

HEALTH RESEARCH AUTHORITY BOARD MEETING

Minutes of the Health Research Authority (HRA) Board meeting, held on 26 March 2014 from 1.00pm in HRA meeting room 1, Skipton House, 80 London Road, London, SE1 6LH

Part 1 – Public Session

Present		Initials
<i>HRA Non-Executive and Executive Directors</i>		
Sally Cheshire	Non-Executive Director	SC
Shaun Griffin	Executive Director of Communications, Engagement and Partnerships	SG
Allison Jeynes-Ellis	Non-Executive Director	AJE
Jonathan Montgomery	Chair	JM
Julie Stone	Non-Executive Director	JS
Janet Wisely	Chief Executive	JW
<i>HRA Directors who attend the Board</i>		
Ian Cook	Director Business Support	IC
Debbie Corrigan	Director of Finance	DC
Joan Kirkbride	Director of Operations	JK
Tom Smith	Director of Quality, Standards and Information	TS
In Attendance		
Clive Collett	HRA Ethics Guidance and Strategy Manager (<i>in part – item – 11</i>)	CC
Jim Elliott	Public Involvement Lead (<i>in part – item 12</i>)	JE
Andrew George	NREAP Chair (<i>in part – item – 11</i>)	AG
Stephen Tebbutt	Board Secretary and Chief Executive Business Manager	ST
Item	Item details	Action
1.	Apologies Hugh Davies, HRA Ethics Advisor	
2.	Conflicts of Interest None to note	
3.	Minutes of the last meeting <u>The Board agreed the minutes were a true and accurate record of the matters discussed with the following amendment:</u> <ul style="list-style-type: none"> The Board agreed the minutes should make clear the process followed to 	

	ratify the decisions made at the last meeting as the meeting had been inquorate.	
4.	<p>Matters arising</p> <p><u>Shared services</u> The Board noted delegated approval had been given to JM at the last meeting concerning the decision regarding the potential shared service migration to arvato. The Board noted there had been a delay to this work and a decision had not been made as yet. The Board agreed to withdraw the delegated approval and await further information.</p> <p><u>IT Services</u> The Board noted TS had reviewed the VIP service offered by ATOS.TS advised however that this was not a suitable option for the HRA.</p> <p>The Board noted approval was anticipated shortly regarding the decision to proceed with separate back-up IT provision at all HRA centres except Skipton House.</p> <p><u>HARP go-live date</u> The Board noted there was the potential for the HARP go live date to be delayed by three weeks.</p> <p><u>London REC office consultation</u> The Board noted the consultation process had now ended with all staff appointments made.</p>	
5.	<p>Update from Chair</p> <p><u>General Medical Council (GMC) news item</u> The Board noted the HRA had met with the GMC to agree text for a news item, concerning research and how it can be supported, which would likely be disseminated in the near future.</p>	
6.	<p>Update from Chief Executive</p> <p><u>HRA Assessment and Approval Business Case</u> The Board noted Earl Howe had announced in the House of Lords that a decision regarding the HRA Assessment and Approval Business Case was expected shortly.</p> <p><u>Research Governance Framework work</u> The Board noted the comment period for the first project of this programme of work had begun. The comment period is taking place in England and also separately in the devolved administrations.</p> <p><u>Sciencewise funding</u> The Board noted a two page concept paper regarding the exploration of public understanding of using patient data, identification and consent in health research had been submitted to Sciencewise. If Sciencewise support this proposal, a full business case will be developed and EMT and Board approval to proceed will be</p>	

	<p>required.</p> <p><u>Ethics Officer pilot</u></p> <p>The Board noted valuable learning points had been identified from the pilot which would feed into future work. An independent review, led by Professor Mary Dixon Wood, of the data collected would be undertaken as the working group agreed there were considerable learning points which could be made. The independent review will be presented back to the HRA for consideration and comment in the autumn.</p>	
7.	<p>HRA Business Plan 2014-15 sign off</p> <p>The Board noted a section on Key Performance Indicators had been added to the plan and found this information reassuring. The Board agreed it was positive to see how much the HRA has progressed since it was established.</p> <p>The Board noted the business plan currently contained paragraphs highlighting different scenarios dependent on the HRA Assessment and Approval business case decision. The Board noted these would be removed from the final version once a decision on the business case is made.</p> <p><u>The Board approved the HRA Business Plan 2014/15.</u></p>	
8.	<p>Transparency update</p> <p>The Board noted the HRA had recently held a workshop on transparency. The workshop considered standards for publication, REC declaration requirements and ways to influence the publication of earlier trials.</p> <p>The Board noted the sponsor declaration page on the REC application form could be updated to seek confirmation from the sponsor that all previous studies sponsored by them have been registered. The REC could check this before issuing a favourable opinion for any new research conducted by the sponsor. The Board agreed if this was to take place there should be a consultation period and a long lead-in time to allow sufficient time for compliance.</p> <p>The Board noted the transparency proposals had been relatively well received by the Phase 1 group. The Board noted the Phase 1 group had greater concern regarding the extension to the approval timelines as per the proposal in the Clinical Trial Regulations. The Board noted JW had confirmed the HRA will maintain the current review timelines to the group. The Board agreed the timelines for approval of phase 1 research in the UK were relatively fast and it would be a positive message to disseminate to journals and contract research organisations.</p> <p>The Board noted at the last meeting there were a small number of Phase 1 studies which had deferred registration and noted these would be audited in the future to check if the study had subsequently been registered.</p> <p>The Board noted a call had gone out from the Medical Research Council for organisations to bid to create a register to detail what is held in research tissue</p>	

	<p>banks.</p> <p>The Board was pleased to the note the transparency agenda update and looked forward to receiving further updates in the future.</p>	
9.	<p>Scheme of financial delegation</p> <p>DC presented the scheme to the Board and advised that the main change to the previous version of the scheme related to an increase to the upper financial limits. DC advised this was as per guidance received from the Secretary of State and in line with practices of other Arm's Length Bodies.</p> <p>The Board agreed the scheme should make reference to the fact that relevant approvals would be required from the HRA Board and HRA pay and remuneration committee before anything is presented to the DH remcom or sponsor for approval.</p> <p><u>The Board approved the scheme of financial delegation.</u></p>	
10.	<p>Call for examples of good practice in identifying patients in health research – Summary of responses</p> <p>The Board noted this was a factual document however identified a number of areas which required further follow up. Work will take place with others to consider the issues and recommendations will be brought to the May Board meeting for discussion.</p>	
11.	<p>Update from the National Research Ethics Advisors Panel (NREAP)</p> <p><i>CC and AG attended for this item</i></p> <p>The Board thanked CC and AG for attending. CC and AG updated the Board on the business conducted by the NREAP over the last year.</p>	
12.	<p>Public Involvement Action Plan 2014/15</p> <p><i>JE attended for this item.</i></p> <p>The Board thanked JE for attending and giving a presentation.</p> <p>The Board noted objective three of the action plan; to develop the role of the HRA with its partners to support the spread of public involvement in health research with a view to this becoming the rule and not the exception, would be a cultural change for researchers. For any change to work the Board agreed a long lead-in time would be required to ensure ethical approval is not seen as a barrier to research.</p> <p>The Board noted the global context of patient and public involvement and the difference between countries and agreed this needs to be carefully considered.</p> <p>The Board agreed examples of instances when patient and public involvement in</p>	

	<p>research design had been beneficial, such as improving patient outcomes, would be useful.</p> <p>The Board noted there were a number of groups the HRA could join, such as the Patient Information Forum and National Voices, and recommended the HRA pursue becoming members.</p> <p>The Board was pleased with the development of the plan and the work which had gone into its development, with the support from patient and public working groups and workshops.</p> <p><u>The Board approved the action plan and commended JE on the work conducted.</u></p>	
13.	<p>Out of session item to note</p> <p><u>GMC list of designated bodies</u> The Board noted a letter has been sent to the GMC requesting the removal of the HRA from the GMC list of designated bodies. <i>Action: ST to follow up with GMC to confirm removal</i></p>	ST
14.	<p>Any other business</p> <p>None to note</p>	
15.	<p>Date of next meeting</p> <p>Monday 12th May, 10.00am – 2.00pm</p>	