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| **Agenda item:** | **8** |
| **Attachment:** | **B** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 21 November 2018 |

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| **Title of Paper:** | **Research transparency** |
| **Purpose of Paper:** | To inform the Board about recommendations from the House of Commons Science and Technology Committee in its recent report and to agree next steps in considering those recommendations. |
| **Reason for Submission:** | Board update and decision on next steps. |
| **Details:** | The recommendations are set out at paragraph 6 |
| **Lead reviewer (if applicable):** | Teresa Allen |
| **Board review required?** | Yes / ~~No~~ |
| **Suitable for wider circulation?** | Yes / ~~No~~  |
| **Time required for item:** | **15 mins** |

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

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| **Name:** | Juliet Tizzard |
| **Job Title:** | Director of Policy |
| **Date:** | 15 November 2018 |

## Research transparency

### Background

* 1. Research has a crucial role to play in improving the health and wellbeing of the population: developing new and better medical treatments and services and promoting good health and preventing ill health. But carrying out research is not enough on its own. Researchers must share their findings so that others can learn from their experience and understand what does and does not work. So, transparency is central to good quality, ethical research.
	2. Transparency in research includes:
* registering research
* publishing and disseminating findings and conclusions
* providing access to data on which finding and conclusions are based
* providing information at the end of research to participants
* providing access to tissue used in research, for use in future research

	1. However, health research in the UK has a patchy record of transparency. Although clinical trial registration and publication has improved over recent years, there is still room for improvement in these types of studies.
	2. In March 2018, the Board agreed a package of work aimed at addressing this poor performance. Based on insights gained from our audits and the literature on research transparency performance, the Board agreed that we should initially focus upon increasing awareness of the importance of transparency and making clearer the expectations and requirements we place on sponsors and investigators. We agreed to monitor the impact of this work and, if there was insufficient progress, consider option for enhancing the incentives for the research community. This would include exploring the possibilities and legalities of sanctions.
	3. Since then, the House of Commons Science and Technology Committee has published two reports of its inquiry into research integrity, with the second report[[1]](#footnote-1) focusing on clinical trials transparency. In this second report, the committee is critical of poor performing sections of the research community, of the government and of the HRA. It makes a series of recommendations for stepping up the effort to improve practice in this area. The committee expects a response to its recommendations with two months of publication, setting out how we plan to address them.
	4. This paper:
* reports on progress since March
* outlines the committee’s recommendations and proposes how we might respond
* sets out a proposed approach for addressing the committee’s recommendations.

### Progress since March

* 1. Since the Board, in March, approved a plan for taking forward our research transparency work, we have:
* Taken views from Transparency Forum members about the automated reminder features we should build into the new IRAS system and the information about individual applications that we could publish on the research summaries database. Those features are now part of the IRAS development plan.
* Carried out a survey of researchers, sponsors, funders and other stakeholders to understand in more details the level of awareness of transparency requirements in the research community, so that we can target our awareness-raising efforts.

	1. We have begun work to raise awareness of transparency requirements and to make it clear what those requirements are.

### The Science and Technology Committee’s recommendations

* 1. The House of Commons Science and Technology Committee, chaired by Normal Lamb MP, published its second report on research integrity on 30 October 2018. In summary, the report recommends that we place greater importance on research transparency than we have done to date, suggesting that the Government directs us to interpret our duty under the Care Act 2014 to promote research transparency as being concerned with driving improvements, rather than promoting transparency as a virtue.
	2. The committee aims some of its recommendations at Government (by suggesting that it instructs or advises us to do certain things), but essentially the recommendations are for the HRA to:
* 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.

	1. The recommendations specifically for Government are to:
* explicitly commit to introducing the transparency requirements within the forthcoming EU Clinical Trials Regulation into UK law after Brexit
* explicitly re-commit to tackling clinical trials transparency
* consider favourably any requests from us for further financial resource to tackle clinical trials transparency
* consult with us about whether to provide us with the power to fine sponsors for non-compliance
* consult with us about whether it is possible to drive improvements within our current legislative remit and, if not, to amend the Care Act 2014; and
* hold us to account for performance in this area.

	1. There are also recommendations for Universities UK and for Public Health England.
	2. Given the strength of feeling expressed in the committee’s report and our existing strategic objective to championing transparency in research, we decided to adopt a positive tone in our media response to the report. The full media response is at Annex A, but the relevant extract is as follows:

‘We had hoped to increase compliance with research transparency requirements by making those requirements clearer, working with funders to align expectations of researchers and introducing automated reminders at the relevant stage of a study in order to make compliance as easy as possible. We’re confident that these measures will have an effect, but it’s not clear that this will be sufficient to deliver the benefits that we want to see. To truly drive innovation and reduce research waste, the HRA will now look how we could take a more robust approach, including potential sanctions, for example not providing ethical approval to new studies until existing ones have been registered in line with the current guidance.’

* 1. This positive tone in our response was well received by transparency advocates.

### Responding to the Science and Technology Committee

* 1. There are two stages to responding to the committee’s recommendations:
* A formal response within two months (by 30 December 2018), indicating whether we accept the recommendation and, if so, a broad outline of how it will be addressed
* A detailed plan for taking forward the work to address the recommendations that we have committed to addressing (see section 5 for a proposed approach to this).

	1. We have the option of either submitting a joint response with Government (led by the Department of Health and Social Care) or submitting our own separate response. Given that most of the recommendations are aimed at the HRA, we propose submitting a separate response, but ensuring that we are aligned with the DHSC as much as possible.
	2. Given that some of the recommendations relate to using powers under the existing legislation and exploring the need to extend our remit, we also propose seeking independent legal advice to inform our policy work in this area.
	3. The table below lists the recommendations that relate to the HRA. It is important to note that we are not expected to set out in the response to the committee what we plan to do to address each recommendation (ie, what our strategy will contain or which sanction we might use). Rather, we need to say whether or not we accept the recommendation and, if we do, give an indication of how we plan to take forward the work to address it. We should not rush to come up with solutions at this stage, not least because we need to take key stakeholders with us.

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| **Committee recommendations to the HRA** |
| 1. We recommend that the Health Research Authority (HRA) should be provided with funding to establish a national audit programme of clinical trials transparency, including the publication of a single official list of which UK trials (trial by trial) have published results and those which are due to but have not. In the first instance this should focus on providing information on whether any results have been published in an academic journal following global best practice, building on the automated methods already developed by others. We recognise that there are other dissemination routes for clinical trials results beyond academic journals that automated methods might not capture. Where alternative means have been used to publish information the HRA can use this process to prompt lead investigators to provide details of where the results have been posted so that the entry for that trial can be corrected as necessary. |
| 2. We recommend that the HRA undertake further work to determine an accurate figure for the cost of such an audit and prepare a funding proposal for the Government to consider.  |
| 3. The Government should direct the HRA to publish information on trials that have received ethical approval but are not registered in a publicly-accessible register, on a trial-by-trial basis.  |
| 4. We recommend that the HRA introduce a system of sanctions to drive improvements in clinical trials transparency, such as withdrawing favourable ethical opinion or preventing further trials from taking place. The Government should consult specifically on whether to provide the HRA with the statutory power to fine sponsors for non-compliance.  |
| 5. We recommend that the Government ask the HRA to publish, by December 2019, a detailed strategy for achieving full clinical trials transparency, with a clear deadline and milestones for achieving this. We also recommend that the Government write to the HRA to clarify that it should interpret the Care Act 2014 to mean that it is responsible for driving improvements in clinical trials transparency—as opposed to ‘promoting’ transparency as a virtue. The performance of the HRA should then be explicitly measured on this basis through its annual report, including through specific measurable performance indicators. If further financial resource for the HRA is required to tackle clinical trials transparency then the Government should consider favourably such requests.  |
| 6. We recommend that the Government consult further with the HRA on whether it is capable of delivering the improvements to clinical trials transparency needed within its current remit. If necessary its remit should be extended through introducing legislation which amends the provisions of the Care Act 2014.  |

* 1. We would welcome Board members’ general comments on the recommendations. We will use the comments to draft a response to each recommendation, taking into account discussions with the DHSC and our own legal advice.
	2. We propose that final approval of the response to the committee is done by the Chair.

### Proposed work plan for addressing the recommendations

* 1. As described above, the Science and Technology Committee has challenged us to take a more robust approach to research transparency. It has made a number of recommendations, one of which is to develop a strategy for tackling poor compliance.
	2. Our proposal is to take that work forward in a structured way, ensuring that we engage and consult to ensure that our policy in this area is targeted, proportionate and effective. With that in mind, we propose to:
* continue our planned work around raising awareness and making compliance easy through to end March 2019
* alongside that work, prepare an outline strategy for addressing the recommendations, taking early thoughts and a forward plan to the Board meeting in January 2019
* consult on a draft strategy and return to the Board after that consultation with recommendations on how we will increase research transparency over time.

### Recommendations to the Board

* 1. The board is asked to:
* consider the recommendation to respond to the committee independently of the Government and to seek our own legal advice to support our strategy
* comment on the committee’s recommendations
* agree that the final response to the committee is agreed out of session with the chair signing it off on behalf of the Board
* consider and agree the recommended next steps at section 5.

## Annex A: HRA media response to the report

**The Health Research Authority (HRA) welcomes** [**the report published today by the House of Commons Science and Technology Committee**](https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2017/clinical-trials-transparency-report-publication-17-19/) **as part of its inquiry on Research Integrity, and the recommendations within it.**

One of the key principles in our [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) is that ‘research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency’. We agree with the committee that clinical trials transparency is a vital component for trustworthy science, and essential if we are to ‘protect and promote the interests of patients and the public’. We are committed to enhancing our work in this area.

Having reflected on the evidence submitted to the committee by ourselves and others earlier this year, we have already begun to take action on some of the areas raised in today’s report.

Our 2016 audit of clinical trials registration showed that whilst compliance rates are improving, researchers and their sponsors still have further to go. As our chair, Professor Jonathan Montgomery, suggested in his written evidence to the committee, the audit showed that engaging with the research community increases the registration rate, by addressing a lack of awareness of basic requirements. We have carried out a survey to explore this issue in more depth and the details will be published next month. One emerging finding is that awareness of end-to-end transparency requirements is patchy and, even where knowledge is good, subsequent behaviour does not always deliver against researchers’ obligations.

We had hoped to increase compliance with research transparency requirements by making those requirements clearer, working with funders to align expectations of researchers and introducing automated reminders at the relevant stage of a study in order to make compliance as easy as possible. We’re confident that these measures will have an effect, but it’s not clear that this will be sufficient to deliver the benefits that we want to see. To truly drive innovation and reduce research waste, the HRA will now look how we could take a more robust approach, including potential sanctions, for example not providing ethical approval to new studies until existing ones have been registered in line with the current guidance.

We welcome the recommendation in today’s report that our current transparency work be brought together into a formal and detailed strategy during the coming year, and will consult with others in the research community before it is finalised. We also welcome a discussion with the Department of Health and Social Care to explore the financial and statutory implications of the HRA taking on a more robust role in ensuring complete reporting and transparency if all of the select committee’s recommendations are taken forward.

We are committed to do more to drive research transparency, which is both a good practice requirement and long-standing ethical principle. Transparency is essential so that participants are protected from unnecessary research and patients benefit from improved outcomes and care informed by high quality studies. We will act on the recommendations published by the select committee today, and report on our progress.

[Teresa Allen](https://www.hra.nhs.uk/about-us/who-we-are/our-board-members/teresa-allen/), Chief Executive

[Professor Jonathan Montgomery](https://www.hra.nhs.uk/about-us/who-we-are/our-board-members/professor-jonathan-montgomery/), Chair

30 October 2018

1. [*Research integrity: clinical trials transparency*](https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2017/clinical-trials-transparency-report-publication-17-19/) House of Commons Science and Technology Committee, (HC 1480) 30 October 2018 [↑](#footnote-ref-1)