Chief Executive Update to the Board, September 2022

Part 1 Public session

Her Majesty Queen Elizabeth II

It is with great sadness that during this reporting period we heard the news of the death of Her Majesty Queen Elizabeth II. The Queen supported numerous health research charities and organisations and was a powerful supporter of the NHS. We pay tribute to her remarkable reign, and her remarkable service to our nations. We offer our condolences to the royal family and all those affected by this news.

The HRA's communications team mobilised quickly to make sure that the HRA's channels appropriately and respectfully reflected the period of national mourning. This included turning the corporate website 'dark' and adding a tribute banner, switching to black logos on our corporate social media channels and adding special headers, and publishing an official message of condolence. The team also provided guidance for HRA staff on behaviour and activity during the mourning period, for example corporate activities that needed to be postponed, how to effectively communicate this to stakeholders (especially those outside the government and health families who might not have needed to make changes in their own work at this time), emotional support for those impacted by the Queen's death and subsequent coverage, and arrangements for the state funeral. The team worked closely with the Government Communications Service (GCS) and the Department of Health and Social Care's ALB comms network to make sure HRA arrangements were in line with national expectations.

Campaigning, promotional and influencing activity was postponed until after 20 September 2022, mostly without incident, though we were challenged on our decisions by some of our public contributors who were not observing the period of mourning themselves. The pause to parliamentary activity meant the date to lay the HRA's annual report before parliament has also been postponed.

Contact Eve Hart, Head of Communications, for further information

Wider policy environment round up

Horizon Europe funding

In July 2022 the UK government published a proposed package of transitional measures to support the research and innovation sector affected by Horizon Europe delays, setting out a preliminary vision for a long term, alternative programme to Horizon should it be required.

In the meantime, the Government has announced an extension to the financial support provided to Horizon Europe applicants, to cover all calls that close on or before 31 December 2022. This means successful UK applicants will continue to be guaranteed funding on those calls. The aim is to support the UK sector whilst the Government continues to seek to formalise UK association, including through the formal consultations, launched on 16 August, with Brussels over the issue

Science and Technology Committee: "Science and technology superpower": more than a slogan?

The House of Lords Science and Technology Committee published the report of its inquiry on delivering a UK science and technology strategy, on 4 August, which can be accessed here. Whilst supporting the Government's ambitions for science and technology, it notes the large number of strategies, initiatives and official bodies in place and calls for sustained focus, implementation and delivery including through the appointment of a Minister for Science, Research and Innovation, the post of which has been empty since July with the resignation of George Freeman MP.

Contact Naho Yamazaki, Interim Deputy Director of Policy and Partnerships, for further information

Independent Review of Research Bureaucracy

The final report from the Independent Review of Research Bureaucracy, led by Professor Adam Tickell, was published on 29 July. The report can be accessed from this link and the Government's initial response can be accessed here. A more detailed response to the recommendations in the report will follow later in the year.

Whilst the focus is largely on research funders, there are elements directed at regulators and the report makes some positive references to the HRA's work to make it easier to do research that people can trust, including the HRA's fast-track ethics review process and HRA/MHRA's combined review. Recommendation 17 is particularly relevant to the HRA's work.

> **Recommendation 17**: Ethical and other regulatory approvals should be the responsibility of the lead partner on a multi-institution research project and counterparties (including the NHS) should not require additional duplicative approvals. Where this is not already the case, the confirmation of approval should be deemed sufficient for all partner organisations. In cases where approval must be obtained from an external body as a statutory obligation (such as the Health Research Authority), the external approval should satisfy

the requirements for the host organisation and any other parties involved in the project.

The Government response provides an opportunity to highlight more of the HRA's work and we are providing our response to the Department for Health and Social Care and Department for Business, Energy & Industrial Strategy, to highlight relevant current and planned activity against the recommendations in the report. See **appendix A**.

We are also planning to write a blog about the work that we are doing to standardise and coordinate approvals, some of which is mentioned in the Independent Review.

Contact Jane Morrin O'Rourke Policy Manager, Policy and Partnerships, for further information.

HRA updates

HRA Strategy leadership

The HRA Strategy, making it easy to do research people can trust, has been received very positively across stakeholders. The balanced and dual aim of focusing on patient and public inclusion and accelerating the approvals and start-up of research in the UK has resonated.

The strategy published some clear and specific commitments, but its primary purpose is to guide our decision making in a rapidly changing environment. Part of that process is to establish strategic leadership teams, led by a director, in each of the priority areas of Accelerate, Digital, Improve and Include. With a couple of gaps due to current vacancies, the teams are as follows:

- Accelerate (includes research systems programme)
    - Janet Messer, director of Approvals
    - Neelam Patel, non-executive director
    - Naho Yamazaki, interim deputy director of policy and partnerships
- Digital (excludes Research Systems Programme):
    - Julie Waters, interim chief digital transformation officer
    - Katie Marriner, deputy director of finance
    - Nicole Mather, non-executive director
- Improve
    - Karen Williams, deputy chief executive and director of finance
    - Richard Cooper, non-executive director
    - Deputy director – to be confirmed
- Include

- Becky Purvis, interim director of policy and partnerships
- Jonathan Fennelly-Barnwell, deputy director of approvals
- Andrew George, non-executive director

Contact Katherine Guerin, Deputy Director Organisational Development, for more information.

Delivering the HRA Strategy

The Organisational Development team are delivering a face-to-face workshop for the executive team and senior management group. This will help us enhance our knowledge and understanding of strategy delivery, understand and identify connections and inter-dependencies. It will directly feed into the Business Planning and prioritisation activities for 23/24 and is part of a wider set of activities aimed at delivering our strategy and fostering a culture of innovation and change throughout the HRA.

Contact Katherine Guerin, Deputy Director Organisational Development, for more information.

Executive Team Appointments

Interim Chief Digital Transformation Officer

Julie Waters has been appointed to the position of Interim Chief Digital Transformation Officer for three months following the departure of Ian Robinson. Julie was the Associate Director in the Digital team. The Executive Committee is currently planning the process to appoint a longer-term replacement.

Appendix A: HRA Bureaucracy Review Response: Actions

Review of Research Bureaucracy- Recommendation	**Actions already underway (with timeframe and with possible case studies)**	**Actions being planned** **(with timeframe)**	**Issues that will be explored following Bureaucracy Review publication** **(with timeframe)**
Recommendation 4: *In the longer term, funding bodies should explore the potential benefits of self-certification and/or earned autonomy as a means of streamlining assurance requirements for institutions with a strong track record of robust assurance.*	The HRA is holding a public consultation considering how we could further improve ethics review as part of the Research Ethics Service. One element of the consultation considers a proposal to delegate ethics review to institutions for sub-studies within larger programmes of research. Programmes of research would still gain ethical approval from a research ethics committee as part of the Research Ethics Service. Sub-studies would then gain subsequent approval from their institution, however still working within the agreed parameters set by the original		

	Research Ethics Service committee. Institutions would need to employ robust governance processes and meet compliance standards in line with the HRA to be offered this type of delegated ethics review. This public consultation is open until 23 September. Final recommendations will be presented to our Programme Board. If any recommendations are then taken forward they will be piloted before implementation		
Recommendation 15: *Universities and research organisations should, wherever possible, use standard templates for contracts and collaboration agreements, recognising that this would not just be faster, but would also facilitate third-party collaborations. This could build on existing work*	Research in health and care sectors have for many years benefitted from standard templates for use between research sponsors and participating organisations. The first template in what is now the suite of UK National Health Service(NHS)/Northern Ireland Health and Social Care (HSC) template agreements was published in 2003.	The HRA and Health and Care Research Wales are collaborating with Health and Social Care Northern Ireland and NHS Research Scotland to deliver a streamlined UK approval service for health and social care research, which will replace HRA Approval and equivalent processes, and site permission and confirmation processes across the UK.	

carried out by the Russell Group. Amendments to these templates by individual institutions, or the use of non-standard templates for collaboration agreements and contracts, should be the exception rather than the norm. While uniformity will clearly not be possible, a fundamental shift is required in universities and other research providers concerning their willingness to accept standard contract clauses and use model agreements.	Following the model clinical trial agreement (mCTA – for commercially sponsored drug trials) came the model non-commercial agreement (mNCA – for non-commercially sponsored interventional research), in 2008. Subsequent work, now overseen by a UK-wide group has focussed on creating additional templates to cater for more study types and scenarios (e.g. the organisation information document and model non -interventional study agreement for non-interventional, non-commercial and commercial research respectively), to maintain existing templates in light of legislative and other developments (e.g. GDPR, UK exit from the EU), replacing nation specific templates with UK-wide templates (e.g. 2018 version of mCTA) and promoting the unmodified use of the templates by all parties.	In 2021 the UK health departments agreed that UK Approval should include costing and contracting reviews such that NHS organisations may take assurance on these matters in place of local review. In 2022 it was agreed that these assurances for non-commercial research should mirror those in place for commercial research – i.e. that unmodified use of the appropriate template UK agreement should be a condition of approval in all but a small number of cases (e.g. where a new study type present for which there is no suitable template). Work continues to 'plug-gaps' in the suite of agreements, to reduce to the minimum the need to bespoke or modified usage. Engagement work will continue into 2023 to prepare the HEI and NHS communities for the strengthening of the expectation of unmodified use. Alongside this work we have started conversations with NIHR	

	Key steps in promoting unmodified usage include the publication of the 2018 version of the mNCA, which addressed key barriers to uptake by university sponsors (including perceived inconsistencies between the template and National Institue for Health and Care Research (NIHR) funding conditions) and the publication in 2018 of the National Directive on Commercial Contract Research. The Directive, a collaboration between HRA, NHS England (NHSE) and NIHR Clinical Research Networks (CRN), uses the standard form provider contract between NHSE and its NHS providers to make unmodified use of the appropriate template for commercial contract research a contractual obligation on the NHS in England. Embedded within the contracting checks that form part of HRA and Health and Care Research Wales (HCRW) Approval, this contractual obligation on the	and DHSC to support the use of unmodified template collaboration agreements for commercial/NHS/HEI collaborations. We are at early planning stages for the replacement of the current mICRA (that combines collaboration and site agreement) with a dedicated collaborator agreement closer to the Brunswick academic collaboration template (adjusted to cater for the NHS element) and are in discussion with NIHR as to supporting standard use of Brunswick (or template/s derived from Brunswick) for non-commercial collaborations between NIHR award holders.	

	NHS in England was expanded to a policy expectation in Wales later in 2018 and work is now being finalised to place the same policy expectation in Scotland and NI, in preparation for the UK Approvals Service replacing HRA and HCRW Approval and equivalent NHS/HSC review and approval processes.		
Recommendation 17: *Ethical and other regulatory approvals should be the responsibility of the lead partner on a multi-institution research project and counterparties (including the NHS) should not require additional duplicative approvals.* *Where this is not already the case, the confirmation of approval should be deemed sufficient for all partner organisations. In cases where approval must be obtained from an*	Health and care research has a system for centralised ethics review. The HRA advises HEIs not to replicate ethics review as part of any institutional reviews. HRA Approval brings together research ethics review and governance and compliance review, meaning that researchers wanting to do research in England and Wales can submit one application for both, removing the need for additional duplicate approvals in organisations that host the research.	Our strategy for the next three years will deliver changes that save money and time so that researchers can focus on doing good research. Our new, simple to use, accessible system will guide researchers through the ideal path for a study, making it easier to do research that people can trust. We'll also make it easier for patients and the public to find out about that research. Together this work will ensure that research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.	

external body as a statutory obligation (such as the Health Research Authority), the external approval should satisfy the requirements for the host organisation and any other parties involved in the project.	Working with the Medicines and Healthcare products Regulatory Agency (MHRA), we have also introduced combined review. This offers applicants and sponsors of Clinical Trials of Investigational Medicinal Products (CTIMPs) a single route and a joined-up review to earn both HRA and MHRA approvals, leading to a single UK decision in a faster overall timeline than the previous separate process. This has halved the time it takes for studies to get approval and cuts the time from application to recruiting a first patient by 40 days. All clinical trials are now reviewed in this way and this benefits both triallists and participants.[i]		
Recommendation 20: *For existing systems, approaches to improving the flow of data between different platforms should be explored, using for example application*	The Integrated Research Application System (IRAS) is the system for applying for approvals for health and care research. It currently provides digital flows of data about	Further development of IRAS is planned, with further interoperability with organisations related to the regulation and delivery of research.	

programming interfaces, point to point integration, and machine learning.	research studies to HRA, NIHR and MHRA.		
Recommendation 21: *The review strongly encourages the use of persistent digital identifiers to drive wider adoption.*	HRA have been involved in the 'Common ID' project with NIHR to use IRAS ID as the common identifier across research ecosystem systems.		
Recommendation 22: *Funders and platform providers should focus in the short to medium term on the creation of common data taxonomies, and the standard questions they will ask. This would make it far easier to repurpose applications for other schemes and funders, to share assurance data, and to conduct 'big picture' analyses of research outcomes in the UK, which are currently inhibited by*		In meetings with NIHR around system touchpoints, we have talked about the need for a common data catalogue and data standards we will use to aid sharing data across the research ecosystem.	

the multitude of systems and interfaces.			
Recommendation 23: *Funding bodies and owners of reporting platforms should review the structure and content of current online forms as a priority, with the aim of removing sections that are unnecessary or unclear*.	We are reviewing IRAS question sets to ensure that data is collected from researchers once and re-used for multiple purposes		
Recommendation 24: *Where relevant, there should be more active, coordinated engagement by funders with the research platform providers that will help address issues and lead to better, harmonised approaches. End-user representation should also be included.*		HRA senior leadership are currently engaged in meetings with NIHR to discuss system touchpoints to ensure we co-ordinate activities for the research applicant and understand what is being done in what system and how this creates a seamless user experience.	

Recommendation 28: *Government, funders and regulators should undertake wide ranging consultation with research organisations prior to the introduction of new regulatory or other requirements.*	The HRA has been working with researchers at all levels, including those who don't yet need to apply for approvals but may wish to in the future, to inform the development of new IRAS and the IRAS website. At the heart of the new website is to make research and applying for research easy to understand, reduce jargon and provide all the support, information and guidance in one place so users are clear on where the single source of truth can be found. As part of the development we have worked with users across the board (researchers, sponsors, commercial and non-commercial sectors etc) to ensure the website is tested and developed with user needs at the centre – making content easy to digest and understand. The new Clinical Trial legislation was influenced by a public consultation receiving 2000+ responses, and these	'Include' is a guiding principle in our strategy over the next three years. We will create more opportunities for people with lived experiences to be involved in our internal decision making and include a more diverse group of people in our regulatory decision-making committees.	

	were from a wide mix of groups including pharmaceutical companies, CROs, patients/public, and charities. The MHRA are currently considering what kind of public involvement will be needed in finalising the legislation so there will be further input as well.		
Recommendation 29: *Government and funders should proactively communicate on new and emerging regulatory issues. The RCAT model is good practice in this regard.*	The HRA has a popular operational change bulletin (HRA Now) so that requirements for research approvals and rationale can always be communicated to researchers and institutions in a timely way. We are working with MHRA to publish guidance accompanying new clinical trials regulation.		

[i] (2) This performance data is taken from timelines for CTIMPs going through separate and combined review from 2018 to present (to February 2022). Combined review halves the time it takes for studies to get approval and cuts the time from application to recruiting a first patient by 40 days