NHS
Health Research Authority

HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1

Minutes of the Health Research Authority (HRA) Board meeting, held on 22nd July 2015 from 1.00pm – 4.00pm in HRA 1, Skipton House

Present		Initials
HRA Non-Executive and Executive Directors		
Ian Cook	Director of Corporate Services	IC
Graham Clarke	Non-Executive Director	GC
Debbie Corrigan	Director of Finance	DC
Deirdre Kelly	Non-Executive Director	DK
Jonathan Montgomery	Chair	JMo
Nalin Thakker	Non-Executive Director	NT
		JW
HRA Directors who attend the Board		
Joan Kirkbride	Director of Operations and Approval	JK
Janet Messer	Director of Systems & Development | Programme Director – HRA Approval	JMe
Tom Smith	Director of Quality, Standards and Information	TS
In attendance		
Clive Collett	HRA Ethics Guidance and Strategy Manager *(in part item 7)*	CC
Andrew George	NREAP Chair *(in part item 7)*	AG
Katherine Guerin	Deputy Director of Corporate Services	KG
Stephen Robinson	Corporate Secretary	SR
Stephen Tebbutt	Board Secretary and CE Business Manager	ST
Observers		
Richard Carter	Department of Heath	

Item	Item details	Action
1.	**Apologies** Allison Jeynes-Ellis, Non-Executive Director Janet Wisely, Chief Executive	
2.	**Conflicts of interest** The Board noted ST would be asking NEDs to complete the declaration of interest form for 2015/16.	

	The Board noted JMo had agreed to sit on the Expert Advisory Group to advise on the scope, governance and operating model of the new Independent Patient Safety Investigation Service, led by Dr Mike Durkin.	
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** <u>Standing item on HRA Approval</u> The Board noted an update on HRA Approval would be provided as part of the Chief Executive's update. <u>HRA Approval – Cohort 3</u> The Board noted a paper would be brought to the September meeting to discuss issues and progress ahead of the go-live for Cohort 3. <u>Finance report forecast graph</u> DC advised the forecast graph was being reworked and would be ready for future reports. <u>Travel costs for January</u> DC clarified the reason why January travel costs were higher than normal was as a result of the earlier pay date due to the Christmas period. <u>Research Ethics Committee Membership Report</u> The Board noted a short information sheet regarding how REC member recruitment takes place had been circulated.	
5.	**Update from Chair** The Board noted the following update from the Chair: <u>*Policy Initiatives*</u> A number of important announcements were made by the Secretary of State for Health earlier this week in a speech *'Making healthcare more human-centred and not system-centred'* (https://www.gov.uk/government/speeches/making-healthcare-more-human-centred-and-not-system-centred). Amongst other things he stressed the importance of transparency about the performance of the NHS and committed to the NHS becoming a more effective learning organisation. A degree of restructuring of the regulatory system will occur with a new jointly-led Monitor and Trust Development Agency, with Ed Smith to be the new chair, supported by Lord Darzi as a new non-executive director. The operating name will be NHS Improvement. They will launch a recruitment process for the new chief executive immediately, which will be completed by the end of September. Dr Mike Durkin's work on safety and quality will move from NHS England to NHS	

	Improvement. Amongst his early priorities will be the establishment of a new Independent Patient Safety Investigation Service modelled on the Air Accident Investigation Branch used by the airline industry and to be operational from 1 April 2016. The Secretary of State also announced the publication of *Learning Not Blaming*, a response to the Freedom to Speak Up Consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and Dr Bill Kirkup's independent report on the Morecambe Bay Investigation. In addition Lord Rose's report *Review of NHS Leadership* was released. *Annual Assessment of NHS England* This document has now been published (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/447026/Annual_Assessment_of_NHSE.pdf) and includes the following paragraph: *There is still more work to be done in terms of consolidating the use of research evidence and promoting a research culture within NHS England. NHS England was slow to develop a research plan and it is working with the Department to improve the way in which excess treatment costs are managed. I know that work on the research plan is ongoing and NHS England will need to ensure that this sets out concrete actions with a timeline and clear methodology for delivery that demonstrates NHS England's direct contribution to the support and promotion of economic growth by the NHS.* *Triennial reviews* The outcomes of triennial reviews were published on 21 July in relation to NICE and the MHRA: https://www.gov.uk/government/consultations/nice-triennial-review https://www.gov.uk/government/consultations/mhra-triennial-review Triennial reviews have commenced this month in relation to the Human Tissue Authority and Human Fertilisation and Embryology Authority: https://www.gov.uk/government/consultations/human-tissue-authority-triennial-review https://www.gov.uk/government/consultations/human-fertilisation-and-embryology-authority-triennial-review *Accelerated Access Review* An online engagement was launched on 15 July: https://www.gov.uk/government/organisations/accelerated-access-review An international review by RAND Europe was published on 10 July. It looked into international examples of best practice where the use of new drugs, devices and diagnostics were already being accelerated. The study explored systems across the world through which drugs, devices and diagnostics pass rapidly, identifying what works both in theory and in practice. https://www.gov.uk/government/publications/improving-access-to-medical-technologies-an-international-review	

	Off-patent Drugs Bill This Bill is expected to have its second reading debate on Friday 6 November 2015. If the text is similar to that of Jonathan Evans MP in the last session, there may be implications for the HRA. The purpose of the bill is stated as to 'require the Secretary of State to seek licences for off-patent drugs in new indications; to require the National Institute for Health and Care Excellence to conduct technology appraisals for off-patent drugs in new indications; and for connected purposes.' http://services.parliament.uk/bills/2015-16/offpatentdrugs.html	
6.	**Update from Chief Executive** The Board noted the following update from the Chief Executive: *HRA Annual Report and Accounts* The Annual Report and Accounts were laid before Parliament on 14th July and will be formally received and approved by the Board today. *Judicial Review* The hearing took place on 16th July with the decision deferred with a HRA statement to be made once we are in a position to do so. We are grateful that Sense About Science participated in the claim. We are also grateful that the Ethical Medicines Industry Group (EMIG) supported the HRA in the case. The HRA remains committed to promoting greater transparency in research. *HRA Approval* A total of 12 studies have now been approved in cohort 1, with a further 5 studies in progress as of 16 July. The range for issuing Approval is 1-15 calendar days with no clock stops (noting that these studies do not require REC review). There have been no significant issues, although individual interaction with sponsors has provided helpful feedback for revisions to process, and we already have feedback from sites too. Recruitment of the next group of assessors and senior assessors is underway, in accordance with plans. New technical assurance staff are currently coming into post at the moment and getting trained up. Planning for cohort 2 is progressing to schedule, and the go live date has been announced as 10 August. Joint working between the Operations & Approval Directorate and the Approval Programme team has resulted in agreed pathways and processes for integrating the REC review and assessment. The significant information systems developments for this cohort are successfully completing testing. Collaborative planning with the Clinical Research Network (CRN) continues positively. Evaluation of the pharmacy technical assurance project with Cancer Research UK is being completed. Excellent progress is being made on collaborative discussions with DH, CRN and the NIHR centre that manages the collection of NHS performance benchmark data. These discussions will shortly be informing conversations between the DH team and ministers about future performance management with HRA Approval	

	– we anticipate continued collection of performance data by DH from individual NHS providers. Importantly these arrangements will be aligned with the CRN's performance management through the local networks and will support collection of data for both portfolio and non-portfolio studies in a way that will enable better understanding of activities across the research journey. *Regenerative Medicine Regulatory Advice Service* Since June 2014, the Human Tissue Authority (HTA), Medicines and Healthcare products Regulatory Agency (MHRA), Human Fertilisation and Embryology Authority (HFEA) and HRA have been working in collaboration to establish and provide a one stop shop service for regulatory advice for those working in regenerative medicine. A project group has been established, which includes staff from these organisations, and this group meets on a monthly basis. Note - whilst not regular members of the project group, staff within Defra and HSE have agreed to provide advice as part of this service, if required (i.e. as part of an enquiry related to genetic modification of organisms). The service, which is hosted by the MHRA Innovation Office, formally launched in October 2014 and was highlighted in the Regenerative Medicine Expert Group (RMEG) Report. Advice through this service is free of charge and may be sought by completing the template on the MHRA's Innovation Office webpage or by sending an email. This provides a single route of entry for an enquirer to access coordinated advice from the relevant organisations. The intention is to pilot the service for a year with a report on it prepared at the end of that time. An interim progress review, six months after launch of the service, found that the demand on the service has been considerably lower than expected and that of those queries received all required advice only from MHRA and HTA. No queries to date have required advice from HFEA or HRA. An updated communications plan is currently in preparation, which includes activities to further promote the service. *Health data programme – external reference group* In recognition that the UK's health data assets should offer clinical researchers a unique data source, whilst bringing significant benefits for patients and the NHS, as well as for the UK economy. The feedback from the stakeholders is that a number of challenges are preventing this widespread data usage, including the data governance and the data quality. In response to this, the Ministerial Industrial Strategy Group (MISG) has asked for a programme of work to be established that will define, agree and implement these solutions. The Maximising Research through Health Data Programme has been initiated to deliver these solutions, and it has sponsorship from senior levels. An important part in the programme governance is the External Reference Group (ERG) that will help to shape the programme and the output it delivers. HRA have been nominated to be a member of this ERG. Bill Davidson is taking the HRA wide lead on data and will attend the external reference group convened by DH.	

EU guidelines on lay person summary of results

At the last European Commission Ad Hoc Meeting on Clinical Trials it was agreed that the UK should lead the development of the EU guideline on lay person summary of results. This will support the implementation of the EU Clinical Trials Regulation and in particular develop upon Annex V of the Regulation, which sets out the elements that should be in this summary. Amanda Hunn is leading but will work closely with Simon Denegri and INVOLVE. The Commission has asked for a first draft for November this year.

UK policy framework for health and social care research

The comment period for the draft UK policy framework for health and social care research closed on 1st May 2015. We received over 60 responses from key partners, national bodies, universities, NHS trusts, local authorities and individuals to our initial call for comments on the new UK Policy Framework for Health and Social Care that will ultimately replace the UK health departments' current Research Governance Frameworks. 36 of the 46 key stakeholders we approached personally replied. Of the 28 unsolicited responses, 11 were from the NHS, 8 from HEIs, 5 from social care, 3 from charities and 1 from industry. Respondents were a mix of national (38), local (25) and overseas (1). Parallel exercises were conducted by the devolved administrations in Wales, Scotland and Northern Ireland. The responses were broadly similar between the four UK countries.

The comments received were generally very supportive, appreciative of the opportunity to comment at this stage and pleased to see a UK-wide approach being taken. Most responses were focused on a variety of drafting issues, mainly the need to avoid overlap in responsibilities between some of the different players. Some responses were out of scope of the UK policy framework, in particular seeking details of HRA Approval or calling for the inclusion of children's social care. The majority of social care respondents asked for better recognition of the issues they face and the RGF steering group agreed a key area of work ahead of the formal consultation will be to consider the needs in relation to social care further. Further social care listening events will be held on 15th, 22nd and 29th September in Newcastle, London and Manchester. It remains our intention to issue a revised version of the policy framework for full public consultation later in 2015. Prior to the consultation period, HRA Board sign off for the consultation in England will be required.

4th international conference – research integrity

Frank Wells attended the conference in Brazil which was attended by nearly 1,000 persons from 60 different countries. Frank presented a work in progress paper on behalf of the HRA regarding *Breach Register and Analysis* under the *Investigator irregularities: Iniquity, ignorance or incompetence?* session and advised it had been well received with calls for its future publication.

Templates and standards

We have opened a call for comments on the protocol template for qualitative research. Work on revising template contracts and agreements for research studies with stakeholders continues, although this is taking longer than anticipated. A workshop with stakeholders to test Information Governance

	requirements and standards has been held. This will inform changes to IRAS and will support the implementation of HRA Approval. *Communications* The communications team has just published the Year in Review and are supporting a stakeholder event in the autumn and HRA Approval. They are about to launch their new SOPs and are starting to plan for Cohort 3 and the consultation on the UK Research Policy framework. *Public Involvement* The Public Involvement team are in process of finalising a suite of HRA-wide policies to support the involvement of patients and public into the work of the HRA. They are also in the final stages of working with 6 Public Contributors to re-develop and rewrite the patient and public area on the HRA website. In addition, scoping and planning work is currently underway on the Public Involvement in HRA Approval Project which is a major programme of work we will be undertaking in 15/16 to use the HRA's influence to increase the amount and quality of public involvement in research design. *HR* The main focus for HR is on taking forward the revision of our HR policies and procedures to meet the requirements of internal QA action plans in readiness for the ISO9001 accreditation process, coupled with the ongoing harmonisation of further HR policies. Early work has begun on preparing for a workforce data audit planned for autumn 2015. *OD & Training* The training team is currently planning training programmes and procuring them for autumn and also processing all PDP requests and designing new technical talent programme for the autumn / winter. *Programme Management Office* The PMO will be implementing the Project Initiation and Closure processes, products and governance. The PMO Manager will develop and deliver a Programme Office Awareness Presentation to further explain and publicise what the PMO does, what support it can provide to projects, programmes and the portfolio, and which team members are responsible for the components. Finally, two new Project Support Officers are joining in the next few weeks and will be inducted into the PMO team. *Arbinger* Around 40 HRA senior staff attended a 2 day event "The connected organisation". The aim of this investment was to support the organisation as it develops, grows and changes. The HRA has seen significant change in the last 12 months with over 50 additional staff in post and more to come. The course provided an opportunity for all to consider how they could personally contribute to greater collaboration, performance and customer service. EMT will decide on next steps in the next few days to ensure that we can build on the positive start made. *Estates strategy work*	

	In line with our estates strategy requirements, applications to enter into new leases for HRA offices in Nottingham and Bristol have been submitted. Our medium term strategy is to remain at the current geographic locations and to maximise use of those sites through greater flexible working to achieve a ratio of 8 desks to 10 staff by March 2016. Plans are progressing to re-order the Manchester office in order to be able to accommodate the greater number of staff who are expected to be in post by October 2015. Plans to extend the digital telephony system (VOIP) beyond London and remote workers into Manchester to support flexible working are progressing. *Finance team* The team has successfully negotiated through a pretty challenging period. The HRA is an organisation which cares for its staff and support has been put in place however, inevitably, for a small team unexpected gaps have a significant impact. A case is being prepared to boost resilience within the team to be able to continue to provide a good service across the finance, estates and procurement services. A replacement finance trainee has been successfully recruited and will start in August. *Procurement* Work has been concentrated on working with the Research Information Systems team to secure contracts for the hosting of our key Research Information Systems alongside initial planning for the work to tender for RIS software and key development services with a view to securing a supplier and having a contract in place from April 2016. *Confidentiality Advisory Group* The HRA CAG Regulations 2015 were provisionally scheduled to be laid prior to summer recess although it is now likely to be upon return. The detail has not significantly changed since previous iterations. Interest is anticipated from the research community and privacy group (MedConfidential) when these come into effect (01 October) and when the CAG commences its advisory role to the HSCIC, with particular emphasis on interpretation and consequences. In establishing the function, public advertisements went out in the Guardian for both the CAG Chair and up to ten new CAG members in preparation for the CAG taking on its new function to advise the HSCIC from end October. Recruitment is ongoing to replace 2 members of the team who are moving on to new roles and recruit for the new function although due to notice periods the earliest in post is likely to be November 2015. We are exploring the feasibility of a short-term interim secondment. *Increasing consistency of validation* The HRA has been developing and testing a more vigorous approach to validation. This improvement aligns with HRA Approval through HRA staff giving additional help to applicants during the ethical review process, which builds on current good practice. The expectation is that this improvement will be rolled out in a phased way over the next few months, so will not come into effect for all studies immediately. The improvement will give additional support and	

	service to applications that will come in to the later cohort roll out of HRA Approval. We do however hope that the improvement can be provided for all studies submitted to English RECs by the end of the year. The HRA has recognised that there is benefit in giving applicants to Research Ethics Committees the opportunity to provide clarification on any inconsistencies within the application or to provide any missing information in advance of the REC review. This means that the REC is able to undertake its review based on clearer and more accurate information. It also means that the applicant has the opportunity to gather information in advance of the REC meeting, which is especially beneficial when the information needs to be gathered from different sources. The HRA has previously investigated benefits through the ethics officer pilot and evaluation. Feedback received so far has been very positive. Applicants have said that they found a lot of benefit in being able to provide information and clarification in advance of the REC meeting as this gave an opportunity to gather the information and improved the experience of attending the REC meeting. We have also noted an increase in the number of favourable opinions being issued as a first opinion which means that research is able to commence sooner. *Research Ethics Committees* A number of REC staff have been successful in gaining promotion to other posts within the HRA in the Systems and Development Team. This is excellent for the staff concerned and also demonstrates the success of our Talent Management Programme as many of these staff were programme participants. However, the REC service now has a significant shortfall in its staffing structure. We are of course actively recruiting to fill the vacant posts.	
7.	**Update from the National Research Ethics Advisors' Panel (NREAP)** The Board welcomed AG and CC to the meeting. AG and CC provided an update regarding the work conducted by NREAP over the last year and the development of the panel's role within the organisation. AG clarified the role of NREAP included being a consultative body for the HRA Operations team and the REC service in England. The panel is also used as a sounding board and provider of advice, largely for Operations. AG clarified NREAP has a role in raising the amount of debate in the REC community, largely through the NREAP hosted REC Chairs' meeting. AG advised some advice had been provided with respect to a challenge against a favourable opinion with a formal process now agreed. AG and CC advised NREAP would like to continue to give advice and guidance but also have certain areas or topics which it would proactively explore to help the HRA. This would include the development of new guidance but also reference to relevant guidance where necessary. The Board noted NREAP had identified two areas to consider for future work; Participant information and Information needed for REC review. The Board noted discussions were taking place with the Devolved Administrations to consider how NREAP can support colleagues in Northern	

	Ireland, Wales and Scotland with CC to attend the next Four Nations meeting. The Board noted the credibility and sense of authority NREAP holds amongst REC Chairs with the NREAP hosted REC Chairs' meetings a good opportunity to bring Chairs together to consider ethical issues and also support the delivery of messaging from Operations. The Board agreed the terms of reference for the NREAP required updating with the need for a legal orientated member removed. The Board noted the panel had relatively good coverage of membership however there was a question mark regarding the need for a social care orientated member which would be considered in the future. The Board noted the possibility of expanding the panel as and when required to obtain people with relevant skills to support a particular topic and agreed co-option powers might be required for the terms of reference if this is to be taken forward. The Board agreed it is important the work of NREAP complements other areas of work conducted by the HRA with priorities agreed to ensure appropriate distribution of resource and value added to the organisation. IC clarified the project management office held a portfolio of projects being undertaken by the organisation and it may be useful for the proposed NREAP areas of work to feed into this.	
8.	**HRA Annual Report and Accounts 2014/15** The Board formally received and agreed the Annual Report and Accounts for 2014/15. The Board thanked those involved, in particular the Finance team, for the work in drafting the report.	
9.	**HRA Year in Review 2014/15** The Board noted the Year in Review and agreed it was an excellent, easy to read document. The Board gave thanks to the Communications team for its work in drafting the document.	
10.	**HRA Code of Conduct** SR introduced the code of conduct and informed the Board regarding the comprehensive consultation process with staff. The Bard recommended updating the code to state 'I will' rather than 'you must'. The Board discussed the possibility of utilising a social contract in conjunction with the code of conduct in future. The Board welcomed the code of conduct and agreed it should be signed by the Board and welcomed staff to sign it.	
11.	**Freedom to Speak up – Francis report on 'whistle blowing' – HRA response** The Board noted their responsibilities in relation to the recommendations of the Freedom to Speak up - Francis report on 'Whistleblowing'. The Board noted the actions EMT intends to take in relation to engaging staff. The Board was	

	reassured that many of the requirements outlined in the report are already covered in our current Whistleblowing policy. The Board noted the policy would be updated to ensure it reflects the key principles and actions outlined in the report. The Board agreed it takes the integrity of the organisation very seriously and agreed it would be appropriate to have a NED to be nominated to support the whistleblowing process. The Board noted DK had agreed to be the nominated NED. The Board agreed an equivalent from the EMT should also be identified. The Board approved the response with IC to clarify the roles of the Exec, the role of DK and also the role of the Audit Chair who is referenced in the policy. ***Action: IC to finalise HRA response including clarifying roles.*** The Board agreed EMT should consider adding the procedures to be followed to noticeboards in each office.	**IC**
12.	**Finance Report** The Board noted the finance report for June 2015. DC flagged the following main points to the Board: Devolved Administrations income has now been finalised at £196k. It is slightly lower (£10k) than originally planned however it is positive that final agreement has been reached. Activity figures relating to the new NDPB statutory functions and additional duties in relation to the Confidentiality Advisory Group (CAG) indicate that a CAG 3 will not be required in 2015/16 and this has been removed from the financial plan both in terms of additional income due and expenditure to be incurred. Actual activity rates will need to be monitored to help inform business planning for 2016/17. Meeting the affordability requirements for CAG 2 have also concluded and been agreed. The reserve set aside in the financial plan will now be deployed and the adjustment to grant in aid has been agreed at £65k part year effect funding for 2015/16. There is a £181k under spend as at the end of June 2015 (£125k May 2015), largely within the Operations and Approval Directorate and mostly due to the number of vacancies that have arisen either because of successful applications for roles linked to HRA Approval or due to the move of RECs between HRA Offices in order to spread the support more equitably. The Board noted the vacancies have had an impact on the KPIs for Operations and this may be noted at the September quarterly update meeting. The Board noted agency staff, via the Government framework, were being utilised with staff also undertaking overtime. DC agreed to circulate a note after the meeting regarding the overtime figures for staff as the Board were aware of the possible impact this may have on staff. ***Action: DC to circulate note re overtime figures***	**DC**

	The Board noted 20% of the financial plan has been spent after 25% of the financial year has passed. The Board noted the positive figures in relation to travel costs and hotel bookings with the HRA the best performing ALB for advanced bookings for rail travel with a £70-80K saving in comparison with if bookings were made on the day of travel. The Board noted the HRA was second behind the Department of Health for hotel booking costs in and outside of London.	
13.	**Quality Assurance update** The Board noted the Quality Assurance update and in particular noted the hard work undertaken by the QA team in increasing the scope of ISO 9001 Certification from the current QA department to HRA wide. TS expressed his thanks to relevant managers for the completion of action plans. The Board noted EMT had agreed to incorporate the QA Management Group formally as part of a yearly EMT meeting to ensure management have oversight of development, issues and routes to continual improvement and to conform to the formal requirement of ISO9001 Certification. GC agreed it would be helpful for a summary of internal QA audit highlight reports to be noted at the Audit and Risk Committee.	
14.	**HRA Audit and Risk Committee Annual Report 2014/15** GC gave thanks to the current and previous Audit Committee members for their work during the period April 2014 – March 2015. GC advised the Committee was satisfied with the execution of work conducted by the Health Group Internal Audit Service and external audit. The Board received and noted the report for information.	
15.	**HRA Audit and Risk Committee Meeting Minutes 21/04/2015** The Board received and noted the 21st April 2015 Audit and Risk Committee minutes.	
16.	**Summary of Freedom of Information requests received by HRA 2014/15** The Board noted the summary of freedom of information requests received by the HRA for 2014/15. The Board noted the increase in requests received in comparison with previous years. The Board noted a number of the requests where for information the HRA does not hold e.g. vehicle fleet information. The Board agreed it would be helpful to provide a breakdown of the types of requests received on the spreadsheet to match that on the cover sheet. The Board noted the good practice in publishing certain information and referring requesters to this information. This may be applicable for some responses e.g. in relation to IT information requests which had seen an increase in the number of requests received for the first quarter of 2015/16.	

17.	**Summary of Complaints received by HRA 2014/15** The Board noted the summary of complaints received by the HRA for 2014/15. The Board agreed it would be helpful in future to note where the complaints had been received from if possible e.g. NHS, public, industry. The Board agreed it would be helpful to receive the user-feedback alongside the complaints information in future.	
18.	**Summary of Appeals against REC opinion received by HRA 2014/15** The Board noted the summary of appeals against REC opinion received for 2014/15.	
19.	**Any other business** None to note.	
20.	**Questions from the public** None to note.	
21.	**Date of next meeting** 16 September 2015	