Agenda item:	8
Attachment:	A

HRA Board paper cover sheet
24 March 2021

Title of paper:	**Ethics Review Programme: update**
Submitted by:	Juliet Tizzard, Director of Policy and Partnerships
Summary of paper:	The paper provides an update on the Ethics 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:	15 minutes

Ethics review programme - update

1. Background

1.1. Research ethics review ensures that the safety, autonomy and dignity of health and social care research participants is protected. It is a crucial part of the wider regulatory and governance system to enable high-quality research to take place as swiftly as possible.

1.2. Building on service improvements already made and the different ways of working during the COVID-19 pandemic, the Ethics Review Programme (formerly Research Review Programme) aims for 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
- valued by researchers and sponsors.

1.3. The programme is coming to the end of Phase 1 (Discovery and piloting) and we are planning the programme priorities for Phase 2 (Design). The paper provides an update on progress and a description of next steps, focussing on:

- Fast-track ethics review pilot
- Research ethics review options for change
- Developing the roadmap for change

2. Fast-track ethics review pilot

2.1. A key part of the discovery and piloting phase is to test a new research ethics review model designed to enable 15-day ethics review (not including time taken by applicants to respond to requests for further information). We launched a pilot in January, open to Phase 1 and global clinical trials.

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. 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.

Progress

2.4. The pilot is running very successfully. There is good demand from applicants and interest in accessing the service beyond the pilot period. Meetings are running well, the quality of review is being maintained and studies are receiving an outcome in a time period which is around 50% faster than normal ethics review timelines.

Evaluation

2.5. We are working with Deloitte to evaluate the pilot and will produce an evaluation report in April. The data will be drawn from the following sources, all of which are underway:

- Timeline and demand data
- Staff resources used/needed
- Applicant satisfaction survey
- REC member satisfaction survey
- Ethnographic study of decision-making and deliberation in the fast-track REC meetings

Next steps for the fast-track service

2.6. Following business and financial planning for 2021-22, we have decided to continue to offer a fast-track service beyond the end of March. This will enable us to meet applicant demand whilst completing the evaluation and determining the appropriate fast-track model for the future. In particular, we will consider how the fast-track ethics review service dovetails with Combined Ways of Working (run with the MHRA), as we roll it out into the standard review service for all clinical trials of medicines.

3. Research ethics review options for change

3.1. The main part of the discovery and piloting phase has been to develop options for changing research ethics review, using stakeholder insights and modelling carried out by Deloitte. 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.

3.2. We are currently developing a roadmap, with the following work packages emerging as priorities for the coming year:

Differentiated review methods
This work will include designing the appropriate model and scope for fast-track ethics review and transitioning into normal service for certain study types. It will also focus on redesigning the review tracks that other types of research follow: review at REC meeting, through light-touch review and through self-assessment by applicants. The aim of this work is to ensure that REC member time is focussed where they add most value, reducing the work pressure on them and reducing bureaucracy for studies with few or no ethical issues.

Streamlined documentation for REC review
REC members often observe that the information provided in response to IRAS questions and in study documentation is burdensome to review. Working with Research Systems Programme, this work aims to clarify questions for applicants and ensure REC members review only the information required for ethics review.

Significantly improved participant information
We know that around 40% of provisional opinions from an ethics committee (prompting requested changes to the study information) are caused by problems with information and consent documentation. This creates additional work for applicants, RECs and staff and extends the timeline to the final outcome. This work will focus on improving participant information before submission (including embedding public involvement in information development) and improving review by the REC.

The right committee meeting format for the future
The use of virtual committee meetings during the pandemic has enabled greater attendance by applicants, made co-opting committee members more straight forward and encouraged a wider group of people to join a REC. This work will design a committee format which takes advantage of virtual working, but retains the sense of community within and between RECs which is so important. This will be aided by different forms of learning and opportunities for REC members to come together outside of a formal REC meeting. Moving to more virtual ways of working will impact on REC members numbers so needs to be done carefully and over a time period that enables us to attract new members who prefer this way of working.

More consistent REC review
Whilst RECs use the same approach to considering ethical issues and work within standard operating procedures, there are differences across the service in how decisions are made and the extent to which the tools available to them are used. This leads to a differing experience for applicants, inconsistency in the focus of ethics review and, potentially, different rates for provisional and favourable opinions at first review. This will be a long-running piece of work to collaborate with REC members in addressing these issues. It will learn from the experience of the fast-track REC and consider how good practice can be propagated across the service.

4. Developing the roadmap for change

4.1. Developing the roadmap for modernising research ethics review is complicated. It requires careful co-ordination with the business and systems changes which are already planned and underway in the Research Systems Programme. It needs to fit within cross-system work to improve the clinical research environment (co-ordinated with the Recovery, Resilience and Growth Programme). Given the Research Ethics Service is UK-wide, close working with partners in the Devolved Administrations is essential.

4.2. Once the UK road map (including statement of ambition) is developed, we will engage with RECs, researchers, patients to build consensus, gather ideas and work together to ensure the changes meet the needs of applicants, RECs and staff and, mostly important, research participants.