

**HEALTH RESEARCH AUTHORITY
BOARD MEETING**

PART 1 – PUBLIC SESSION

**Draft Minutes of the Health Research Authority (HRA) Board meeting, held on
20 March 2019 at the Nottingham HRA Centre, The Old Chapel, Standard Court
Nottingham, NG1 6FS**

Present	Initials	
<i>HRA Non-Executive and Executive Directors</i>		
Teresa Allen	Chief Executive	TA
Graham Clarke	Non-Executive Director	GC
Ian Cook	Director of Transformation and Corporate Services	IC
Richard Cooper	Non-Executive Director	RC
Dr Nicole Mather	Non-Executive Director	NM
Professor Sir Jonathan Montgomery	Chair	JMo
Karen Williams	Director of Finance, Procurement and Estates	KW
<i>HRA Directors who attend the Board</i>		
Dr Janet Messer	Director of Approvals Service	JMe
Juliet Tizzard	Director of Policy	JT
In attendance		
Johnathan Fennelly-Barnwell	Deputy Director, Approvals Service	JFB
Katherine Guerin	Deputy Director, Corporate Services	KG
Penelope Gregory	PA to the Chair and Committee Secretariat	PG
Observers		
Christine Holmes	Department of Health and Social Care (via t/c)	

Item	Item details	Action
1.	Apologies Professor Andrew George (<i>written comments received prior to meeting</i>)	
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.	

<p>4.</p>	<p>Matters arising</p> <p><u>NED Portfolios</u> JMo confirmed the portfolios for new NEDs were as follows: Audit and Risk – Professor Andrew George and Richard Cooper Transparency – Professor Andrew George IT Reprovision – Richard Cooper Engagement – Dr Nicole Mather</p> <p><u>Deep dive</u> JMo reported the deep dive into the strategic risk register occurred on the 5th February 2019.</p>	
<p>5.</p>	<p>Update from Chair</p> <p><u>PACE trial</u> JMo confirmed the Select Committee had been informed that there were no regulatory issues with reference to the PACE trial. JMo advised should any further enquiries or questions be received in respect of the trial, these should be directed to Eve Hart, Comms.</p> <p><u>Progress re successor</u> JMo reported the recruitment process is likely to commence in April with a replacement anticipated in July.</p>	
<p>6.</p>	<p>Update from Chief Executive</p> <p>The following update from TA was tabled at the meeting:</p> <p>1. Research Systems Business Case and team changes</p> <p>The HRA have now received confirmation from the treasury and the DHSC Policy team that we have been allocated most, but not all of the funds that we requested to complete the work to replace IRAS and to move HARP onto the new Pega platform. As outlined at the last board meeting, we have now reached the stage where we need to re-procure additional analysts and implementation support for the next phase of the development which starts at the end of April. Ian Cook has been working with respective parties to ensure that we have a good handover to our own Research Systems team and the small team of seconded Pega developers.</p> <p>We have recently had to revise our plans for the next phase of the platform development following discussions with the MHRA.</p> <p>The formal consultation period with staff in the research systems team has now finished and we need to give this team the much-needed clarity over the roles and skills that we need as we enter the next phase of software development. We must reach a stage over the next 2-3 months where we have created a single integrated team which blends together expertise</p>	

from the business, technical and testing experts and both experienced and new HRA “apprentice” Pega developers all working together to fulfil one of our requirements which will be able to take control over our own development in house for the longer term reducing reliance on a single supplier.

2. Annual Report and Business Planning for 2019/20

We are now working on the final draft of the business plan for next year. We have a challenging year ahead of us financially despite the additional investment we expect to receive for the new IRAS platform.

Once again during 2018/19 we have packed a huge amount of activity into the current financial year and have managed to maintain our performance across all teams and I would like to thank everyone for their hard work and support. We have received feedback from a number of external companies that we are seen as a progressive and responsible regulator and our efforts to make things easier for research applicants have been well received. We recognise however that there is still a lot to do.

3. Staff Survey

The headlines for the staff survey have been received and 72% of our staff completed the survey and gave us their feedback. We decided to issue the survey despite being in the middle of staff consultations and anticipated that some of the scores would be lower than we would have liked to see. The full report will be available for discussion with the Board and staff forum members at the next board meeting and we are committed to working with staff to ensure that the HRA is a great place to work.

4. Data

The HRA has been involved in a number of meetings recently to discuss data. The wider clinical community and innovators are still seeking some clarity around the challenges presented by data driven technology, collecting a sound evidence base through high quality research and the need to adopt and spread innovation quickly.

We have also heard reports that the introduction of the GDPR on top of existing legislation around data has created some confusion at hospitals. We are now considering whether to write directly to hospital Caldicott guardians to direct them to our guidance and help dispel some of the myths.

5. Transparency

We have now started to receive responses to the letters issued to hospital trusts seeking a current understanding of their compliance status for

	<p>Clinical Trials Transparency and the barriers that are preventing compliance. It appears that several hospitals have attempted to submit updates to the EudraCT database and the majority of these updates have then had to be directed via the MHRA as accounts are locked and some reported significant issues with uploading documents. Many hospitals are also reporting incorrect registry assignment with Clinical Trials that have been incorrectly assigned to universities and vice versa and Trials which were stopped still showing on the registries despite hospitals receiving acknowledgements that their updates had been actioned.</p> <p>6. Brexit</p> <p>During the last few weeks we have been fully integrated into the DHSC Brexit planning processes, together with the other arms-length bodies and the NHS and care provider organisations and we have a weekly call within the HRA to consider commissions and to discuss our status and any new Brexit related issues.</p> <p>While uncertainty remains about the outcome of Brexit, we have been asked to continue with our planning. If a delay to the exit day is negotiated work will be required to update our website advice relating to 29 March.</p> <p>7. Joint Head of Policy changes</p> <p>On behalf of the Senior Leadership team I would like to personally recognise the contribution of our two joint Heads of Policy who will be leaving the HRA at the end of the month following the restructure of this team. Both individuals have made a notable contribution to our understanding of social care research, tissue and data, and have co-ordinated updated versions of the UK Policy Framework and GafREC.</p>	
<p>7.</p>	<p>HRA Directorate Update</p> <p>Staff Survey</p> <p>IC reported the staff survey had been completed and there will be a presentation to all staff on the 10th April 2019. The full results of the staff survey will be considered at the HRA Board in May.</p> <p>Action: IC to circulate the full Staff Survey report to the Board as soon as this becomes available.</p> <p>The following update was tabled at the meeting:</p> <p>Approvals Directorate</p> <p>HRA Approval</p> <p>Actions continue to prepare for the implementation of the new structure and processes from April 2019. A separate paper reviews the change programme to</p>	<p>IC</p>

date. Performance has remained excellent throughout this process due to the commitment of the teams, and we continue to be grateful to them for engaging productively in the process.

Technical Assurance

The second phase of roll out of pharmacy technical assurance is commencing, although numbers of applicants remain low. Communication about the process and its benefits is increasing to encourage more applications.

Confidentiality Advice Team

We continue to work with NHS Digital to agree a Memorandum of Understanding for providing formal advice, building on the informal arrangements that have been in place so far.

Programme activities

Student projects form a significant proportion of our activity, and take disproportionate time due to levels of queries raised and very variable quality of applications. The extent and quality of supervision and institutional support is a contributing factor. We have therefore taken various steps to support both supervisors and students:

- Three bitesize online training modules specifically targeted at students, sponsors and academic supervisors
- Updated webpage on HRA website, specifically for those conducting student research
- Ensuring that policy changes were reflected across a wide range of internal and external documents and procedures.
- Higher Education Institution (HEI) distribution list (those active in health and social care research) to support targeted communications for this hard to reach stakeholder group.

There was an accompanying communication plan, supported by NIHR, which has resulted in visits to our student research webpage increasing significantly.

After much work led by Mary Cubitt with the devolved administrations, we have confirmed plans for publication on 5 June 2019 of template Organisation Information Documents to form part of a Local Information Pack for use between sponsor and site. A single approach to NHS site set-up across the UK will support cross-border studies, with different versions of the document for commercial and non-commercial studies.

We are working with the Department of Health and Social Care to address concerns raised by the pharmaceutical industry with the Master Indemnity Agreement (MIA) for loaning equipment to sites for clinical trials. It would appear that HRA had not been advised of changes made to the MIA that impact on the use of equipment for clinical trials, so we are now liaising between the parties to seek agreement on an alternative approach.

Learning and Development

Following the soft launch of the HRA's online Learning Management System at the end of December, the Learning and Development team have been working with the developers to resolve any outstanding issues. We are now receiving positive feedback about the system and are already working on new resources for the platform, in collaboration with the HTA, NIHR and the R&D Forum.

The LMS gives our staff access to the technical resources from our face to face member and researcher training days, for the first time.

Our central learning and development provision for staff has increased significantly during 2018/19. In addition to the extended online provision, we have had 650 staff attendances at live learning events. Staff who don't usually work outside the organisation, have been taking advantage of the 'external experience' opportunity, which encourages them to explore the wider world of research and the range of organisations which all contribute to this.

Guidance and Advice

Supporting work elsewhere in the organisation, the guidance team are preparing guidance in IRAS to enable the ongoing UK roll-out of radiation and pharmacy assurance, and the implementation of the UK Local Information Pack later this year.

Work is completing on a revision to the UK Human Resources Good Practice Resource Pack in IRAS. The NIHR website has held information for several years and we have agreed that the revised version will be hosted on IRAS to support its UK-wide adoption.

The latest audit of registration of clinical trials is now underway. This audit is of a cohort of clinical trials that are one year later than the last cohort audited.

Janet Messer external meetings/visits

- Champions for Research Support (national NHS R&D representatives)
- MHRA/RES project group and MHRA clinical trials programme board Four nations' policy meeting
- NHS Digital Research Advisory Group streamlining working group
- Clinical and Contract Research Association seminar – presentation on Combined Ways of Working
- Excess Treatment Cost/ Contract Clinical Research Senior Oversight Group
- HRA/NIHR Funders Forum
- NHS-HE Information Governance Working Group
- Meeting with Vincenzo Libri, Director of the NIHR UCLH Clinical Research Facility and REC Chair on REC consistency in decision-making
- National Data Guardian event
- Discussions on interoperability with NIHR

Policy Directorate

Data-driven healthcare technologies

We ran a productive workshop with Understanding Patient Data for fellow regulators and other organisations on 31 January. We are now taking forward work with a working group to develop learning, tools and information for NHS organisations and technology companies about appropriate research approvals and use of patient data in data-driven technology.

We published new high-level information about data driven technology on our website to coincide with the publication of the revised DHSC Code of conduct on data-driven healthcare technology in February.

Research transparency

Our response to the House of Commons Science and Technology Committee report on clinical trials transparency was published on the committee's website on 22 February and the committee gave a positive reaction to our response to their recommendations. Since then, we have been working to establish a new Transparency Strategy Expert Group, chaired by Professor Andrew George, to help us develop the strategy.

The Expert Group, consisting of 12 people across the research community, will meet for the first time on 3 April and we plan to consult on a draft strategy over the summer. The Expert Group will recommend a final strategy to the HRA Board at its November meeting.

Policy and engagement team

The new Policy and Engagement team officially starts on 1 April. Some existing members of staff have secured roles in the new structure, and we have appointed to one further role, so we will be able to continue with our work plan. However, we are yet to appoint to the Head of Policy and Engagement role and two further band 7 roles, so capacity will be tight until the summer.

Corporate Services

Public Involvement

The Public Involvement in Ethical Review (PIER) programme within the Service Improvement Programme (SIP) is drawing to a close with the development of expectations for public involvement in applications for Approval. An initial draft was shared at the National REC Chairs day in December and has been further developed through a Task and Finish group of REC Chairs and public contributors, including a workshop on 7th March. This will be finalised in discussion with the Approvals, Member Support and Communications teams. Prior to publication on the HRA website we will engage with stakeholder networks such as the Collaboration and Development Forum to raise awareness of the expectations and what they will mean for them.

The main focus of the benefits realisation of the PIER programme was the analysis of a sample of applications for ethical review before and after the introduction, in April 2018, of new guidance on public involvement. Initial results show that the guidance has led to a small increase in the numbers of applications that provide information on public involvement that helps their ethical review. A full report

from the work will be made available in April / May 2019 and the analysis will be repeated at regular intervals to provide a new performance indicator for public involvement in applications for Approval.

The HRA was confirmed in early March 2019 as a member Patient Focused Medicines Development (PFMD), which is an international partnership of pharmaceutical companies and not for profit organisations that represent the interests of patients. PFMD provides a means of sharing best practice in the involvement of patients in developing new medicines and will give the HRA a way of supporting and encouraging more pharmaceutical companies to improve the reporting of their public involvement in their applications for Approval.

Communication

The communications team is still under capacity pending the start of our new Communications Manager in mid-April.

The team has produced a series of comms to help health and social care researchers prepare for EU Exit, including publishing curated guidance from the wider health and social care sector, and HRA specific information, on a new section of the HRA website.

The communications team supported the policy and engagement team in two major strategic areas, producing a new section of the website and supporting social media content for the data driven technology project, and supporting the transparency project by redeveloping the relevant sections of the website and managing the comms response to high-profile statements, including our formal response to the Science and Technology Committee on the PACE trial.

New organisational communications have been produced and signed off since the last update to this group, including Lines to Take, a banner stand for HRA events and a refreshed organisational slide deck. These are now being built into staff inductions, before a roll out to all HRA staff.

A new internal communications strategy has also been signed off, with a focus on using the same metrics-based evaluation that we use for external comms to inform the best way to share information with HRA staff. The strategy includes a new reward and recognition programme.

Following recommendations made by the task and finish group, plans to improve the information we provide to student researchers on our website have been operationalised and enacted. This included updating and simplifying the information on our student research webpage, increasing visibility of the page within the site and embedding three new bite-size eLearning modules on the page (removing the requirement to log in to the LMS). Multiple communications channels and methods were used as part of the strategy, including gifs made in house which induced high engagement on social media. This project required effective working between internal HRA teams, external developers and partner organisations.

The final instalment of a series of blog posts published across the last quarter has attracted good readership. The series included researcher, patient and carer and

the lay REC member voices, to demonstrate the value of using the HRA public involvement guidance in a meaningful way.

This last period has also seen a higher than usual number of media enquiries which could be down to the increased attention focussed on the organisation given the strategic work mentioned above.

IT Service

The main focus has been around supporting the Win10 roll out which has been delivered successfully so far. This has entailed creating and managing the O365 tenancy where all the user accounts and software is administered, we have also procured and assigned additional software packages such as Adobe Acrobat DC to ensure the teams have full functionality of the new IT. We have deployed ATP (Advanced Threat Protection) managed again via a Microsoft portal, ATP allows us to pro-actively managed any cyber threats to our devices in line with DHSC guidelines.

The VC will finally be available on the new hra.nhs.uk domain by the end of March giving HRA ownership and full control over the solution.

We will now be moving on to the next stage of Win10/O365 programme by migrating email over to Exchange Online which again will give HRA ownership of our email solution and added improvements to performance and the email service in general.

Programme Office

The 2018/2019 portfolio dashboard is being updated each month and is being used to report the status of programmes and projects at to the Transformation Board and Leadership Team Meeting.

Benefits are being reported and reviewed each month at the Leadership Team meeting. The benefits and KPIs for 2019/2020 are being agreed.

Sessions on Benefits Realisation and Planning have been delivered by the Project Delivery Capability Manager from DHSC. A further session on Why Projects Fail has been planned. A webinar on Project Management at HRA has been published and one on Benefits Realisation is being developed.

Finance Directorate including Corporate Secretariat

Financial Planning

Financial plans have been developed for 2019/20 and approved by Leadership Team. Financial plan is included in the HRA business plan for 2019/20 and will be discussed at the March Board meeting.

Key financial drivers for 2019/20 include:

- Grant in aid funding is based on the current spending review allocations (£100k reduction, 4% in real terms),

- Cost pressures from new Agenda for Change terms and conditions (2018 contract) will now only be 50% met by DHSC - £120k cost pressure
- Cost pressures arising from changes to NHS pension scheme regulations partially funded (6.3% increase in employers' contributions, 2.5% unfunded; 3.8% funded), £173k cost pressure
- Research systems second phase development funded 75% by DHSC EU Exit £4.5m.
- Organisational change processes have secured savings of £330k in addition to £400k efficiencies achieved in previous years.

Year-end preparations

Interim audit has been performed with not significant issues raised at this stage. Preparations for the year-end are well developed with a keen focus on year-end financial management to ensure activity is correctly accounted for.

Procurement

The negotiation of 'plus 1' contract terms with BGO have been completed and a CCN has been agreed with BGO for 2019/20.

DHSC commercial team has been assigned to HRA to support RS phase 2 commercial activity. Meetings have been held to agree how this will be managed.

Contract management training has been provided to all HRA contract managers to support them in this important role. The training was well received and puts us in a good position to manage our contracts during 2019/20.

ESR and Electronic expenses

Our project to roll out electronic expenses is progressing well with roll out in April 2019 confirmed. All staff will be trained next week in using this functionality with electronic expenses being implemented from April for staff. In 2019 we will explore rolling this functionality out further to members.

In the meantime a simpler processing approach is being piloted for member expenses to reduce administrative time and release capacity within HRA approvals member support team.

We will also be introducing manager self service in ESR from April 2019, providing automated tools for managers to support their people. This includes system based workflows for changes to staff hours / cost centres etc as well as 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.

Estates

A revised head lease for our Manchester office has been finalised, 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 are close to agreeing the sub-

	<p>lease with HS2 to share one of our Manchester office meeting rooms and generate approximately £20k/annum in additional revenue. Approval is being sought from Cabinet Office and then the lease can be signed by Secretary of State.</p> <p>Corporate secretariat</p> <p>Administration review</p> <p>A project to review our approach to supporting administration and corporate meetings at the HRA has been completed with a number of recommendations to improve and simplify processes. These recommendations will be implemented over the coming months.</p> <p>Information governance</p> <p>The annual review of our information asset register is complete and will be discussed at IGSG in March 2019. In addition, we have completed all mandatory recommendations in the Data Security and Protection Toolkit, and will submit our return by 31 March 2019.</p>	
8.	<p>Transformation Programme update</p> <p>The Board noted the Transformation Programme update indicating the Service Improvement Programme is due to end in March and that a full closedown report will be presented the Board in May. The Chair advised it would be useful to capture in the report, evidence of whether benefits are working from a user’s perspective.</p> <p>Action: Forward any comments re areas to be covered on in the closedown report to Katherine Guerin</p>	ALL
9.	<p>HRA Engagement Strategy</p> <p>The Board received the Engagement Strategy paper. JT provided an overview and background, advising the document will be brought to the HRA Board in July for consideration after further development. NM stated it is important to consider how and who the HRA work with and be focussed on what the organisation wishes to achieve. The Board discussed the paper, acknowledging that whilst there was no desire to change the current broad HRA vision statement, consideration should be given to what it means. The Board agreed that the use of bullets and unpacking the vision statement would add value.</p> <p>The Board considered the questions in part 4 and was supportive of the planned approach which included the following comments:</p> <ul style="list-style-type: none"> • para 2.3 may benefit from sub-division • para 3.2 currently does not mention either staff or members 	
10.	<p>HRA Performance Report (Quarter 3 2018/19)</p> <p>- Including Finance Report (February 2019)</p> <p>The Board reviewed and approved the HRA Performance Report (Quarter 3) and finance report for February 2019. The Board was impressed with the financial</p>	

	performance and acknowledged the hard work which had been undertaken throughout the year in sometimes, challenging circumstances.	
11.	HRA Corporate Risk Register (Quarter 3 2018/19) The Board noted the Quarter 3 Corporate Risk Register for February Audit and Risk Committee and March Board.	
12.	A review of the terms of reference of the Transparency Forum & the Collaboration & Development Forum The Board noted the terms of reference and acknowledged these would be submitted to the Board at a later date once finalised. CH requested the DHSC to be listed as an observer. KW advised that it was important from a governance perspective to detail decision making and delegated powers. Action: Observations re terms of reference to be submitted to Juliet Tizzard	ALL
13.	Summary of the HRA Audit & Risk Committee meeting held on 05 February 2019 The Board noted the summary of the HRA Audit and Risk Committee held on 05 February for information.	
14.	Approvals Workforce Programme – review and status update The Board noted the review and status update. JFB provided the background and gave a summary of the approvals workforce programme. The Board thanked JFB and acknowledged the hard work which had been undertaken to reach this point. The Board noted that whilst not currently in a position to generate a ‘Lesson’s Learned document’, it would be useful to see this once it becomes available. Action: Lessons Learned Document to be forwarded to the Board	JMe/JFB
15.	Out of session business conducted / External areas of interest since previous meeting <ul style="list-style-type: none"> - Response to House of Commons Science and Technology Committee report, <i>Clinical Trials Transparency</i> submitted 05 February 2019 - Notification of the publication of the Code of Conduct for data driven technologies in the NHS which points to a newly created section on the HRA website (www.hra.nhs.uk/datadriventech) which clarifies the approval pathway for data-driven research studies and offers tips and advice for researchers looking to undertake this kind of research. 	
16.	Any other business None to note	
17.	Questions from the public None to note	

18.	Date of next meeting 15 May 2019, London HRA Centre	