Agenda item:	9
Attachment:	B

HRA Board paper
20 January 2021

Title of paper:	**Research review programme – update**
Submitted by:	Juliet Tizzard, Director of Policy and Partnerships
Summary of paper:	The paper provides an update on the Research Review Programme and outlines next steps
Reason for submission:	For information
Further information:	N/A
Budget / cost implication:	Funds allocated for 2020/21 and spending tracking within budget. Funding for 2021-22 subject to spending review bid
Dissemination:	Communications and Engagement activity around the programme underway and described in the paper
Time required:	20 minutes

Research review programme - update

1. Background

1.1. The Research Review Programme aims to develop a revised model for research ethics review, building on service improvements we have already made and different ways of working during the COVID-19 pandemic. We want research ethics review to be more:

- proportionate to the ethical issues raised by different research
- conducted to timelines that reflect the priorities of the overall research ecosystem
- user-friendly for researchers and sponsors
- valued by researchers and sponsors.

1.2. The autumn period saw an intensive period of work on the programme, involving staff across the organisation. This paper provides as short update on that work and an outlook for the next three months, leading up to the end of the financial year. Key areas covered are:

- Fast-track ethics review pilot
- Findings from engagement programme
- Options for future ethics review model
- Planning for 2021-22

2. Fast-track ethics review pilot

2.1. The aim of the fast-track ethics review pilot is to test a new committee model designed to enable 15-day ethics review. It is open to Phase 1 and global clinical trials and we expect to review 40-60 studies through this pilot.

2.2. The key features of the model are:

- A dedicated fast-track Research Ethics Committee (REC)
- A paid committee chair
- Committee members drawn from a panel of existing members, rather than a set committee membership
- Dedicated approvals staff
- Shortened timelines between submission and REC meeting and between REC meeting and outcome

2.3. Following expressions of interest from a strong field of applicants, we have appointed Professor Alan Lamont to be chair of the fast-tract REC. He is joined by two vice chairs and 40 existing REC members who have volunteered to be on the committee. We have also identified approvals specialist staff to support the pilot.

2.4. The pilot will test the demand, feasibility and cost of this model. It will enable us to determine whether a fast-track service should be offered in future and, if yes, whether this model is the appropriate one. We are working to an evaluation framework with four assessment domains: sustainability, consistent quality, efficiency and value for money.

2.5. The evaluation framework, designed with the help of Deloitte, is designed to answer the key questions about the pilot that will enable us to determine the demand, feasibility and cost of this model without creating a complex and labour-intense evaluation process. Where possible, we are relying on existing data collection (study approval data, for example).

2.6.   The evaluation criteria are:

	Assessment Criteria	Pilot validity criteria	Measured through	Measurement	Minimum threshold
Sustainability	REC process and satisfaction	REC members experience	REC member survey	Score 0-10 of satisfaction	≥ current level of satisfaction or 7/10
Sustainability	Appropriate pipeline	Number of applications	Programme records	Number of fast track applications submitted	>20 fast track applications
Consistent quality	User satisfaction	Applicant experience	Applicant survey	Score 0-10 of satisfaction	≥ current level of satisfaction or 7/10
Consistent quality	Consistent and high-quality REC decision making	Approval officer reporting to Programme Manager	REC meeting recordings	Review recordings to ensure decision-making consistency and discussions across required domains	Conversations cover all domains required and are consistent across REC meetings
Efficiency	Ability to deliver on time	End to end REC timeline (without clock stop)	Existing MI methodology	Number of days	Mean 15 calendar days
Value for Money	Economic benefit	Provides economic benefits to researchers (and UK plc)	Applicant survey	Answer to question – 'Did the fast-track process provide your organisation with an economic benefit?'	Majority of applicants say yes and select one of a number of potential economic benefits shown

2.7.   The pilot was officially launched on 6 January, with a news release and endorsement from Lord Bethell. The pilot has been well received and there was media pick-up in the trade press, reflecting the interest from the pharmaceutical industry in the pilot.
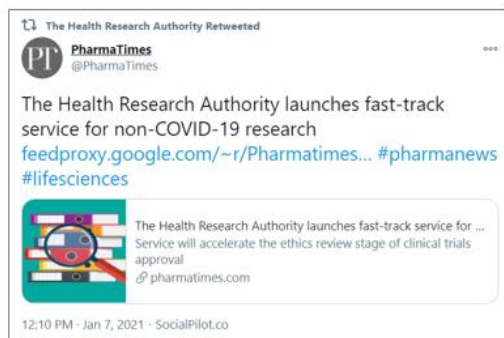
2.8.   Following targeted communications and engagement with trade bodies, industry stakeholder groups and key contacts carried out in late 2020, the demand for the pilot is currently good. The first fast-track REC meeting, held on 13 January, reviewed five studies and there is a good flow of bookings for the January meetings.

3.   Findings from engagement programme

Engagement to inform ethics review model development

3.1.   Running alongside the pilot is a discovery phase for the development of a revised research ethics review model. This discovery work aims to identify opportunities for improvement and gather early ideas for a streamlined and accelerated future service. This engagement has so far involved interviews with key external stakeholders from industry and academia, a workshop with partners, a REC member survey and, in early January, workshops with patients, researchers, sponsors and REC members.

3.2.   Stakeholders are keen to engage with us on this topic and we are gathering useful insights. Thankfully, there have been no surprises in the feedback about the current service. For researchers and sponsors:

- IRAS is not intuitive and there is a lot of information to submit
- The review isn't always proportionate to the ethical issues
- It's hard to attend committee meetings in person
- Decision-making can be inconsistent between RECs
- Requests for changes aren't always clear.

3.3.   For REC members:

- The burden on REC members is significant
- Proportionate review (by correspondence rather than in committee) is burdensome
- Information from applicants can be unclear
- Participant information is often long and complicated
- Some researchers have not involved the public to address ethical issues in the study.

Engagement to support the detailed design stage

3.4. The next phase of the engagement activity will support a detailed design stage to take forward key aspects of the new model (see below). Engagement will be central to this, the key part of which is an Advisory Group made up of key stakeholders who will provide more focussed and ongoing input. We expect to start this group by March. Close ongoing engagement with REC members is also crucial to designing and implementation a sustainable model.

4. Options for future ethics review model

4.1. We are currently working up options for a future research ethics review model, to enable the Board and the Four Nations Policy Leads to make a decision about the most appropriate model. We are characterising the options as 'incremental change', 'moderate change' and 'transformative change', with a description of the status quo as a benchmark. We then have three cross-cutting domains, with incremental, moderate and transformative change options for each: type of review, decision-making and committee culture and process changes.

4.2. Some of the changes under consideration for **type of review** are:

- Differentiated review methods – fast-track review, a reformed proportionate review track and self-assessment
- AI enabled application and review approaches

4.3. Some of the changes under consideration for **decision-making and committee culture** are:

- Decision-making frameworks
- Greater use of approval specialists
- Paid REC chairs
- Focus on key ethical issues
- Improved participant information

4.4. Some of the changes under consideration for **process changes** are:

- Virtual committee meetings
- Greater pre-application support.

5. Planning for 2021-22

5.1. Planning for activity within the programme in the financial year 2021-22 is underway, as part of our business planning cycle. This will be iterative, given the future model options are currently under development.

5.2. An outline timetable is as follows:

Phase 1 (August 2020 to April 2021): discovery, piloting, modelling:

Activity	Timeframe
Fast-track: Designing, rolling out and evaluating a fast-track ethics review pilot for global and phase I clinical trials	September 2020-March 2021
Ethics review: Discovery, engagement, modelling	November 2020-January 2021
Ethics review: Agreeing a revised model for research ethics review	December 2020-March 2021

Phase 2 (February 2021 to March 2022): detailed design and roll-out

Activity	Timeframe
Prioritisation based on chosen model work and confirmation of funding	Feb-March 2021
Establish Ethics Review Advisory Group	March 2021
Start implementation of service changes which can be rolled out without further design	April-July 2021
Concurrent design projects on proportionality, decision-making, participant information and committee membership	From April 2021

5.3.   Implementation of service changes will take place through existing programmes such as Research Systems and through core service delivery. It will be crucial to ensure that change to the research ethics model are integrated with the approvals service as a whole and, for clinical trials, become part of the Combined Ways of Working service.

5.4.   Further funding for this programme has been requested through our Comprehensive Spending Review and our plans are likely to be modified as funding availability becomes clearer.

6.   Recommendation to the Board

6.1.   The Board is invited to consider the report and the following questions:

- Is this the right level of information about the programme?
- Is the Board satisfied with the programme's progress?