

**HEALTH RESEARCH AUTHORITY  
BOARD MEETING**

**PART 1 – PUBLIC SESSION**

**Minutes of the Health Research Authority (HRA) Board meeting, held on 17<sup>th</sup>  
February 2016 from 1.00pm – 4.00pm in Bristol HRA Centre / VC with London  
HRA Centre**

<b>Present</b>		<b>Initials</b>
<i>HRA Non-Executive and Executive Directors</i>		
Graham Clarke	Non-Executive Director	GC
Ian Cook	Director of Corporate Services	IC
Debbie Corrigan	Director of Finance, Procurement and Estates	DC
Allison Jaynes-Ellis	Non-Executive Director	AJE
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	JK
Janet Messer	Director of Research Systems, Standards and HRA Approval Programme	JMe
<b>In attendance</b>		
Will Bowen	Collaboration & Development Manager/ South London Regional Change Lead	WB
Chris Cannaby	Head of Assessment and Assurance	CC
Jonathan Fennelly-Barnwell	Head of Collaboration and Development	JFB
Katherine Guerin	Deputy Director Corporate Services	KG
Stephen Robinson	Corporate Secretary	SR
Stephen Tebbutt	Board Secretary and Chief Executive Business Manager	ST
<b>Observers</b>		
Sue Cartwright	Department of Health	
<b>Item</b>	<b>Item details</b>	<b>Action</b>
<b>1.</b>	<b>Apologies</b>  Deirdre Kelly, Non-Executive Director Tom Smith, Director of Quality, Guidance and Learning	
<b>2.</b>	<b>Conflicts of interest</b>	

	None to note	
<b>3.</b>	<p><b>Minutes of last meeting</b></p> <p>The Board agreed the minutes of the last meeting were a true and accurate representation of the matters discussed without amendment.</p>	
<b>4.</b>	<p><b>Matters arising</b></p> <p><u>HRA Approval Critical Path</u> GC advised he had reviewed the critical path documentation and had held discussions with various leads. GC advised minor updates to the documentation were required however GC confirmed he was assured the work was sufficient and appropriate. The Board was satisfied the recommendation relating to the critical path from the Healthcheck review was now resolved.</p> <p>JW flagged the request made at the last Board meeting for a wider look at the dependencies had been raised at the recent Interdependency Board. JW clarified the Interdependency Board had confirmed it was happy to support this request. JW flagged this had also been noted at the United Kingdom Ethics Committee Authority (UKECA). The Board noted the next Healthcheck review is scheduled for March with the Association of the British Pharmaceutical Industry (ABPI) and Ethical Medicines Industry group (EMIG) agreeing to identify people to be interviewed as part of the process.</p> <p><u>Raising concerns policy</u> The Board agreed for instances when DK may be unavailable JMo would be the Non-Executive Director lead contact.</p> <p><u>Meeting with Kinsley Manning</u> JMo advised the meeting had been scheduled for 14<sup>th</sup> March 2016.</p>	
<b>5.</b>	<p><b>Update from Chair</b></p> <p><u>Recent estates announcement</u> JMo flagged the recent estates reorganisation announcement from DH with a move away from Richmond House in the future. DC confirmed HRA staff had been notified.</p> <p><u>Conference for ALB NEDs</u> The Board noted NT had attended this conference last week which focused on the spending review and lean processes.</p>	
<b>6.</b>	<p><b>Update from Chief Executive</b></p> <p><b><i>Research Systems</i></b></p> <p>Developments to enhance the functionality of our research systems continue with further updates. HARP was updated to v2.5 in January to add functionality for both REC and HRA Approval purposes. The CAG version of HARP was also updated to v1.1 and a new Member Portal for CAG members has been</p>	

completed. IRAS was updated to v5.2.1 at the end of January to incorporate a number of fixes and maintenance matters.

Additional guidance is now available on IRAS, signposted from the log in page, to explain how to convert REC and R&D forms that have not been signed off or submitted to an IRAS form for HRA Approval application (a simple step with no loss of data), so that researchers who have not yet submitted applications can benefit from HRA Approval. Cohort 4 and 5 studies are able to use the existing functionality in IRAS.

The detailed specification for switching off the interface with the NIHR Coordinated System for gaining NHS Permission (CSP) before the end of March is being finalised with the CRN. This will be taken forward in phased steps, first disabling the e-submission and subsequently removing the interface entirely once the CRN is ready for a new interface with the Central Portfolio Management System (CPMS) to be established.

### ***HRA Approval Programme***

Extensive training activities are underway to prepare sponsors and researchers for the completion of the roll out of HRA Approval. Following the workshop with EMIG members reported previously, two train-the-trainer workshops took place in January and February with the Association for the British Pharmaceutical Industry (ABPI) reaching a further 40 companies. These were rated very highly, achieving an average feedback score of over 9/10 across all elements. A similar workshop targeted at Clinical Research Organisations, hosted by the Contract Clinical Research Association (CCRA) in February will reach 20 companies. Two workshops with the Institute for Clinical Research (ICR), also in February, for both commercial and non-commercial stakeholders are due to reach a total of 400 delegates. A briefing session is scheduled in March with the NIHR Office for Clinical Research Infrastructure (NOCRI), which regularly interacts with companies in the UK and elsewhere. Regular engagement with ABPI and with its commercial Clinical Operations Group continues, with positive feedback about the progress and plans.

A briefing session with non-commercial funders is being arranged with AMRC, and the regular NIHR-HRA Forum with the NIHR funders also meets in March. We have made contact with Universities UK and are exploring options for provision of training and guidance to university research offices. Having tested the training material with live audiences, it will be made available along with the handouts to support those delivering training within their organisations. A suite of leaflets for researchers for different study types has been tested with NHS R&D and will also be available online.

Our team of change leads continue to engage extensively with local NHS R&D, working alongside Local Clinical Research Networks. They are supporting local conversations about models for delivery of activities aligned to HRA Approval, and encouraging local collaborations with non-commercial sponsors.

A total of 156 studies have been received (as at 9 February), with HRA Approval being issued to 73 in a median time from application to approval (without any

clock stop) of 15 calendar days (noting that the majority of studies that have completed the process are not studies requiring full REC review). Studies are tracked through the process and the timelines for components of the overall process being measured to identify delays.

The HRA website and HRA Latest newsletter confirmed at the end of January that cohort 4 (clinical trials and investigations) and cohort 5 (single site with same sponsor) studies could be submitted. So far two cohort 4 studies and one cohort 5 study have been received. The number of enquiries per week about submission has doubled since the start of February. Whereas previously many enquiries were about studies that were found to be not eligible at that stage, the number of ineligible studies has dropped significantly as only educational studies are currently not being accepted. It should be noted that applicants may then take several weeks to finalise their applications following enquiry.

### ***Research ethics service***

#### ***Recruitment of Expert Members***

An advertisement has been placed in the BMJ which has resulted in 10 expressions of interest in membership of a REC.

#### ***City Road and Hampstead REC***

The Board were advised at its previous meeting of the suspension of the above REC primarily due to difficulty of quoracy at meetings. The REC has now been advised that the REC will be closed and members have been offered the opportunity to become members of other RECs. To date 7 members have taken up this offer.

#### ***REC Members' National Training Days***

Two national training days will be held this month. Topics include: bringing together public's views and HRA policies; the virtuous ethics committee; involving children in research; and the participant information sheet – autonomy, paternalism and risk mitigation.

#### ***Phase 1 Advisory Group***

The Group met last week and received MI data on Phase 1 reviews. The CRO representatives expressed their appreciation for the collaborative working with the HRA on agreeing a process for generic review of pre-study screening procedures and their satisfaction with the timelines for the review of studies and for generic advertisements.

### ***Stakeholder Management***

The stakeholder management and engagement strategy has been drafted for review at this board. The stakeholder management group are continuing to meet monthly to co-ordinate and join up activity where possible and share relevant information. The group is continuing to evolve. A quarterly planning

session is planned for March which will enable us to reflect on our progress and plan for the next quarter. Activity continues to take place led by business areas.

### ***Communications***

A significant piece of activity has been underway to develop the homepage of the website to make it easier for visitors to find the content they need. The development and resulting front page was based on evidence from user research and feedback. We are continuing the development of the approach for further work on the website and have had helpful input from the DH digital communications team which is informing our approach in ensuring we are able to comply with the Government Digital Service best practice guidelines and also our renewed approach to resourcing this activity.

The stakeholder newsletter, HRA Latest, has also been redesigned to be more impactful and in undertaking this work we are now also able to provide more evaluation and analysis in relation to individual articles which we will be able to use to further develop the newsletter and content in future.

The Communications team has worked closely with the Policy team to support the consultation on the UK policy framework for the conduct and management of health and social care research, both building awareness and encouraging stakeholders to attend one of the seven themed consultation events in February and March (120 people currently registered). Further waves of communications are planned to draw in formal responses to the consultation from both individuals and organisations during March.

On-going communications support is also been given to the HRA Approval programme, including confirming cohort 4 and we are following up on opportunities for further activity. We are also providing communications support to augment the activity underway to recruit members for CAG.

We have continued in our active contribution to some activity taking place across the Health Hub for ALB communications, which is potentially beneficial for the HRA as a smaller ALB and also important in ensuring the perspectives of smaller ALBs are heard within the broader ALB communications discussions.

### ***Public Involvement***

The public involvement team ran a successful internal workshop on 10<sup>th</sup> February attended by 22 members of staff representing HRA Approval, Operations, Collaboration and Development, Communications, Policy and Guidance and Learning. The purpose of the workshop was to present information, discuss and secure feedback on our plans\* to influence public involvement through the process of ethical review. Involving staff from teams/directorates across the HRA allowed the public involvement team to gain insight on wider organisational issues, processes and projects which will impact on or influence our planned work programme on public involvement. Attendees also committed their support and time post-workshop to collaborate with the public involvement team to successfully deliver this programme of work.

\*Planned work programme outputs include: development of expectations/standards for public involvement against which we can provide training and guidance to HRA staff and REC members, incorporating a staff validation of public involvement within assessment process, revision of q.14 (the public involvement question on IRAS and issuing updated/new HRA guidance for researchers on public involvement.

#### ***Human Resources***

The key findings of the 2015 Employee Engagement Survey were presented at the All Staff Video Conference on 22nd January and will be presented at this Board.

The new "Raising Concerns" policy was approved by EMT in January and has now been published. The policy includes the role of the Freedom To Speak Up Guardian who for the HRA is Deirdre Kelly with the HRA Chair nominated deputy.

#### ***Team development***

Directors have been identifying team development opportunities for staff. The Operations Directorate are holding a training day for REC staff on 23 February to include sessions on: Home Working, Proportionate Review, Annual Reports, Responding to Queries and Complaints, REC Applications in the Media, REC Member Recruitment, HRA Approval Interactions. An all HRA staff day is planned for May 2016.

#### ***Technical Talent Launch – 2016***

This programme will launch on 3<sup>rd</sup> March with 16 participants from Operations, Systems and development and Corporate Services. Participants visit external partners and R and D departments as part of this self-managed programme, which supports learning of the wider research agenda.

#### ***Inspiring Leaders – Leadership Talent Programme 15***

Our Leadership talent programme which ran in 2015/6 with 6 modules, with 15 people attending, finished in December 2015. As part of understanding more about the programme, as well as stretching participants, three participants attended EMT to present on the programme. One of the pieces of feedback was that some participants would have liked to have been able to manage a project as part of this, we will try to build this in to future programmes.

#### ***Programme Management Office***

The PMO is primarily engaged currently with supporting Directorates and the EMT with Business Planning and ongoing Portfolio Management for 2016/17.

This involves:

- The definition of potential initiatives for inclusion in the Portfolio (along with recurrent, mandatory work and current projects which will continue in 2016/17)
- Development, integration and support for Resource Management and Forecasting to include tools and process
- Development of a generic approach to Benefits Management to integrate into Project and Programme Start-up, Initiation and delivery processes
- Developing ongoing pipeline and portfolio review, maintenance and delivery processes
- Identifying requirements and next steps for increasing HRA capabilities in Benefits, resource, project, programme and portfolio management

Other work includes the definition of a Communications strategy and plan for PMO stakeholders and the provision of project support and assurance to current projects.

#### ***Business Unit***

Gateway review: Further check 2016 – scheduled to take place 29<sup>th</sup> – to 31<sup>st</sup> March, with the same panel. Arrangements are underway, with a planning meeting scheduled for 11<sup>th</sup> March. The review will focus on Industry readiness and feedback and EMIG and the ABPI have offered to use their networks to identify individuals for us.

Administrative support to Communications and Policy team in preparation of the forthcoming new UK Policy Framework for research conduct and management consultation events planned in February and March.

#### ***Finance***

Financial position – December position and latest forecasts all revisited. Month 9 returns all submitted to deadlines to DH and good engagement on the position with Sponsor and Finance colleagues. Budget setting and business planning progressed. External audit visit completed week commencing 25<sup>th</sup> January.

Cycle to work – paper and proposal presented to EMT which resulted in further questions and information being sought relating to the balance of the benefits the proposal offers to staff versus the small additional cost, the marginal increase in workload within the HRA and the small additional risks.

#### ***Estates***

##### ***Bristol Proof of Concept project***

Report and presentation made to EMT on the success of this project and next steps agreed. This will include further specialised support for each HRA Office

to enable more staff to embrace the flexibility that occasional working from home brings, should they wish to participate. Training on the tools available, the lessons learned and the cultural changes required will be provided over the next few months.

#### London property update

We continue to await further information on progress regarding a new lease for Skipton House. An update is expected towards the end of February.

#### Nottingham

Completion of project to alter the main offices. All work completed over weekends. All 4 of the temporary offices at Standard Court have now been vacated at the end of January. All staff are now based together within the Old Chapel, following successful modifications. There has been positive feedback about the look and feel of the office.

#### **Learning**

Work to broaden the HRA reach of learning materials appears successful, and the number of attendees on Researcher Training Days has been increased with the programme developed to integrate HRA Approval. The circulation of the monthly HRA Researcher Bulletin has also increased, with circulation now reaching university health ethics leads. The Point of Care Trials event, learning materials have been added to training area of the HRA website, with full open access. In partnership with MRC, NHR and CRN, a Learning Development network has been initiated which will allow further HRA awareness to the research community, with an initial meeting held in January. The MRC have invited the HRA to join as partners in a series of shared workshops on Health Related Findings, providing a new opportunity for researchers and REC members to learn together.

Both the CTIMPS and Equality & Diversity e-learning modules are complete and subject to final sign-off, ready to be uploaded to the LMS platform. A meeting is planned with suppliers to explore open access to platforms, rather than current 'log-in' system, so we can actively promote the open access beyond the REC community. We continue to work through the complex practical and information technology issues relating to procuring and enabling access to learning materials, to facilitate webinar/ podcasts to complement face-to-face training.

An update to the Board is planned for May.

#### **UKCTG**

The UK Clinical Trials Gateway (UKCTG) Project Advisory Board has asked the HRA to provide advice and recommendations to support the developmental approach of the design and provision of UKCTG as a recruitment route for clinical studies. The HRA has agreed to undertake this, seeking advice from an expert advisory group of REC members. The first meeting will take place on 17

	<p>February 2016 as the first advisory phase, Chaired by Mark Taylor.</p> <p>A further update to the Board will follow at the end of the first stage.</p>	
7.	<p><b>HRA Key Performance Indicators Quarter 3 2015/16</b></p> <p>The Board noted the latest KPI report for Quarter 3. The Board noted a significant piece of work is being undertaken to identify the quality of the services we provide, as well as the quantitative target outputs to better understand the impact and effect we may have. A revised report will be brought to the April Board meeting.</p> <p>With regard to A1-A4 DC noted the timelines continue to be good despite the vacant positions within the REC service. JK flagged the service provided is broader than the KPIs with other factors, such as quality which may have deteriorated, harder to capture. JK flagged the variability between centres with some centres carrying greater vacancies or having lots of new starter in comparison with others which were more static which may have masked certain aspects of the management information.</p> <p>With regard to A9 the Board queried how many vacancies are currently within the Confidentiality Advisory Team (CAT). JK flagged CAT was fully staffed with new starters joining recently. JK flagged there was currently only one long term experienced member of staff within CAT however an action plan was in place to address the back log. The Board requested a further update at the next meeting.</p> <p style="text-align: center;"><b>Action: JK to update Board on CAG backlog at next meeting</b></p> <p>With regard to C2 the Board noted the increase in number of requests for deferral of the publication of research summaries on the HRA website. JW flagged the data was currently being considered and explored further to understand the reasons behind this however noted the number of requests for deferral of both clinical trial registration and full entry of the research summary on the HRA website continue to be low.</p> <p>With regard to G the Board noted these indicators are detailed as reporting annually. The Board queried if it would be possible to provide some sort of reporting sooner than this. JMe advised this should be possible in particular for G4, G5 and G6 with reporting more frequently next year. JMo flagged the targets will become clearer however it is difficult to know exactly when this will be with work with stakeholders still required to finalise. JMe highlighted reassuring comments had been received from industry thus far.</p>	JK
8.	<p><b>HRA Corporate Risk Register Quarter 3 2015/16</b></p> <p>The Board received and noted the Quarter 3 summary of risks and the corporate risk register. The Board noted the HRA risk management process means that all risks are discussed by EMT before they come through to the Board. This means there is some lag potentially if issues emerge close to the Board meeting. Recent events mean there are a number of issues that fall in to this category and the Board noted JW circulated a briefing to NEDs out of</p>	

	<p>session. These risks, if accepted by EMT, will be formally reported to the Board after the close of Quarter 4.</p> <p>The Board noted reputation risk 376 and the issue of maintaining UK wide compatibility with the handling of operational issues. The Board was reassured there was not a risk to the delivery of HRA Approval with significant mitigations in place including a workshop which has been scheduled to finalise the remaining issues and agree practical ways forward.</p> <p>The Board noted the social care related risk 288 and the unknowns around the scope and expectations for an extended remit to the REC. The Board noted the HRA is the appointing authority for the Social Care REC and was fulfilling its responsibilities, as a minimum under the Care Act 2014, however there was still uncertainty regarding future expectations with further work required to understand these.</p>	
9.	<p><b>HRA Corporate Risk Policy and Procedure</b></p> <p>The Board noted the documents had been reviewed by the Audit and Risk Committee and EMT with the recommended changes incorporated into the policy and procedure. GC flagged the Audit and Risk Committee had discussed the need for a corporate assurance framework with ST to consider further with Zafir Ali from the Health Group Internal Audit Service. The Board approved the revised policy and procedure.</p>	
10.	<p><b>HRA Business Plan 2016/17 (Draft)</b></p> <p>The Board noted the draft version of the business plan with the finalised version to be submitted to DH on 25<sup>th</sup> March 2016. The Board agreed to send any detailed comments to SR via email.</p> <p style="text-align: center;"><b>Action: Board to send any comments to SR asap</b></p> <p>IC introduced the portfolio planning paper which highlighted the background to the development of the HRA Portfolio and the recent work carried out in attempting to prioritise major areas of work.</p> <p>The Board noted a top down and bottom up process has been undertaken in identifying priorities for next year. DC flagged the pressure to identify further savings and the impact this may have on what can be achieved. The Board accepted this challenge and agreed the prioritisation of activity by EMT was key and there may be areas which will need to be considered in the longer term.</p> <p>JW and SR highlighted a report considering the strategic landscape is expected shortly and would be circulated to Board next week. This would support the HRA's 3-5 year strategic plan which would be considered at the September Board meeting.</p> <p style="text-align: center;"><b>Action: ST to circulate strategic considerations paper when finalised</b></p> <p>The Board agreed greater emphasis, taking into account the Government's priorities, should be added regarding helping other organisations to be more efficient and the relevant savings therein.</p>	<p><b>ALL</b></p> <p><b>ST</b></p>

	<p>The Board noted the value provided by the HRA's REC committees and the voluntary time given. The Board noted the benefit provided for the cost was considerable value and should be incorporated into the future benefits realisation work.</p> <p>The Board noted details regarding the data scenario should be added to the introduction and ambition sections.</p>	
<b>11.</b>	<p><b>Stakeholder Engagement and Communications Strategy</b></p> <p>KG introduced the strategy and advised the approach builds on the direction of travel outlined in the paper the Board reviewed in February 2015.</p> <p>KG advised the strategy is designed to support the HRA for the next financial year in line with the proposed business plan. It is recognised that as the strategy for the organisation is developed the stakeholder and communications approach will need to be revisited and updated in line with the ambitions of the organisation.</p> <p>The Board approved the strategy whilst noting the complexities regarding UK wide working and the possibility for a more coordinated engagement strategy. The Board queried the prioritisation of activities and noted a process of resource prioritisation will take place.</p>	
<b>12.</b>	<p><b>Finance Report – December 2015</b></p> <p>The Board received and noted the formal report for December 2015. The Board noted DC had provided a verbal update on the December position at the 18<sup>th</sup> January EMT meeting and 20<sup>th</sup> January Board meeting.</p> <p>DC provided a verbal position regarding the January position and advised there continue to be no additional surprises. An overall underspend of £428K was reported with broadly a break even for in month spend with overspend from the Estates and Finance Directorate following the Bristol proof of homeworker concept and the Nottingham office estates work.</p> <p>DC flagged a meeting with DH sponsor and finance colleagues had recently been held with a focus on what more could be done to deliver further savings in light of our current position. DC flagged the uncertainty regarding delivering further savings with the doubt concerning additional expectations with regard to social care.</p> <p>The Board noted the uniqueness of the current year and the significant extent of vacancies and its impact on the financial position.</p>	
<b>13.</b>	<p><b>Report of Evaluation of the Radiation Technical Assurance pilot undertaken in collaboration with Cancer Research UK and the UK Experimental Cancer Medicine Centres</b></p> <p>The Board thanked CC for attending to present this item. The Board was pleased</p>	

	<p>to note the removal of duplication in the wider research system with the quality of the review improved and fewer mistakes made. The Board agreed it would be beneficial to have a sense of any savings and any other measures if possible.</p> <p>The Board noted the devolved administrations had been involved in this initial stage and queried if there were plans to develop this further. The Board noted UK wide policy discussions will be required to consider UK wide compatibility.</p> <p>The Board noted the work will continue to be evaluated as it progress to identify how complaints may be reduced and how the improvement in quality can be defined.</p>	
<b>14.</b>	<p><b>Protocol Templates and accompanying guidance</b></p> <p>The Board thanked JFB and WB for attending to present this item. The Board noted a collaborative approach had been undertaken in the development of both protocols with a wide range of stakeholders involved. The Board noted the quantitative template was consistent with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidance.</p> <p>The Board discussed the benefits of having detailed guidance versus being overly prescriptive. The Board agreed the level of guidance was helpful for those researchers who may have had limited involvement in research previously and required additional support. The development of the templates as electronic tools will also be helpful in ensuring the templates allow appropriate and proportionate completion dependent on the type of research.</p> <p>The Board noted there was less guidance available for qualitative research and agreed the qualitative template was a useful tool which should be clearly highlighted on the HRA website and made widely available to researchers.</p>	
<b>15.</b>	<p><b>NHS Pension Scheme – Employers Charter</b></p> <p>The Board noted the amendments recently made to the NHS Pensions Employers Charter.</p>	
<b>16.</b>	<p><b>Any other business</b></p> <p>None to note</p>	
<b>17.</b>	<p><b>Questions from the public</b></p> <p>None to note</p>	
<b>18.</b>	<p><b>Date of next meeting</b></p> <p>13<sup>th</sup> April 2016, London HRA Centre</p>	