HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 16 May 2018 at the London HRA Centre

Present		Initials
HRA Non-Executive and Executive Directors		
Teresa Allen	Interim 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		
Stephen Tebbutt	Head of Corporate Governance	ST
Observers		
Stergios Aidinlis, Member of the Public Katherine Guerin, HRA Christine Holmes, DHSC	*(in part items 1-7)*	

Item	Item details	Action
1.	**Apologies** Janet Wisely	
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**	

	July Board seminar on Board effectiveness update ST and AJE informed the Board the seminar would be external facilitated with the facilitator to hold individual phone calls with members of the Board prior to the seminar. Future direction of travel for the Research Ethics Service Board seminar The Board noted this has been scheduled for early 2019. Reasons for breaches and application of learning The Board noted this document had been circulated by JMe. CEO update - TA to add benefit of meeting with stakeholders to future CEO updates The Board noted this would likely be ready for the July Board meeting. ***Action: Benefit of meeting with stakeholders to be added to CEO update***	**TA**
	Staff survey – JMe to provide verbal briefing to Board on case studies for managing poor performance The Board agreed this would be added to the July P2 Board agenda ***Action: JMe to provide update at July P2 Board meeting***	**JMe**
	Metrics – industry perceptions The Board noted this would be covered under the agenda timeline item. R & D forum presentation The Board noted the forum had been successfully held earlier this week. Transparency JT informed the Board that work continues to progress with a more detailed update to follow at the July meeting. The Board noted the report from the Select Committee is anticipated to be published in early June. ***Action: JT to provide update at July Board meeting***	**JT**
	Research Systems team and Leadership Team to review systems risks The Board noted this would be covered under the agenda item on risk.	
5.	**Update from Chair** CEO advert now published JMo advised the advert for the CEO position has now been released. JMo advised if any staff wished to discuss the role or had any concerns, he or Michele Ekins, Head of HR, would be happy to discuss further. 'Research Integrity, Conflicts of Interest and the end of Expertise' JMo advised he had recently given a lecture on 'Research Integrity, Conflicts of Interest and the end of Expertise' at the Research Institute for Ethics and Law event at the University of Swansea. JMo advised a draft of the presentation was available to Board members if they wished to read it. Data JMo advised he had attended a number of events on data, including co-chairing	

	a meeting of the AMS which discussed access to medical data and giving a talk on genomics at University of Kingston. The Board recognised the increased focus on data and expected this to continue. <u>Genome editing</u> JMo advised he head recently attended an event on Genome editing at the Vatican and flagged the importance of the UK being positioned as an excellent place to conduct genome editing.	
6.	**Update from Chief Executive** The HRA business plan for 2018 received sponsor approval at the end of March and now that the local elections have been completed is available on the HRA website. The annual report is in its final draft stage ready for the audit and approval stages over the next month and we have taken the opportunity to use advice from the National Audit Office to refresh the way that some of our performance information is presented. We anticipate that this will be ready for signoff by the auditors by the end of the month and by the Audit and Risk Committee on 06 June. Consistent with last year we will be requesting a chair's action at the Board meeting on the 16 May to provide the Board sign-off of the accounts on 14 June. Karen will provide Jonathan with the ARC papers when they are distributed together with any adjustments agreed at the meeting to give him sufficient time to review and provide sign-off. This is consistent with last years' approval timeline. Following the development of the refreshed strategic aims last year we developed a planning grid which has helped us to directly align strategy, operational initiatives and personal objectives and this has been updated for the 2017/18 year. I am delighted to report that our performance across all areas last year was strong and that shortened timelines for our approval service continued to fall and were maintained throughout the year benefitting the wider research community with their study set up. We continue to progress our service improvement programme and a number of projects are now entering the delivery stage. During April the new verification tool in IRAS went live. This should help to reduce the number of studies which are submitted that are incomplete, delaying study start up and generating extra non-added value work. Last year over 36% of study applications submitted were incomplete and we anticipate that we will start to see this reduce with new applications coming in now. The HRA continues to provide guidance and support to the wider research community on the General Data Protection Regulations and have updated this on a regular basis ahead of the deadline of the 25th May. We have also developed our own implementation plans for readiness internally. Our workforce project has now started and affects most of the approvals teams. This will be one of the most important pieces of work this year and will deliver a truly integrated service to our users. It will also identify the role changes which are needed to underpin other projects which are progressing around proportionality and amendments.	

	The executive team and the transformation board are still developing a longer-term target operating model to ensure that we can help staff to visualise what we anticipate the HRA will look like over the next few years to assist our longer term workplans. A team of over 20 HRA staff contributed to the success of our all staff day at the end of April. The organisation of the event and the selection of the external speakers resulted in a really engaging day and staff were then able to select from a series of 8 workshops on a range of topics from managing their own wellbeing to the changes to the Clinical Trials Regulations. Staff health and wellbeing is a key theme for the year following the feedback in the staff survey and we are using the survey outcome and feedback from the staff forum to ensure that we support both the physical and mental health of our most valued resource. During the event we were able to show a short animation celebrating the contribution and success of everyone during the last year. The procurement process for the IRAS replacement is reaching its final stage and we anticipate that we will be able to confirm the preferred supplier over the coming weeks. This has been a particularly intense period of activity for a number of people across the HRA and our priority once a decision has been taken will be to ensure that we have adjusted our wider workplan to give this work priority over the coming months. External visits/meetings - Dame Sally Davies Commemoration Oration Kings College London (networking) - Christine McGrath R&D Direction University Hospital Southampton NHS Trust meeting to discuss new Research Leadership Organisation for R&D Directors and tour of research unit. - National Perinatal Epidemiology Unit, Oxford University. Visit to R&D team to learn about their work and have demonstrations of their approach to patient involvement and engagement. - Mark Walport CEO UKRI, Introductory meeting. - Nick Hirst NIHR CIO – external advice and assurance on planning for new systems implementation. - Digital Health, NHS London Digital Accelerator. Undertaking assessment of new technology from SMEs to inform HRA planning. The Board noted there had been an increase in apps recently and expressed its concerns regarding the regulatory arrangements for these apps with some developers seemingly unaware or unclear on the necessary regulatory measures they must abide by. The Board noted the joint guidance on the regulation of software development developed by NHS Digital, MHRA, DHSC and the HRA however was unclear how easily locatable the guidance was. The Board recommended further cascading of the guidance, potentially by the Russel Group and Universities UK, and requested an update at a forthcoming meeting. ***Action: TA to provide update on regulation of new technology at future Board meeting***	**TA**
	- Monthly catch up meetings Jonathan Sheffield CEO NIHR, Matt Cooper,	

	NIHR. - Department of Health Clinical Trials Regulations Steering Group. - UKCRC Board Meeting MRC. - Universities UK - Research Integrity Forum to hear how universities plan to respond to the select committee hearing.	
7.	**HRA Directorate update** **General Data Protection Regulation – operational arrangements** The General Data Protection Regulation (GDPR) has less impact on health and care research than on other sectors due to the existing good practice already in place. Nevertheless, there is significant potential for confusion by stakeholders due to specific arrangements for research that do not apply to other activities of sponsors and sites. The HRA's objective is to put in place simple, streamlined and standardised operational processes to support compliance and maximise consistency for sponsors and sites. In addition to publishing ongoing updates to guidance for the UK health and care research community, we have put in place arrangements to manage queries from researchers and sponsors. The UK study-wide criteria are being updated so that new studies will be assessed for compliance against GDPR. Our guidance includes standardised wording to be used to support transparency requirements for existing and new studies. In recognition that many companies in the UK will have had wording stipulated by European or global headquarters, we have also put in place arrangements to review proposed wording for compliance at a sponsor level. With colleagues across the UK we are also finalising arrangements for organisations to update or put in place standard contractual arrangements between controllers and processors. We are providing a large number of webinars that are proving very popular (currently 15 webinars with 700 people signed up), as well as supporting train-the-trainer workshops in collaboration with the NHS R&D Forum and the MRC Regulatory Support Centre. The national data opt out is also being launched from 25 May, The Confidentiality Advisory Group have been liaising with team leading the programme to agree arrangements for affected research. **HRA Approval** A pilot of joined up outcome of review, with just one set of queries back to the applicant, is underway along with producing the final approval from both REC and assessment jointly. We have also begun testing the notion of setting a quality threshold for applications to proceed to REC review, so that the time of volunteer members is not wasted on reviewing and providing detailed and extensive feedback on poor quality applications. The verification tool in IRAS has now gone live, ensuring that applicants have included key information and documents prior to submission to avoid delay and re-working. This includes a requirement to provide a funder reference number	

	to improve tracking through the research journey for funders and HRA. Initially this caused a spike in enquiries as many applicants were unused to the check. Historically, most applications were not valid for REC review, and even when valid to proceed to REC over 36% have still not been valid for assessment. With joined up validation now in place, this should reduce re-work and enable assessment to start sooner. The model non-commercial agreement was held back from release to allow inclusion of updated clauses to reflect the requirements of the General Data Protection Regulation. The revised agreement is scheduled to be released in early summer. As part of our project on Public Involvement in Ethics Review, the guidance in IRAS is being updated to help applicants better explain about the public involvement they have undertaken and what difference it has made. **NHS England Consultation on supporting research in the NHS** NHS England has published their response to the consultation on proposals to address ongoing issues across the NHS in England with Excess Treatment Costs for non-commercial studies and variability in contract value for contract commercial trials. We continue working with them and the NIHR Clinical Research Network to take forward implementation by NHS England and the Clinical Research Network. **UK-wide NHS/ HSC compatibility programme** We have supported Health and Care Research Wales (HCRW) as they took the step in April to align with HRA Approval as an interim step towards wider UK compatibility. Wales is using the same HRA Approval processes and we have supported their staff with training. England and Wales are issuing HRA Approval and HCRW Approval in one letter – one less step for cross border researchers. **Technical Assurance roll out** Radiation Assurance was opened to all oncology studies taking place in the NHS in England from 16 April 2018, with updated guidance in IRAS. Work is underway with experts across the UK to update wider guidance to support radiation review. **Learning and Development** For some time we have been working to develop an effective system for delivering webinars to members and the wider research community – commercial and non-commercial sectors. We launched the first webinar '*Applying for HRA Approval – getting it right first time*' in February, followed by '*Managing your Approval – 35 day no objection for amendments*'. These are scheduled monthly throughout the summer in to October. The webinars on GDPR (see above) are also being recorded to be posted on the HRA website. Although a few participants have experienced minor problems	

with the technology, initial feedback is extremely positive. We are evaluating the sessions and will continue to develop the content and the webinar series.

In addition, the team supported the planning and delivery of a successful All Staff Day.

Combined Way of Working with MHRA

The private pilot to test a combined way of working between MHRA and Research Ethics Committees opened to applications by invitation and prior agreement from the beginning of April. The first applications are expected towards the end of May, but regular calls have been held with the test sponsors to ensure they are suitably prepared. The RECs and staff involved have been trained on the process, including reviewing dummy applications.

The process involves a single submission of an application dossier which includes an application for a Clinical Trial Authorisation from the MHRA and to the REC. There will be a single validation undertaken by the MHRA and then the application will be reviewed by the MHRA and REC with co-ordinated communications to the applicant. This part of the pilot will remain invitation only and submission with prior agreement until we have received sufficient applications to effectively test the process and to develop the supporting guidance. Once we have reached this point, we will open the pilot to live submissions.

Collaboration & Development

The May meeting of the Collaboration & Development Forum heard about the Academy of Medical Science work on patient data and future data-driven technology, and explored issues around communicating to those involved in software and algorithms about regulating data.

Janet Messer external meetings/visits

- MHRA/RES project group
- Four nations' policy meeting
- HRA Transparency Forum – presentation on potential new IRAS
- IRAS Partners Board
- UK Research Ethics Development Group
- Information Commissioner's Office – to discuss operational guidance on GDPR
- Institute of Clinical Research – presentation on HRA activity
- NHS Digital Research Advisory Group streamlining working group
- NHS England Excess Treatment Cost working group
- NHS England, NIHR Clinical Research Network and Association of UK University Hospitals – to discuss NHS England response to consultation on commercial clinical trials
- NHS Digital Research Advisory Group
- UK Caldicott Guardian Council – presentation on proposals for changes to approval applications to -support GDPR
- Jo Burns NIHR Clinical Research Network – to discuss NIHR Digital Strategy and interoperability

- Ministerial Industry Strategy Group Clinical Research Working Group
- External Learning Reference Group – cross agency alignment on learning
- Collaboration & Development Forum
- David Newton UKCRIS – governance arrangements for biorepositories and databases
- Experimental Cancer Medicine Centres Annual Conference – presentation on HRA approaches to platform trials
- Clinical Practice Research Datalink 30th anniversary event
- NHS R&D Forum – several staff presenting, chairing and supporting the stand

Social care research

We are planning a roundtable event on social care research in June to explore how we can best support this type of research. Drawing together key people in academic, voluntary sector and funding organisations, the roundtable will examine the specific ethical issues in social care research, determine the needs of participants and work with partners to agree further work in this area.

Electronic consent

Our work on collecting consent via electronic means is coming to fruition. We have agreed a joint statement with the MHRA which sets out the legal and ethical framework for both providing patient information and recording consent using digital formats. All studies can use provide patient information digitally and most studies can use simple electronic signatures. Only higher risk studies, such as phase I clinical trials, need use advanced forms of electronic signatures. We will publish the statement in June, along with advice to applicants about how to submit digital patient information and consent tools for HRA Approval. We will then update our website guidance for researchers on consent.

Public Involvement

Young patient advocates from the GenerationR initiative delivered a keynote presentation and two workshops at the HRA All Staff Day, facilitated by the Public Involvement Team. These workshops focused on the impact of Public Involvement; staff feedback from the day has been very positive. The team will be working with GenerationR and the NIHR CRN Patient and Public Involvement Priority Lead, Jenny Preston, to explore opportunities for further collaboration.

In April the Public Involvement Team launched supplementary guidance for applicants about what information about Public Involvement it is most useful to include in the current IRAS question on involvement (QA14-1) and five other main questions for the purposes of REC review. The guidance has been integrated throughout the IRAS Question Specific Guidance, and the team is now working with Comms to implement the rest of the dissemination plan for the guidance. This has included presenting at each of the regional Chairs' Network Meetings and arranging visits to the RES Team meetings for REC staff in each office in order to reinforce stakeholder collaboration and engagement with the Public Involvement in Ethical Review (PIER) work programme. The Team has also redeveloped information about Public Involvement ahead of an

	update to the HRA website which will focus on user needs and on contextualising the importance of Public Involvement within the HRA's core mission and values. **Communications** Have developed and delivered GDPR content on the website working with policy, Approvals and promoted the supporting webinars. They have been working with other stakeholders such as NIHR, and AMRC to identify opportunities to reach a wider audience with our guidance and materials in this area. Other headlines: • Published the HRA business plan for 2018-19 • Prepared and delivered communications support for the NHS R&D forum conference • Developed an animation on HRA performance of the previous year for publication to the website soon • Agreed communications about combined ways of working pilot with MHRA • Responding to media queries • Delivering workforce related communications for the Approvals directorate • Delivering internal communications including the all staff VC and weekly newsletters and regular updates to the intranet • Planning ahead for international clinical trials day and developing our approach for NHS 70 • Equipping and developing the team to be able to make multi-media communications products quickly and effectively through use of mobile technology, recording and animations **2017/18 year-end accounts and audit** Year-end annual report and accounts process is on track to meet expectations and to date no significant issues have been raised. As previously reported, key the policy change for this year's audit is our revision of the useful economic life for IRAS. Working with the communications team, we have also started to change the format of the report and accounts to help make the report more accessible, better reflecting our 'house style'. This builds on the performance animation produced for this year's all staff day. **Oracle: chart of account hierarchy and forecasting** We have changed our reporting hierarchy in Oracle to provide improved analysis and simpler reporting. Management information will reflect this changed structure for 2018/19. All staff have been updated of the changes at our recent all staff vc and finance are working with budget holders and our shared service providers to help roll out the new reporting. **Employee self service** Employee self-service for ESR (electronic staff record) has been rolled out to all staff, enabling better access to their own personal data and also providing our	

	staff with the ability to update their personal data directly without the need for unnecessary form filing and sign off. Pilot supervisor self-service has also been rolled with approximately 35% of our managers being trained directly. Phase 2 is now planned so that supervisor roll out is complete by the end of this quarter. This will enable our managers to input sickness reporting and appraisal information directly into the ESR system without the need for shared service support nor duplication of entry – a streamlined, more efficient and accurate process. **Procurement** A number of activities continue to be supported by the finance team this quarter including: • RS procurement • Learning management system – contracts and implementation • Printer sourcing for regional offices – Bristol and Manchester We have also adopted the NAO contract management framework as the core document to support contract management at the HRA. Finance business partners will be using this document when supporting contract managers at their monthly / quarterly meetings. **Estates** Newcastle office move to NHS BT blood centre is complete and all snagging dealt with. We are also exploring opportunities to share space in our Manchester office. Following the organisational change process in finance we have created a new role with a focus on finance and estates contract management. We are now transitioning to this new approach and visiting all regional offices building on the good work performed the corporate SIP estates project team. Initial areas of focus include: confidential waste management, PAT testing and printer provision. **General Data Protection Regulations – corporate readiness** We are in the final stages of agreeing with NHS BSA that they will provide our Data Protection Officer function. Chris Gooday – who has recently led the NHS BSA GDPR project internally – will provide this service on our behalf. We are currently agreeing the contractually terms as well as the induction plan for the role. We anticipate that Chris will meet with Audit and Risk Committee in August (when the GDPR internal audit report is due to be discussed) and be a member of our information governance steering group. All our information governance policies and procedures have been reviewed by independent legal advisors to ensure they meet GDPR requirements. Our approach to privacy for IRAS has been reviewed by our information governance steering group and is now being finalised on advice from our legal advisors. Our approach to GDPR readiness has been based on the ICO 12 steps methodology and has been led by the corporate secretary and information governance steering group.	

	Emergency incident response exercise Senior managers took part in a simulation incident exercise which tested our response to a ransomware attack on our research systems. The simulation was observed by members of the Business Continuity Team at NHS BT. The findings from the exercise will be considered in due course by the Audit and Risk Committee.	
8.	**HRA Business Plan 2018/19** The Board noted the HRA Business Plan for 2018/19 has now been published following the end of purdah.	
9.	**Timelines to first patient recruited performance update** JMe presented the latest timelines from application submission date to date first participant recruited into the trial, using combined data from several sources. JMe gave a caveat regarding the quality of some of the data however advised it was a fairly large data set and should still give a good indication of the current timelines. The Board noted 100 days from submission to first patient recruited is a key target for industry and the data showed this target being met from September 2017 for a sub-set of trials, illustrating what was possible with well-prepared studies. The Board noted the timelines for NHS permission of first site to first recruit had remained relatively constant during the reporting period at approximately 30 days and the Board noted this is higher than other countries. The Board noted some of the delays related to the negotiation of costs for each site. The Board agreed it is important this information is used more widely to demonstrate the current timelines and highlight the issues which are preventing the timelines from being further reduced. The Board agreed text is needed to support the graphs and further consideration required regarding how the HRA can deliver this information and engage with particular audiences and opinion formers to support further improvement to the system. ***Action: JMe to finalise presentation including explanatory text***	**JMe**
10.	**Service Improvement Programme update** IC presented the latest update on the Service Improvement Programme to the Board flagging the programme remains green and on track. Key progress to note includes agreement to move to the Windows 10 operating system by the end of the calendar year and the development and implementation of the IRAS verification tool. ESR employee self-service has also been implemented with supervisor self-service in the process of being rolled out. The Board recognised the ongoing workforce pressures and risk of insufficient 'people' resource to deliver the programme.	

11.	**Performance Report Quarter 4 2017/18 including Finance report** The Board received the quarter 4 performance report for 2017/18 report and agreed it had been a great year with considerable achievements made over the last 12 months. The Board expressed its thanks to all staff for their hard work over the last year. KW highlighted the amber reporting for IT and ensuring staff have the tools to enable them to perform well. KW flagged the recent decision to move to Windows 10 and Office 365 would hopefully support the improvement to the service over the coming year. The Board noted the sickness absence was higher than the target number of days lost to sickness (1500) at 2517. KW flagged wellbeing is a key focus for 2018/19 and there had been well attended and well received wellbeing sessions held at the all staff day last month. The Board noted the final finance report for the year with an end of year underspend position of £4K (0.03% of total budget). KW advised close monitoring of our forecast and nimble investment decisions to best meet our strategic objectives have ensured we have fully utilised our available resources this year. KW flagged the HRA has reduced its cash position in year to better reflect our annual requirements. Our cash position at the end of the year was £965k compared to £3,485k at 31 March 2017.	
12.	**Corporate Risk Register Quarter 4 2017/18** The Board reviewed and noted the Corporate Risk Register for Quarter 4. The Board noted the Audit and Risk Committee had reviewed the register at its last meeting and had been assured the risks were being appropriately managed. The Committee had requested management consider the risk of the expectations of the HRA's stakeholders, both internal and external, not being met in relation to the functionality of the new IRAS. The Board was assured this risk would be considered by the Research Systems team. The Board noted the decrease in the score of the transparency risk and queried if the score was appropriate. JT advised, since the last quarter, there had been considerable work to understand the issues and how these could be addressed however recognised the risk was still a high one and the score would likely change again following the publication of the report from the Select Committee.	
13.	**Summary of 14.02.2018 Audit & Risk Committee meeting** The Board noted the summary of business conducted at the last Audit and Risk Committee meeting. GC highlighted the substantial rating received for the key financial controls audit, with no recommendations, which was an excellent result. GC advised a deep dive had been held considering GDPR; both the HRA's internal readiness and the HRA's external responsibility in providing guidance	

	and training to the research community. GC advised there are a few things still outstanding for the internal readiness however the Committee was assured there were no major issues anticipated. KW flagged confirmation had been received regarding the HRA's Data Protection Officer, with an experienced individual from NHS BSA to provide two days a month support to 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: - R & D Forum held on 14 & 15 May 2018 - Update on research systems procurement timeline and shortlisting circulated for information - HRA Approval directorate proposed changes FAQ and presentation circulated to Board for information - Pre-election period 'purdah' guidance on conduct circulation for information - Statement from the House of Lords debate (18 April 2018) on the European Union Withdrawal Bill in relation to the EU Clinical Trials Regulation circulated for information - Medicines & Healthcare products Regulatory Agency 5 year Corporate Plan published https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702075/Corporate_Plan.pdf	
15.	**Any other business** None to note	
16.	**Questions from the public** None to note	
17.	**Date of next meeting** 24 July 2018, London	