HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 17 January 2018 at the London HRA Centre

Present		Initials
HRA Non-Executive and Executive Directors		
Teresa Allen	Interim Chief Executive	TA
Graham Clarke	Non-Executive Director	GC
Ian Cook	Director of Transformation and Corporate Services	IC
Allison Jeynes-Ellis	Non-Executive Director	AJE
Deirdre Kelly	Non-Executive Director	DK
Jonathan Montgomery	Chair	JMo
Nalin Thakker	Non-Executive Director	NT
Karen Williams	Director of Finance, Procurement and Estates	KW
HRA Directors who attend the Board		
Janet Messer	Director of Approvals Service	JMe
Juliet Tizzard	Director of Policy	JT

In attendance		
Amanda Hunn	Joint Head of Policy	AH
Stephen Tebbutt	Head of Corporate Governance	ST

Observers		
Bill Davidson, HRA		
Katherine Guerin, HRA		
Christine Holmes, Department of Health		

Item	Item details	Action
1.	**Welcome and apologies** The Board noted apologies from Janet Wisely. The Board welcomed JT to the HRA noting it was her first Board meeting since joining the HRA at the start of January.	
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**	
	HRA Code of Conduct	
	The Board noted this had been reviewed by the Leadership Team and noted no new changes had been made to the Code.	
	Communication lists for NEDs	
	ST confirmed NEDs would be added to the HRA news invite list, the HRA intranet and other relevant email circulation lists by end of January.	
	HRA Endorsement of registries in England	
	AH advised an update will be provided at the next Board meeting.	
	Action: AH to provide update on Endorsement of registries in March	**AH**
	Presentations / briefings for NEDs	
	The Board noted the briefings relating to sites and REC decisions would be provided prior to the next meeting. The Board agreed it would be helpful to understand further what areas of HRA business would be useful to brief NEDs.	
	Action: Briefings to be provided to Board prior to next meeting	**ST**
	Social Care Research to be added to a future Board meeting	
	The Board noted this was provisionally scheduled for the May Board meeting. JMo and TA advised a constructive meeting had been held with the Association for the Directors of Adult Social Services (ADASS).	
	Discussion regarding volunteer role with Stephen Powis	
	JMo advised no discussion had taken place as yet however a meeting has been scheduled for 10 April 2018.	
	Reasons for breaches and application of learning / guidance / training	
	The Board noted this would be provided at the next Board meeting.	
	Action: Ann Tunley / Catherine Blewett to provide update on reason for breaches at March Board	**AT/CB**
5.	**Update from Chair**	
	Janet Wisely, OBE	
	The Board was delighted to note Janet Wisely has been awarded an OBE in the New Year Honours list in recognition of her service to health and social care research. The Board agreed the honour was well deserved and passed on its congratulations to Janet.	
	Meetings	
	- Chaired the UKCRC Regulatory and Governance Forum on 06 December 2017. The focus of the meeting was to consider the strategic agenda of the forum going forward.	
	- Professor Jane Dacre, Professor of the Royal College of Physicians. JMo	

	advised the meeting had been to discuss potential synergies between the RCP and the HRA and any mutual areas of opportunity. JMo agreed to keep the Board informed.	
6.	**Update from Chief Executive** TA provided the following written update to the Board: We were all delighted to hear the news that Janet Wisely has been awarded an OBE in the New Year's Honours. This is a huge endorsement of the massive contribution that she has made to the research system for the benefit of patients and the public. I would like to formally welcome Juliet Tizzard our new Director of Policy who joined us this month from the HFEA, we are all looking forward to working with her. Juliet's arrival completes our executive restructure and brings valuable experience and additional resource to strengthen our executive and policy teams. During December the executive team took the opportunity to look back over our challenges and achievements in 2017 and we have pulled together some key messages which we will be sharing with our staff during January. Without exception, every team across the HRA has made a positive impact this year and our overall performance has remained strong. We are now well into the business planning round for the next financial year and to ensure that we remain resilient our two main priorities will be the successful delivery of the Service Improvement Programme and changes to our IT Systems HARP and IRAS. Both of these will bring benefits to research applicants and our own staff and are being aligned to ambitions in the Life Sciences Industrial Strategy our own strategic aims and the collaborative work with NIHR. Brexit, GDPR and the use of Data in Health & Care Research will also feature in the plan alongside a change to our Desktop Services supplier and the move of the Jarrow office into new accommodation. In our follow up meeting with Professor Sir John Bell, we took the opportunity to discuss our thoughts around the new data hubs which are planned for the autumn. We are willing to play a key role in the development of a communication plan including a dialogue with the public about the benefits to society of data sharing for research and the changes that will be put in place to protect their interests but would welcome some strong clinical leadership and a system wide collaborative approach so that messaging is consistent. We were also able to hear more about the plans for the use of Artificial Intelligence in Diagnostic Imaging which has recently been covered in the media. We have responded to a letter from Rt Hon Norman Lamb MP following a Select Committee meeting on research integrity which took place in December. Dr Ben Goldacre and Dr Simon Kolstoe both spoke at this meeting and Simon submitted some suggestions on the role that the HRA can play in terms of research transparency. We believe that there are a number of opportunities here but they need to offer value for money and to be easy to implement and maintain.	

The new IRAS build in combination with new intelligence from other sources may assist. The HRA has now been invited to provide verbal evidence to the Select Committee.

At the end of December we received approval to commission the services of an implementation partner to help us through the procurement and development of our IT systems and the business case for the new system has been approved by Government Digital Services. As we will only have a 12 month window to complete this work we will be using an Agile approach and have started training staff in this way of working so that we will be ready to start work immediately.

88% of Staff in the HRA who completed the staff survey have supported formalising our relationship with the Unions and we are currently in the process of drawing up an agreement.

External engagement activity

Contacts	Name of organisation	Purpose of meeting
Prof Rosalind Raine - Director	NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames, UCL Partners	To discuss the use of Health Data in light of the LSIS
Jonathan Sheffield -CEO Jon Fundry -COO Sam Atkinson – Director of Transformation	NIHR MHRA MHRA	To discuss workshop to create a Digital roadmap for HRA/MHRA and NIHR
Mike Rawlings - Chairman Ian Hodson -CEO	MHRA	Regular catch – up including update on CTR and joint planning
National Chairs day	HRA	HRA hosted meeting to update REC chairs on Policy developments and legislative changes
Dez Holmes - Director of Social Care	Research in Practice and Research in Practice for Adults, Devon	To explore challenges of social care research and identify useful contacts for strategy development
Margaret Wilcox, President	Association of Directors of Adult Social Services (ADASS)	To learn about ADASS research approval and to discuss how HRA and ADASS can work together
Ben Goldacre	University of Oxford – Nuffield Department of Primary Care	To learn about the tools which have been developed to monitor research publications and to follow up on select committee
Prof Julia Newton Dr Alan Bagnall	Newcastle Clinical Research Team	To meet the team, listen to feedback about the HRA, share

	Yan Yiannakou Paddy Stevenson Aileen Burn Ian Campbell Gill Chater Angela Topping Susan Ridge		information about current and planned activity and to explore different ways of working of mutual benefit to research	
	Clair Harris	Clinical Research Matron, ACET Kings College Hospital Clinical Trial Unit	To meet the clinical trials team, listen to feedback about the HRA, share information about current and planned activity	

Late January Planned Meetings

Forward Planning Meeting with DH Policy team
Turing Institute - Use of AI Regulatory Case Studies
Professor Leon Feinstein – Director of Evidence Children's Commissioner
Maya Zlatanova CEO at FindMeCure & NIHR – Linking patients with Clinical Trials

7. HRA Directorate update

HRA Approval

HRA Approval performance continues to be stable.

The roll out of joined up validation is underway, with training being delivered to teams. Wales is also scheduled to join the process.

The SIP workstream focussed on supporting applicants to 'get it right first time', with input from IRAS Partners, has signed off a specification for a verification tool in IRAS that will automate the checking of key data, authorisations and documents to support applicants to submit a valid application.

The proportionality workstream is analysing feedback from stakeholder interviews, and further discussions about prioritising actions in this area are to be taken forward.

We are preparing to begin testing a new Activity and Cost Attribution Template, building on the Schedule of Events used in HRA Approval. This new template will be tested by funders for use early in the research journey, so that the information can be captured and taken through the research process to minimise duplication of provision of financial information by applicants.

NHS England Consultation on supporting research in the NHS

HRA has supported listening events with the NIHR Clinical Research Network and NHS England for a consultation on proposals to address ongoing issues across the NHS in England with Excess Treatment Costs for non-commercial studies and variability in contract value for contract commercial trials.

UK-wide NHS/ HSC compatibility programme

Work on compatibility of processes in site set-up continues, identifying and resolving differences in processes that can be streamlined to the benefit of researchers undertaking cross-border studies. Discussion is focussed on clarifying which aspects of process are nation-specific and which should be UK-wide.

EU Clinical Trials Regulation implementation

Work continues towards a live pilot starting of an integrated process between REC and MHRA starting in April 2018 with a limited pool of applicants. This includes committees from the Devolved Administrations.

General Data Protection Regulation implementation

Work is underway to publish operational guidance and establish internal arrangements for supporting the research community with making appropriate changes needed for compliance with the General Data Protection Regulation. This will supplement the policy briefing information being published by HRA and developed by a range of bodies across health research.

Collaboration & Development

A joint project with NIHR CRN, CQC, HRA, patient representatives and MHRA to identify and agree indicators for inclusion in CQC review of data and inspections is in its third month. HRA is represented on Project Board and on the Operational Group. Additionally, Juliet Tizzard was nominated by Jonathan Montgomery to oversee and support the project board.

The Operational Group is working to identify markers for monitoring by February in accordance with CQC timeframes, and markers for inspection by Autumn 2018. The project aims to introduce a mixture of markers, some of which will be quantitative data (for monitoring) and others descriptive/ qualitative (for inspection.)
The following three levels for assessment will be used for assessment:

1. How organisations promote research awareness for patients
2. How organisations facilitate research
3. How organisations show equity of access and improvement

Different levels of assessment aim to generate enthusiasm for improvement from both research active and less research active Trusts. On consultation with senior representation from the R&D community, including R&D Forum leadership, it is felt that the move will assist R&D Departments in developing and maintaining the profile of, and support for research activity and R&D departments within respective Trusts, across which there is varying understanding of and support for research activity and its effective management.

Learning and Development

HRA Learning and Development (L&D) continues to reach new users. The newly re-vamped intranet pages include the Learning Zone, which was the HRA intranet's most visited page over the 90-day period up to December. In the last quarter of 2017, HRA L&D delivered 2,400 hours of learning to over 400 people. The eLearning modules were accessed by almost 800 unique IP addresses (which doesn't account for more than one user accessing from the same organisation). Increasingly we are working to engage with other stakeholders, either through the development of collaborative learning opportunities or by supporting staff to visit other organisations. The focus for 2018/19 will be on improving the quality of learning offered and the development of more online opportunities.

Finance

Our finance business partners have been working with budget holders and managers to collate the 9 month forecast for the year and are now starting to pull together draft detailed budgets. This year, to release capacity in service delivery and also target savings where possible, this first stage will be performed centrally based on current performance and known external environmental changes. We are also working to utilise more of our accounting system functionality in order to further improve our budgeting and forecast process for next year. This includes using forecasting capabilities in the system and also rationalising the chart of account (particularly the number of cost centres) to increase value from our financial management processes.

We are also rolling our employee self-service for ESR (electronic staff record) which will improve control and reduce manual processes in our payroll management. Additional resource has received DH approval for this and we are now recruiting to this role to take forward this project.

Estates

Our move to NHS BT blood centre in Newcastle is provisionally planned for 16th March. There are still a few details to confirm (head lease landlord permission, BT line, refurbishment completion date) which means this date may move – but hopefully our team in Jarrow will be settled in their new location by the end of the financial year.

Internal audit

Discussions have started with internal audit to develop the 2018/19 internal audit plan with a keen focus on value and ensuring we target our internal audit resource where is will add most benefit for the HRA next year, particularly given our extensive transformation programme.

Joint HRA/HTA public dialogue on tissue and data sharing

The public dialogue on tissue and data sharing is drawing to a close. The Oversight Group will meet on 19 January to consider a draft report with recommendations, covering:

- Understanding of research, tissue and data
- Views of linking tissue and data:
- What should be included in broad consent
- Genomics
- Dynamic Consent

Transparency

The House of Commons Science and Technology Committee's enquiry into research integrity has sought further written evidence from the HRA, focussing on our role in ensuring that a greater proportion of studies are published. A further oral evidence session, which we may be called to, is scheduled for late January.

National data opt-out programme

The national data opt-out programme will allow NHS patients to opt out of uses of information about them for purposes other than their direct care. We have been working through the programme board and programme advisory group, and with NHS Digital and partners, to encourage co-ordinated communications, realign the timetable to the introduction of GDPR and resolve outstanding policy issues, e.g. what information should the opt-out apply to and should there be an opt-out for research separate from other secondary uses.

GDPR preparation

HRA has worked with partners to develop briefing documents on the EU General Data Protection Regulation. These were published before Christmas and cover four topics where the Regulation has particular implications for research: legal basis for processing; safeguards; transparency; and data subjects' rights. The guidance has been well received.

Work is now underway to publish operational guidance and establish internal arrangements for supporting the research community with making appropriate changes needed for compliance with the General Data Protection Regulation. This will supplement the policy briefing information being published by HRA and developed by a range of bodies across health research.

Access to patient information

DH policy and process (in England) has been that all organisations (not just in England) that have access to NHS patient information must provide assurances that they are practising good information governance and must use the Department of Health's Information Governance Toolkit (IGT) to evidence this by the publication of annual IGT assessments. This means that organizations anywhere that want to receive confidential patient information under Section 251 have to demonstrate a satisfactory IGT score, even though the IGT does not otherwise apply outside of England. The burden is exacerbated because there are often comparable assurances that they have already achieved, but they have to repeat the effort by doing an IGT assessment. After receiving

correspondence from researchers, CMO took an interest and asked us to find a solution. We have now reached agreement with DH that other information governance assurances can be accepted too (e.g. ISO27001 certification, ISO27002 certification, Information Security Toolkit assessment in Scotland, Public Benefit and Privacy Panel approval in Scotland). We are working with the Confidentiality Advice Team to implement this solution as soon as possible.

Governance Arrangements for Research Ethics Committees

A further policy issue has been identified regarding research involving analysis of previously extracted DNA. The agreed policy position is that research involving extraction of DNA from "relevant" material (i.e. tissue) or from acellular material for the purpose of research analysis is to be subject to REC review; however, this appears to leave a gap for research that does not involve extraction but uses previously extracted DNA instead. We are working with HTA to clarify and address this apparent inconsistency in safeguards before finalizing the revised edition of GAfREC for 4 Nations' agreement.

Research Ethics Committee Accreditation status

Name of REC	Accreditation status as at 01 December 2017
Scotland A	Full accreditation under 2016 scheme (after completion of action plan)
East of England – Cambridge East	Full accreditation under 2016 scheme (after completion of action plan)
Yorkshire & the Humber – Leeds East	Full accreditation under 2016 scheme (after completion of action plan)
East Midlands – Leicester South	Full accreditation under 2016 scheme (after completion of action plan)
London – Surrey Borders	Full accreditation under 2016
North East – Newcastle & North Tyneside 2	Full accreditation under 2016 scheme (after completion of action plan)
London – Chelsea	Full accreditation under 2016 scheme
London – Westminster	Accreditation with conditions (action plan pending completion)
Wales REC 2	Full accreditation under 2016 scheme
Wales REC 3	Provisional (action plan pending completion)
Wales REC 1	Full accreditation under 2016 scheme
North East – Tyne & Wear South	Full accreditation under 2016 scheme

Service Improvement Programme/Transformation Board

- Detailed planning exercise to be held on 22 Jan which will detail work/products required to deliver necessary business changes (by March 2019) to ensure projected benefits are realised.
- Programme will now be accountable to the Transformation Board (inaugural meeting on 24 Jan) which will also have oversight of the Research Systems Programme
- The Transformation Board will be responsible for the delivery of the

Transformation Programme (TP). The TP is the vehicle by which the HRA intends to reshape its organisation in order that its people, structures, systems, processes and capital resources are aligned in a way that offers the HRA the most effective business model to deliver its strategic objectives

Research Systems Programme

Progress is being made in the following areas:

- Engaging a procurement partner to lead on getting to Market and selecting supplier (target April 2018)
- Engaging additional internal resource to support internal team
- Designing and delivering a programme of 'Agile' Training for RS staff (Agile will be the methodology by which the new system will be developed)
- Development of Programme Initiation Document which will detail the scope/structure/objectives of the work
- Producing high level requirements document (identifying what we want the new system to do)
- Identifying how best HRA works with the MHRA in developing systems in response to EU Clinical Trials

IT Service

- In addition to ongoing management of the service from ATOS via IMS3 there are several items being progressed to support internal users, including laptop refresh and additional wifi devices for use in offsite REC meetings. An HRA technical roadmap is also being drafted to help inform how the organisation might want to move from its current state to a future state, which will help inform the budgetary planning process.

- The HRA continues to engage with the Future Services Programme (replacement for ATOS) and recent engagement has included involvement in developing the programme objectives and high level requirements. The design phase of the programme is expected to start shortly, being led by DH.

HR

- A New Employee Assistance Programme (EAP) was launched in January - the Workplace Wellness EAP operates a free, confidential counselling and information service available to all staff on a 24 hours a day, seven days a week basis

- A manager's e-handbook is being developed to help support line managers in undertaking the main people management aspects of their role. We aim to roll it out by end March 2018

- Trade union recognition - work has begun on drafting a partnership agreement in response to the strong result in the staff survey

	supporting the development of working more closely with Unison • Review of our flexible working policies is being undertaken - any changes will be implemented in time to support the move of Jarrow staff to Newcastle in March • Working with Finance, work progresses on arrangements to roll out a staff salary sacrifice car lease scheme during Q4 **Communications** • The communications team have been undertaking further work to embed new processes around the website, begin the knowledge transfer from our fixed term post holder (Naomi) to the rest of the communications team and have developed a training programme which they will begin to roll-out at the end of this month for those who will update content. • The team have also provided communications delivery and support for the staff survey, the CAG chair recruitment, service improvement programme, GDPR guidance and the public involvement analysis publication. • The new Head of Communications is due to join the team at the beginning of February.	
8.	**HRA Staff Survey 2017** IC presented a summary of the staff survey to the Board, noting this had also been shared with HRA staff. IC clarified the final report is in the process of being finalised by BMG. The Board noted the final report would be at an organisational level with no break down by HRA office. The Board noted the full report would be available following the all staff videoconference on 23 January. The report would be subsequently reviewed by the Leadership Team and the Staff Forum before being reviewed at the next Board meeting. The Board noted staff forum representatives would be invited to join the Board at the next meeting to discuss the findings and consider the action plan to address any areas of concern. IC flagged this year's response rate had been the highest rate since the HRA began undertaking staff surveys. The Board noted there were many positives to take from the responses received, in particular with regard to the questions concerning change management. The Board expressed concern with regard to number of people looking to leave the organisation in the next 12 months combined with the lack of opportunities for career development or progression. The Board however noted last year there were considerably more opportunities available as a result of the roll out	

	of HRA approval. The Board also accepted those staff at the beginning of careers may only be anticipating to spend 12 months in any role before moving on to another position. The Board agreed the HRA should be helping with career progression, even if staff move onto other organisations. The Board agreed there may be career opportunities in other areas of the research community which may be of interest to staff. The Board questioned whether it would be possible to identify where recent leavers of the HRA have moved on to.

The Board agreed further analysis of the new question around health and wellbeing would be beneficial to understand if the HRA should be concerned by the findings.

The Board agreed it is important the staff survey is not seen as the only route for providing feedback on their experience.

The Board was pleased to note the percentage of staff who had received an appraisal in the last 12 months was 98% however agreed providing the provision of appropriate appraiser training was important to ensure staff gain the most from their appraisal.

The Board agreed lunch with the staff forum representatives and the NEDs should take place as part of the March Board day. | |
| 9. | **Proportionality project**

AH gave a presentation to the Board providing an update on the Proportionality project. AH flagged as part of the project she had interviewed DK and NT.

The Board discussed the issue of NHS Staff studies not requiring REC review and noted these studies may be diverted elsewhere, such as University ethics committees, for review which may add strain elsewhere in the research system.

The Board discussed whether there was any potential manipulation of the proportionate review process by researchers to avoid having to go to full REC review for example through the removal of sensitive questions from questionnaires.

The Board agreed this is important work and momentum should be continued. The Board noted a report would be taken to the Transformation Board meeting in February with a set of recommendations to follow. | |
| 10. | **Finance report**

The Board received and approved the Finance report for the eight months ended 30 November 2017. KW flagged the underspend position of £51k (0.6%) on revenue expenditure and £89k (16.4%) underspend on capital expenditure and anticipated this may grow slightly prior to the end of the year. SLT has reviewed our reserves position and are actively redirecting this predicted underspend on planned activities to invest in capacity for our service improvement programme, research systems programme and investment opportunities that will reduce our cost base in future years. | |

11.	**Out of session business conducted** None to note.	
12.	**Any other business** None to note	
13.	**Questions from the public** None to note	
14.	**Date of next meeting** 21 March 2018, Newcastle	