NHS
Health Research Authority

HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 20th January 2016 from 10.15am – 3.00pm in HRA 1, Skipton House

Present		Initials
HRA Non-Executive and Executive Directors		
Graham Clarke	Non-Executive Director	GC
Ian Cook	Director of Corporate Services	IC
Debbie Corrigan	Director of Finance, Procurement and Estates	DC
Allison Jeynes-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 *(in part items 1 – 12)*	JW
HRA Directors who attend the Board		
Joan Kirkbride	Director of Operations	JK
Janet Messer	Director of Research Systems, Standards and HRA Approval Programme	JMe
Tom Smith	Director of Quality, Guidance and Learning	TS
In attendance		
Stephen Robinson	Corporate Secretary *(in part – item 13)*	SR
Jonathan Sheffield	Chief Executive, National Institute for Health Research, Clinical Research Network *(in part – item 9)*	JS
Stephen Tebbutt	Board Secretary and Chief Executive Business Manager	ST
Observers		
Richard Carter	Department of Heath	
Sue Cartwright	Department of Health	
Katherine Guerin	HRA	
Christine Holmes	Department of Health	
Atul Patel	HRA	
George Pinnington	Health Group Internal Audit	

Item	Item details	Action
1.	**Apologies** None to note	

2.	**Conflicts of interest** None to note	
3.	**Minutes of last meeting** The Board agreed the minutes of the last meeting were a true and accurate representation of the matters discussed without amendment.	
4.	**Matters arising** Code of Conduct The Board noted that all staff have now signed the code. Benefits realisation work The Board noted the Benefits Realisation piece would be brought to the April Board meeting. UK Policy Framework for Health and Social Care Research The Board noted the consultation has begun with a very good response rate so far. Over 60 responses have been received with over 2000 hits on the webpage. Events have been scheduled throughout February and March with further details available at http://www.hra.nhs.uk/about-the-hra/consultations-calls/uk-policy-framework-health-social-care-research-consultation-active/.	
5.	**Update from Chair** Deirdre Kelly CBE The Board congratulated DK on being awarded a CBE for services to Children and Young People with Liver Disease in the New Year's Honours List. Chief Scientific Adviser The Board noted Professor Chris Whitty has been appointed as the Chief Scientific Adviser with the Research and Development Portfolio for DH. Director of Research and Development at the Department of Health The Board noted Louise Woods had been announced as the replacement for Dr Russell Hamilton. Permanent Secretary at the Department of Health The Board noted Chris Wormald had been announced as the new Permanent Secretary for DH following Dame Una O'Brien's recent announcement to step down from the role. Council for International Organizations of Medical Sciences (CIOMS) Working Group on the Revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects JMo advised the revisions were now open for comment available at http://www.cioms.ch/index.php/guidelines-test.	
6.	**Update from Chief Executive**	

Research Systems
As previously advised to the Board, following completion of the procurement process, it was agreed to award a contract for three years (with an option for two further years) to BGO Media Ltd. The team are now developing plans for overseeing performance and delivery against the new contract. HARP was updated to v2.4 and IRAS was updated to v5.2 at the end of November, primarily to incorporate a number of developments for HRA Approval. Continued work 'under the bonnet' on IRAS is being undertaken to improve the underlying technology and architecture.

Collaboration & Development
We continue to provide support and advice to the Genomics England team as it works with the increasing number of Genomic Medicine Centres. Work on the protocol template for qualitative research has been completed and plans for engagement with the research community are being drawn up. Information about these will be shared with the Board at its next meeting.
Further work to push through the changes to funders' processes to maximize the benefit from HRA Approval is being prioritized, the Association of Medical Research Charities (AMRC) has agreed to promote and support the work proactively including organisation of an awareness and training event for HRA Approval.

HRA Approval Programme
Cohort 3 went live on 30 November as planned. Early studies for the cohort include the first cross-border studies with the devolved administrations which are being processed according to agreed arrangements. A UK-wide call for comments on the local information package for sites has been issued. Planning training for industry stakeholders has been the key focus, to support the early testing of cohort 4 studies in advance of March 2015. Following input on the training package from the commercial Clinical Operations Group (cCOG), a workshop with the Ethical Medicines Industry Group (EMIG) has taken place, with further workshops scheduled in January and February with the Association for the British Pharmaceutical Industry (ABPI), the Institute for Clinical Research (ICR) and the Contract Clinical Research Association (CCRA).

A total of 107 studies have been received (as at 11 January), with HRA Approval being issued to 62 in a median time from application to approval (without any clock stop) of 16 calendar days. Studies are tracked through the process and the timelines for components of the overall process being measured to identify delays. Due to the nature of the early cohorts, and the additional time to complete the REC review process, only four of the studies with HRA Approval so far involved full REC review (median 53 calendar days).

European Clinical Trials Regulation – update on expected date of application
As previously noted, an essential component of implementing the new arrangements set out in the EU Clinical Trial Regulation will be the dedicated IT infrastructure (the 'EU portal' and 'EU database'), which the European Medicines Agency (EMA) must set up and maintain. Therefore, the timing of the application of the Regulation has been made dependent on the EU portal and EU database being confirmed as fully functional through an independent audit

	(refer to Article 82 and Article 99 of the Regulation). The actual date when the Regulation will become applicable will be six months after the European Commission publishes the notice in the Official Journal of the European Union (OJEU) confirming the IT infrastructure is fully functional. In October 2015, the EMA published their anticipated timelines for the development of the IT infrastructure and thus the expected date of application of the Regulation (December 2017). Following a discussion at the EMA's Management Board in December 2015 the previously announced timelines have been revised and new dates published. The new timeline anticipates that: - The EU Portal and EU Database will be available for independent audit by August 2017; - The European Commission will publish the notice in OJEU in March 2018 (assuming that the independent audit confirms that EU Portal and EU Database are full functional); - The Regulation will become applicable by October 2018 It should be noted that in publishing these revised timelines, the EMA have stated "this is the maximum timeframe and every effort will be made to shorten it and bring the Regulation into operation as soon as possible." ***Estates*** *<u>Move towards 8:10 staff to desk ratio - Hot desking</u>* The proof of concept project to test out home working across Directorate staff within the Bristol office completed just before Christmas. A draft report has been received and a final meeting to review is due. Early indications are that the project has been successful in helping staff transition to more effective home working with some key learning points highlighted. Findings following the final review meeting will be shared across the organisation. *<u>Digital telephony – VoIP</u>* This has now been introduced into all offices across the organisation. The system allows staff to view availability and location of all HRA colleagues who are on-line, to instant message them, to phone them and collaborate through video conferencing or shared desktops. The system works at any location with an internet connection, although quality of connection can impact on the reliability of the system. *<u>London property update</u>* Confirmation that DH has submitted formal notice requesting a new lease to the landlord following the end of the current lease in December 2016. This is the knowledge that the landlord has plans to redevelop the site at some point in the future. *<u>Nottingham</u>* 4 temporary offices at Standard Court to be vacated at the end of January. All staff to be based together within the Old Chapel, following modifications. Contingency of home working to be tested and progressed to ensure resilience	

	of service provision. *Bristol* New 5 year lease agreed from 11 January 2016. ***Finance*** Month end completed in 4 days and team analysing the resulting position. Month 9 (December) reports work in progress and external auditors due week commencing 25th January. 2016/17 Business planning work budget setting work ongoing. Issues were resolved following the unavailability of the finance system due to problems with our IT provided service. New banking regime commences on 18th January. ***Public Involvement*** The public involvement team will be holding a consultation workshop on 10th February for internal HRA staff to receive information and discuss the work programme the public involvement team will be leading on to influence public involvement through the process of ethical review. Planned work programme outputs include: development of standards for public involvement against which we can provide training and guidance to staff and REC members on public involvement, incorporating a staff validation of public involvement within the assessment process, revision of q.14 (the public involvement question on IRAS), issuing updated/new guidance for researchers on public involvement within ethical review/HRA Approval (including a reissue of the joint HRA/INVOLVE statement on public involvement in research and REC review). Feedback and discussions in the workshop will help the public involvement team to: - Identify staff and teams across the organisation who can support and work with us to deliver above stated projects. - Working with REC staff to put in place audit type activity to understand better current practice - Understand wider organisational issues, processes or projects currently being undertaken which may impact on or serve to influence our planned work programme on public involvement. The new patient and public area on the HRA website is planned to be going live in the next 6 weeks. New public involvement information and linked resources for staff will be uploaded on the intranet in parallel with the go live date for the HRA patient and public website area. ***Communications*** The Communications team has delivered significant pieces of work to support	

	HRA Approval (cohort 3) and the launch of the public consultation on the UK policy framework for the conduct and management of health and social care research. Though it was launched just before Christmas (18 December), it took just 3 weeks to get 2000 hits on the webpage. As of 11 January, 43 formal responses had been received, and 59 places reserved across the seven themed consultation events in February and March. We have plans in place for further communications during the consultation, and are reviewing and implementing these (in the light of the level of interest and response) on a weekly basis. The work with the website supplier on changes to the front page has been booked in for late January following discussions and subsequently approval from the DH Digital spend control panel for the activity. In line with the agreed Government approach this will be carried out during a short but intense period and will be done in line with the approach expected as part of the best practice guidelines for this type of activity. We have been unable to progress the recruitment of the temporary project manager as the professional services business case we submitted was turned down, we are considering next steps in response to this to enable the web development project to move forwards. We have been contributing to activity across the Health Hub for ALB comms, 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 comms discussions. ***Programme Management Office (PMO)*** The PMO is primarily engaged currently with supporting Directorates and the EMT with Business Planning and ongoing Portfolio Management for 2016/17. Other work includes the definition of a Communications strategy and plan for PMO stakeholders, the provision of project support and assurance to current projects. The PMO continues to give extensive support to HRA Approval. ***HR*** The full analysis of the 2015 Employee Engagement Survey is now available and a presentation on the key findings is being given at the All Staff Video Conference on 22nd January. The report will be circulated to the Board with an initial management response for discussion at the next Board meeting. An employee data check was conducted during November to ensure accuracy and completeness of employee data held on our HR system. The audit was undertaken as accurate and full data helps with workforce planning and also means we have up-to-date contact information in case of emergencies Work on HR policy harmonisation and revision is ongoing. The whistleblowing policy has been renamed as the “Raising Concerns” policy and has been revised to include the role of the ‘Freedom To Speak Up’ Guardian and to meet ISO9001 certification standards and best practice. Deirdre Kelly has agreed to be the Freedom to Speak Up Champion and has already met with HRA staff partnership forum representatives. The policy was discussed at the December Staff Partnership Forum meeting. ***OD and Training*** Technical talent Programme: This programme received good reviews last year and 40% of last year’s participants had job moves or promotions after the	

programme. We have had 12 applicants for this year's programme and the programme will commence in March.

Senior leadership programme: This programme will start in February and will take a cohort of 36 of our senior leaders and develop them together, to create a shared approach to leadership across the organisation. The programme will be run internally to achieve VFM and also importantly, allow for discussion to support the continued development of shared approaches to achieving high performance.

Civil service learning: We have been live with civil service learning since October. This gives access to a large number of both e-learning packages and face to face training.

All Staff day: The All Staff Day will take place on 5th May in Birmingham. The themes this year will be Genomics and Data as well as effective across organisational working. A team of staff are leading on the design and will be supported to facilitate the event; this approach received a very positive response last year and so is being repeated.

Review of response to REC provisional opinion

We have started a pilot scheme to assess whether staff can come to the same decision as REC Chairs/Members when applicants provide a response to a provisional opinion. Should the pilot be successful we will delegate response to provisional opinion more frequently to staff which should lead to improved timelines for review, particularly for PR studies. The delegation to staff has been an option in Standard Operating Procedures for many years, the pilot is to test further before we consider greater promotion of the option to RECs to reduce the burden on volunteer members and introduce efficiencies to the overall review process.

A challenging ethical issue

A group of researchers is looking to develop an application to test the ethical acceptability of "Designing a study to investigate if method of birth affects mothers and child health in later life". We are assisting them by facilitating the establishment of two focus groups of REC members to work through some of the issues with the researchers, to discuss ethical judgement, the basis for decisions and to help identify ways that the ethical considerations could be ameliorated in order to facilitate research.

Interviews for Officer Roles

Interviews were held on 1 December 2015 and seven people were successful in their application for REC Chairs and Vice Chair roles. Appointments will be made to vacancies and others will be added to the waiting list we hold as part of our overall process to support REC members and management of membership.

Ministry of Defence REC (MoDREC)

HRA staff attended the recent national MoDREC training day and delivered training to members.

Media Spokespeople

	A number of experienced REC Chairs have been identified and approached to see if they would be interested in undergoing media training so that we can develop a bank of people who could speak to the press on ethical issues should the need arise. ***REC Chairs' Training Day*** A very successful Chairs' Training Day (UK wide) was held in December. There was a lot of interest, support and questions on HRA developments. The workshop to consider a proposal to resurrect an appraisal-type scheme for Chairs was held with mixed but reasonably positive feedback. ***Proportionate Review*** A project is being undertaken to review whether there is benefit to a slightly longer PR review process which puts greater focus on facilitating applications through the review process and working more closely with applicants to ensure better quality applications are prepared. This is due to a high number (23%) of PR applications being invalidated and rejected before reaching the REC for review. The current PR process requires an opinion to be issued by the Committee within 14 calendar days, the revised process will allow up to 21 calendar days. There are 16 REC involved in the pilot UK wide. The aim of the pilot is to assess whether a longer period of time for review is more effective and efficient by increasing the number of applications which go through the system on first submission: by decreasing the not valid rate and increasing the number of favourable opinion issued as the REC (including allowing more time for the REC to contact the applicants on valid applications regarding points of clarity). Additionally, we will be assessing satisfaction levels of REC staff, REC members and applicants to see whether the lengthened period of time is preferred. ***CAG terms of reference*** The policy team [Bill Davidson] and Operations Directorate [Catherine Blewett] are working together to develop robust terms of reference (ToR) for CAG, in light of a gap analysis by Internal Audit (IA). These will cover the whole of CAG's role, i.e. its advice to: HRA on processing of confidential patient information for research; to the Secretary of State (SofS) on processing for other purposes; to the Health and Social Care Information Centre (HSCIC) on publication of confidential information; and to the Human Fertilisation and Embryology Authority on disclosure for research of information that it holds. The new ToR document is being modelled on *Governance Arrangements for Research Ethics Committees*, which IA finds easy to use for audit purposes. A draft has been to the CAG chair [Mark Taylor] for comments and will be shared with CAG and IA. The document will be finalised in accordance with the IA action plan timetable, i.e. intended to come to the Board for sign-off in February.	
7.	**HRA Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions; and HRA Delegation of Financial Powers** The Board queried whether travel insurance should be provide for inside the	

	EU. DC advised she had canvassed other ALBs and the document mirrored the content of their policies. DC clarified staff would need to have an E111 European Health Insurance Card. The Board noted a paragraph regarding the process for the recruitment of the Chief Executive should be added to section 3.6 Employment. The Board noted the increased delegated levels. DC clarified the levels had been brought in line with the standard for other ALBs however the majority of the HRA's transactions were below the threshold. DC added all contracts over £100K would still be reported to the Audit and Risk Committee and Board and all ICT contracts over £100K had to be approved by the DH Senior Sponsor and the Board. The Board invited the Audit and Risk Committee to look at the levels once there is a pattern of transactions with the Audit and Risk Committee to confirm it is happy with the levels at the next annual review of the documents, or sooner as required. The Board approved the documents subject to the above comments.	
8.	**Estates Strategy – update on progress and next steps** DC provided the Board with an update regarding the Estates work with the strategy to be updated and brought to an upcoming Board meeting. DC flagged the move to adopt 8 desks to 10 people was progressing well. The Board noted there had been good engagement with staff regarding homeworking which had required a culture shift with the proof of concept scheme having recently finished at the Bristol office. DC highlighted homeworking being a success was reliant on the IT systems working well. The Board noted the long period of time and effort which has been required to obtain lease exemptions for the Manchester, Bristol and Nottingham offices and noted other ALBs were in the same position.	
9.	**HRA Approval Programme** *Dr Jonathan Sheffield, Chief Executive of the National Institute for Health Research, Clinical Research Network joined for this item.* <u>HRA Approval progress report</u> JMe introduced the paper providing a summary of activity across all work streams of the HRA Approval Programme. JMe advised a baseline figure for the number of studies was not available however an estimate of 6000 applications a year had been made. The Board discussed the critical path for the programme and the need for assurance whilst noting the fact there are interdependences which the HRA did not own which needed to be accounted for. The Board agreed a seminar style event might be beneficial in providing an overview across the programme including interdependences with others.	

	Management response to Healthcheck report The Board noted the management response from JW and Dr Clare Morgan, Research Delivery Director, NIHR CRN which had been tabled today. The Board was supportive of seeking opportunities to collaborate further with the NIHR CRN to assess remaining issues for the LCRNs and seek where possible joint resolution. JS was supportive of this approach and would be looking for the relevant Chief Operating Officers to be supportive of those involved in the permissions processes. The Board agreed it may be beneficial if the joint messaging could be expanded to R & D departments outside the NHS such as Universities and the Wellcome Trust. The Board noted a joint communication between the HRA and NIHR CRN would be released shortly regarding the collaborative work undertaken concerning metrics. The Board agreed joint communication should be made regularly to reinforce the messages and work being undertaken. JS agreed and advised JW and JS could do NIHR TV together with the briefings linked to all staff. The Board was assured that regular meetings are held between the communications teams and agreed this should be strengthened further where possible. JS provided an update regarding the timings of the Central Portfolio Management System go live. JS clarified this would take place from April 2016 with CSP to no longer receive new studies from April. The Board noted collective training events by the HRA and NIHR CRN with industry had been scheduled for the next few months. AJE advised positive feedback had been received and the Board agreed it would be good to roll out further. The Board noted the next HealthCheck would take place in February to check on readiness for industry and UK Wide aspects. The Board thanked JS for attending.	
10.	**Finance report** The Board received and noted the Finance reports for October and November 2015 with DC providing a verbal update on the position for December 2015. The Board noted the November report had shown an increase in the underspend with December showing a further increase in the underspend position. DC advised this was against the trend which was anticipated with an overspend having been expected for the remainder of the year. DC flagged the 9 month accounts were due tomorrow; DC advised she would be notifying DH Sponsor and Finance colleagues tomorrow prior to submission to forewarn them of the position. The Board noted budget setting conversations were currently taking place with areas of underspend to be considered to ensure better profiling for next year. The Board noted the unprecedented year in terms of recruitment with the high	

	number of vacancies for the HRA over the last year. 128 Vacancy Control Forms (VCFs) were made in the last 9 months in comparison with 48 in total over the previous 12 months. DC highlighted approximately half of the 128 VCFs had been for the Operations Directorate.	
11.	**Research Ethics Committee decision making in relation to novel methodologies for efficient trial design – 'Mystery shopper'** The Board noted the report and the management response. JK flagged the report concluded the REC system was working well which was reassuring to the Board. The Board noted a similar exercise to review the administration aspect may be undertaken to consider consistency further. The Board discussed ways the HRA can identify and prioritise future developments which may require guidance for RECs to ensure consistency and provide clarity to RECs as required.	
12.	**"Point of Care" trials (PoCTs): Their importance for public and patients and helping RECs review them fairly** The Board noted this item was for information with the Policy team wishing to have some early discussions with one or two NEDs in the future to support the business planning process. The NEDs agreed they wished to invite the policy team to come and talk to them as a group.	
13.	**Update on business planning 2016/17** SR attended to provide a verbal update on the business planning process for 2016/17. The Board noted the first draft will be provided to DH next week with the final draft to be sent to DH on 22nd February. Prior to this, the Board will review the business plan at its next meeting on 17th February. The Board noted the DH Shared Delivery Plan (SDP) had now been published with a specific objective regarding supporting research, innovation and growth detailed. The HRA Business Plan will include how we will contribute to this overall DH objective. SR agreed to circulate the SDP spreadsheet. The Board noted the business planning had followed a 'bottom up' process with the Programme Management Office more rigorously tied in this year. The Board queried if there was any risk of silo thinking using this method however were assured that EMT had held initial discussions and would have further discussions to consider the cross organisational impact of local plans with the prioritisation of plans to be considered. SR agreed to circulate a timeline for the business planning process after the meeting. ***Action: SR to circulate business planning timeline***	**SR**
14.	**Out of session business** The Board noted the following out of session business had been conducted: <u>Board Stakeholder Event</u>	

	The Board noted a sub-group of the Board had met prior to Christmas to finalise the arrangements for the stakeholder event to support the HRA's development of strategic objectives with a view to a 3-5 year strategic plan. The event would take place on 7th and 8th March in London.	
15.	**Update from Confidentiality Advisory Group (CAG)** MT and ND attended to provide the Board with an update on the CAG over the last year. MT expressed his thanks to members of the CAT for their support. The Board noted CAG had moved to two meetings a month with further member recruitment taking place to protect against quoracy issues. The Board noted the resource challenges faced by CAG and the continued uncertainty regarding the flow of work. The Board noted the regulations had not been published as yet and considered if there was any support the HRA could provide in the absence of the legislation. JMo advised a meeting with Kingsley Manning, HSCIC Chair may be helpful once the recommendations have been issued by Dame Fiona Caldicott, National Data Guardian.	
16.	**Any other business** <u>REC suspension</u> The Board noted the London City Road and Hampstead REC had been suspended due to long terms issues with constitution of the REC and maintaining quoracy at meetings.	
17.	**Questions from the public** None to note	
18.	**Date of next meeting** 17th February 2016, Bristol HRA Centre	