the cross-border arrangements, with the first study led by Scotland included in the pilot. This is informing the development of new functionality in IRAS and our case management systems, to support the new process. **Technical Assurance** Pharmacy Assurance opened its first phase of roll-out in October as planned. It 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. We have also moved to the second phase of Radiation Assurance. In addition we have worked with the professional community across the UK to revise the guidance on the definition of research exposures to radiation, which we will publish shortly. **NHS England actions relating to Excess Treatment Costs and commercial contract research** New processes for improving management of excess treatments costs in non-commercial research, and improving commercial clinical research set up and reporting are now being implemented.	

	The new arrangements are mandated through a new National Directive from NHS England, and will be managed through the NIHR Clinical Research Network. The new tool for capturing information about excess treatment costs has been developed by the HRA, building on the template already used for HRA Approval. The model agreement and costing tool mandated for commercial studies are those already in use for HRA Approval. A single contract review process is being implemented to further streamline study set-up. **Learning and Development** Planning for the annual National Chairs' Day in December is progressing well. Work is nearing completion on a series of mini e-learning modules aimed at students and supervisors. The intention is to provide simple advice and navigation support to those who do not have local institutional support. Our aim is to improve the quality of applications, as we are concerned that supervisors are not providing a sufficient quality check and review of these applications is disproportionately time-consuming. A soft launch of the new Learning Management System is scheduled for 27 November with staff. Following final testing the system will launch fully in December and will be accessed from the HRA website. **Guidance and Advice** The roll out of technical assurances has been accompanied by updates to guidance in IRAS. In response to feedback, we have improved the guidance in relation to amendments across the UK, particularly in relation to the addition of new NHS/HSC sites. As part of our service improvement programme, we developed a customer charter with staff, and this has now been published on the HRA website, setting out what our customers can expect from us but also what we expect of them in return. Other areas of the customer support workstream have been developed into an implementation plan, and a project board is being established. **Collaboration & Development** The Collaboration & Development team are part of a workforce consultation with the Policy team, on proposals relating to a new Policy structure. **Janet Messer external meetings/visits** • Presentation to MRC clinical trials unit governance forum on GDPR and transparency • Presentation to Northern Ireland R&D Directors and staff on HRA Approval and CWOW • Presentation to Ministry of Defence Research Ethics Committee	

- Presentation at Research Quality Association annual conference on GDPR
- Presentation to NHS R&D Forum conference on sponsorship
- Presentation to Human Tissue Authority annual conference on GDPR
- National Information Board Leadership Meeting (on behalf of Teresa)
- Meeting with UKCRC accredited CTUs and MHRA about non-commercial phase 1 trials
- Round table meeting with International Academy of Clinical Research
- Meeting with Ben Goldacre on transparency
- Meeting with Shaun Treweek on studies within trials
- EMIG Parliamentary dinner
- MHRA/RES project group and MHRA clinical trials programme board
- DHSC clinical trials steering group
- NIHR Funders/HRA Forum
- Ministerial Industry Strategy Group Clinical Research Working Group
- Four nations' policy meeting
- NHS Digital Research Advisory Group and streamlining working group
- NHS England Excess Treatment Cost/ Commercial Clinical Research working group
- NIHR Interoperability – workstream co-chair

Policy

Data-driven healthcare technologies

There has been lots of activity around data-driven healthcare technologies across the research community this autumn. Policy staff gave presentations at conferences on data-enabled randomised controlled trials, the use of AI in clinical imaging research and a DHSC workshop on the regulation of emerging healthcare technology. Our focus in this engagement work has been to emphasise the importance of the appropriate use of patient data and effective and sustained public involvement.

We have also focussed on building awareness of the appropriate approvals for the development of data-driven technologies. Following our workshop in September about the legal audit of the Streams app data breach, we have started work to revise the guidance on the appropriate approvals for software development in the NHS. We have also contributed to the next version of the DHSC's Code of Conduct on data-driven healthcare technology, which will be published shortly.

Electronic consent

In late September, we published new guidance on the use of electronic methods for seeking consent. The guidance, backed up by a joint statement with the MHRA, advises sponsors and researchers on the use of electronic signatures, video participant information and the use of tables for recording consent.

Corporate Services

Communications

Emily Howlett has joined the HRA Communications team as a Communications Officer on a fixed term contract until April 2019. Emily comes from Cancer Research UK where she was part of the Research Information team. Her role will increase our capacity to support the stakeholder communications and engagement work which is key to the success of the combined ways of working pilot with the MHRA, and the ongoing redevelopment of the IRAS system.

A key focus over the past two months has been our work with colleagues in the policy team. We worked closely together to demonstrate how the HRA was continuing to promote the transparency agenda, including significant work to respond to the Select Committee report. The two teams also met for a planning day in Manchester, where future work to present the HRA's approach to AI and related research was discussed.

The team continue to provide communications support to the operational aspects of the business. We've worked closely with the MHRA around the Combined Ways of Working pilot, notably producing a case study showing how the process works well in practice. We've also worked closely with IRAS partners as the new IRAS project continues to develop, and with partners from NIHR and NHS England around a project to promote changes to excess treatment costs arrangements and to better support commercial contract research. Other operational support of note included the publication of the HRA's customer charter, joint guidance on eConsent and planning for the new LMS and bite-sized modules aimed at student researchers.

Internally, the focus remains on supporting the workforce board to ensure appropriate and effective communications around the planned workforce changes. We advised on communications around the recently completed consultation period for aspects of the approvals directorate, and continue to offer our expertise in this area.

Public Involvement

HRA Public Involvement team planning day held on 9th October to develop a forward plan determining key objectives/deliverables for the remainder of the PIER work programme.

An output of the above day was a paper setting out where we have got to (and come from) on the PIER journey. The paper will be presented to the HRA Transformation Board on the 28/11 to secure buy in on what we have set out to achieve by the closure of PIER and to discuss areas of work that won't be completed within the programme timeframe

Draft paper on expectations for Public Involvement in applications to the HRA to be submitted to Nov 18 PIER Programme Board.

Research Systems

The Deputy Director of Research Systems is currently in negotiation with BGO Software regarding the contract extension 2019/20.

	Staff from the Research Systems team are working with colleagues from the Approvals directorate and MHRA on systems changes required to support the Combined Ways of Working programme (CWOW) There is a need for MHRA and HRA to finalise the CTR data dictionary and process map as this is currently delaying the interface specification work **IT Service** A move to Windows 10 is being planned and will be done incrementally, to ensure the business change of introducing a new operating system can be managed well. **Future Services Programme** One of the other consuming organisations, the Care Quality Commission, has undertaken an independent review of the programme via Cap Gemini. This report was shared with the programme board this week and provided some valuable feedback on prioritisation of critical aspects of the programme in order for it to stay on track. The Deputy Director of Research Systems is chairing a Technical Assurance Group for the programme. **HR** HR continues to provide support to the Approvals Service workforce change programme. Staff consultation ended 15 November with feedback and outcomes being given to staff on 19 November. The focus is now on the job allocation process to identify suitable roles in the new structure for 120+ staff. This involves staff expressing interest in new roles, followed by interviews and skills assessments taking place through to early January 2019. HR is also providing support for proposed changes to the Policy and Collaboration & Development teams. The staff consultation ends 22 November with feedback and outcomes of consultation to be given to staff w/c 26 November The revised sickness absence management policy was approved recently by Leadership Team. Supporting documentation is being developed prior to the updated policy being rolled out **<u>Finance & Corporate Secretariat</u>** **Year-end preparations** Mazars and the NAOs presented their 2018/19 audit plan to November's Audit and Risk Committee. The plan was approved and preparations are now being put in place to support the annual accounts process. We have also aligned the annual business plan process and annual report and accounts process to ensure consistent messages across both key corporate documents. Policy and Communications teams are involved in the process as well as finance colleagues.	

Members' expenses

Following a finance team away day we have designed a simpler and quicker process to manage member expenses. This is being piloted with CAG in November with the aim that the new process is rolled out throughout the HRA in the new-year. It is anticipated that this new process will speed up payment for members, significantly reduce the number of touch points internally and release capacity within the service teams.

Asset verification

In preparation for Windows 10 roll out, finance is leading an asset verification exercise to confirm all equipment held by staff. This process will enable us to confirm our existing records and ensure that the planned roll out of Windows 10 in the new- year is based on accurate records.

Retention periods

The finance team have reviewed and revised the retention periods for key finance corporate records based on best practice. The team is now determining how the retention periods are implemented including consideration of filing conventions to support annual review and disposal.

Estates

Draft heads of terms have been prepared for our planned office sharing at Manchester.

Discussions have been had with NHS Property and NHS England to explore sharing office space at Skipton House following the end of NHS BSA MOTO in September 2019.

Business continuity planning

The annual review of our business continuity plans has commenced. This year our review will be relatively light touch given the organisational change process in train. It is expected that the 2019 review will be more in depth needing to consider the new processes and ways of working following implementation of the new structures in April 2019.

Information governance

Annual information governance report was approved by Audit and Risk Committee in November.
NHS BSA have been commissioned to enhance their information governance training for the HRA to ensure we meet GDPR requirements. This training is based on an existing NHS BSA module adapted to take into account HRA's specific policies and requirements. This training will be rolled out with the new learning management system later this month.

Audit & Risk Committee membership

	Marc Taylor's contract as an independent member the HRA Audit & Risk Committee has been extended for a second term until October 2020.	
8.	**Research transparency: next steps** The Board received a paper which detailed the recommendations from the House of Commons Science and Technology Committee in its recent report and set out the proposed next steps for the HRA in considering those recommendations. JT highlighted the paper also provided a summary of progress regarding the HRA's research transparency work since March 2018. The Board noted part of the work included the completion of a survey of researchers, sponsors, funders and other stakeholders to understand in more detail the level of awareness of transparency requirements in the research community. The Board noted the report would be published on the HRA website this month and publicised in the December edition of HRA Latest. The Board noted a formal response to the recommendations from the Select Committee is due by 30 December 2018. The Board noted a discussion had been held in the morning Board seminar regarding the recommendations and expressed its commitment to solving the problems identified. The Board gave approval for the sign off of the final version of the response to be delegated to the Chair. The Board agreed it would be useful to discuss the recommendations further as part of a meeting with the Rt Hon Noman Lamb MP in due course. The Board agreed the HRA will need to work with others in the development of the strategy and will need to consider carefully how any sanctions may operate. The Board recognised the importance of maintaining our supportive and enabling approach with researchers whilst driving improvements in research transparency. The Board agreed it is important the needs and safety of patients and participants are kept at the forefront of any future strategy. The Board recognised the improvements in transparency compliance within the commercial sector. The Board however noted, in general, the lower compliance rates for the NHS and Academic sectors. The Board agreed it will be important to understand and consider the various approaches available and understand the incentives for compliance for each sector. The Board agreed a further update should be brought to the January Board meeting. ***Action: ST to add Transparency strategy to January 2019 Board meeting***	**ST**
9.	**Transformation Programme update** The Board received an update on the current progress of the programme. IC highlighted since the compilation of the update the most recent progress report showed the RSP Programme moving to a red RAG status. The Board noted this was due to interface dependencies with difficulties with the data catalogue and process map. The Board was assured work to resolve the issues were underway.	

	The Board noted the difficulty in delivering critical functionality and/or connectivity with MHRA necessary for the Clinical Trial Regulations. The Board noted the misalignment between the programmes however was assured a piece of work has been undertaken to clarify what information is required and develop a technical solution. The Board requested an update on the development of new IRAS be provided out of session in December. ***Action: IC to provide out of session update on new IRAS to Board*** The Board noted the red RAG status for the e-submission of amendments. The Board noted the e-submission would make submission much simpler for researchers and also for the HRA as a manual system is currently in place. The Board noted a project specification has been developed however, at present, there is insufficient capacity within the organisation to take it forward at this stage. <u>End to end performance metrics</u> The Board reviewed a report which consisted of combined metrics using data from the MHRA, HRA and NIHR. The Board agreed it was helpful to have the end to end timelines however recognised these were headline figures at present. The Board noted the importance of consistency of timelines, in particular for commercial sponsors. The Board recognised the impact the reduction of provisional opinions can have on timelines and discussed how the HRA can work with researchers to help improve applications. The Board noted the date of last patient recruited is similarly important and reflected the true end to end dates. <u>System benefits</u> The Board reviewed a report detailing the high level view of system benefits. The Board agreed it was comfortable with the direction of travel demonstrated in the report. The Board agreed it would be useful to consider how the reporting of benefits could link with the performance report and tie in with the overall strategic objectives.	**IC**
10.	**HRA Performance Report Quarter 2 including September Finance report** The Board reviewed and noted the Performance report for Quarter 2. The Board was pleased to note 82% of applicants rated the overall service received highly. The Board noted the planning process for next year's business plan and associated performance indicators had begun. The Board reviewed and approved the September 2018 finance report noting there were no significant variances at this stage of the year.	
11.	**HRA Communications – six months in review** KG, EH and DM presented an update to the Board on HRA communication	

	activity over the last six months. The Board recognised the considerable work undertaken by the team and agreed the HRA was well placed to collaborate and engage with stakeholders due to much of this work.	
12.	**HRA Corporate Risk Register Quarter 2 2018/19 (Part 1)** The Board reviewed and noted the Corporate Risk Register for Quarter 2. The Board was satisfied the key risks had been discussed as part of the Board agenda and did not warrant further discussion.	
13.	**Summary of 07.11.2018 Audit and Risk Committee meeting** The Board received and noted the summary of the Audit and Risk Committee meeting held on 07 November 2018. The Board noted a deep dive had been held regarding preparedness for Brexit and the EU Clinical Trial Regulations. The Board noted the Committee was relatively assured by the level of preparation undertaken by the HRA.	
14.	**Out of session business conducted / External areas of interest since previous meeting** The Board noted the following out of session business / external areas of interest since the last meeting: - Update regarding Policy Directorate and Collaboration and Development team consultation circulated 24 October 2018 - HRA response to Science and Technology Select Committee Report on Research Integrity circulated on 29 October 2018	
15.	**Any other business** <u>Final meeting of three NEDs</u> The Board noted it was the last meeting of AJE, DK and NT with their terms of office due to end on 31 December 2018. On behalf of the Board and the HRA JMo thanked AJE, DK and NT for their important contribution, challenge and support to the HRA over the years. Christine Holmes also expressed her thanks to AJE, DK and NT on behalf of DHSC.	
16.	**Questions from the public** None to note	
17.	**Date of next meeting** 23 January 2019, Skipton House, London.	