

**HEALTH RESEARCH AUTHORITY
BOARD MEETING**

**Minutes of the Health Research Authority (HRA) Board meeting, held on 21st
January 2015 from 1.30pm – 4.00pm at ETC Venues, Avonmouth House, 6
Avonmouth Street, London, SE1 6NX**

Present		Initials
<i>HRA Non-Executive and Executive Directors</i>		
Ian Cook	Director of Corporate Services	IC
Graham Clarke	Non-Executive Director	GC
Debbie Corrigan	Director of Finance	DC
Allison Jaynes-Ellis	Non-Executive Director	AJE
Deirdre Kelly	Non-Executive Director	DK
Jonathan Montgomery	Chair	JMo
Nalin Thakker	Non-Executive Director	NT
Janet Wisely	Chief Executive	JW
<i>HRA Directors who attend the Board</i>		
Joan Kirkbride	Director of Operations and Approval	JK
Janet Messer	Director of Systems and Development / Programme	JMe
Tom Smith	Director – HRA Approval Director of Quality, Standards and Information	TS
In attendance		
Bill Davidson	Policy Projects Lead	BD
Stephen Robinson	Corporate Secretary	SR
Stephen Tebbutt	Board Secretary and CE Business Manager	ST
Observers		
Sue Cartwright	DH Sponsor team	SC
Christine Holmes	DH Sponsor team	CH
Katherine Guerin	Deputy Director of Corporate Services	KG
Item	Item details	Action
1.	Welcome and Apologies JMo welcomed everyone to the first meeting of the HRA as a Non-Departmental Public Body (NDPB). There were no apologies to note.	
2.	Executive Appointments	

	<p>The Board formally appointed Janet Wisely as Chief Executive of the HRA and endorsed the appointments of Ian Cook and Debbie Corrigan as Executive Directors.</p> <p>The Board endorsed the appointment of Joan Kirkbride, Janet Messer and Tom Smith as Directors required to attend the HRA Board.</p> <p>The Board endorsed the continuation of Stephen Robinson as the Senior Information Risk Owner for the HRA.</p> <p>The Board endorsed the appointment of Ian Cook as Caldicott Guardian when Hugh Davies, HRA Ethics Advisor, retires from this role at the end of April 2015. Recognising that this needs to be a Board level appointment but that preference is also given to a clinician appointment to the role, the Board endorsed Sheila Oliver (Head of NRES and a nurse clinician) to take within her role a formal responsibility for leading and advising on correspondence with patients and for providing support to the Caldicott Guardian as required.</p>	
3.	<p>Conflicts of interest</p> <p>The Board noted the declaration of interest policy and agreed it is important all Board members return the declaration of interest form to ST so any conflicts can be recorded and published on the HRA website.</p> <p>The Board noted a Research Ethics Committee (REC) application from DK had been received recently and noted that other NEDs may be listed on REC application forms in the future, in particular DK, AJE and NT. The Board noted RECs had been asked to record in their own minutes the conflict of interest for any instances where a NED is listed on an application form, on an interim basis. After the publication of today's minutes this will no longer be necessary as the Board minutes will form a record capturing the interest.</p> <p>The Board noted there were no conflicts of interest relating to the business to be discussed today.</p>	
4.	<p>Minutes of last meeting</p> <p>The minutes of the previous meeting were accepted as a true and accurate record of the matters discussed with the following amendment:</p> <ul style="list-style-type: none"> - <i>Page 1 – Tom Smith was present</i> - <i>Page 6 – The Annual report will be prepared up to 31st December 2014</i> - <i>Page 9 – Frank Wells had yet to attend the conference in Rio</i> 	
5.	<p>Matters arising</p> <p>None to note</p>	
6.	<p>Welcome and update from Chair</p> <p>JMo welcomed everyone and noted the Board was required to populate the</p>	

	<p>Audit and Risk Committee and the Pay and Remuneration Committee. The Board noted GC would chair the Audit and Risk Committee and DK and NT would join as members. The Board noted all NEDs would sit on the Pay and Remuneration Committee.</p> <p>JMo advised as a continuation from the HRA as a Special Health Authority AJE had agreed to continue as Vice-Chair of the HRA for a further 12 months.</p>	
<p>7.</p>	<p>Welcome and update from Chief Executive</p> <p>JW tabled the following update:</p> <p><u>HRA as a NDPB and transition issues</u> JW was delighted to report a successful transition, including the new appointments to the Board and to welcome and congratulate Allison, Graham, Deirdre and Nalin on their appointments. JW advised the statutory accounts for Special Health Authority, the part year 9 months, are in hand and nearing completion prior to submission of the draft to DH. Including a review, in summary form, with Graham the new Audit chair. JW gave particular thanks to SR and CH for their working in ensuring the transition went as smoothly as possible.</p> <p><u>Estates strategy</u> The Board noted the ongoing and important piece of organisational development for the HRA, to enable us to deliver efficiencies by better use of existing space to accommodate new staff. Phase 1 for the Skipton House changes are expected next weekend. The ways of working review commenced with a visit to Manchester and there will be visits to other HRA Offices. The Board will have an opportunity to consider long term plans for the HRA estates strategy.</p> <p><u>Programme Management Office (PMO)</u> JW advised the PMO is already providing expert and robust support to HRA Approval. EMT will be considering shortly other major projects and programmes of work, which are underway or are due to start, and identifying a priority list to ensure we are able to match capacity to ambition. The agreed portfolio will be monitored and reported on by the PMO.</p> <p><u>Communications and the HRA first Perception Audit</u> JW advised the HRA Latest was issued on Monday as planned. The perception audit will be presented to the February Board on results from survey of the public, key opinion leaders, researchers and REC members (carried out Nov/Dec 2014).</p> <p><u>Information systems</u> JW advised the first release (9 January) on IRAS since we took over management of the code for IRAS went live without any 'down time', on schedule and with no unforeseen problems. Information systems are a key dependency for the delivery of HRA Approval and this, building on the successful delivery of the new ethics information system 'HARP' last year maintains confidence in our ability to deliver.</p>	

	<p><u>HRA Approval Programme</u> Progress continues to plan, with good joint working with the National Institute for Health Research Clinical Research Network (NIHR CRN). Appointments to operational roles are underway.</p> <p><u>Collaboration and Development Programme</u> Two calls for comment are currently open following extensive collaborative work: Guidance and template for protocols for clinical trials, and revision to the model non-commercial agreement.</p> <p><u>Quality Assurance</u> The HRA Quality Assurance Department, which holds ISO9001:2008 Certification has received a 'Substantial' rating (the highest rating) from a recent DH/PWC audit, which as we move forward with the wider rollout of quality principles across the HRA, is highlighted to provide assurance to the Board – details to go to the Audit Committee in due course.</p> <p><u>Clinical Trial Regulations and transparency</u> Ahead of the implementation of the EU Clinical Trials regulations a public consultation has been launched today, in connection with the detailed implementation arrangements for the transparency provisions. The HRA will be responding in due course, and are arranging with the Medicines and Healthcare products Regulatory Agency (MHRA) to issue a joint press release supporting the consultation and seeking that the research community actively consider and respond. As part of our continuing Transparency agenda, the next workshop will be held on Thursday 5th February 2015, building upon the work of previous discussions. The focus will be around end of research reporting / publication and highlight the potential measures work. The proposals on possible measures were taken to the UK Ethics Committee Authority (UKECA) earlier this week.</p> <p><u>Other meetings to note</u></p> <ul style="list-style-type: none"> • The DH Chaired HRA – NIHR interdependencies Board • HRA Collaboration and Development forum • Executive Management Team • HRA Approval Programme Boards • UK policy framework Steering Group • HRA – ABPI engagement meeting <p>Meetings in the next couple of weeks include a presentation to the NIHR Advisory Board; the first HRA Chaired R&D Champions meeting; HRA hosted early trial and AllTrials meeting; HRA sponsorship meeting and numerous other engagement activities.</p> <p>Members of the Board noted they should contact ST if they wished to attend any of the above meetings or required any further information.</p>	
8.	<p>Establishment of the HRA as a Non Departmental Public Body</p> <p><u>Framework Agreement</u></p>	

	<p>The Board noted the current version was with the Treasury for comment with the final version to be signed off at the HRA Board meeting in February. The Board noted the document was fit for purpose and the main changes to the previous version used by the HRA as a Special Health Authority largely related to the revised Board composition and legal requirements of the HRA as a NDPB.</p> <p><u>Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions & Scheme of Financial Delegation</u></p> <p>DC clarified the limits for the different tiers of management and advised the main change related to the arrangements for when the Chief Executive is unavailable. In this instance, the 3rd Executive Director will operate at Gold level. The Board formally adopted the above documents.</p> <p><u>Adoption of Policies</u></p> <p>The Board formally adopted all policies and procedures for the HRA as a Special Health Authority. The Board noted the HRA was currently undertaking a harmonisation process which will take a further 8-12 months for completion. The Board agreed the review date for the policies would remain as detailed on each policy rather than being updated to today.</p>	
9.	<p>UK Policy Framework for Health and Social Care Research</p> <p>The Board noted the HRA took responsibility for the publication of guidance on the principles of good practice in the management and conduct of health and social care from the Department of Health upon becoming a NDPB on 1st January 2015. The HRA has been working with the Devolved Administrations via a UK wide steering group to develop a policy which is compatible across the UK. The latest draft of the policy framework was shared, in confidence, with the Board for it to comment on the direction of travel ahead of the document being published by each nation in due course. The Devolved Administrations were in the process of notifying Ministers of the policy's release for comment.</p> <p>The Board was asked to delegate the decision to issue for comment and also for formal consultation to the UK wide steering group. The Board noted it would need to formally sign off the document for use in England after the formal consultation period had closed. This would take place sometime after purdah.</p> <p>The Board noted the comment period would involve engagement with relevant stakeholder groups to test out the principles in the policy framework. JW flagged a number of individual projects had already taken place to inform the development of the policy framework which had involved opportunity to comment periods and testing of ideas through workshops and seminars.</p> <p>BD flagged the document would be an important platform to support the implementation of HRA Approval in England and also the EU Clinical Trial Regulations plus it would provide a hook for future guidance to hang off. The Board noted additional guidance would support the policy framework, much of which already exists and work will be undertaken to check what is relevant to link back to the policy. The Board agreed it would be helpful to highlight where other processes are detailed to avoid the possibility of others feeling the need to develop their own processes.</p>	

	<p>The Board noted there would be executive summaries for a range of different groups e.g. the public to support the use of the policy. The Board noted an important part of the implementation of the policy framework will be challenging behaviours and working with researchers and others in an attempt to switch off bad practice.</p> <p>The Board discussed the possibility of restructuring the document as it read largely from a civil service viewpoint at present. BD agreed to consider restructuring once the Ministers in each Devolved Administration had been contacted.</p> <p>The Board noted any comments should be sent to BD. An updated version of the document would be developed and released for comment by the 18th February Board meeting.</p> <p>The Board agreed to delegate responsibility to the UK Wide Steering Group for sign off for the comment period and consultation in England.</p>	
<p>10.</p>	<p>Finance Report – November and December 2014</p> <p>DC introduced this item and explained the process behind the compilation of each month’s finance report.</p> <p>DC flagged the following key points from the finance reports:</p> <ul style="list-style-type: none"> - Year to date under spend of £301k - This is largely due to variances within Corporate Services and Systems and Development directorates (£71k contribution to in month swing) - The forecast under spend is broadly similar to that reported in November. November Board report was £2.07million to £2.95million. Preliminary discussions about the growth in under spend have been held with the DH Sponsor and the risk of an increase flagged to ALB Finance colleagues. - Main reason for the movement is the time it has taken and is taking to recruit successful candidates to HRA Approval posts. The expectation now is that 36% (rather than 61%) of the 87.5 WTE will have been fully recruited to by March. This, alongside the significant reduction in linked pay and non-pay related costs, is the main reason forecast under spend, together with changes to plans for desired early transfer of posts to support HRA Approval and systems transition and the non-deployment of contingencies. - Continued need for approvers to review their invoice workflow on a daily basis. - Increase in cash surplus as a result of the forecast range increasing 	

	<p>The Board approved the report.</p> <p>The Board noted the plans for HRA Approval have had to be updated to deal with the longer than expected time to recruit however the programme of work is still on track to be completed on time.</p>	
11.	<p>HRA Draft Business Plan 2015-16</p> <p>The Board noted the finalised business plan would be brought to the February Board meeting for approval.</p> <p>SR introduced the plan and advised it was broadly consistent with the previous year's plan, as requested by DH, to allow continuity of the major streams of work, such as HRA Approval, which are well underway. The Board noted however that the Business Plan for 2016/17 and beyond would be a fresh start to the business planning process to become more inclusive involving the whole organisation and supporting the implementation of the 'Golden Thread' methodology.</p> <p>The Board noted any comments on this year's business plan should be sent to SR.</p>	
12.	<p>Any other business</p> <p>None to note</p>	
13.	<p>Questions from the public</p> <p>None to note</p>	
14.	<p>Date of next meeting</p> <p>2 February 2015 (Board Seminar) 18 February 2015 (Board meeting)</p>	