

**HEALTH RESEARCH AUTHORITY
BOARD MEETING**

**Minutes of the Health Research Authority (HRA) Board meeting, held on 29th
October 2014 from 1.15pm in HRA 1 Skipton House and Manchester HRA
Centre via videoconference**

Present		Initials
<i>HRA Non-Executive and Executive Directors</i>		
Sally Cheshire	Non-Executive Director	SC
Debbie Corrigan	Director of Finance	DC
Shaun Griffin	Executive Director of Communications, Engagement and Partnerships	SG
Allison Jaynes-Ellis	Non-Executive Director	AJE
Jonathan Montgomery	Chair	JMo
Julie Stone	Non-Executive Director	JS
Janet Wisely	Chief Executive	JW
<i>HRA Directors who attend the Board</i>		
Ian Cook	Director Corporate Services	IC
Joan Kirkbride	Director of Operations and Approval	JK
Janet Messer	Director of Systems and Development / Programme Director – HRA Approval	JMe
In attendance		
Stephen Robinson	Corporate Secretary <i>(in part – items 9 - 13)</i>	SR
Stephen Tebbutt	HRA, Board Secretary and CE Business Manager	ST
Observer		
Christine Holmes	DH Sponsor team <i>(in part – items 8 – 13)</i>	CH
Helen Penistone	REC Manager	HP
Item	Item details	Action
1.	Apologies Tom Smith, Director of Quality, Standards and Information Hugh Davies, HRA Ethics Advisor	
2.	Conflicts of interest None to note.	
3.	Minutes	

	The minutes of the previous meeting were accepted as a true and accurate record of the matters discussed without amendment.	
4.	<p>Matters arising</p> <p><u>Research Ethics Committee (REC) member diversity findings and exit reasons</u> The Board noted a report would be brought to a Board meeting in the new year. ST advised an exit questionnaire had now been introduced for departing REC members.</p>	
5.	<p>Update from Chair</p> <p><u>Meeting with George Freeman MP</u> JMo advised he was pleased to report that he had met with the HRA's new Minister, George Freeman MP, who is very enthusiastic about his new brief and particularly the opportunities that come from being a Minister in both the Department of Health (DH) and the Department for Business Innovation and Skills (BIS). He has stressed the interdependence of the NHS and economic agendas, saying that sustainable strength in each is dependent on the other.</p> <p><u>Conference presentations</u> As detailed at the last meeting, JMo presented at a conference in Plymouth and to the Academy of Medical Sciences (AMS) (the latter with JW). At both, progress on HRA Approval was acknowledged and welcomed. Other presentations at Plymouth highlighted a range of issues about regulatory complexity, but not with ethics approvals. Fellows of the Academy welcomed progress and raised a number of specific issues and JW is following these up.</p> <p>Presentations on the HRA work scheduled between now and the November Board meeting include the launch of University College London's (UCL) Clinical Research Governance Committee on 10 November, the National Ethics Committees Forum of the EU (on transparency work) on 18 November, and a European conference on Responsible Research and Innovation on 20 November (on transparency and research integrity).</p> <p><u>NHS England's Five Year Forward Look</u> The Board noted NHS England has now published its Five Year Forward Look, which includes reference to research. Following an email discussion, prior to the launch, with Sir Malcolm Grant about a number of issues relating to NHS England's plans to support research in the NHS and at his suggestion, JMo met with Sir Bruce Keogh to pursue this. JW and JMo are due to meet him on 10 November to explore this further.</p> <p><u>Other stakeholder meetings</u> Other stakeholder meetings in the next month include the Ethical Medicines in Industry Group annual dinner and the Association of the British Pharmaceutical Industry (APBI) Patient Organisation Forum.</p> <p><u>Off-Patents Drugs Bill</u> JMo advised the second reading of the Off-Patents Drugs Bill is scheduled for 7 November, sponsored by Jonathan Evans MP. This Bill is aimed at securing</p>	

	<p>licences for repurposing medicines after the expiry of the original patents. It is likely that the HRA will be named as an organisation that might apply for such licences. This may not be legally possible, and JW has written indicating that it would not feel an appropriate role. JMo advised he had met with Mr Evans to discuss the issues.</p> <p>The Board noted the objective of the bill is consistent with the aspirations of the HRA in a number of respects. It addresses legal barriers that make it difficult for the NHS to gather and use research data to answer questions of clinical significance. It also seeks to ensure that we maximise the value of the contributions of research participants. JMo advised he had indicated that he is supportive of the general intent and would be happy to work to seek more practical solutions if the Bill progresses.</p> <p><u>New HRA Board</u></p> <p>During the past few weeks, recruitment has been open for the Non-Executive Director (NED) positions on the Non-Departmental Public Body (NDPB) Board. The closing date was last week. JMo advised a large number of applications were received, currently under review for shortlisting, with interviews scheduled for 7 and 14 November. JMo advised on initial review, there seems to be a good field and he was grateful to the search consultants, Russell Reynolds, for their work in identifying potential candidates and encouraging them to apply. It is anticipated that appointments will be confirmed in time for the new Board to take office on 1 January (although the first formal meeting will be later in the month). However, it is unlikely that we will have announcements by the time of the November Board meeting.</p> <p><u>Talent Management Programme</u></p> <p>The Board seminar in September discussed our talent management programme, which has now gone live, and also the Executive Management Team's (EMT) continuing development work. JMo advised NED colleagues attended an event for the DH Arm's Length Body (ALB) sector on Talent Development and Succession Planning on 8 October. After attending this event, the Board was reassured that the work conducted in this area and the efforts of Sue Nunn, was exemplary and should be offered to other ALBs as a good working example.</p> <p><u>All staff day</u></p> <p>The Board noted the all staff day was scheduled for 13 November.</p>	
6.	<p>Update from Chief Executive</p> <p><u>Presentation and meetings held by HRA senior team</u></p> <p>The Board noted the Communication team keeps a full list of the extensive set of meetings and presentations undertaken by the HRA senior team. Over the last month, the following have taken place:</p> <ul style="list-style-type: none"> - <i>NIHR Advisory Board (September)</i> included HRA update with focus on the Approval programme - <i>Ministerial Industry Strategy Group Clinical Research Working Group (MISG CRWG) (October)</i> included HRA updates on transparency and 	

HRA Approval

- *UK Clinical Research Collaboration (UKCRC) Board (October)* included presentation from the HRA to provide an update, in particular focussing on transparency and the HRA Approval Programme.
- The HRA has also been referenced in presentations from Genomic England and the MHRA update on EU Clinical Trial Regulations. Genomics England gave particular credit to HRA for the support from HRA which included an ethics workshop and agreeing an appropriate approval pathway which includes the independent REC opinion.
- *Academy of Medical Science (October)* set up specifically for AMS fellows to hear and challenge progress on HRA Approval, a joint presentation from JW and JMo and the meeting concluded with expressed confidence in the HRA.
- *Thought-Leadership Event: The 21st Century landscape for Life Sciences (October)* A by invitation event from George Freeman MP attended by JW
- *Association of Medical Research Charities (AMRC)* – An introductory meeting has been held with the new Chief Executive, Aisling Burnand
- *HRA transparency workshop (September)* at which the responses to the call for comments were presented, and the next steps fully endorsed. All the papers and presentations are available on the HRA website.
- *HRA workshops* convened in Edinburgh and Belfast with another scheduled in Cardiff, to provide an update and an opportunity to discuss how we will maintain UK compatibility as we implement HRA Approval. Presentations were received from JW, Wendy Fisher and country hosts.

Confidentiality Advisory Group (CAG)

CAG Standard Operating Procedures (SOPs) have been agreed by the HRA Operational Management Group (in line with delegated responsibility from the United Kingdom Ethics Committee Authority (UKECA) for REC SOPs). Adoption will require a review of the previously agreed terms of reference for CAG which, ahead of formal SOPs, covered operational activities that are now provided for in SOPs. The revised terms of reference for CAG will be notified to the Board. The CAG SOPs will be published shortly.

Collaboration and Development Forum

The Board noted the forum (under revised terms of reference and focus as a forum from the previously named steering group) continues to meet regularly as an information and discussion forum for key stakeholders.

Business planning and annual report

The Board noted the format would be the same as last year with a first draft to be provided to the DH sponsor team by mid-December. JW advised SR will lead this work.

	<p>JW flagged the HRA will need an annual report and accounts for the period through to close of the Special Health Authority (01 April 2014 – 31 December 2014). Part year accounts will not be required for the new NDPB as the January 2015 – March 2015 accounts will be included in 2015-2016 annual report. The HRA public facing annual review, as a non-statutory document, will cover the normal reporting period through to end March 2015.</p> <p><u>Technical talent management programme</u> The Board noted this was formally launched last week.</p> <p><u>Consent for simple trials consultation</u> The Board noted this consultation is currently active with more information available at http://www.hra.nhs.uk/about-the-hra/consultations-calls/consent-simple-trials/</p> <p><u>Guidance on participant information at the end of a study</u> The Board noted the comment period had now closed with the vast majority of responses supportive of the revised guidance which will be introduced shortly.</p>	
7.	<p>Key Performance Indicator report Quarter 2</p> <p>The Board received and approved the Key Performance Indicator (KPI) report for quarter 2.</p> <p>The Board noted the improvements in precedent set review applications being reviewed within timescale by CAG. The Board noted there had been an improvement in the processing of CAG amendments however agreed further work is required for a continued increase.</p> <p>The Board noted there had been an increase in long term sickness rates. The Executive Management Team however provided reassurance to the Board that the occurrences were genuine with no cause for concern.</p> <p>The Board was pleased with the KPIs relating to Research Ethics Committees (RECs) and offered its thanks to staff for their continued hard work. JK flagged there was an increase in REC applications being reviewed by proportionate review. The cause for this required further investigation but may have been due to the introduction of the new central booking system. The Board noted there were some capacity issues due to this increase however the Operations directorate was in the process of addressing this issue. JK advised further additions would be made shortly to the No Material Ethical Issues Tool (NMEIT) which distinguishes which applications are suitable for proportionate review. This would likely lead to a further increase in studies reviewed this way.</p>	
8.	<p>Gateway review</p> <p>JW advised the Gateway Review had been very useful in providing assurance regarding the HRA Approval Programme and the recommendations made were acceptable and sensible. An amber rating had been given which seemed appropriate with the programme still achievable however requiring substantial</p>	

	<p>attention from senior management. The Board noted minor corrections had been made to the initial version of the report received from the review team which related to points of accuracy and clarification.</p> <p>The Board noted the recommendations were as follows:</p> <ol style="list-style-type: none"> 1. To ensure a Stakeholder Analysis is carried out to strengthen stakeholder management and the Communications Strategy. 2. To ensure that a detailed Programme Plan is developed as soon as possible, with dependencies, milestones and critical path in order to demonstrate that delivery to the timescale required is achievable. 3. To develop a comprehensive HR Plan. 4. To review the proposed approach on developing the IS proposals, their impact on the critical path and the robustness of the potential for alternative solutions in order to provide assurance that the proposals will meet requirements. 5. To develop a Transition Plan to take the Programme into mainstream business as usual for the HRA. 6. To develop and agree a Benefits Realisation Plan with appropriate metrics by which to evaluate success. <p>The Board noted recommendations 2,3,4,6 were not a surprise and aligned with the priorities HRA had already identified. Recommendation 5 was something that had already been considered, but the HRA now accepted that there was a need to formalise thinking in this area. Recommendation 1, upon reflection, highlighted that communications for HRA Approval required further consideration with plans in place for additional resource in JMe's team to provide greater supporting documentation and information regarding HRA Approval.</p> <p>The Board noted the Programme plan was scheduled to be reviewed at the November Programme Board meeting and should therefore be added to the November Board meeting agenda for information.</p> <p>The Board noted a transition plan to business as usual could not be undertaken yet however should be worked into the plan to ensure the transition is as seamless as possible.</p> <p>The Board agreed the next Gateway review should be schedule for March 2015 unless a more natural time is identified during the planning process.</p>	
<p>9.</p>	<p>Estates strategy</p> <p>The Board reviewed the estates strategy and noted it was in line with government strategy and would provide immediate savings. The Board approved the strategy.</p>	

10.	<p>Finance report September 2014</p> <p>The Board received and approved the finance report for September 2014.</p>	
11.	<p>National Information Board strategy</p> <p>SR advised high level Board support from ALB organisation was being sought for the National Information Board strategy. The latest version of the strategy would be circulated out of session and the Board agreed to send any comments to SR. Subject to any additional out of session comments, the Board agreed the strategy was consistent with the interests of the HRA and high level support could be offered. The Board noted a number of detailed issues were still to be worked through and looked forward to receiving sight of any implementation plans.</p>	
12.	<p>Any other business</p> <p><u>Transition to NDPB status</u> The Board agreed it would be helpful to have an update on the transition to NDPB at the next Board meeting.</p> <p><i>Action: SR to provide NDPB status update at November Board</i></p>	SR
13.	<p>Date of next meeting:</p> <p>26 November 2014</p>	