NHS
Health Research Authority

Agenda item:	8
Attachment:	B

HRA Board paper
15 July 2020

Title of paper:	**A research review model for the next decade**
Submitted by:	Juliet Tizzard, Director of Policy and Partnerships
Summary of paper:	The paper describes how the UK's approach to reviewing research has changed over the years and how we have improved it further since the creation of HRA Approval. It sets out a new project, identified in the 2020/21 Business Plan, to evolve our research review model further. The project aims to capitalise on the experience of reviewing research during the Covid-19 pandemic, both in accelerating planned improvements and in potentially introducing more significant changes to increase efficiency and proportionality and to improve the experience for applicants.
Reason for submission:	For approval
Further information:	The paper covers the rationale for the project, scope, engagement approaches, governance and likely phases
Budget / cost implication:	Costs are yet to be finalised, though likely to be circa £200k, including programme management, externally sourced engagement and modelling review approaches
Dissemination:	Communications and engagement plan for the project to be developed. HRA Latest to be used to announce the work to stakeholders
Time required:	15 minutes

A research review model for the next decade

1. Background

1.1. This paper describes a proposed project to agree and implement an evolved model for research approval and support which is more proportionate, streamlined and user friendly for researchers and research sponsors, meets the needs of study reviewers (ethics service, Confidentiality Advisory Group and other regulatory/NHS checks) and supports good practice in research. We want to take advantage of the opportunities and expectations prompted by Covid-19 and build on the improvements to health research regulation that we have made during the last decade.

2. The first 10 years

2.1. The Health Research Authority was established in 2011 to address a problem in UK health research. The regulatory framework for research had become unnecessarily complex and burdensome. There were significant delays in setting up studies in the NHS, caused by duplicated reviews and permissions carried out in individual Trusts across the UK. Research ethics review, review of studies using patient data without consent and governance review was carried out across a number of bodies.

2.2. The result was confusion for researchers, delays in setting up studies and duplication of effort across the system – to the detriment of patients, researchers and the public purse.

2.3. In 2010, the Government commissioned the Academy of Medical Sciences to review the regulatory framework for research and make recommendations for improvement. It recommended the creation of the HRA, bringing together IRAS, research ethics review, gene therapy ethics review, review of patient data without consent and, crucially, NHS permissions. Besides these structural changes, the review also recommended that the HRA:

- work in collaboration with the MHRA to make clinical trials regulation more proportionate and streamlined
- work with the devolved administrations to create a more joined up UK approach to research regulation
- support researchers to raise standards and be a single point of contact for researchers
- lead on proportionate approaches to research review and approval
- consult and engage widely, including with patients and public.

2.4. The HRA was established in December 2011 and became an arm's length body of the Department of Health and Social Care in 2014, by which time the functions of the National Information Governance Board relating to use of patient data without consent had been transferred to the HRA in the form of the new Confidentiality Advisory Group. These changes brought a more coherent approach to research review, but it wasn't until the implementation of HRA Approval in 2016 that a step-change in research review took place. HRA Approval centralised the regulatory and NHS standards review into a single authoritative review by the HRA on behalf of the NHS in England, confirming when all other relevant approvals for a study are in place.

2.5. Since the establishment of HRA Approval, we have streamlined and facilitated research even further through our ongoing service improvement work, with a particular focus on UK compatibility. These include:

- The creation of a single IRAS form and Local Information Pack across the UK
- The development of a combined and streamlined review process (combined ways of working, or CWoW) with MHRA of clinical trials of medicines, resulting in a 40% reduction in approvals timelines
- The roll-out of a new IRAS module for clinical trials of medicines applications (currently available to CWoW pilot participants only)
- The introduction of integrated approvals processes underpinning HRA Approval. The result has been a simpler pathway for applicants after submission, with fewer touchpoints with the HRA and a single outcome
- The roll-out of online services for booking a study into a REC meeting and submitting an amendment
- The introduction of a number of initiatives to support faster and more consistent study set-up in the NHS across the UK, including pharmacy and radiation assurance, costings templates and model agreements.

3. Where we are today

3.1. Due in large part to this series of policy, process and technology developments led by the HRA, the regulation and governance of health and social care research in the UK today is largely unrecognisable from the system described in the AMS review report a decade ago. The external environment has changed too. The UK's departure from the European Union creates new challenges and opportunities for research. It gives us policy and process flexibility, but places greater onus on needing to maintain the UK as an attractive destination for global clinical research.

3.2. Whilst we have continued to introduce improvements to our approvals service, our focus has shifted to the technology which enables that service. With the successful roll-out of a new application portal for CWoW pilot participants running clinical trials of medicines, and some online services for all research types, we are now preparing to replace the whole of IRAS and our UK case management system. This will result in an intuitive, user-friendly application and review system for applying for research approval in the UK for all the other study types that make up the bulk of our work.

3.3. The Covid-19 pandemic has caused us to focus our services to respond to the national research effort to tackle this virus. We have demonstrated to ourselves and the external world that we can operate effectively and at speed whilst delivering 100% of our services remotely. We have been able to offer a much faster service to applicants for Covid-19 research approvals, co-ordinated across the four nations. The median approval timeline for standard review is 80 days, whilst the median approval timeline for Covid-19 fast-track review is 7 days. This represents an impressive 90% reduction in average timelines.

3.4. This has been made possible by:

- Enhancements to approvals processes, staff roles and technology over the past few years
- A 30% reduction in applications for new studies and amendments during the Covid-19 pandemic
- All staff and volunteers working from home, with some working evenings and weekends
- Pre-submission advice on applications
- All committee meetings taking place virtually
- Staff working in different ways, with many being diverted from other work to support Covid-19 research approvals, public involvement and transparency
- Project activities postponed

- 150 volunteers being available to join ad hoc committees at short notice

3.5. Unsurprisingly, applicants and stakeholders, who have praised the HRA for our great service, are hoping that we can continue to offer it in the future. Our response to Covid-19 has created high expectations. However, the current operating model is only sustainable for the short term and offers no resilience. What is working in a pandemic (staff and volunteers going the extra mile, a clear, national focus and energy, applicants being receptive, and funders organised) is unlikely to work when paused research restarts.

4. Evolving our research review model for next 10 years

4.1. Whilst our Covid-19 service has created high expectations, it also gives us an opportunity to make changes much more rapidly than we had planned and to consider service models which we may not have thought possible at all. With the investment in our research technology and the planned replacement of IRAS and back-end systems over the next few years, we also have the opportunity to implement policy and service changes through our technology, creating a research review service which is built around the needs of researchers from start to finish and which makes good use of volunteer time.

4.2. This paper outlines a project to identify and implement a service model for the next 10 years of the HRA's life. This will involve developing costed models for research review and a supporting service which take account of feasibility, affordability and benefit to UK research. These models will be explored on a UK-wide basis with stakeholders to ensure we are considering the impact on the research community, the life sciences industry and patients. Any preferred model will need careful consideration by the devolved administrations, fellow regulators and Government.

4.3. The scope of the project will include:

- defining which types of research study we review (linking with work on student research)
- who does the review according to study type or level of complexity/risk (researchers themselves, staff, sub-committees or full committees)
- how we support research to submit applications that are right first time
- whether and to what extent committees continue to be held virtually
- what study information is submitted by applicants and, of that, what is then put before the reviewer
- whether we should introduce fast-track review approaches for particular types of research
- whether or not we charge applicants or pay committee members for value added services such as fast-track review
- what policy changes are needed to support the desired approach.

5. Engagement

5.1. Effective engagement will be key to developing a research review model that is:

- Accepted - by all stakeholders as being fair and reasonable
- Understood – by applicants, research ethics committees and staff
- Appropriate/ethical – is consistent with legal frameworks, policy frameworks and the HRA strategy
- Feasible – possible within HRA resources, skills and experience

5.2. There is likely to be a range of views about which is the most appropriate model for how we review research in the future. When we identify the preferred model, we will need to be able to communicate on what basis that decision has been made.

5.3. For example, a model which includes a fast-track review process for clinical trials of medicines would be straightforward to administer as there are established definitions of these studies and will help with faster development and deployment of medicines. Such a scheme would need to treat all funding sources as equitable. This proposal however, raises the question of whether CTIMPs are the most important studies to review quickly. To answer that question, we would need to clearly define what 'most important' means, to agree who defines it and on what basis. Equally, we could propose that it would be more appropriate to favour "important" or "high-quality" research but again we would need clear definitions to determine what 'high-quality' means. Whether that is determined by the HRA and devolved administrations for by others (such as funding bodies or expert panels), this type of approach may be contested by researchers.

5.4. Engagement with internal stakeholders, Research Ethics Committee volunteer members and external stakeholders is therefore crucial to help HRA Board and our colleagues in the devolved administrations to take a decision which is evidence-based, accepted by the research community and patients and is sustainable in the long term. We need to work closely with fellow regulators, particularly the MHRA, to ensure that the research review model is fully aligned and integrated with their policies and processes.

5.5. We will engage an external supplier to help us develop possible research review models. This would include an initial assessment of the impact on cost, people, the research community, patients and the economy. We will also engage an external supplier to support the engagement work and analyse the findings from the consultation.

5.6. We plan to form an advisory group, chaired by an HRA non-executive director, which will include colleagues from the devolved administrations and key stakeholders from patient, research, funder, government, regulatory, and life science sectors. The advisory group will help us to agree research review options which could be tested with stakeholders through a public consultation. After the consultation, the group will advise on the most desirable model for agreement by the Four Nations Policy Group and the HRA Board.

6. Governance and phasing

6.1. The project to evolve our research review model needs to be well-coordinated and planned. We need to ensure that we have enough time to properly define and test the new research review model. However, we must take the opportunities afforded by the ways or working during the Covid-19 pandemic and the wider stakeholder interest in that. We must not delay work that can be progressed before the outcome of this project is known.

6.2. The project will sit within the governance structure of the wider Transformation Programme to ensure that it has senior oversight and the interdependencies with other strategic programmes are well managed. This piece of work is very closely linked to the Research Systems Programme, as service model changes will need new technology to support them and therefore need to be scoped in as soon as possible. Other linked programmes include:

- How we review and support student research in the future
- Streamlining of the review of studies using large datasets and AI
- Implementing our research transparency strategy
- How we recruit, work with and value our volunteers
- Further streamlining within our approvals processes including document management, committee logistics and use of technology

6.3. This is likely to be a two-year programme of work, with most of the model development taking place in the current financial year and the implementation phase beginning in 2021. Close working between policy/engagement and operational functions will be crucial throughout, to ensure feasibility and stakeholder acceptability is kept in mind.

6.4. A rough timetable for the work is as follows

Quarter 2 (July-September)
• Announce programme to stakeholders • Form advisory group • Engage an external supplier to help us develop possible research review models • Engage an external supplier to support the engagement programme • Hold initial stakeholder workshop to inform options development
Quarter 3 (October-December)
• Finalise research approval options • Start public consultation period
Quarter 4 (January-March 2021)
• Complete consultation and analyse findings
Quarter 1 (April-June 2021)
• Agree final research review model in May 2021 • Start implementation phase

7. Next steps

7.1. If the Board is content for the project to progress, we plan to discuss the work with colleagues in the devolved administrations at the next Four Nations Policy Group meeting on 28 July.

7.2. We will then finalise the scope of this work, establish the project teams to deliver the work and agree the roadmap.