

**HEALTH RESEARCH AUTHORITY
BOARD MEETING**

Minutes of the Health Research Authority (HRA) Board meeting, held on 24 September 2014 from 1.30pm – 4.00pm in HRA meeting room 1, Skipton House

Part 1 – Public Session

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 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
Janet Messer	Director of Systems and Development / Programme	JMe
Tom Smith	Director – HRA Approval Director of Quality, Standards and Information	TS
In Attendance		
Sheila Oliver	Head of National Research Ethics Service (NRES)	SO
Stephen Tebbutt	Board Secretary and Chief Executive Business Manager	ST
Observer		
Simone Bayes	Deputy Director – Head of Research Standards and Support, Department of Health	SB
George Binney	Executive Coach and Organisational Consultant, Ashridge	GB
Item	Item details	Action
1.	Apologies Hugh Davies, HRA Ethics Advisor Joan Kirkbride, Director of Operations and Approval	
2.	Conflicts of interest None to note	
3.	Minutes of last meeting	

	<p>The Board agreed the minutes of the last meeting were an accurate reflection of the matters discussed with the following amendment:</p> <ul style="list-style-type: none"> - Item 12 – minor typographical error 	
4.	<p>Matters arising</p> <p><u>Research Governance Framework replacement programme of work – How to best support educational research in the NHS</u> The Board noted the report had been finalised and published on the HRA website.</p>	
5.	<p>Update from Chair</p> <p><u>Director of Systems and Development</u> The Board expressed its congratulations to JMe on her appointment as the Director of Systems and Development.</p> <p><u>Parliamentary Under Secretary of State for Life Sciences</u> The Board noted George Freeman MP had been appointed.</p> <p><u>Non Departmental Public Body (NDPB) establishment</u> The Board noted the establishment of the HRA as a Non Department Public Body is scheduled to take place on 01 January 2015.</p> <p><u>New HRA Board</u> As part of the transition to NDPB status, the HRA will formally become a new organisation with a new Board. The Board noted JM will remain the HRA's Chair with the Department of Health to recruit to the four Non-Executive Director (NED) posts from the end of September 2014.</p> <p><u>Arm's Length Bodies (ALB) Chair and NEDs' workshop on whistleblowing</u> The Board noted JM and the NEDs had recently attended this workshop. The Board agreed whistleblowing and fraud is an important subject the HRA must maintain consideration of in the future.</p> <p><u>The Academy of Medical Sciences – A discussion with the HRA</u> The Board noted JW and JM were attending this event on 15th October 2014.</p> <p><u>Plymouth Hospitals Annual Research Conference</u> The Board noted JM was a speaker at this conference on 26th September 2014.</p>	
6.	<p>Update from Chief Executive</p> <p><u>Update on recruitment</u> The Board noted Janet Messer has been appointed as the Director of Systems and Development. JW advised the selection process included a presentation to a patient panel, as agreed within the patient and public involvement strategy to include patient representatives in key decisions such as the appointment of directors. The panel specifically rated presentation skills and explored with</p>	

candidates the approach to patient involvement. This method will be evaluated and repeated for senior / other relevant posts.

The Board noted recruitment continues to progress with a number of new starters joining the HRA over the summer. One area the HRA has struggled to shortlist candidates is Information System (IS). The Board noted IC has put in place a framework to contract short term expertise which will be used as required to ensure the HRA can acquire the required support to the IS team. The Board noted the importance of recruiting to the IS team to ensure HRA Approval could progress

The Board noted the following new starters had joined since 1st August:

- Alastair Nicholson – Policy Development Lead – HRA Assessment and Approval
- Stephen Roberts – Research Regulation and Management Specialist
- Paul Mills – Research Regulation and Management Specialist
- Nathan Pipe – Business Manager to Programme Director HRA Approval
- Robert Allen – PMO Manager
- Sharon Hards – Project Officer
- Jennifer Harrison – Change Manager
- Nicola Williams – Strategic Change Management Advisor
- Mark Taylor – Project Lead – Information Governance

The Board noted the following people were due to start in the near future:

- Richard Hart – Project Lead – Systems and Information (October 2014)
- Dhimitir Celanji – Finance Manager (October 2014)
- Andrew Pennington – Regional HRA Approval Change Lead (October 2014)
- Claudio Melchiorri – Regional HRA Approval Change Lead (October 2014)
- Philippa Collins – Regional HRA Approval Change Lead (October 2014)
- Rebecca Smith – Regional HRA Approval Change Lead (October 2014)
- Samantha Jones – Regional HRA Approval Change Lead (October 2014)
- Bill Davidson – Policy Projects lead (November 2014)

Phase 1 Advisory Group

The Board noted there were discussions with the group regarding the timelines associated with the implementation of the EU Clinical Trials Regulations. JW advised the group had been assured that the HRA was aware of the need to comply with revised, shorter timelines and it is in the early stages of considering what new arrangements will be required.

Electronic Review of Papers

The Board noted electronic review of Research Ethics Committee (REC) papers was taking place at REC meetings for two RECs; one in Manchester and one in Bristol.

Regenerative Medicine meeting

JW advised the role of the Application Manager had been welcomed at a recent

meeting. The HRA, Medicines and Healthcare Products Regulatory Agency (MHRA) and Human Tissue Authority (HTA) had agreed to establish a 'one stop shop' via the MHRA Innovation office for regenerative medicine studies.

Genomics England - 100,000 Genomes project

JW advised the HRA has been working with the team undertaking this project. A small group of REC Chairs, facilitated by Hugh Davies, has been established to help advise the research team and their RECs in relation to some of the ethical issues linked to the project.

Expedited REC review for Ebola vaccine

The Board noted a vaccine for the Ebola virus disease (EVD) was recently approved at a REC using the Standard Operating Procedures (SOPs) for expedited review.

Staff forum

JW advised the staff forum meeting had been held in the Jarrow office with video conference to London and phone link to Manchester. The meeting included further discussion of the staff survey results and the move to NDPB status. The forum also agreed that the simplest way to ensure representation of new staff was to keep to a simple geographical model. The Board noted the two year terms of membership were coming up for completion for some forum members however the terms included an option to extend for a second term.

The Board noted the forum felt there should be two representatives for both London and remote workers, and the HRA should more formally appoint and recognise deputies. This will mean a process will be required to elect one new representative for London and remote workers as well as opportunities in all offices for appointment as a deputy. JW advised it was also agreed that staff should be encouraged to observe staff forum meetings and that the staff forum should work to make the role more visible across the organisation.

Transparency

The Board noted there had been a good response to the call for comments on the reporting, publication and REC declaration requirements. The HRA has agreed to proceed with the proposals to update the REC declaration. 198 direct responses were received:

- 155 positive responses from individuals
- 27 positive responses from organisations
 - Some of the above did either have some minor queries or sought that proposals should go further
- 15 responses highlighted significant largely practical concerns
- 1 response stated there was no benefit and the proposals were disproportionate

The Board noted the findings and next steps were discussed at a workshop on 18th September and a date has been set for a further workshop in February. The REC declaration will be updated in September and again in April in line with the proposals set out.

JW advised the HRA has also issued for use and comment guidance for best practice at the end of the study, including making findings accessible to participants.

The Board noted there has been specific interest from the phase 1 industry on the EU legislation and the HRA attended a recent MHRA convened meeting with Contract Research Organisation (CRO) representatives. They expressed support for the HRA approach and there was mutual recognition of the need to influence and agree what was meant by commercial confidential information as applied to transparency beyond registration fields.

HRA Approval

JW advised the gateway review was ongoing, with interviews held yesterday and the report expected to be received tomorrow. JW agreed to share with the Board and more widely once the report outcomes have been considered. JW advised the communications plan had been approved by the Programme Board. The Board noted JMe has been invited to the London Health Commission Reception following input into the London-wide proposals for research that will support the implementation of HRA Approval. The Board noted positive feedback continued to be received from stakeholders regarding the role of Application Managers with early improvements for researchers identified.

NHS England

JW advised the HRA was liaising with the CE policy team to inform NHS England 5 year forward view to gain understanding and commitment from NHS England to support HRA activity; in particular HRA Approval.

Chief Scientist Office (CSO) and HRA workshop in Edinburgh

The Board noted this was organised by the CSO and was very well attended and a positive meeting held. JW and Wendy Fisher presented with the aim to provide an overview of the HRA and its functions with a focus on HRA Approval and Transparency. JW advised the workshop concluded that the event should be repeated in a year. The Board noted similar events are planned in Wales and Northern Ireland.

Public Health England (PHE)

The Board noted PHE had been invited to join the collaboration and development forum.

Confidentiality Advisory Group (CAG)

The Board noted there was continued good progress to set out the expectations for the new remit of CAG with the following work streams agreed:

- Development of Health & Social Care Information Centre (HSCIC) policies and procedures
- CAG SOPs
- Regulations
- Resources

The Board noted there had been acknowledgement that the HRA could not develop CAG SOPs until there is a better understanding on what the role will

	<p>require in terms of advice on HSCIC policies and procedures and the individual review. JW advised there was agreement that the basis will be for HSCIC referral to CAG of edge cases where the policies and procedures do not clearly recommend a particular course of action.</p> <p><u>Public confidence in research - metrics and benefits</u></p> <p>The Board noted an initial, internal scoping meeting is due to take place on Tuesday to consider how public confidence in research can be built and measured.</p>	
7.	<p>Key Performance Indicator report Quarter 1 2014/15</p> <p>The Board noted the report. The Board agreed the new format, with gradual shading from red to green, was useful in showing the progress against particular objectives. The Board noted the statutory requirements for RECs were all on track.</p> <p>The Board agreed the narrative commentary, as used on previous versions of the report, was a useful method for providing background to some of the indicators. The Board noted more qualitative indicators were in the process of being considered.</p> <p>The Board noted measures and definitions were being worked up with regard to HRA Approval. JM advised the measures would be ready after the benefits realisation plan has been finalised which was reviewed by the Programme Board at its last meeting. JM advised the plan would likely be in a format for discussion at the next Board meeting.</p> <p>The Board noted the work to monitor the diversity of the REC member profile was underway which would give a better understanding of the volunteer community. The Board agreed an understanding of the reasons why REC members leave would be also useful.</p> <p>Action: REC member diversity findings and exit reasons to be brought to future Board meeting</p>	ST
8.	<p>Risk register</p> <p>The Board approved the risk register and noted there had been a reshuffle of risk owners due to the organisational restructure. The Board noted the new risks related to CAG and HRA Approval. JW clarified administrative resource was being identified and refocused to help support the increased workload for the CAG team.</p> <p>The Board noted the HRA Approval risks and assurance sources. The Board queried if a narrative to support the risk register would be helpful to link the risks to the overall representation of what will be delivered and show how the changes will help make the UK a great place to do research. The Board flagged the importance of understanding timelines, including those for industry.</p> <p>The Board flagged the importance of communications of for the HRA Approval Programme. SG agreed to share the communication plan with the Board which</p>	

	<p>had recently been reviewed by the Programme Board.</p> <p>Action: SG to share Communication plan for HRA Approval with Board</p>	SG
9.	<p>Finance Report July 2014</p> <p>The Board approved the finance report for July 2014 and DC presented the latest August 2014 financial position. ST agreed to circulate the August 2014 finance report, which was approved by the Executive Management Team (EMT) earlier this week, after the meeting.</p> <p>Action: ST to circulate August Finance Report</p> <p>DC advised there were no matters of significant concern. The Board noted the yearly underspend to date was £103,000 with the early forecast underspend set at £1.645 million largely due to delays in recruitment, vacancies arising and the cancellation of a small number of REC meetings. The Board noted regular meetings are held with DH and ALB finance colleagues to ensure they are kept aware of the underspend position.</p> <p>DC advised a Value-Added Tax (VAT) compliance visit from the Her Majesty's Revenue and Customs (HMRC) was held this week. A discussion was held regarding the change to VAT handling for agency staff with the potential of a four year clawback of reclaimed VAT for agency staff. DC advised a paper would be prepared for EMT and the Audit Committee in October. The Board noted this uncertainty and DC clarified this potential cost would be factored into accruals with DH being kept abreast of the situation.</p> <p>The Board was pleased to note the reduction in travel costs.</p>	ST
10.	<p>Annual Report Summary for RECs in England</p> <p>The Board reviewed and approved the Annual Report Summary for RECs in England for 2013/14. SO advised this report was supported by 69 individual REC reports with 5 regional centre reports available on request. These would be published on the HRA website shortly.</p> <p>The Board noted 181 members had left and 157 members had been recruited over the year. The Board noted attempts to increase the number of medic members was being made with adverts being placed in the BMJ and through the Royal Colleges.</p> <p>The Board thanked SO and Ann Tunley for developing the summary and acknowledged and expressed its thanks for the hard work of staff over the year in producing an excellent set of reports.</p>	
11.	<p>Quality Assurance update</p> <p>The Board noted and endorsed the work over the last 12 months and supported the next steps proposed for the coming year. The Board expressed its thanks to the members of the Quality Assurance team for their hard work over the year with a high degree of assurance received.</p>	

12.	<p>Appointing Authority Update</p> <p>The Board noted the appointing authority update.</p>	
13.	<p>Protocol for public and parliamentary accountability</p> <p>The Board noted the update to the protocol for public and parliamentary accountability.</p>	
14.	<p>Payments over 100k</p> <p>The Board noted there were no payments over 100K made in this quarter.</p>	
15.	<p>Any other business</p> <p><u>Electronic Staff Record</u> The Board approved the decision for Stephen Robinson to assume the role of Registration Authority (RA) Sponsor.</p>	
16.	<p>Date of next meeting</p> <p>29 October 2014</p>	