|  |  |
| --- | --- |
| **Agenda item:** | **9** |
| **Attachment:** | **B** |

**HRA BOARD COVER SHEET**

|  |  |
| --- | --- |
| **Date of Meeting:** | 23 January 2019 |

|  |  |
| --- | --- |
| **Title of Paper:** | **Research transparency strategy development** |
| **Purpose of Paper:** | To outline the planned approach to developing a research transparency strategy, for delivery by December 2019 |
| **Reason for Submission:** | To seek views and thoughts from the Board about developing the strategy before we start the process |
| **Details:** | See paper |
| **Lead reviewer:** | Teresa Allen |
| **Time required for item:** | **15 minutes** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Recommendation / Proposed Actions:** | **To approve** | |  |
| **For information / to note** | | **Yes** |
| **For discussion** | | **Yes** |
| **Comments** |  | |

|  |  |
| --- | --- |
| **Name:** | Juliet Tizzard |
| **Job Title:** | Director of Policy |
| **Date:** | 15 January 2019 |

## Research transparency strategy development

### Background

* 1. The HRA has had a statutory duty to promote research transparency since 2014, although we have been working to promote transparency since we were established in 2011. Transparency is central to good quality, ethical research and consists of:
* registering research
* publishing and disseminating findings and conclusions
* providing access to data on which finding and conclusions are based
* providing information about findings to research participants
* providing access to tissue used in research, for use in future research.  
  1. We have seen some improvements in transparency, particularly amongst commercially-sponsored research. However, university-, NHS- and charity-sponsored research has a poorer record of registration, publishing results and feeding back to participants.
  2. We have few regulatory powers in relation to research transparency. Our regulatory focus is on reviewing studies before they start and approving them on the basis that the research team will carry out the study in the way that they set out in the application for ethical review. However, registration is a condition of ethical approval for clinical trials (of medicines, devices and other clinical interventions), a requirement we have had in place since 2013.
  3. Research transparency has moved up the political agenda in recent years. The House of Commons Science and Technology Committee held an inquiry into clinical trials in 2013, with a recommendation that ‘the HRA… ensures that all trials have been registered and published according to an agreed timeline, rather than performing checks on a sample basis. In addition, there must be penalties for non-compliance.’
  4. Although the promotion of research transparency has remained central to our values since then, we have channelled resources towards establishing HRA Approval, rather than towards driving improvements in transparency. However, since we refreshed our strategic objectives and created the Director of Policy post in early 2018, we now have the focus and capacity to take forward this work. When the Science and Technology Committee returned to the issue in 2017 and [published recommendations](https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/148002.htm) in October 2018, we were in a position to respond positively to the committee’s recommendations and commit to taking action.
  5. The committee recommended that the HRA should:
* establish a programme to monitor compliance with requirements around registration and publication of clinical trials
* prepare a funding proposal to the Government to fund such a programme
* publish information gathered through the monitoring programme about the individual trials which have gained ethical approval but a) not registered within the expected timeframe, and b) not published in an academic journal within the expected timeframe
* develop within 12 months a detailed strategy for achieving full clinical trials transparency; and
* introduce a system of sanctions to drive improvements.

### Purpose of this paper

* 1. In November 2018, the Board discussed our response to Science and Technology Committee, agreeing that we engage positively with the committee’s recommendations and acknowledge that we need to change our approach: to move away from promoting the benefits of transparency to driving improvements. The response commits us to enhancing our work in this area: to develop a research transparency strategy, explore our enforcement powers and submit a business case to DHSC to fund a monitoring function.
  2. Following discussion at the Board in March 2018, work is underway to increase awareness of research transparency requirements and to make compliance with those requirements easier. This paper sets out proposals for taking forward the Science and Technology’s recommendations for additional activity, particularly around developing the strategy.

### Developing our research transparency strategy

* 1. The committee has recommended that we produce a research transparency strategy by December 2019, setting out how we will achieve full clinical trials transparency, with a clear deadline and milestones. We propose developing the strategy through engagement with key stakeholders and the wider research community, to ensure that it is feasible and achievable and has research community buy-in (an approach is set out below). Although the contents of the strategy will be shaped by this engagement process, we expect it to contain:
* Overarching principles and desired outcomes
* Key ways of delivering those outcomes
* Specific policy and operational measures to enable the outcomes.  
  1. The strategy could include specific time-bound targets to work towards, with progress reporting along the way. This will create momentum and enable us to celebrate progress.
  2. The overarching principles and desired outcomes could include:
* All clinical trials must be registered before recruitment starts
* Researchers must have a clear plan for making findings public and feeding back to research participants
* We will be clear about what is required of researchers and what will happen if they don’t do that at each stage of the process
* We will redesign our research systems to make compliance easy (clarity of requirements, reminders, performance reporting, opening up access to sponsors)
* We will invest resources in monitoring performance and publishing information about sector improvements
* We will publish trial-by-trial information using information from our monitoring – so that investigators, sponsors and funders can check and compare their performance.  
  1. The key ways of delivering those outcomes could include:
* Focussing on gathering data about registration, making findings public and feeding back to participants, requiring investment in systems and people achieve this
* Focussing on ensuring that researchers report information to us, rather than checking ourselves for evidence of registration or making findings public
* Considering making evidence of registration a condition of favourable ethics opinion (ie, trial must be registered before ethics review).

### Engagement plan

* 1. For the strategy to be effective, particularly where our regulatory powers are limited, we need well-planned engagement with investigators, sponsors, the wider research community and patients. This will enable us to:
* Develop a strategy which is credible and has stakeholder buy-in – and partners who will champion it
* Gather feedback on the proposals and plans to assess acceptability, feasibility and impact from a range of stakeholders
* Give early warning that we will be ensuring better compliance from a future date.  
  1. We plan to do this by using existing stakeholder forums, particularly the Transparency Forum, as sounding boards for our proposals and how we consult on them. We also plan to form a small Expert Reference Group, to help us develop a robust, feasible strategy. This reference group should include an HRA non-executive director and representatives of different types of funders and sponsors,
  2. The rough timeline would be as follows:

|  |  |
| --- | --- |
| **Month** | **Strategy milestone** |
| January 2019 | Strategy plan to Board meeting  Share plan with Four Nations policy leads and Transparency Forum |
| February/March | Expert reference group meeting to agree shape of strategy |
| April | Expert reference group meeting to finalise draft strategy |
| May | Draft strategy to Board  Transparency Forum – discuss plans for consultation |
| June/July | Run strategy consultation, with engagement events  Share draft strategy with S&T committee |
| September | Expert reference group meeting to consider consultation feedback  Discuss consultation findings with Board and Transparency Forum |
| November | Final strategy to the Board  Final strategy to the Science and Technology Committee |

* 1. We would welcome views from the Board about the main elements of the strategy and the planned process for developing it.