HEALTH RESEARCH AUTHORITY
BOARD MEETING

PART 1 – PUBLIC SESSION

Minutes of the Health Research Authority (HRA) Board meeting, held on 24 July 2018 at etc. Venues, Avonmouth House, London

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
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		
Juliet Tizzard	Director of Policy	JT
In attendance		
Sue Bourne	Head of Guidance & Advice	SB
Gaynor Collins-Punter	Deputy Director – Research Systems *(items 1-8)*	GCP
Nick Hirst	Implementation Partner & IT Advisor *(items 1-8)*	NH
Amanda Hunn	Joint Head of Policy *(items 1-8)*	AH
Stephen Tebbutt	Head of Corporate Governance & Risk	ST
Observers		
Katherine Guerin, HRA Christine Holmes, Department of Health & Social Care *(items 1-8)*		

Item	Item details	Action
1.	**Apologies** Allison Jeynes-Ellis, Non-Executive Director Janet Messer, Director of Approvals Service	
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** <u>Annual Report and Accounts</u> The Board noted the HRA Annual Report and Accounts for 2017-18 has been published. <u>Chief Executive update</u> The Board noted TA had added the benefit of the meetings with stakeholders to the Chief Executive update. <u>Staff survey</u> The Board noted an update would be provided in Part 2 regarding case studies for managing poor performance <u>Transparency update</u> The Board noted an item to this effect was detailed on the agenda. <u>Regulation of new technology</u> The Board noted an update would be provided at the September Board meeting. ***Action: TA to provide update at September Board meeting*** <u>Timelines to first patient recruited performance update</u> The Board noted this was in the process of being finalised and would be circulated out of session. ***Action: JMe to circulate timeline presentation out of session***	**TA** **JMe**
5.	**Update from Chair** <u>CEO recruitment</u> A recommendation is being made to the Secretary of State (SoS) following the interviews held on 9 July. We do not know when we will receive a response, as the induction of Matthew Hancock as SoS is no doubt very full. Submissions will be considered by him throughout the summer so there is no delay due to the Parliamentary recess. <u>NED recruitment</u> There is a maximum 12 week recruitment timetable. A job description has been submitted to DH that identifies (in additions to the generic NED criteria) digital technology transformation, senior experience in health/social care research, and industry (Pharma, Biotech or other life science) as headline criteria. We should be able to refine this in the search process. We have been given the go ahead to start generating candidates through networking now prior to an official campaign being launched early September, with a view to appointments being confirmed in December. <u>Key stakeholder contact meetings since the last Board meeting</u> (NB also various meetings related to CEO recruitment) Nicola Blackwood & Alan Marriott Smith (Human Tissue Authority) Sir David Haslam (Chair NICE) Academy of Medical Sciences Forum event (speaker Sir Malcolm Grant &	

	various others attending) Evidence Week at Parliament Maria Palmer (NHS R&D Forum) Christine McGrath (R&D Directors group) Jonathan Sheffield (NIHR)	
6.	**Update from Chief Executive** The HRA annual report has recently been published and laid before Parliament. I would like to take the opportunity to thank everyone who worked on this publication which takes a number of months to prepare and highlights work that we have delivered during the last year in line with our business plan towards our strategic aims. Following discussions with Jonathan Sheffield and Ian Hudson, senior Representatives from NIHR, HRA, MHRA, a number of researchers, data and systems experts recently came together to discuss and agree how we can collectively achieve a digitally enabled, interoperable research service across the NHS and the UK as a collective response to the Life Science Strategy. The outcome of the first workshop was a set of principles to guide a research "systems approach" to facilitate the exchange of data between different organisations, a list of benefits of working in this way and a set of barriers and potential solutions. The group also agreed a set of actions which will deliver a set of data standards which would be applied system wide for all new digital solutions. TA agreed it would be helpful to share the principles with the Board and have a further discussion at the next meeting. The Board was supportive of the approach and looked forward to receiving more detail in due course. ***Action: TA to share interoperability workshop principles with Board with a further discussion to take place at next Board meeting*** The work to support the implementation of the updated EU Clinical Trials Regulation is one of the main Brexit responses from the HRA. This requires us to deliver a new IRAS system by the end of March 2019. I am pleased to report that work is now underway with both new and existing suppliers supporting these changes. We have also been working closely with MHRA to refine the scenario planning for the EU Clinical Trials Regulation and with their system supplier. HRA are currently preparing responses to the following live consultations and calls for evidence which are relevant to our work: • Consultation on the Centre for Data Ethics and Innovation from the Department for Digital, Culture, Media & Sport. • Nuffield Council on Bioethics' working group on research in global health emergencies: ethical issues. The HRA were delighted to join the rest of the NHS by holding a number of 7Tea parties and charitable fundraising events across our offices to celebrate the 70th anniversary. We also had a number of invitations to the services at York and Westminster.	**TA**

Members of the HRA senior leadership team made a commitment at last years' annual, Research Ethics Committee Chairs' meeting, to visit all of the research ethics committees this year. We are now a third of the way through the visit programme. We have been made very welcome and are taking the opportunity to discuss ways of supporting their work. Members have also helpfully offered up a number of suggestions about how we might maximise the value of their expertise and the ethics review process.

We have held our first formal meeting with Unison focussing largely on the current restructure proposals across the HRA approvals directorate.

External engagement activities

Key Stakeholder	**Purpose**	**Outcome**
Lord O'Shaughnessy	Key Stakeholder Discuss status of Brexit/Life Sciences re: Research	No new actions for HRA but new issues raised by other participants
London -Surrey Borders Research Ethics committee	Direct Engagement with volunteer members – Observation of new EU CTR pilot	A number of actions and proposals have been put forward at these meetings. The HRA Policy team are collating the feedback which will be used to develop a plan including testing out a number of the proposals
NE -Newcastle & North Tyneside 1	Direct Engagement with volunteer members	
Oxford REC C	Direct Engagement with volunteer members	
Allan Marriott Smith & Nicola Blackwood	Key Stakeholder meeting Introductory meeting with Nicola following her appointment as chair. To discuss shared interest agenda and future initiatives	Both organisations happy with progress of collaborative work on Tissue and Data (published this last week) Insights into HTA agenda and priorities Opportunities for secondment across HRA and HTA
Aisling Burnand AMRC	Key Stakeholder – Discussions included potential impact of mCTA changes	HRA to raise AMRC concerns at meetings with NHSE HRA invitation to work being led by AMRC following Patient First Conference
Jonathan Sheffield & Jo Burns	Key Stakeholder – Strategic alignment around interoperability of HRA,NIHR and MHRA for research	Set of objectives for cross system working for future workshops agreed
Dept of Health & Social Care	Key stakeholder –Steering group monitoring cross system progress against	Updates provided on progress to date, agreed that new reporting

	Brexit & Life Sciences Strategy	requirements across NIHR,MHRA,HTA were required	
Pega Systems Meeting with Doug Kra –Vice president Pega	New Key Stakeholder – Introductory meeting with executive directors to discuss how to set ourselves up for success	Both Pega and HRA took away actions regarding the Discovery sessions and agree how the executive directors will engage with senior Pega personnel as the work evolves to replace IRAS	
Will Smart CIO NHSE/NHSI	Key Stakeholder – Introductory meeting	HRA to be involved in forthcoming meetings	
National Information Board	Workshops with senior stakeholders from NHSE/NHSI/NHSD & CEOs	TA has received invitation to NHSE Digital Strategy meetings	
Evidence week-opening Parliamentary Session	Met a number of ministers (event hosted by Sir Norman Lamb)	Increased coverage of HRA via social media and hits to website	

7. HRA Directorate update

HRA Approval

Integrated Approval Service Improvement Programme

Significant progress has been achieved on a number of the work streams and the pilots within the Approvals Service Improvement Programme.

Reports from two pilots on Approval Finalisation and Ready for Review Thresholds will be reviewed by the Transformation Board on 25 July. These are also being shared with the devolved administrations to enable exploration of potential for UK-wide approaches to next steps.

The ready for review testing work involved testing a new threshold for an application to reach in order to be 'ready for review' for REC review and HRA assessment. The testing involved assessors and REC managers assessing against and completing a 'ready for review' tool when undertaking their standard assessment or validation process, so was not a full live testing. The purpose of this was to test an integrated assessment of readiness, and also to test the development of criteria to ensure that staff and volunteer time is not wasted on reviewing applications that are not suitable for review by identifying upfront the elements that could be corrected by the applicant.

The approval finalisation was tested through a small, live pilot testing how we could integrate the process for approval finalisation. The pilot involved testing the following changes to the current process:

i. Assessors sharing their comments with the REC in order that the issues relating to the assessment could be notified to the REC Manager and REC members rather than assessors contacting the applicant directly.
ii. The REC members using the revised Initial Assessment for REC form and

REC Managers encouraging them to use the form during the meeting (and to raise any relevant queries with the applicant).

iii. REC Managers producing a joint status update after the meeting informing the applicant of further information needed for the ethical review and/or the assessment.

iv. Applicants providing a single response to both sets of queries.

The pilot involved 7 RECs, 3 Assessors and 4 REC Managers and was tested for REC meetings held in May and June. 31 HRA Approval studies were reviewed by these RECs during the testing period. A formal evaluation report has been produced which includes a number of recommendations and suggestions for further testing and a plan for further roll out.

The workforce aspects of HRA Approval service improvement are progressing. A skills mix review is in progress, based on SIP evaluations to be submitted to Transformation Board, to determine the grouping of activities into new roles in an integrated Approval function. The Workforce Board are reviewing the progress on the creation of the new structure and roles, with a final proposal planned for the August meeting, following review of the pilot reports above to the Transformation Board in July. Consultations would then go live in autumn for new structure to begin in April 2019.

Training needs for the new roles are being assessed, and support is also planned for staff on managing organisational change for middle managers, and application/interview skills for all affected staff.

<u>Revisions to Quality Assurance</u>

Revised Quality Assurance arrangements for operational services, which separate out the review of the responsibilities of the research ethics committee from those of staff have been tested, and will be discussed with the devolved administrations. Additionally, all archived historic paper reports from the REC service (within existing retention policies) are now stored electronically.

<u>Student Research</u>

To address findings from the workstream on student research, resources for students, academic supervisors and sponsors is being prepared for delivery in the autumn.

<u>Volunteer member recruitment and management</u>

Many of the products from the volunteer recruitment and management have now been delivered. Historic processes did not provide sufficient oversight of the process for taking potential members through recruitment to allocation to RECs.

The backlog of candidates (107) waiting for an interview to be a REC member has cleared with only one person outstanding: 38 people appointed to RECs; 35 people awaiting appointment to a REC; 29 people withdrew application. The high dropout rate may be due to considerable length of time some candidates were on the waiting list. Dates for the rest of 2018 and first part of 2019 scheduled – soon to be published. We plan to seek feedback from volunteers on process in October (online survey). A pilot of a different and targeted approach to member recruitment is scheduled to start in October in Liverpool.

Model agreements

The recently revised model agreement for commercial sponsors are being updated, with support from ABPI, to incorporate GDPR compliant clauses.

The model non-commercial agreement has been through a lengthy process of discussion with both NHS and university sponsors from across the UK. A final version has now been agreed by the stakeholder group and the guidance is now being drafted, with the aim of releasing during the summer.

Technical Assurance

Radiation Assurance was rolled out to the first phase of oncology studies in April 2018, and the first radiation assurances are now feeding in to applications to REC. The radiation authorisation process builds on and standardises the existing radiation authorisation process required in applications to REC, to allow the committee to assess risks and benefits in an informed way.

Recruitment of pharmacy reviewers opened 12 July 2018, with a plan to roll out the first phase of pharmacy assurance in autumn 2018.

UK-wide NHS/ HSC compatibility programme

A significant step in UK compatibility has been achieved with the release on 28 June of functionality in IRAS and HARP to allow e-submission of the IRAS form for devolved-administration led studies. Previously, although there has been a single IRAS form, the submission to RECs UK-wide has been electronic, but a separate email submission has been required to the devolved administration NHS/HSC coordinating centres. Further HARP development to provide enhanced functionality for Northern Ireland, Scotland and Wales to differentiate between single and multi-centre projects will be released in August.

It has been agreed across the UK to delay the development of the Local Information Pack until we can develop it as part of the wider new developments for IRAS, and take advantage of the enhanced technology.

Combined Way of Working with MHRA

This pilot is testing a single application submission which is reviewed by the MHRA, REC and study-wide assessment (in England and Wales for NHS studies) independently but in a co-ordinated way. Single communications go to the applicant and a single approval which includes the MHRA Clinical Trial Authorisation and the REC favourable opinion (and Approval in England/ Wales for NHS research where possible) is issued.

The Combined Ways of Working Pilot has now received 6 live applications.

- 1 has received a MHRA CTA and REC favourable opinion (issued in 48 days from date of submission with no clock stops) but is still awaiting HRA Approval (due to the need to move to GDPR compliant transparency wording).
- 3 have been reviewed by the MHRA and REC and requests for

	information have been issued to the applicant. Responses are awaited. - 1 has been reviewed by the MHRA and REC and there are no requests for further information so the CTA and REC opinion will be issued imminently (this is a non NHS study so HRA Approval not required). - 1 has recently been submitted and has not yet been to a REC for review. We continue to receive interest from sponsor and CROs who would like to be involved in the pilot and have been notified of a further 4 applications which will be submitted into the pilot shortly. **Collaboration & Development** <u>Research in CQC inspection criteria</u> The CQC Partnership presented and had a panel session at the annual R&D Forum Conference in May. Both sessions were well received and the audience seemed encouraged by the positive impact that CQC inspections could have on research across the NHS. Brief guides for CQC inspectors are being drafted by the partnership to assist with learning. Research indicators are being embedded in current Well-Led inspection criteria. <u>Platform trials</u> Work progresses with the parameters project. We are working with a wide range of external stakeholders, led by the Experimental Cancer Medicine Centres to produce a consensus statement on definitions and pathways for complex clinical trials (platform trials) for publication in Nature Oncology. DH Sponsors have been briefed on HRA activity in this area after the late Dame Tessa Jowell's work towards raising the profile of clinical trials in cancer treatment. The Non Commercial Sponsors Reference Group is reinstated with expanded remit and membership, independently chaired by an NHS sponsor. The recent meeting showed an enthusiasm to try and improve quality of sponsorship and a positive change in attitudes towards HRA. **Confidentiality Advice Service** A positive meeting has been held with Scotland's Public Benefit and Privacy Panel and MRC with the aim of discussing alignment in future developments, and to mutually understand working processes better. **Learning and Development** The learning & development team are implementing a new Learning Management System over the summer, which should streamline the process for booking and managing training and learning resources. We continue to deliver webinars on '*Applying for HRA Approval – getting it right first time*' and '*Managing your Approval – 35 day no objection for amendments*'. We have completed delivery of regular scheduled GDPR webinars, but will continue to monitor the need for ad hoc webinars.	

Following a review of the training needs for flagged RECs, a programme of offerings, including regional training and online resources, are being prepared to ensure that members remain suitably trained. A longer term learning and knowledge management framework is under development with input from a number of REC members.

Janet Messer external meetings/visits

MHRA/RES project group
Four nations' policy meeting
IRAS Partners Board
Information Commissioner's Office – to discuss operational guidance on GDPR
NHS Digital Research Advisory Group streamlining working group
NHS England Excess Treatment Cost working group
NHS Digital Research Advisory Group
NIHR Interoperability Workshop with NIHR and other partners
HRA/NIHR Forum
Research Support Champions

REC Accreditation status update

Name of REC	**Accreditation status as at 06 June 2018**
London – Westminster	Full accreditation under 2016 scheme (after completion of action plan)
London - Stanmore	Full accreditation under 2016 scheme (after completion of action plan)
East of England – Cambridgeshire & Hertfordshire	Full accreditation under 2016 scheme
London – Queen Square	Accreditation with conditions (action plan pending completion)
North West – GM East	Accreditation with conditions (action plan pending completion)
HSC REC A	Full accreditation under 2016 scheme
London – Camden & King's Cross	Full accreditation under 2016 scheme
South East Coast – Brighton & Sussex	Provisional (action plan pending completion)

Communications

A new Communications Officer has been recruited to the team. Emily Howlett joins from Cancer Research UK and starts on 10 September. She's employed on a fixed term contract until April 2019 to build capacity within the team and provide extra resource to support the communication and stakeholder engagement programme which is part of the IRAS development.

The team supported Evidence Week at parliament with blog posts and an animation on the HRA website and social media posts. The content fed into a communications buzz around the event and saw a spike in engagement with the

HRA's channels and a gain in followers. We can now build on this to continue to communicate about our work to a wider, engaged audience.

The HRA worked with NIHR to support a media briefing on and resulting coverage of the publication of the results of PARAMEDIC 2 (the adrenaline trial). A proactive approach, with an agreed response about the ethical approval of studies prepared ahead of time, was taken. Much of the coverage touched on how trials like this raise ethical questions, but a clear and robust line about the review process, shared during the briefing, supported understanding. Taking this approach helps to manage resource, being much less intensive than responding reactively.

The communications team organised a programme of internal engagement activity as part of the NHS's 70th birthday celebrations. Feedback from staff was that they enjoyed the opportunity to attend tea parties in each of the offices. All staff members were invited to put themselves forward to attend two of the nationally organised events and names were picked out of the hat to join Teresa and Jonathan at the services at Westminster Abbey and York Minster.

The team continues to support the internal communications process behind the reorganisation of teams within the approvals directorate

Public Involvement

As part of the public involvement in ethical review (PIER) project under SIP, the team have integrated guidance on public involvement into IRAS. The intention is to help researchers improve the quality of the information they provide on how they've involved patients and public in their applications and the difference it has made. Work is now underway to sign up a number of organisations to be test beds for the guidance; discussions have already taken place with a number who have expressed interest in participating. The focus of the team is now turning to develop expectations and standards on public involvement that are linked to the national standards for public involvement but have are specific to what the HRA would expect to see demonstrated in an application. This work as it its early stages but will develop over the coming months.

We also participated in a collaborative workshop hosted by the ABPI and Shared Learning Group on Involvement in Research intended to further the development of work between UK charities and industry in working together to involve the public in research.

Research Systems

Having signed the contract with Pegasystems at the end of June, the Research Systems team have been busy with training and planning the first Agile sprints. A detailed plan was produced for Sprint 0, which started on 16 July, which is helping set the scene and bottom out any technical dependencies needed for onward sprints. The first fortnight is an intensive period of colocation at Skipton House, which will be followed by extensive collaboration with subject matter experts across August, after which Sprint 1 will commence with a backlog of user stories for implementing in the Pega product.

Business Unit

Redfern (now known as Corporate Travel Management)
Following a successful procurement exercise by the CCS for Travel and accommodation solutions, various options were made available to ALBs. Our current suppliers, now known as Corporate Travel Management (formerly Redfern) were successful in their bid to get on the framework. Discussions have taken place between Finance and Corporate services business support as to which solution is efficient and preferable for the HRA. There is broad agreement that we will opt for Solution 4 with a direct award to CTM. The process to complete the enabling agreement before the deadline of 6th August 2018 is in progress. Along with the new solutions, the CCS have implemented a virtual portal (Digits) which is compulsory whichever solution an organisation opts for.

Recycled paper
Quarter 1 (April – June) figures from CCS show that nearly 81% of all paper purchased by the HRA was recycled.

Programme Office
The 2018/2019 portfolio dashboard has been developed and is being used to report the status of programmes and projects at to the Transformation Board and Leadership Team Meeting. A project brief has been created for benefits management to develop a system wide view of benefits in addition to HRA specific benefits. In liaison with DHSC project management/support job shadowing opportunities are being organised for several members of staff to support their development.

Finance

New structure
We are implementing the new finance structure with a more proportional approach to business partnering and increased responsibility for estates contract management for the whole HRA, releasing capacity in the regional teams to focus on service improvement programme.

Agenda for change pay award
Agenda for pay new contract for 2018 has now been agreed by Unions and funding allocated. Increased pay will be processed in time for the July payroll with any backdated amounts (award was from 1 April 2018) paid in following months.

Oracle: chart of account hierarchy and forecasting
As previously reported we have changed our reporting hierarchy in Oracle to provide improved analysis and simpler reporting. Management information will reflect this changed structure for 2018/19.

Procurement

A number of activities continue to be supported by the finance team this quarter including:

- RS procurement – contract signed and agreed with Pegasystems

	• Printer sourcing for regional offices – Bristol and Manchester **Estates** We are working with the government property agency and another government body to progress sharing space in our Manchester office. We will be contracting NHS Property to support us in re-gearing the lease to enable sub-letting and potentially an extension to the current lease term. **Corporate secretariat** <u>New structure</u> We are transitioning to the new management structure for our corporate secretariat team with Head of Corporate Governance and Risk taking on a broader role with responsibility for Risk Management and Business Continuity. The Director of Finance, Procurement and Estates takes on HRA senior information responsible officer role. **Information governance** <u>General data protection regulations</u> We have a MOU with NHS BSA to provide our Data Protection Officer function. Chris Gooday – who has recently led the NHS BSA GDPR project internally – will provide this service on our behalf. The GDPR preparedness internal audit review is due to commence this week, terms of reference have been agreed. All our information governance policies and procedures have been reviewed by independent legal advisors to ensure they meet GDPR requirements. We have developed an overarching privacy notice for HRA with more detailed notices provided for certain personal data categories such as employment, recruitment, research data in IRAS and research participant data in TOPS. We have provided updates to our staff at two all staff VCs – the first a general updated on progress, the second, focusing on DPO, personal data breach reporting and data subject rights requests. **Policy** <u>Research transparency</u> The work agreed by the Board in March is moving ahead. We have established a formal project with two initial work streams: • Raising awareness of current compliance standardsMaking compliance easyA third work stream on the related issue of competing and conflicting interest, is in the planning stages. A fourth work stream – introducing new requirements – will commence in 2019/20 if we don't see improvements through the first two. Our first areas of focus is on benchmarking, both on current compliance with requirements and on researchers' understanding of those requirements. We are also working on reviewing the wording in our REC approval letter and the transparency questions the next version of IRAS, thereby making our requirements around registration and publication clear to applicants at different stages of the HRA Approval process. The House of Commons Science and Technology Committee has published the	

	first of two reports following its inquiry into research integrity. The first report, available on the committee's website, focusses on fraud, misconduct and mistakes in research and is not directly relevant to us. A second report, due after the summer, will focus transparency and we expect it to contain recommendations for the HRA. We have been more vocal about our commitment to research transparency by taking part in Evidence Week, a week of activities in Parliament to highlight the importance of evidence and how MPs can ask the right questions. We sponsored the day devoted to health evidence, giving us a presence in the exhibition in the House of Commons and speaking opportunities in a number of events. See the annex for more details and an assessment of the impact of taking part. Consent for use of tissue and data On 18 July, we published our research into public attitudes towards their tissue and data being used in research. Working with the Human Tissue Authority, we commissioned Ipsos Mori to carry out the research. It showed that patients would be happy to share personal data alongside tissue that they have donated to biobanks – if they are given a clear explanation of how their data would be used. The research is part of a project to make better use of tissue samples in biobanks, many of which are not useful in research without access to linked patient data. Using the findings of the research, we are now working with the HTA to produce guidance for biobanks around access committees and on good quality consent and information in this area. There is a news story on our website, where the full report can also be accessed. Social care research Our roundtable with key stakeholders in social care research is due to take place on 30 July. We have prepared a background briefing setting out what we know about social care research, what the distinct ethical considerations are in this area and how we might support researchers both in terms of research ethics and governance. We will return to the board in the autumn to consider next steps. Data-driven healthcare technologies We have begun scoping out work in artificial intelligence and other data-driven technologies by engaging with stakeholders in technology companies, pharmaceuticals, fellow ALBs and NHS institutions doing work in this area. We have also mapped out the key issues, focussing on what is distinct about these technologies, what good research looks like and what new standards and requirements we might need to support researchers, protect participants and ensure legal and ethical use of patient data. We will return to the Board in the coming months to set out proposed areas of work. Evidence Week 2018: evaluation	

	We recently took part in the UK's first Evidence Week, which took place in the House of Commons between 25 and 28 June. Organised by Sense about Science, the Parliamentary Office of Science and Technology, the House of Commons Library and the House of Commons Science and Technology Committee, the week aimed to educated parliamentarians about the important of evidence in public policy making and how to understand and question evidence presented to them.	
8.	**Transformation Programme Update** IC presented the latest update from the Transformation Programme to the Board. IC highlighted the amber boxes on the overview reflected the continued challenge of ensuring the business change delivers the efficiencies with a reduction in budget coupled with the need to invest in additional capability. IC advised this was not a significant risk with discussions in place to consider how benefits can be maximised in the future. The intended benefits will likely be discussed in more detail at the September Board meeting. ***Action: IC to draft intended benefits paper for September Board meeting*** The Board noted the overall programme remains green and on track with the new approvals directorate structure to be in place by the end of the financial year. The Board noted the discovery piece taking place to consider solutions to manage the considerable amendment workload. The Board noted amendments require considerable resource from the HRA but also the whole sector and it would be beneficial to release capacity by identifying a solution. <u>SIP customer support</u> The Board welcomed SB to the meeting. SB clarified the workstream is looking at delivering an integrated approach to managing the HRA's relationship with its customers ensuring that all queries are managed effectively. The Board noted there are a considerable number of different routes for queries to come into the HRA and one solution to improve consistency may be to reduce the number of generic email accounts used and have potentially one point of contact as a triage point. The Board discussed the capacity for utilising systems to help manage the customer relationship and noted the Pega platform may be able to support the development of a suitable system. SB advised the implementation plan would be considered at the August Transformation Board meeting. The HRA Customer Charter would also be reviewed at the August Transformation Board meeting. <u>Research Systems Programme</u> The Board welcomed NH and GCP to the meeting. The Board noted sprint zero has begun and is currently on track. This sprint's purpose is to breakdown the functionality requirements of the programme. Due to the short timeframe of the programme and the Board not meeting again until September, the Board agreed it would be helpful to be kept updated out of	**IC**

	session as required. JMo and TA agreed to discuss how best to keep the Board informed. ***Action: JMo and TA to consider how to keep Board informed of Research Systems Programme*** <u>SIP Proportionality project</u> The Board welcomed AH to the meeting. AH provided an update on the outcome and actions planned as a result of the SIP HRA Approval – Proportionality work stream. AH advised one recommendation is to further refine the risk categories and whether very low risk studies could be handled in a simple manner, for instance by staff, with escalation available as required. A pilot is to take place this year. The Board agreed it is encouraged by the progress made thus far however had some concern regarding the 'proportionate' title. The Board discussed whether a proportionate application package should be utilised for all research applications and agreed every review should be proportionate to the level and complexity of research taking place. The Board agreed the communication and messaging regarding this work needs to be carefully considered to avoid the possibility of other bodies setting up review processes for research which the HRA may no longer deem requires REC review. The Board agreed it is a good news story about how the HRA is adapting its approach to reviewing research and this should be communicated appropriately. The Board queried if there are any timelines in place which could be provided to the Board for information. ***Action: IC agreed to circulate after the meeting*** The Board was pleased to note the progress made thus far.	**JMo/TA** **IC**
9.	**Update on progress of research transparency work** JT provided an update to the Board. Following the Board meeting in March 2018 where the transparency proposals were discussed, two initial work streams have begun. These relate to raising awareness of current compliance standards and making compliance easy. A third work stream on the related issue of competing and conflicting interest is in the planning stages. A fourth work stream relating to introducing new requirements will commence in 2019/20 if improvements are not found through the first two work streams. The Board noted the House of Commons Science and Technology Committee has published the first of two reports following its inquiry into research integrity, to which the Health Research Authority gave oral and written evidence. The first report focuses on fraud, misconduct and mistakes in research whilst the second report, due after the summer, will focus on clinical trials and research transparency. The Board noted the HRA has been more vocal about its commitment to research transparency by taking part in Evidence Week, a week of activities in Parliament to highlight the importance of evidence and how MPs can ask the	

	right questions. The HRA sponsored the day devoted to health evidence, giving the HRA a presence in the exhibition in the House of Commons and speaking opportunities in a number of events. The Board requested to receive an update from the next transparency forum via the directorate update. ***Action: JT to add transparency forum update to November Directorate update*** The Board agreed it would be beneficial to take stock of the transparency and collaboration & development forums in 2019 and requested a review of the terms of reference to ensure the HRA has the right forums in place to appropriately engage with stakeholders. ***Action: ST to add terms of reference of transparency and collaboration & development forums to January 2018 Board meeting*** The Board noted the requirement for registration is currently only for clinical trials and queried what arrangements are being considered for other studies, in particular those involving data. The Board noted other bodies such as funders and journals are requiring the sharing of data and the HRA needs to understand further how this environment is changing.	**JT** **ST**
10.	**Pilot proposal for an HRA Accountable Centre Model for Improvement evaluations** The Board received and discussed the proposal for a pilot for a new model for the governance of evaluations of healthcare improvement activities, to be piloted by The Healthcare Improvement Studies (THIS) Institute, University of Cambridge. The Board discussed the importance of avoiding confusion and the removal of any unnecessary barriers in the system whilst noting a query regarding how the model might be funded in the future if approved. The Board agreed it was happy to support the pilot and looked forward to receiving the results in due course where further consideration of any potential future activity would be considered.	
11.	**Finance report – April to June 2018** The Board received and approved the latest finance report. The Board noted there were no significant variances at present. KW flagged additional funding for the research systems transformation had been approved by DHSC; a one off sum of £1.75 million. KW also advised it is anticipated an additional sum of £120,000 will be provided to cover the agenda for change pay proposals with discussions currently taking place with DHSC. The Board noted confirmation had been received from DHSC regarding the provision of cash to cover future commitments and help cash flow.	
12.	**HRA Freedom of Information request summary 2017/18** The Board noted the requests received during the period 01 April 2017 – 31 March 2018.	

13.	**Complaints register 2017/18** The Board noted the complaints register for 2017/18. The Board noted five complaints related to the HRA Approval process and agreed this was a relatively low figure in comparison with the total number of applications reviewed each year and staff should be congratulated on their hard work and commitment. The Board agreed it would be helpful to provide a summary of complements received, such as findings from user satisfaction, alongside the complaints report next year.	
14.	**Audit and Risk Committee meeting summary – 06 June 2018** The Board noted the summary of the key items discussed at the last Audit and Risk Committee, which focused on a review of the HRA Annual Report and Accounts for 2017/18 and also included a deep dive into the research system procurement process.	
15.	**Out of session business conducted / External areas of interest since previous meeting** The Board noted the following out of session business / external areas of interest since the last meeting: - Update regarding recruitment of Nick Hirst to support Research System Programme circulated 07 June 2018 - Statement issued by NIHR regarding Improving Performance in Initiating and Delivering Clinical Research circulated 07 June 2018 - Update regarding two research studies to be published circulated 17 June 2018	
16.	**Any other business** None to note	
17.	**Questions from the public** None to note	
18.	**Date of next meeting** 19 September 2018	