NHS
Health Research Authority

HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1

Minutes of the Health Research Authority (HRA) Board meeting, held on 21st October 2015 from 1.00pm – 4.00pm 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	JW
HRA Directors who attend the Board		
Janet Messer (part)	Director of Research Systems, Standards and HRA Approval Programme	JMe
Tom Smith	Director of Quality, Guidance and Learning	TS
In attendance		
Katherine Guerin	Deputy Director of Corporate Services	KG
Amanda Hunn	Engagement and Policy Manager	AH
Leonard Key	HRA Project Manager	LK
Sheila Oliver (for JK)	Head of Research Ethics Service (England)	SO
Stephen Robinson	Corporate Secretary	SR
Observers		
Richard Carter	Department of Heath	

Item	Item details	Action
1.	**Apologies** Joan Kirkbride — Director of Operations	
2.	**Conflicts of interest** None identified	
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** None not already on agenda	
5.	**Liabilities Session** A discussion item to inform consideration of the risk register and business planning. SR opened a discussion around areas of existing activity and new functions which can generate potential liabilities. Discussions, led by Directors, sought to identify areas and potential risks to inform Board consideration of the issues under the categories of: **Corporate** **Operations** **HRA Approval** **Policy** In more general terms members discussed whether the consideration of liability should be a separate topic or picked up under the risk assessment process – noting risks and liabilities may be reputational as well as financial. It was agreed that this required consideration at Board level with sufficient time for full consideration against a background of the Board 'appetite' for risk – Executives agreed to give further consideration based on the reactions provided by the Board.	
6.	**Policy Team update including Social Care remit** A briefing and information item for the Board ahead of consideration at the November Board of the formal consultation version of the new policy framework and business planning for 2016 – 2017. BD indicated that there is continued support for a UK, rather than country by country, approach. Subject to engagement with Social Care and Contract Research Organisations the framework will be revised and issued for full public consultation to expected schedule later this year. Updates were also provided on policy related work and government including, for example research involving the use of psychoactive substances and the Medical Innovations Bill. HRA are working with MHRA – as lead organisation for UK – on the implementation of the new EU Clinical Trials Regulations.	

	The Cities and Local Government Devolution Bill includes a proposal to amend S251 of the 2006 NHS Act which covers the processing of confidential patient information. A taskforce is formulating guidance on proportionate consent to cover, for example, consent in research involving licensed drugs or questionnaire studies and on the identification of participants who may be invited to join research (although this latter will be deferred pending a report by Dame Fiona Caldicott). AH introduced information on the Social Care Research Scoping Project. A series of interviews and listening events has been held to identify issues including definitions of child and adult social care and to gain a clearer understanding of what is classified as research. One issue highlighted is a misunderstanding that projects with ethical issue will not necessarily fall within the remit of the HRA if they are not research. For example an evaluation project may be labelled as research in order to obtain full review. The SCREC reviews in the order of 50-60 applications per year – however, similar research reviewed via University RECs will be 'invisible' to SCREC/HRA. Researchers in Wales are able to use SCREC; Scotland puts no such research through RECs; the health and social care system is fully integrated in NI. Where social care research, not reviewed via an NHS REC, involves more than three English LA areas, researchers need to apply via the ADASS process. There are parallel processes in Scotland and Wales but no reciprocity across borders. England has no national process to review social care research in children which has been raised through these events (an issue considered when the HRA clauses were crafted for the Care Act and these exclude children's social care from the remit of the HRA). There is a still a held belief that the HRA and NHS RECs do not fully understand social care research – and is a view enhanced because of the NHS branding of the HRA. The recent listening events had reinforced support for HRA having a role in social care, partly because it is felt currently to be under-regulated. For example, the responsibility for research governance in Care Homes. The HRA needs to carefully consider next steps as significant unknowns remain around volume and current activities even after the listening events convened to date. Priorities would, therefore, appear to be: - identify research leads in Local Authorities; - define a clearer role for sponsors; - clarify the position of research in self-funding nursing homes - further work with Universities to scope the volume of social care research. Noting that where HRA is asked to review Social Care research in children, it would be ultra vires the issue of the management of those studies needs consideration and explanation.	
7.	**Update from Chair**	

	The Chair had nothing to report.	
8.	**Update from Chief Executive** The Board noted the following update from the Chief Executive: **<u>Procurement of major contract</u>** Good inter Directorate team approach to securing DH and HRA Sponsor approval for the DH ICT spend approval business case document. This is a major milestone and key dependency as the ITT cannot be published without this. Additionally the team has been working hard on developing and finalising • Project governance • Service specification • Tender evaluation methodology • Pricing model • Planning of key tasks and milestones for the procurement plus resourcing The plan is to agree the award of the contract by the 4th December followed by a standstill period of 10 days and publishing of the OJEU award by the 31 December. [DC confirmed that DH approval had been received and that an invitation to tender would be published on 29/10/2015 with a view to the contract commencing in April 2016] **<u>Estates</u>** <u>Manchester</u> office refurbishment work has largely completed and the final product is excellent. However, a number of issues were raised during the project. As an organisation that wants to learn a meeting is planned with staff in Manchester on the 15 October to review the issue log and to reflect and learn. <u>Move towards 8:10 staff to desk ratio - Hot desking</u> – A proof of concept project to test out home working across Directorate staff within the Bristol office is due to kick off in October following the roll out of VOIP to the Bristol office. The project will run for 8 weeks and findings will be shared across the organisation. <u>London property update</u> – confirmation of expectation by DH of agreeing a 3 year extension to the lease at Skipton following the end of the current lease which ends in December 2016. This is subject to further work and negotiation. <u>Nottingham</u> – Meeting held with office based staff on 8th October to update on expected plans to close the Standard Court offices and accommodate all staff within the Old Chapel by January 2016 at the latest. Additional resources secured to help with this work and some minor modifications to the Jarrow office. **<u>Finance</u>**	

	Team away day afternoon held on 30th Sept to reflect on achievements, reflect on improved team working both within and across teams and to focus on the Directorate business plan for 2016/17. Policy updates – additional resource secured to progress this important area of work and to ensure that all finance policies are updated and submitted for approval. September month end completed alongside Agreement of balances work and monthly DH returns. Work on completion of the consolidation Schedule for September has begun. DH internal audit - Finance audit - nearing completion and QA in house audit due to commence shortly. **HARP REC Member Portal** The member portal went live for all REC Members from 1 October 2015. This followed a test period involving 5 RECs after which comments and feedback were collected and improvements to the portal implemented to make it more user friendly for members. We have also improved the instructions provided to members, arranged webinar training sessions and created an instructional video. Additionally, REC staff have had training and have been briefed on the importance of promoting use of the portal as well as training and supporting members as required. Initial positive feedback from members suggests that the portal will be a great benefit for members and a positive move forward to reduce the volume of paper being posted out to members, thus reducing costs and reducing the impact on the environment. **The Over Volunteering Prevention System (TOPS) audit** The scope of the TOPS audit focused on assessing the adequacy of the policies, procedures and controls which had been put in place by the HRA to ensure the security and ongoing quality of the data maintained within TOPS. The assessment also included a review of the data migration controls utilised as part of the implementation of the new TOPS database which was launched in October 2014. It was acknowledged in the audit report that the TOPS database had a number of in-built validation checks to ensure that required fields were completed by the individual Clinical Trial Units (CTUs), and that access to make changes to data was restricted to members of the HRA TOPS team who required a formal request to be submitted. There were five recommendations included in the audit action plan which will be received by the HRA audit committee **Researcher Training Day** A Researcher Training Day held in Manchester was attended by 55 delegates from NHS and Academic organisations. The programme includes advice for researchers in the completion and submission of applications, gaining an understanding of IRAS, providing guidance on consent and participant information sheets and giving researchers an insight into the ethical issues considered by RECs. These are a long-standing part of the HRA training programme.	

Confidentiality Advisory Group – new function establishment update

New members and staff have been recruited and the first Manchester meeting will be on 05 November. The new function formally commences from 01 November 2015. The Regulations that will set out formally factors and matters the CAG should have regard to when advising the HSCIC, and HRA / SofS decision makers have been delayed pending the outcome of the National Data Guardian's review on consent and objection management (due January 2016) as this may impact on the handling of consent when CAG provides advice. Advice is pending from DH on suggested interim approach, with possibility to follow the current intention of the new Regulations. Manchester CAG will proceed with induction activities and research application review.

Public Involvement

The public involvement team is completing the final editing of revised content of its section of the web site for approval prior to going live. They are also seeking feedback from the team of public contributors who co-produced the new content.
The team continue to work with the Programme Management Office to finalise the detailed project plan for the work to use HRA Approval as a means of increasing the amount and quality of public involvement in research applications. They are starting to plan a consultation workshop for December with stakeholders across the HRA to shape the details of the projects and secure input to deliver them.
The work to analyse the responses during 2014 to the public involvement question on the IRAS form for comparison with those from 2010 and 2012, which is part of the latter programme, is progressing well. Draft initial findings indicate that the amount of involvement in applications has continued to rise from 2012 to 2014, having risen between 2010 and 2012: in all studies from 19% in 2010 to 28% in 2012 to around 40% in 2014 (subject to confirmation). There look to be similar rises in all the different detailed areas of analysis (commercial vs non-commercial, and by type of funder), details of which will be confirmed by the end of October for discussion within the HRA from early November.

Communications

The Communications team has worked closed with the HRA Approval team to plan communications around Cohort 3 of the HRA Approval Programme, and has begun to implement these. They have also drafted plans to support the consultation on the policy framework. In the last month, they have also supported six events, including the transparency forum.

Executive meetings and conferences

Meetings in this last month have included the UKCRC Board, NIHR Advisory Board and the MISG Clinical Trial working group. Plus the REWARD / EQUATOR conference in Edinburgh.

BMA shared interests

The BMA presented some initial findings from work they have commissioned looking at GP views on research, how they are approached and the barriers and incentives it gaining support of GPs for research – to access data, patients or to consent. This is of direct relevance to our existing work on pragmatic trials and proportionate consent as well as having cross over to other areas of work, including effective study design and standards. The HRA is exploring how we can use these findings and work with the BMA to bring these GP perspectives in to the existing work streams.

Training/OD

Civil Service Learning went live on 1st October giving staff access to a large range of personal and leadership development resources for a cost of approximately £14 per person per year. CSL will provide a huge range of training opportunities for staff at all levels of the organisation. A large number of courses are e-learning and are free for all staff to access.
The 'All Staff Day' is planned for February 2016 and the Staff Survey is due to go live w/c 26 October.

Business Unit

Organisation wide roll-out of use of recycled paper to meet Government target – Key messages have gone out to all staff via All staff VC, and HRA news.
Efficiencies in travel and accommodation bookings - Redfern training has been provided for bookers on making the best and most cost effective use of the system. Using the system more effectively could potentially lead to further cost savings for the HRA in terms of travel and hotel bookings.

Programme Management Office

A PMO Communications strategy to explain and promote the PMO function and its support and QA of new projects is also under development in October.
These developments are designed to increase the competencies and maturity of the Project Management and PMO functions within the HRA.
Portfolio Management is being further developed by the PMO in the support of the 16/17 Business Planning process
The PMO is also offering significant support to the 'policy management' project which intends to deliver a robust process by which documents are developed and managed using a consistent and clear mechanism for preparation, review, approval, dissemination, communication, implementation, and version control. The eventual process will also increase accountability, ownership, buy-in, efficiency, reduce duplication and provide auditable trails.

Research Systems

The team continue to work to release updates to HARP and IRAS on a monthly basis. There is also extensive work on developing the specification for the invitation to tender for the new contract.

	Collaboration & Development The C&D Forum met on 6 October and focussed particularly on considering baseline information about metrics and user experience of the existing processes, with helpful sharing of data collected by Cancer Research UK and the Ethical Medicines Industry Group. The NIHR:HRA Forum with the NIHR funders has explored mutual interests in support of the NIHR 'pushing the pace' agenda and HRA's streamlining agenda. **EU Clinical trial regulations** An expected timetable has been made public which would see implementation no earlier than late 2017. The transparency rules have also been published and confirm the expected option to defer, although it does also require a justification but not permission, the member state having provision to override if it is in the public interest. **HRA Approval Programme** The planned date for cohort 3 has been announced as 30 November. Following discussions with the devolved administrations, cohort 3 will include cross-border studies. Collaboration with the CRN about their readiness for HRA Approval continues. Engagement with wider stakeholders is increasing with meetings with or presentations to ABPI, NHS Chief Executives, Clinical Trials Units, and non-commercial sponsors in recent weeks. Recruitment to new posts continues, although the latest round for senior assessors did not identify sufficient candidates of suitable calibre and additional re-advertising is underway. However, there is a good pool of candidates for assessor posts. The Approval Programme Healthcheck has just been completed and reported overall as amber. This being a confidence assessment of the programme as a whole not just readiness for cohort 3. The report will be presented to the November Board.	
9.	**HRA Approval** JMe reported that Cohort 2 went live in August – 35 applications have been processed and approved of which around 4 also required REC review. There is a need to build upon that experience for Cohort 3. Average review time is 17 days (range 2 to 47 including the time that queries are with the researcher i.e. no clock stop). Most applications involve more than 5 sites, with some bigger (eg 2 involve the whole NHS). Cohort 3 will go live on 30 November 2015.	
10.	**Business Plan and Strategic Planning update** SR presented a paper describing the application of the Golden Thread principle. Discussions had commenced in August including staff engagement. Documentation had been considered by EMT earlier this week and refinement continues.	

	A meeting 19/11/2015 will discuss and identify 'big ticket items' and may be refined in the light of the Comprehensive Spending Review. DH will require the draft plan at the turn of the year. JMe queried whether the process had also identified what the HRA does *not* need to do. SR indicated that the process had started from a point of including everything and paring that list down. Board was asked to note the timetable.	
11.	**REC Annual Report summary** SO identified the highlights in this report. It was agreed to formally thank one member for their extensive support of the Service by sitting on multiple meetings and sub-committees, that Operations should be congratulated for their resolution of issues within London RECs and that members should be congratulated for their continuing contribution.	
12.	**Finance Report** DC summarised the position set out in the circulated paper as at 31 August, and provided a verbal update on the position as at 30 September. The year to date underspend in September has decreased slightly due to the transfer of agreed operational savings to reserves and a year-end underspend is projected. Staffing has had a significant impact on the financial position due to timing of recruitment to vacancies, and at which point on incremental scales they will enter alongside the effect of transfers/promotions – 'leavers' at high incremental scale points replaced at lower scale points. DC provided explanation of the reasons why Operational performance is high alongside an underspend position and vacancies. Firstly, that the numbers of REC meetings have been reduced from 11 to 10, plus the member portal which allows more circulation and review of papers electronically yielding time and copying cost savings. Overtime has also been a factor.	
13.	**Update from website working group** KG introduced a paper reflecting the current position on work to update the HRA website including the revision of some pages and guidance. Current focus is a review against business requirements for the HRA. Future developments will involve observer feedback. The Board noted the early progress.	
14.	**Appointing Authority update September 2015** This report was received and noted.	
15.	**Any other business** BD advised the Board that the Government is using the Cities and Local	

	Government Devolution Bill 2015-16 to introduce an amendment to Section 251 of the National Health Service Act 2006. The amendment will be considered at Commons Committee stage this afternoon [3.30 p.m. Wednesday 21st October 2015]. The amendment is intended to clarify that the information in scope includes Local Authority social care service users' information and that the purposes for which information may processed include the provision of Local Authority social care. The Government's legal advice is that this amendment will not affect the existing Section 251 Regulations under which processing of confidential NHS patient information is currently approved, on advice from the Confidentiality Advisory Group, by the Secretary of State or the Health Research Authority.	
16.	**Questions from the public** None forthcoming.	
17.	**Date of next meeting** 18 November 2015 – at the Nottingham REC Centre	