NHS
Health Research Authority

HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 18th November 2015 from 11.30m – 4.00pm in the Nottingham HRA Centre

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
Joan Kirkbride	Director of Operations	JK
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	Director of Research Systems, Standards and HRA Approval Programme	JMe
Tom Smith	Director of Quality, Guidance and Learning	TS
In attendance		
Bill Davidson	HRA Policy Projects Lead *(in part item 9)*	**BD**
Marc Taylor	HRA Critical Friend	**MT**
Stephen Tebbutt	Board Secretary and Chief Executive Business Manager	**ST**
Observers		
Richard Carter	Department of Heath	
Christine Holmes	Department of Health	
Mary Cubitt	HRA *(in part item 7)*	

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** None to note.	
5.	**Update from Chair** *Accelerated Access Review* JMo advised the Accelerated Access Review: interim report had been published and was available on the gov.uk website at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/471562/AAR_Interim_Report_acc.pdf. *Excess Treatment Costs* The Board noted guidance on Excess Treatment Costs had recently been published and was available on the NHS England website at: https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf	
6.	**Update from Chief Executive** *HRA Approval Programme including cohort 3 NHS readiness survey* Work continues towards the planned go live for cohort 3 of 30 November, with advance publication of the guidance, standards and updated documents. The NHS readiness survey findings were received by the Approval programme Board on Monday 16th November. Key figures: – National response rate to readiness survey was 72% (168/232) *Of the organisations that responded*: – 87% of organisations had reviewed or partly reviewed guidelines on website (62% if include non-responders) – 48% actively preparing, or ready to respond – 42% Watchful waiting – 10% uncertain what to do, further information The response rate itself indicating good buy in and the local change leads will continue to follow up with all Trusts to support readiness for cohort 3 and 4. Productive discussions with operational representatives from the devolved administrations have resulted in agreed arrangements for handling compatibility for cross-border studies. A UK-wide call for comments on the local information package for sites has been agreed. Collaboration with the CRN about their readiness for HRA Approval continues, and an additional 'healthcheck' review for the NHS with LCRN Chief Operating Officers and others is being undertaken. Engagement with wider stakeholders is increasing – presentations have included university research governance teams, MRC trial coordinators, MRC centres, and Clinical Trials Units. A training package for non-	

	commercial sponsors has been piloted, and a package for commercial sponsors is being tested. Recruitment to new posts continues, with three new assessors appointed. A comprehensive package of training for assessors is underway. Collection of performance data for studies processed through HRA Approval is being refined. Janet Messer has presented at a meeting of a new clinical research network being established in Denmark, sharing the UK experience on streamlining regulation and adopting tools and templates to increase consistency. *Research Systems* The team continue to work to release updates to HARP and IRAS on a monthly basis. The team is providing extensive support to the NIHR Clinical Research Network to support the development of a new interface from IRAS. Design work with the devolved administrations to enable adoption of the combined IRAS form and shared use of HARP for cross-border information exchange for R&D purposes is underway, which will ensure UK compatibility alongside HRA Approval. Following publication of the invitation to tender, the team are responding to questions from interested suppliers in accordance with the strict procurement protocol. Arrangements for the evaluation are planned, and plans for migration are being put in place, should the tender be awarded to a new supplier. *Collaboration & Development* Support and advice to the Genomics England team continues, to address issues being encountered with engagement with the NHS. *Procurement of major contract* Good inter-directorate team approach continues to support this work. The team is supported by a procurement specialist provided by the Commercial Services team at the Department of Health (DH). The Invitation to Tender (ITT) document was submitted in line with plans on the 30th October to the Official Journal of the European Union (OJEU). It has been published on contracts finder. The deadline for the submission of tenders is Friday 27 November at 14:00, and potential suppliers have the opportunity to send in questions until Friday 13 November at 14:00. 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. *Estates* *Manchester office refurbishment* Work has completed. Meetings have been held with staff based in Manchester and the contractor to discuss issues which arose during the project, with a view to learning and improving. One key issue raised was the amount of	

	simultaneous change being asked of staff – change to laptops, change to digital telephony, changes to the office environment and home working. Plans for other offices have therefore been adjusted to take on board this feedback. *Move towards 8:10 staff to desk ratio - Hot desking* A proof of concept project to test out home working across Directorate staff within the Bristol office kicked off on 29 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. *London property update* 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, no further updates from DH have been provided. *Nottingham* Clarification on end dates of the 4 temporary offices at Standard Court now agreed and communicated to affected staff. Aim is for all staff to be based together within the Old Chapel by the end January 2016 at the latest. Additional resources secured from the Business Services Authority to help with this work and some minor modifications to the Jarrow office. *Finance* Good bilateral meeting held with the DH Sponsor, DH Finance colleagues and HRA. Substantial rating received in November for a Financial Management and Control internal audit report. ISO9001 certification audit completed. Report and any action plan expected shortly. Month end completed in 4 days once IT issues were resolved following the unavailability of the finance system due to problems with our IT provided service. Policy updates – additional resource progressing this important area of work. Good progress made. *Public Involvement* The public involvement team is finalising the content for the new patient and public area on the web site for approval**.** Once it has gone live, the public involvement team will take the opportunity to present this work to the HRA board highlighting the importance of involving patients and public in a project, such as this. Feedback from the patient and public website group who co-produced the new content will be collected into December and made available in January. The new policy for involving the public in HRA staff recruitment will be published in November setting out an expectation that recruiting managers will give due consideration to involving public contributors in staff recruitment for posts graded at band 8 and above and also for posts where the involvement of	

	the public would be relevant to the role being advertised. A new question has been added to the VCF form to reflect this change in policy and to provide some assurance that recruiting managers will have read the policy by asking them to state the reasons they will not be involving public contributors in recruitment for the role being advertised. We are continuing 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. The consultation workshop with stakeholders across the HRA to shape the details of the projects and secure input to deliver them is now being planned for January to avoid clashes with work on the latest cohort of HRA Approval. 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, continues with a view to drafting a report and paper for publication by the end of December. As indicated last month the findings show that the amount of involvement in applications has continued to rise from 2012 to 2014, having risen between 2010 and 2012 i.e. 38% of studies in 2014 indicated involvement in application compared with 19% in 2010 and 28% in 2012 *HR* This year's Employee Engagement Survey is being carried out currently. The closing date is 27th November and preliminary findings are expected mid-December. Work on HR policy harmonisation and revision continues. Since the last Board meeting two new harmonised policies and two further policies and procedures have been published following revision to meet ISO9001 certification standards, current legislative requirements and best practice. Our shared services provider, NHSBSA, will be undertaking an audit of our employee data in late November with a view to gaining greater accuracy and completeness of data, including Equality & Diversity information, for workforce planning purposes. *Communications* The Communications team has supported a number of initiatives in the last two months, including Cohort 3 of HRA Approval and the development and launch of this year's Staff Survey. We have created a communications plan together with the team responsible for the UK Framework for Health and Social Care, which was well received by the UK-wide steering group. We are now working to support the establishment of the website improvement project and are taking forward the work with the both the web supplier and the organisation for a redesign of the front page. We have also worked with a wide range of partners to identify the channels (and their requirements) we could access to help us disseminate our communications, thereby increasing the capacity and reach for future initiatives.	

Programme Management Office

The PMO is primarily engaged currently with supporting Directorates and the EMT with Business Planning and ongoing Portfolio Management (work prioritisation) 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)i.e. the "Demand"
- The development and use of an approach for prioritisation and a portfolio template
- Integrating the "Supply" details i.e. resource availability and budget to confirm the business plan

Other work includes completing a Communications strategy and plan for PMO stakeholders, and the provision of project support and assurance to several current projects Including the Research Systems Procurement and Policy Maintenance projects and the Estates Programme.

Business Unit

Gateway review further check – 14th to 16th December - Focused interviews for the NHS with CRN Chief Operating Officers and others. Arrangements in progress and on target.

Redfern - New Travel and Accommodation contract will be in place in December (with current provider), training for bookers has been arranged in the Manchester HRA Office in January 2016. Hope to roll out further training to other offices later in 2016.

Use of recycled paper – 100% Roll-out of use of recycled paper across HRA offices appears to have gone well overall

Organisational Development and Training

All staff day will be held in May/June 2016. This is an opportunity for all our colleagues to meet together to celebrate progress that has been made and consider the challenges ahead as well as an opportunity to further strengthen a 'one organisation' culture

Arrangements for 2016/17 Talent Management Programme currently being developed

Research Ethics Service

We received a request for support and advice from the Isle of Man Department of Health and Social Care, Isle of Man Government. Katie Urch, Chair of the West London and GTAC REC was approached and has kindly offered to work with the Isle of Man REC. We have also been contacted by Graham Love the CEO of the Irish Health Research Board, the main funder for health research in the Republic of Ireland. The Department of Health in the Republic of Ireland has asked him to look into potential improvements to the research ethics process and he is seeking advice from those who have done it well in other jurisdictions. Sheila Oliver attended the Social Care REC meeting to discuss the further

	integration of the Social Care REC within the research ethics service. The SCREC will come in to line with other HRA RECs, to discontinue reviewing staff research and service evaluation. We will also flag three other RECs to review Social Care research ensuring appropriate expertise and training. *NREAP hosted Chairs meetings* The autumn round of NREAP hosted Chairs meetings are underway with a varied agenda. Up-date items from NREAP and Operations have been well received and the meetings have been supportive of HRA activities.	
7.	**HRA Approval Gateway Healthcheck** Marc Taylor, HRA Critical Friend, gave a presentation to the Board regarding the findings from the recent HRA Approval Gateway Healthcheck. The Board noted a formal response has not as yet been provided however JW advised the recommendations were largely in hand. The Board noted the main recommendation which required further work by the HRA related to communications. The Board noted the HRA had produced a number of excellent briefings however these were often overly detailed for senior stakeholders. The Board agreed it is important communications are written and pitched for the correct level of audience to allow buy in from senior leads and for this to cascade down through their organisation. The Board discussed the resource requirements to allow a coherent communications strategy to be put in place. With regard to recommendation 1 relating to the risk register, the Board noted the Healthcheck team had only received the HRA Approval Programme risk register as part of their review. The Board was reassured by the HRA's comprehensive risk management process in place with other risk registers held for wider areas of HRA business which would include external stakeholder risks. The Board noted work on benefits realisation for HRA Approval was well underway however further work was required for the wider HRA benefits realisation plan. The Board agreed it would be helpful to receive the work conducted on benefits realisation for HRA Approval. ***Action: JMe to share benefits realisation work for HRA Approval***	**JMe**
	The Board agreed going live with cohort 3 should help researchers to understand HRA Approval as it will be used in practice. The Board agreed the critical path should be circulated for information but agreed it is important the softer activities are captured as well. ***Action: JMe to circulate critical path to Board***	**JMe**
	The Board noted the future readiness review will lead into how the HRA manages the recommendation to grow and develop ownership from other organisations. The Board noted this may raise some difficult messaging and the report may require review in the Part 2 – confidential session of the Board.	

	The Board discussed any potential risks to funding. DC clarified a recent bilateral meeting between the HRA, Sponsor and DH Finance had been held which did not give the impression that there was considerable risk to funding. The Board consider having stakeholders present when future discussions are held regarding HRA Approval after March 2016. MT flagged the need to include HRA staff as a stakeholder in these potential discussions. JW advised a management response to each recommendation will be made ahead of the next Board meeting in January. The Board agreed it would be helpful to provide clarity of actions and a timeline in the HRA's response. The Board gave thanks to everyone involved in delivering the programme as considerable progress has been made. The Board thanked those from the HRA who had supported the Healthcheck process.	
8.	**Finance Report September 2015** The Board received and noted the report for September 2015. DC advised the position at the end of October was that the HRA has spent £6.9 million year to date. The Board noted the forecast positon for end of year is ongoing. An expected underspend of £300,000 has been reported to Department of Health (DH) colleagues with the expectation that this will grow by the end of year. The Board noted the underspend is largely a result of vacancies in the Operations Directorate which have arisen either because of successful applications for roles linked to HRA Approval or due to the move of Research Ethics Committees (RECs) between HRA Offices in order to spread the support more equitably.	
9.	**UK Policy Framework for Health and Social Care Research** BD attended to present this item to the Board. BD highlighted the main revisions to the version the Board received earlier this year related to additions concerning the Social Care aspect following listening events held with the Social Care community. BD clarified the UK Policy Framework for Health and Social Care Research was shorter, more focussed and followed a principle based approach in comparison with the Research Governance Framework. The Board expressed its support for the new framework. The Board noted the consultation and its linked communications is due to take place at a similar time as the next stages of the HRA Approval Programme and queried if there was any possibility for confusion amongst stakeholders. BD agreed to take this account however flagged the UK Policy Framework for Health and Social Care Research was a UK wide piece of work and therefore any confusion should be minimal. The Board noted specific invitations for key stakeholders will be made seeking a response to the consultation alongside the questionnaire being made available	

	on the internet. This will include Social Care stakeholders to ensure the UK can be confident by the end of the consultation that the views of Social Care as a whole have been appropriately captured. The Board noted six engagement events have been scheduled to take place in England in February and March next year. The Board queried if any events were due to take place outside England. BD advised this would be discussed at the next UK Wide Steering group meeting however the Devolved Administrations (DAs) were aware of the England located events. The Board was reassured of the UK wide ambition to have a policy framework applicable across the UK. The Board queried the process for engaging with researchers. BD advised one engagement event was specifically targeted at researchers. The Board advised it might be beneficial in involving health research funders and asking them to circulate to their researchers. The Board noted the possibility of adding a link to the questionnaire to REC letters / on IRAS / and on operational staff email signatures. The Board queried the issue of supporting guidance and whether this could make the framework overly complicated. BD advised there would be a proportionate approach to what guidance was, and was not, required. BD flagged an item on the next UK Wide Steering Group meeting will be to consider the approach to ensure UK wide compatibility. The Board agreed to send BD any final comments by next Wednesday. ***Action: Board to provide final comments to BD***	**ALL**
10.	**HRA Key Performance Indicators (Quarter 2)** The Board received and approved the KPI report for Quarter 2. The Board discussed the format of the report and noted the lengthy process in collecting and compiling the report and the difficulty in presenting this to the Board within proposed timescales as detailed in J2. The Board agreed it did not necessarily need to review the same information which is considered by the EMT. The Board agreed a good cover sheet with narrative flagging the key areas of interest for that quarter would be sufficient with the full report provided as an appendix. The Board queried how the softer measurements could be reported and agreed this should not be lost sight of. The Board noted there was certain information, such as indicators relating to projects and programme activity which are not currently captured in this report. ST agreed to meet with Rob Allen, Programme Office Manager to discuss how this activity can be captured and reported to Board. ***Action: ST to discuss reporting of programme activity with Rob Allen*** The Board agreed it would be helpful to have a Board discussion to agree a dashboard which meets the needs of the Board and EMT once the Business Plan and KPIs have been agreed.	**ST**
11.	**HRA Corporate Risk Register (Quarter 2)**	

	The Board received and approved the Quarter 2 risk register. The Board noted the large number of risks which had been removed or closed since Quarter 1. In particular the Board queried why HRA206 – Metrics identification and HRA215 – Stakeholder expectation had been removed. JMe advised a considerable amount of progress had been made between the Clinical Research Network and the HRA with the minimum data set recently signed off and HRA215 related to the 70 day benchmark. The Board noted the risk register reflected the Quarter 2 position and the HRA Approval Programme Board had not yet had chance to review the HRA Approval Gateway Healthcheck recommendations and any associated risks were not therefore captured in this iteration of the risk register. The Board noted the new risk HRA303 – Insufficient resources to handle new site amendments relating to legacy studies. JMe advised there were currently a number of unknowns regarding this HRA Approval related risk however there was likely to be a considerable amount of work required hence the risk being raised to the Corporate Risk Register. The Board noted the updated risk relating to IT.	
12.	**Quality Assurance Update** The Board noted the Quality Assurance Update which included the REC Accreditation Scheme report for April – September 2015, the User Satisfaction report for April – September 2015, and the continuing development through to ISO 9001 Certification external audit in Q4 this year. The Board noted a discussion had been held at the October Audit and Risk Committee concerning how achieving ISO9001 accreditation supports the HRA in conducting its business. The Board was pleased to see the excellent feedback from respondents with regard to HRA staff and expressed its congratulations. The Board noted the feedback from respondents with regard to IS systems and agreed this was partly due to the expectations of users increasing. The Board was assured systems are stable and reliable and the feedback points towards users wanting the HRA to make further improvements.	
13.	**IRAS briefing to Board** TS tabled a briefing for the Board to outline some of the wider context of the Integrated Research Application System (IRAS), to provide more detail to support the Board on re-contracting for a research systems supplier, as well as to inform future discussions about HRA priorities. The Board discussed the issue of cyber security and was reassured regarding the regular testing and review which takes place. The Board queried if a regular update on security was required however noted any security test failures would be escalated to the Board. The Board also noted the reassurance the Audit and Committee receives through the review of audit reports concerning HRA Information Systems.	

14.	**Changes to Bank Account Arrangements** The Board noted the paper confirming the changes that are taking place with regard to the HRA bank account arrangements.	
15.	**Any other business** None to note	
16.	**Questions from the public** None to note	
17.	**Date of next meeting** 20 January 2016, HRA 1, Skipton House	