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| **Agenda item:** | 9 |
| **Attachment:** | D |

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# **HRA Board paper**

# **18 November 2020**

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| 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 since the July Board meeting and outlines next steps |
| Reason for submission: | For information |
| Further information: | N/A |
| Budget / cost implication: | Budget secured by 2020/21. Further work subject to spending review bid |
| Dissemination: | Communications and Engagement activity around the programme underway and described in the paper |
| Time required: | 5 minutes |

## Research review programme - update

### Background

* 1. At the July meeting, the Board approved the establishment of a new piece of work 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, both in terms of fast-track review and the way in which Research Ethics Committees (RECs) are currently operating.
	2. This paper provides as short update on progress since July and sets out planned activity over the coming months. It covers:
* Establishing the programme –defining the scope, resourcing the programme and procuring external consultancy support
* Discovery work and early engagement – carrying out interviews with staff and stakeholders, analysing data to identify strengths and weaknesses of the current service and carrying out early engagement to seek views and raise awareness
* Designing and planning a fast-track ethics review pilot

### Establishing the programme

* 1. The Programme Board has identified the programme as having two key phases: setting up and running the fast-track ethics review pilot and developing a revised research ethics review model. There is overlap between the two phases but the priority for this financial year is in setting up and running the pilot and developing a pilot evaluation framework.
	2. We have identified the costs associated with the programme for the 20/21 financial year and begun to appoint relevant staff. Key costs in this financial year relate to programme staff (programme management, communications and additional capacity in key teams to support existing staff members’ involvement in the programme) and the cost of the fast-track ethics review pilot.
	3. We have gone through a procurement process to secure external consultancy support for the programme. We have selected Deloitte, who have begun work to:
* Develop an implementation plan and assessment framework for the fast-track pilot
* Develop a revised Research Ethics Review model, incorporating a fast-track service and a roadmap for implementation
	1. Deloitte will be working with us until the end of January 2021. They are also carrying out an options appraisal for the registration of clinical trials and other studies which is a deliverable for the Research Transparency implementation programme.

### Discovery work and early engagement

* 1. Running alongside preparation for the pilot is a discovery part of the second phase (developing a revised research ethics review model), working with Deloitte on some aspects. This involves carrying out interviews with key HRA staff and non-executive directors and external stakeholders from industry and academia to identify strengths and weaknesses in the current service. We are also analysing existing evidence on our current service: performance data, service costs and insights from previous surveys and pilots.
	2. One key source of information for the discovery phase is a survey of REC members about preferred future ways of working. Carried out by the Approvals Support team the survey focussed on the format of meetings and support for members and has provided some valuable insights. REC members are a key stakeholder for this programme, and we will be carrying out focused engagement with them over the next 6-12 months.
	3. We have also done early engagement with key partners. We held a roundtable discussion in October with DHSC, Office for Life Sciences, NHS England, NIHR Clinical Research Network, MHRA, Health and Care Research Wales/Welsh Government, Chief Scientist Office Scotland, Health and Social Care Northern Ireland. The meeting aimed to raise awareness of our plans and understand how they might dovetail with post-COVID activity in partner organisations.
	4. We are also engaging with sponsors likely to be part of the fast-track pilot, such as those involved in Phase I research and pharmaceutical companies running global clinical trials. We are aiming to raise awareness of the pilot and to discuss the entry criteria.

### Designing and planning a fast-track ethics review pilot

* 1. Activity is focussing on setting up the fast-track ethics review pilot, which is due to open in early January 2021.
	2. We have determined that the pilot will be open to a subset of global clinical trials of medicines and Phase I studies. The pilot will run from early January until the end of March and will consist of 10 weekly meetings of one fast-track committee. The committee will have one chair (who will recruited to a part-time paid role) and a panel of existing REC members who will be selected to sit on the fast-track committee as little or as many times during the pilot as they are able to.
	3. Detailed evaluation criteria are being worked on at present, but the key aim is to test whether it is feasible to provide ethics review of these studies within 15 days and the cost of rolling out such a service to a wider group of applicants.

### Next steps

* 1. For the period from now until early January, we will be focussing on:
* Setting up the fast-track ethics review pilot and finalising the evaluation criteria
* Carrying out focussed engagement, particularly with industry and REC members
* Establishing an Advisory Group for the programme, which will include Research Ethics service users (researchers, REC members and research participants)
* Carrying out planning a prioritisation for the second phase of the programme