BU Consultation Response

Make it Public – Health Research Authority

Submitted: 5th September 2019

Link to HRA survey
Link to strategy

This BU consultation response was led/prepared by Jane Forster, OVC

The HRA's consultation gives everyone involved an opportunity to influence the Health Research Authority's future strategy to improve public access to information about health and social research in the UK. We conducted an internal consultation and the responses are described below to inform our institutional responses.

We had 20 responses to the institutional survey which ran from 24th June 2019 to 16th August 2019 and was publicised within FHSS and by RDS. 11 academic staff, 3 PSS staff and 6 others (members of PIER).

What the strategy covers

This strategy covers health and social care research taking place in the UK which involves people, their tissue or their personal data. Information about research studies of this kind should be made public.
The initial focus of this strategy is on clinical trials. These are research studies that test the safety and effectiveness of patient interventions such as medicines, medical devices, surgical techniques, public health measures and behavioural therapies. We will consider other types of research, such as observational studies and questionnaires, at a later stage."

Research transparency refers to:

- *registration (making it public that a study has started)*
- *reporting results (making public what the study has found)*
- *feeding back to participants (informing those who took part what the study has found), and*
- *sharing study data and tissue (enabling further research).*

All these types of transparency are important. However, the initial focus of this strategy is on registration, reporting results and feeding back to participants. We believe that these are the priority areas for the HRA. Others in the research system are best placed to continue to enable appropriate sharing of study data and tissue.

1. Please indicate the extent to which you agree with the following statement. The strategy should focus initially on clinical trials

Agree

Please explain your answer:

We believe that it is helpful to focus on clinical trials initially but we believe that the results of other studies should also be more transparent

2. Please indicate the extent to which you agree with the following statement. The strategy should focus initially on registration, reporting results and feeding back to participants

Agree

Please explain your answer:

We agree that these are important and should be priorities, particularly feedback, which we believe is not currently done consistently well

Supporting good practice, making compliance easier

We have already decided to make a number of changes to support good practice and make compliance easier. We plan to:

- *be clearer about what we expect of sponsors and researchers at the different stages of the process*
- *develop new learning packages to support them*
- *share best practice and celebrate improvement*
- *make it clear what information from applicants we will make public and what we will share with others*
- *introduce automated reminders for researchers and sponsors to submit transparency data and to view the status of their studies*
- *give sponsors and researchers feedback on their transparency performance.*

3. Please tell us how important you think these changes are in improving research transparency. This will help us to prioritise

Being clearer what we expect of sponsors and researchers	• **Very important** • Moderately important • Of little importance • Not important • I don't know
Developing new learning packages to support research transparency	• **Very important** • Moderately important • Of little importance • Not important • I don't know
Sharing best practice and celebrating improvement	• **Very important** • Moderately important • Of little importance • Not important • I don't know
Making it clear what information from applicants we will make public and what we will share with others	• **Very important** • Moderately important • Of little importance • Not important • I don't know
Introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies	• Very important • **Moderately important** • Of little importance • Not important • I don't know
Giving sponsors and researchers feedback on their transparency performance	• Very important • **Moderately important** • Of little importance • Not important • I don't know
Flagging up individual studies where transparency information is overdue	• **Very important** • Moderately important • Of little importance • Not important • I don't know

Sharing transparency performance data with funders, other regulators and registries	• **Very important** • Moderately important • Of little importance • Not important • I don't know

4. What else, if anything, do you think we should do to improve feedback to participants?

We believe that it is important to:

- **ensure that there is adequate patient and public involvement in studies, i.e. as part of the study design and with participation in the team: it is too often an afterthought.**
- **ensure that there is an opportunity for participants to feedback on their experience of participation – and require researchers to act on the feedback in future studies**
- **make it clear to participants how they will receive feedback and maintain contact with them, including giving progress updates over a long term study**
- **provide training support for presentation of results; include participants in the writing process to ensure that they are presented in a way that is meaningful for the audience**

5. Which of the options do you think is the most appropriate to ensure registration of clinical trials (please select only one):

Something else

Please explain your answer. If you have picked 'something else', tell us what you have in mind:

Confirmation of registration should be required before final confirmation of approval is given as an additional step. It is important that HRA is able to manage this, but ideally an HRA registry should be linked to other trial registries to avoid duplication of work.

6. To what extent do you think that these steps will improve the reporting of results from clinical trials?

We believe that these steps will improve the reporting of results from clinical trials

What else, if anything, do you think we should do to improve the reporting of results?

nothing else to add

7. To what extent do you think the following actions would be appropriate?

Publish an annual 'transparency league table' highlighting individual studies which have information that is overdue	• Not at all appropriate • Not appropriate • **Appropriate** • Highly appropriate • I don't know
Take into consideration the extent to which sponsors have fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval	• Not at all appropriate • Not appropriate • **Appropriate** • Highly appropriate • I don't know
Fining sponsors with very poor transparency compliance rates (this would require a change in legislation)	• Not at all appropriate • **Not appropriate** • Appropriate • Highly appropriate • I don't know

Please explain your answer:

A league table should highlight the positive – i.e. flagging high performers rather than focussing on (apparently) poor ones – good case studies could also be published alongside the rankings.

Fines are not appropriate because there may be reasons why results are not published.

8. Please tell us about anything else that might make it hard to be transparent, as well as anything that would make it easier.

There is a challenge with timing fitting in with publication requirements. Results that are shared may need to be embargoed until published, although this may be hard to manage in practice.

9. Please give us any other feedback about the strategy or our work to improve research transparency.

It is important not to introduce too much bureaucracy or too many additional processes and changes should be introduced with this in mind

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