

Management in Confidence

HRA Board meeting minutes (Part 1 – Public Session)

Date:	16 September 2020	
Time:	10.30am – 12.55pm	
Present:		
	Teresa Allen (TA)	Chief Executive
	Ian Cook (IC)	Director of Transformation & Corporate Services
	Richard Cooper (RC)	Non-Executive Director
	Graham Clarke (GC)	Non-Executive Director
	Professor Andrew George (AG)	Non-Executive Director
	Dr Nicole Mather (NM)	Non-Executive Director
	Dr Janet Messer (JM)	Director of Approvals Service
	Juliet Tizzard (JT)	Director of Policy
	Professor Sir Terence Stephenson (TS)	Chair
	Karen Williams (KW)	Deputy Chief Executive & Director of Finance
In attendance:	Dr Tony Calland (TC)	CAG Chair
	Teagan Allen (TAI)	Staff Forum Representative
	Natasha Dunkley (ND)	Head of Confidentiality Advice Service
	Jonathan Fennelly-Barnwell (JFB)	Deputy Director Approvals Service
	Penelope Gregory (PG)	PA to Deputy Chief Executive
	Katherine Guerin (KG)	Deputy Director Corporate Services
	Stephen Tebbutt (ST)	Head of Corporate Governance & Risk
	Matt Westmore (MW)	Wessex Institute
	Helen Nolan (HN)	Wessex Institute
Observers:	Eve Hart (EH)	HRA
	Catherine McCarthy (CM)	HRA
	Naho Yamazaki (NY)	HRA
	Alison Barbuti (AB)	HRA
	Will Griffiths Stent (WS)	HRA
Apologies:	Mary Cubitt (MC)	Research Systems Programme Director
Venue:	Zoom	

No.	Record of discussion	Action owner
1	Welcome, introduction and apologies TS welcomed everyone to the meeting. No apologies were noted.	
2	Conflicts of interest There were no conflicts of interest.	

Management in Confidence

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3	<p>Review of minutes from meeting held on 15 July 2020</p> <p>The Board reviewed and accepted the minutes of the previous meeting as a true and accurate record of events with the following correction.</p> <p>Conflicts of Interest: GC advised he had been appointed to the Department of Health & Social Care led Therapeutics Taskforce.</p>	
4	<p>Review of actions from previous meeting / matters arising</p> <p>There were no matters arising.</p>	
5	<p>Update from Chair</p> <p>TS advised since the last Board meeting, he had received much praise regarding the work currently being undertaken by the HRA and the organisation as a whole.</p>	
6	<p>Update from the Chief Executive</p> <p>The Board received and noted the update from TA.</p> <p>TA advised many of the fast track studies currently being submitted are 'less urgent' than at the beginning of the pandemic and therefore less applications are being processed through the 72 hour time frame. TA confirmed turnaround times for Covid-19 applications are clearly stated on the HRA website.</p> <p>TA and TS acknowledged the extensive work which has been undertaken in relation to the spending review and expressed thanks to all concerned.</p>	
7	<p>Board Effectiveness – review of action plan</p> <p>The Board received and noted the Board Effectiveness review of action plan 2020. The Board noted a number of recommendations from the review are already captured within programmes and the business plan for 2020/21.</p> <p><u>A representative of the Staff forum to be formally invited to future Board meetings.</u></p> <p>TS formally welcomed TAI, Staff Forum Representative to the Board meeting. A representative of the Staff Forum will attend all future HRA Board meetings. RC advised Staff Forum Members are welcome to reach out to the Non-Executive Directors in a confidential manner at any time.</p> <p><u>NED lead for Equality, Diversity and Inclusion group to be identified</u></p> <p>RC confirmed as NED lead for Equality, Diversion and Inclusion group.</p> <p><u>Invite individual teams / leads to Board meetings to provide feedback at each meeting instead of written Directorate update</u></p>	

Management in Confidence

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	<p>ST advised the directorate update has been removed from the Board agenda. ST confirmed directorate teams will be asked to attend the Board to present items on a regular basis.</p> <p><u>Board discussion to be held to consider further what culture across the HRA is desired. To include consideration and timing of new Chief Executive</u> TS stated 'organisational change' in this context was not a criticism of staff. The discussion regarding HRA culture would reflect on the need for improvements to current processes The Board agreed it would be beneficial to await the appointment of the new Chief Executive before undertaking a Board seminar to look at the culture of the HRA.</p> <p><u>Potential for Human Tissues Authority / Human Fertilisation & Embryology Authority (HFEA) / HRA sharing of Board / NED resource / observation / development opportunities</u> TA confirmed action currently in progress.</p> <p><u>BAME representation at HRA Board</u> The Board acknowledged there is currently no BAME representation at the HRA Board. The Board noted recruitment for new Chief Executive and Non-Executive Director is in progress but agreed it would be beneficial to investigate other avenues to ensure BAME representation at HRA Board. Action: IC to provide options to TS/TA The Board agreed to elevate BAME Board representation to a strategic risk. Action: ST to add to Strategic Risk Register.</p> <p>The Board agreed ST to formally thank AC for assistance with the Board Effectiveness Review. Action: ST to contact AC.</p>	
8	<p>Performance report – 2020/21</p> <p>The Board received and noted the Strategic performance report: April-July 2020 and the Finance report - for the 4 months ended 31 July 2020.</p> <p>JT provided feedback regarding the Research Review Programme stating the scoping has been completed, programme manager vacancy advertised, and the procurement of external supplier is underway.</p> <p>The Board reviewed performance noting the target for standard clinical trials of investigational medicinal products (CTIMPs) to be reviewed within 60 days (where a statutory timeline is applicable) is 100%. The Board noted this target had not been achieved from April to July 2020 and requested more information as to why this was. JM stated there had been some issues with respect to staff sickness, completion of minutes/issuing of letters and also REC member capacity in relation to reviewing responses. AG enquired how many additional days were applications reviewed outside the 60 day timeline taking. JM stated she did not have these figures to hand but would provide the data after the meeting. Action: JM to provide further data re CTIMPs reviewed outside 60 day target, to include information re number of days for review to be completed.</p>	JM

Management in Confidence

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9	<p>Confidentiality Advisory Group caseload update</p> <p>The Board received and noted the update on Confidentiality Advice Team caseload which provided information on how this has been managed, how the team are moving forward and looking ahead to the impact of cross-agency exit strategies for expiry of the Control of Patient Information (COPI) Notice.</p> <p>The Board welcomed Natasha Dunkley, Head of Confidentiality Advice Service to the meeting. ND expressed thanks to Paul Mills, Confidentiality Advice Service Manager for preparing the report. ND confirmed to the Board the team now has a full complement of staff and historical issues and backlog have been closed.</p> <p>The Board noted applicants who had experienced delays were contacted by members of the Confidentiality Advice Team and queried what feedback had been received. ND responded that many applicants had been understanding of the situation and no direct concerns had been received by the team.</p> <p>TS questioned had it not been for a colleague raising a concern, whether the CAG backlog would have come to light and what measures have been put in place to prevent this happening again. JM responded the directorate was aware the team was understaffed however did not know the extent of the backlog due to a lack of automated process and being reliant on staff numbers. JM confirmed directorate management was in the process of addressing the situation when TS alerted them of the concern. JFB expressed thanks to Paul Mills on key systems within the team which have now been implemented. TA acknowledged there were no standard operating procedures for CAG and an information technology solution had not been available to CAG to enable efficient tracking however a manual process has now been implemented to address this. After further discussion, the Board agreed on the importance of early warning mechanisms being in place to identify any issues, particularly in relation to smaller teams.</p> <p>TC expressed thanks to the Board for the investment which has been critical to getting back on track and also to the CAG team for their hard work. TC updated the Board on additional subgroup meetings which CAG are undertaking to assist with amendments and the COPI notice. New members to CAG are being recruited and many of the existing committee members have elected to continue their membership with CAG. The Board noted there was a risk, potentially of an influx of applications at the end of the COPI notice which could impact on future workload.</p> <p>TC advised the vast majority of applications under COPI have been fine however there does appear to be a small number of applications who have previously been refused on more than one occasion but have subsequently resubmitted under COPI.</p> <p style="text-align: center;">Action: KW to investigate further ascertain if there had been any fraudulent activity from the researcher</p>	KW

Management in Confidence

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	<p>The Board agreed it would be helpful if the table on page 2 of the report could be included in future performance reports.</p>	
10	<p>Proportionate review of research for educational purposes</p> <p>The Board welcomed Matt Westmore and Helen Nolan to the meeting.</p> <p>The Board received and noted the paper Proportionate review of research for educational purposes submitted by Matt Westmore, Helen Nolan and Katie Meadmore (Wessex Institute), with input from Janet Messer, Teresa Allen and Juliet Tizzard (HRA). The Board noted the paper presents recommendations for the HRA Board to consider in relation to when/if the embargo on approvals for research for educational purposes is lifted and what it is replaced by. The recommendations were developed following cross-sector stakeholder engagement.</p> <p>MW introduced and explained the background to the paper and summarised their recommendations to the HRA Board.</p> <p>The Board discussed the paper and student research in detail, acknowledging there was often good quality student research conducted, however noted the research outcomes may be unlikely to change clinical practice. The Board considered the amount of time and resource spent by the HRA reviewing student research projects. The Board acknowledged on occasions, in relation to poorly prepared student submissions or research which could have been reviewed elsewhere (for example university ethics committees), that this was a disproportionate use of HRA time and resources (REC members and HRA staff). In addition, it was not appropriate to use the HRA as a training function.</p> <p>After discussion, the Board was in favour of supporting <i>Option A: Proportionate eligibility across health and care students</i> however agreed a final decision could not be made today as there was uncertainty on the outcome of the spending review and how resources may be allocated. The Board agreed a further paper should be submitted to the HRA Board in March or May 2021 when a final decision would be made. In the interim, the Board agreed to continue with the current embargo on reviewing applications for individual undergraduate and master's student projects until 31 August 2021.</p> <p>The Board acknowledged consideration must be given to course organisers and universities and providing sufficient notice of this change. JM confirmed further discussions will take place with the devolved administrations as it had been agreed at the start of this work that a UK wide approach would be taken.</p> <p>The Board thanked Matt Westmore and Helen Nolan for their helpful and informative paper.</p>	
11	<p>Strategic risk register</p> <p>The Board received and noted the HRA Strategic Risk Register. The Board noted the register was reviewed at the August 2020 Audit & Risk Committee.</p>	

Management in Confidence

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	<p>The Board accepted the risks detailed on the strategic register and was satisfied the risk tolerance levels were appropriate. In future, the Board will receive updates to the register in summary form as part of the regular performance report.</p>	
12	<p>Corporate risk register (Quarter 1 2020/21)</p> <p>The Board received and noted the risk overview summary and the detailed Corporate Risk Register for Quarter 1 2020/21.</p>	
13	<p>Freedom of Information and complaints summary 2019/20</p> <p>The Board received and noted the FOI & Complaints summary 2019/20 which provides an overview of Freedom of Information requests, Data Subject Right Requests, Parliamentary Questions, complaints, third party concerns and compliments received during the period 01 April 2019 – 31 March 2020.</p> <p>ST summarised the information to the Board, stating the increase in complaints in the Autumn 2019 reflects the challenges encountered whilst embedding the new ways of working within the Approvals directorate, which correlates to the decrease in user satisfaction scores at that particular time. ST confirmed on occasions, freedom of information requests may lead to complaints which are not necessarily about the HRA but regarding a third party. Complaints raised about third parties may include concerns regarding the protocol or conduct of the sponsor. ST advised the volume of complaints in terms of output remains low and many compliments are received regarding the level of service HRA staff and volunteers provide to the research community.</p>	
14	<p>Summary of Audit & Risk Committee meeting</p> <p>The Board received and noted the summary from the Audit & Risk Committee meeting held on 11 August 2020.</p> <p>The Board noted an assurance mapping exercise had been conducted to consider the quality and consistency of REC decision making. The findings were largely positive with three recommendations identified to further strengthen this area (one relating to the Shared Ethical Debate (ShED) process which is in the process of being relaunched, one relating to the reintroduction of Quality Control meeting observations, and the third relating to the better use of decision data at regional REC Chair meetings. The Board noted the Audit and Risk Committee was satisfied the level of assurance in place was appropriate for the likelihood and impact of the possible risks.</p> <p>The Board noted the Audit and Risk Committee received the Information Governance and Security Annual Report 2019/20 which provided an assessment of information governance and data protection in the HRA, outlining progress made throughout the year and providing relevant assurances.</p> <p>TS expressed thanks to RC who has agreed to become the Chair of the Audit and Risk Committee in 2021.</p>	

Management in Confidence

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15	Out of session items None to note.	
16	Any other business / agenda items for next meeting None to note.	
17	Questions from members of the public None to note.	
18	Date of next meeting: 18 November 2020	