HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 22 November 2017 at the Nottingham 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
Karen Williams	Director of Finance, Procurement and Estates	KW
HRA Directors who attend the Board		
Janet Messer	Director of Approvals Service	JMe
In attendance		
Chris Cannaby	Head of Assessment and Assurance	CC
Stephen Tebbutt	Head of Corporate Governance	ST
Ann Tunley	Head of Research Ethics Service (England)	AT
Observers		
Ellen Swainston, HRA Juliet Tizzard, HRA Director of Policy from January 2018		

Item	Item details	Action
1.	**Welcome and apologies** Nalin Thakker, Non-Executive Director Janet Wisely, HRA On behalf of the Board, JMo welcomed Juliet Tizzard to the meeting and looked forward to her joining the HRA from January 2018 as the new HRA Director of Policy.	
2.	**Conflicts of interest** JMo advised he had recently been appointed to the Board of Health Data Research UK (HDR UK) as a Non-Executive Director. JMo confirmed he had sought agreement from the DH sponsor prior to accepting the position. JMo	

	advised he would complete a revised declaration of interest form in due course. The Board noted there were no declarations to note in relation to today's agenda.	
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>Strategic ambitions website feature</u> The Board noted the website went live on 07 November. <u>Joint Chairs Day/Policy event 24th November</u> The Board noted invites had now been sent to NEDs however agreed the communication process could have been more efficient. ST agreed to follow up to ensure NEDs are on relevant distribution lists and receive information in a timely manner. ***Action: ST to follow up on communication lists for NEDs***	**ST**
	<u>Life Sciences Industrial Strategy: HRA response</u> The Board noted this would be considered in Part 2 today. <u>Relevant strategies from other organisations</u> The Board noted there were no relevant strategies to note at this meeting however in future these would be recorded with any out of session items. <u>Update on HRA Endorsement of registries in England</u> JMo confirmed he, NT and JMe had met with AH with agreement reached for the group to appear more like an ethics committee. JMo advised AH was in the process of modifying the policy and ST agreed to follow up with AH as to when this will be finalised. ***Action: ST to follow up with AH re finalisation of policy***	**ST**
5.	**Update from Chair** JMo informed the Board the NED reappointments have been confirmed as follows: - AJE reappointed from 01 January 2018 to 31 December 2018. - GC reappointed from 01 January 2018 to 31 December 2020. - JMo reappointed from 11 June 2018 to 10 June 2020. The Board noted a seminar had been held this morning to consider Board effectiveness with a subsequent session to be held next year which would include a review of Board membership requirements in the future. JMo flagged the following recent announcements which may be interest to the Board:	

	- Dr Patrick Vallance, President, R&D, GlaxoSmithKline appointed as UK Government's Chief Scientific Adviser. - Professor Stephen Powis appointed as National Medical Director at NHS England. - The *London Health and Care Collaboration Agreement* and *London Health Devolution Agreement* signed on 15 December 2017. JMo advised he had attended the following events: - Ethical Medicines Industry Group (EMIG) dinner where positive feedback had been received in relation to the work conducted by the HRA. - Liverpool Health Partners Annual Lecture. JMo advised he had also taken the opportunity to meet with R & D staff in the city and asked staff how confident they were in relation to HRA Approval. JMo advised the feedback had been mixed with some still not believing it worked however when asked for examples of problems no recent examples were provided. JMo advised the following meetings/events are scheduled: - Meeting with Professor Sir John Bell 23/11 - HRA National Chairs' Day and Policy Event 24/11 - Health data use in light of the Life Sciences Industrial Strategy 27/11 - Interviews for Confidentiality Advisory Group (CAG) Chair 04/12 - HRA / Medicines and Healthcare Products Regulatory Agency (MHRA) meeting 19/12 - HRA / Association of Directors of Adult Social Services (ADASS) meeting 22/12 GC advised a paper regarding drug repurposing is due to launch shortly which will be looking at whether the mechanism to support repurposing can be improved.	
6.	**Update from Chief Executive** Following a meeting with NHSE in September, we were invited to participate in a further piece of work which aims to accelerate research applications by reducing costing negotiations between companies and Trusts, which delay study start-up times significantly and to simplify the whole process associated with NHS excess treatment costs. This work links well to the work which Alastair Nicholson in HRA has been leading in collaboration with ABPI on a new Commercial Agreement which is currently being finalised, and will be followed by a new non- commercial agreement, due for completion early in the New Year. A series of proposals arising from the group will be subject to consultation over the next two months. HRA has already responded to an earlier NHSE consultation during November to change the service condition wording in section 26.4 of the 2018 variations to the NHS contract which relates specifically to research.	

Activity around Brexit is increasing and we are moving our Brexit planning into a more formal project so that we can co-ordinate activities and improve communications across the HRA over the coming months. DH have agreed that activity around the Clinical Trials Regulations related to joint work between HRA and MHRA will be reported back to the DH via a group which will be chaired by Louise Wood.

We are getting into a state of readiness within HRA to prepare for the Systems Changes to IRAS in anticipation of the approval for our Business case. This work includes establishing an appropriate governance structure. We have already held our first workshop to collect user stories and to agree how we mobilise resources to prepare ourselves to go to market as soon as is possible. We are keeping our colleagues in the four Nations and IRAS partners board updated.

Interviews for a new chair for CAG are currently scheduled to take place on 04 December. Interviews took place recently for the Head of Communications and we are pleased to report that we have made an offer.

We issued our annual staff survey at the beginning of November and hope to be able to share the staff responses with the board early in the New Year. One of the key questions we are asking staff is whether or not we should be entering into a formal agreement with Unison who have been actively increasing membership across HRA offices. To support this work our HR team have looked at the approach being taken by other ALBs so that we adopt a proportionate approach if staff would like us to formally recognise this type of arrangement.

We have now finished the consultation with our staff at the Jarrow office over the proposed move to the NHSBT building in Newcastle and are currently working with staff affected by the move to ensure that we are able to cover any excess travel costs. This consultation work has highlighted a need to review our flexible working arrangements.

We have a follow up meeting with Sir John Bell on 23 November 2017.

External engagement activity

Contact	Name of organisation	Purpose of meeting
Prof Sir John Bell	University of Oxford	Follow up meeting
Clare Morgan and Jonathan Sheffield	NIHR	Monthly catch up – NIHR Digital Strategy and change to some key personnel
Ian Dodge & others	NHS England, DH, NIHR, NHSI	Meeting to discuss changes to NHS contracting arrangements and ETCs for the 2018 contracting round
Pharma Integrates	Conference	Challenges facing pharma and networking
NHS & Social Care under a minority Government	Kings Fund	Breakfast meeting to discuss key impact of minority government decision making powers and Brexit

	EMIG	Reception	Networking meeting	

Forward Planning
Brexit Programme Board
Preparatory work for IRAS development

7. HRA Directorate update

HRA Approval

HRA Approval performance continues to be stable. Further details are provided for the Board separately.

The pilot of joined up validation in the Service Improvement Programme (SIP) has been evaluated and found to have successfully improved joined-up working, reduced separate communications with applicants, and received positive feedback from staff and applicants. The report produced by the pilot team has been accepted by the SIP Board and a roll out plan is underway. The existing pilot will continue during this time. Positive discussions have also taken place with the devolved administrations about this model to support implementation of full e-submission of the combined IRAS form for the devolved administrations.

The SIP workstream focussed on supporting applicants to 'get it right first time', with input from IRAS Partners, is developing a specification for a verification tool in IRAS that will automate the checking of key data, authorisations and documents to support applicants to submit a valid application.
HRA is delighted to be working with the NIHR Clinical Research Network to support NHS England with a 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.

UK-wide NHS/ HSC compatibility programme

Work on compatibility of processes in site set-up continues, identifying and resolving differences in processes that can be streamlined to the benefit of researchers undertaking cross-border studies.

EU Clinical Trials Regulation implementation

Alongside ongoing preparation for implementation of the regulation, consideration of potential alternative arrangements to the EU Portal for the UK continues, as mitigation to the risk of the delay in development of the EU Portal impacting on the UK use post-Brexit. Pilot work on new processes for research ethics committees continues, with expansion to additional committees.

A business case for funding has been submitted for additional development to support a UK portal and additional requirements aligned with the Life Sciences Industry Strategy. The development of requirements has commenced, with full involvement of the IRAS Partners. A fixed term/ secondment role is being

advertised to support stakeholder engagement with this process.

Guidance

Following the successful launch of the new website and the new guidance sections in IRAS, there is ongoing work to identify and resolve broken links and address minor points of feedback from stakeholders. Work is also underway to ensure that there is full alignment of IRAS, wider guidance and queries line with the new policy framework.

New guidance is being developed to support the UK compatibility work, as well as updating the IRAS e-learning tool to reflect the latest functionality updates to IRAS.

Audit of clinical trial registration

An audit has been undertaken of registration of clinical trials to assess compliance with the condition of the REC favourable opinion for registration. The report has been presented to the HRA's transparency forum and there are plans for members of the forum to publish a paper on the findings in a relevant journal.

External collaboration and engagement

Engagement with the NHS has focussed on supporting implementation of the new Policy Framework for health and care research, drawing attention to new areas of focus such as proportionality.
Collaboration with NHS Digital continues, to support better alignment of processes and standards for applicants seeking data from NHS Digital. Recent discussions have focussed on facilitating appropriate use of data linkage for research.

The Collaboration and Development team is supporting two initiatives led by Cancer Research UK. Most noteworthy is discussion with methodologists and researchers in the ECMC network, the MHRA, and CRN to firmly establish regulatory parameters around adaptive trials involving IMPs, and to develop a set of common definitions in these studies, using cancer as an example disease group where such studies are common. Overlapping with SIP work packages on proportionality and 'getting it right first time', HRA can examine wider implications, and facilitate obvious implications and benefits for CRN and the researchers themselves.

Communications

Interviews were held on Friday 17th November for the new Head of Communications and we are pleased to say that the post was offered, and has been verbally accepted, by the successful candidate. Formalities are currently being concluded and we hope to be able to announce a start date within the next week.

Research Systems

IRAS V 5,6 was released on 18 October and featured the new multi file upload function, great for the applicants as it will save them lots of time uploading documents. It also included updates to prison establishments within the HMPPS form. There will also be a TOPS (The Over-Volunteering Prevention Service) update during the evening of 20 November

The HRA is being held up as an excellent example of how to go about adopting the Crown Hosting framework for outsourced infrastructure support and a case study has been produced collaboratively between HRA, DH, Crown Hosting and Vysiion as a way of attracting other public sector organisations to these facilities which offer quality as well as cost savings

HARP V 2,14 was released on Sept 27 and included a number of email templates and changes to MI reports, also combining the HRA Assessment and REC records

Research Systems Programme - specific points of note;

- Continued link with EMA and MHRA for EU Portal aspects of CTR

- Pending the outcome of the Business Case for additional resources to support EU CTR and additional UK improvements, Gaynor Collins-Punter facilitated a workshop on 2 November to start analysing business requirements. The Research Systems team is also taking steps to get into a state of readiness in planning some high level milestones on necessary activities that need action in advance of any procurement starting.

Public Involvement

The next stage in the PIER programme is to pilot interim guidance for applicants on how to record information about public involvement in IRAS. This guidance should help researchers improve their applications by making the information on how the public have contributed to the design of studies more relevant to the issues that RECs are concerned about.

Off the back of the pilot, the effectiveness of this guidance will be reviewed with RECs and applicants/public contributors (whoever fills in the form using the new guidance). The results of the pilot and impact of the new guidance will support the development of the new info requirements/guidance in IRAS and website and the support and resources on PI for applicants/RECs.

HR

The staff survey is currently live and closes on the 4th December. The topline report will be available around two weeks after that date.

It's good to report that appraisal rates currently stand at 97% (this was a targeted objective as a result of last year's survey which indicated that only around 70% of staff had had one).

	Programme Management Office The PMO continues to focus on the definition and collaborative development of an HRA Portfolio framework and approach to Benefits Management and Realisation to integrate with the business strategic aims planning exercise, portfolio, programme and project management. A PMO QA service process is currently being rolled out initially for SIP. A Resource Management project is currently being initiated and managed by the PMO and a resource scheduling and management process definition workshop will be held shortly. The PMO is collaborating with Staff Learning and Development, developing and delivering lunchtime sessions on specific topics (PMO, Project Management, Prince2, Governance, Initiation and Managing Successful Programmes). These sessions are currently underway with visits to all offices scheduled in October/November **Joint Chairs Day/Policy Event** A policy day is organised for 24th November. The venue is De Vere Grand Connaught Rooms near Covent Garden. On the day we will be covering: • Proportionality – parameters work • Ethical issues with AI as a health care research intervention • GDPR • The Policy Framework • Proportionate GCP **Joint HRA/HTA Public dialogue on tissue and data sharing** MORI is producing a draft report for December 2017. The Oversight Group will meet in January 2018 to approve the final draft. NB. Amanda Hunn will deliver a joint presentation of early findings with Chris Birkett at the Policy event on 24th November. **UK Policy Framework for Health and Social Care Research** The Policy Framework has been very well received and feedback since its publication last month has been overwhelmingly positive. It is the most viewed page on the HRA web site after the home page, getting even more hits than the search page. We will continue to collect comments and queries and develop FAQs where appropriate in light of these.	
8.	**HRA Assessment Performance Report** CC presented the latest performance report highlighting that HRA Approval is operating very much as business as usual with the assessment and assurance team well established and an integral part of the HRA.	

	CC advised commercial training visits, which were conducted last year, have been repeated this year. The feedback from these visits has moved from a focus on the HRA and understanding the changes, to how sites are engaging with the process. The Board was pleased by the metrics highlighted in the report, notably figure five which showed the decrease and stabilisation of total number of amendments open at the end of the month from the roll out to September 2017. The Board noted the different structures in place in the devolved administrations however was assured the working relationships with colleagues in the other countries was very good with Mary Cubitt's role as Programme Implementation Manager - 4 Nations NHS/HSC Compatibility and HRA Approval extended. The Board discussed the potential for greater proportionality in relation to amendments and whether this could be further defined to remove administrative amendments as opposed to aspects requiring approval. The Board discussed the importance of messaging to sites to remove any unnecessary duplication. The Board agreed sites should be clear that they can rely on the HRA to fulfil its duties and can therefore focus on their responsibilities. The Board agreed it would be helpful to have two or three key lines with any relevant statistics to support this message and if there are any further things the HRA can do to help this process it should be considered. ***Action: CC to draft a few key lines to support removal of duplication at site level*** The Board expressed its thanks to Chris and the team for the work undertaken.	**CC**
9.	**Service Improvement Programme update** The Board received and noted the latest SIP update. The Board agreed the format of the update was much improved and highlighted the key issues clearly. The Board queried if any particular challenges had been highlighted however noted the challenge is likely to come when roll out takes place. IC confirmed staff are extremely enthusiastic with individuals keen to be involved. The Board was pleased to hear the bottom up approach appeared to be working with good input from staff received. The Board agreed the communications regarding projects which are not being taken forward at this stage, due to the SIP business case not receiving funding, will be important. The Board however noted the areas being postponed largely related to technological improvements with the manual process to continue in the meantime therefore this would be maintained going forward.	
10.	**HRA Performance Report Quarter 2 2017/18** The Board received and noted the HRA performance report for Quarter 2	

	2017/18. The Board agreed the format of the report was clear and helpful. KW highlighted the project section of the report provided opportunity to focus on some of the highlights over the last quarter. In relation to the new HRA website project, the Board noted the bounce rate appeared relatively high. KW advised there had been specific high traffic volume to the new UK Policy Framework for Health and Social Care Research document which may explain why the bounce rate was particularly high. The Board noted the KPIs for HRA Approval had shown marked improvement from previous reports except for Non-REC studies. The Board agreed it would be helpful to have clear messaging demonstrating that this issue is being picked up and resolved. The Board noted the performance in relation to Proportion Review applications had decreased since the time limit for review had increased from 14 to 21 days. The Board agreed it would be helpful to have additional text added to the report to clarify the reason for this metric being missed and noted it may be appropriate to show the average number of days to review the study as opposed to a percentage.	
11.	**HRA Corporate Risk Register Quarter 2 2017/18** The Board reviewed the Quarter 2 risk register for 2017/18. The Board noted the Audit and Risk Committee had commented at its last meeting regarding the lack of change in impact score on the register over previous quarters and expected to see movement in future quarters.	
12.	**Audit and Risk Committee meeting summary (2017.11.01)** The Board received and noted the summary from the latest Audit and Risk Committee meeting. The Board noted a deep dive discussion had taken place with regard to social care research with colleagues from King's College London joining to support the discussion. The Board noted the social care risk had been on the HRA corporate risk register for a long time and there are still a number of unknowns which require further exploration. The Board noted the Audit and Risk Committee was reassured that there is ethical review taking place by a number of organisations, including the HRA, and that ethical review is required for funding to be received and publication in journals to take place. The discussion however also reinforced the concern that this is a complex area with a number of areas which remain unclear and require further investigation. The Board noted the impact and likelihood risk score would likely decrease for this risk however it still posed a considerable risk to the organisation and should be added as a substantive item to a future Board agenda. The Board agreed it would be helpful to understand the assurances in place by other organisations. The Board noted JMo and TA are due to meet with the President of ADASS next	

	week. ***Action: ST to add Social Care Research to a future Board agenda***	**ST**
	The Board noted a discussion regarding the HRA's volunteer membership had also taken place at the meeting. The Committee was assured there are mechanisms in place to engage with members and seek feedback however felt this could still be improved. The Board agreed the volunteer members played a crucial role for the organisation and were highly valued and this should be demonstrated more. The Board noted the Corporate SIP would be looking at the way the HRA supports its members further including looking at recruitment, expenses and Chair honorarium processes. The Board agreed the website could make better reference to the work the volunteer members undertake and it may be appropriate to seek quotes or feedback from members to make this more personal and understand the member's perspective more.	
13.	**Annual report summary for RECs in England 2016/17** AT presented the summary report for 2016/17. The Board noted the ongoing concern in relation to recruiting sufficient expert, in particular clinical, members. AT advised work to improve the recruitment material has taken place with more targeted advertisement being undertaken. AT flagged an advert in the BMJ would be issued this month and wider organisations were being targeted for members. The Board discussed the underlying issue of clinicians not being released to participate in voluntary work. The Board noted a letter from the General Medical Council (GMC) with signatories including Dame Professor Sally Davies had been issued a number of years ago and agreed a more recent statement or letter may be beneficial. The Board agreed it may be opportune for TA and JMo to discuss with Professor Stephen Powis at their upcoming meeting. ***Action: TA / JMo to discuss volunteer role with Stephen Powis***	**TA/JMo**
	The Board agreed there may be other organisations, such as leadership development companies, which may be worth targeting. The Board noted the proportion of favourable, provisional and unfavourable decisions varied between offices and agreed it would be helpful to have a brief detailing the reasons behind the apparent variations. ***Action: AT to provide brief and assurance regarding varying decisions between centres***	**AT**
	The Board agreed it would be beneficial to have a short slide deck available regarding RECs; for both public and researcher facing communications. ***Action: AT to consider presentation regarding RECs for NED use***	**AT**
	The Board approved the report for publication on the HRA website. The Board congratulated AT and staff and members for their hard work this year. The Board also recognised the work conducted by Sheila Oliver and Joan Kirkbride over the last year prior to their retirements.	

14.	**Appeals report 2016/17** The Board noted the report for information. The Board was reassured by the low number of appeals made over the last year.	
15.	**Breaches report 2016/17** The Board noted the report for information. The Board noted breaches in relation to recruitment and informed consent were the highest occurring breach over the last three years and questioned if there was any further training or guidance the HRA could provide to organisations to reduce future occurrences. ***Action: AT and Catherine Blewett to consider reasons for recruitment breaches and any relevant learning, guidance or training which can be applied***	**AT/CB**
16.	**Out of session business conducted** None to note.	
17.	**Any other business** None to note	
18.	**Questions from the public** None to note	
19.	**Date of next meeting** 17 January 2018, London HRA Centre	