

UK policy framework for health and social care research: call for comments

Please send your comments to policyframework@nhs.net by 1st May 2015. The HRA would find it particularly helpful to receive comments on the following issues:

1. Is there anything more the policy framework should say in order to meet the ambitions set out in the “Purpose” section?

Yes No Undecided

Please provide details:

We agree that clinical research should be seen as a core ‘everyday’ part of the health service provision.

Our report [Children and clinical research: ethical issues](#) (published 14th May) concludes by highlighting the central importance of further work exploring the most effective methods of increasing knowledge and awareness of research, and the means of implementing them. For research to become part of the ‘core business’ of the NHS and other health services, it is important that we see an increasingly positive attitude towards research among potential participants and health professionals, together with confidence in the ethical robustness of that research.

2. The policy framework will be implemented by operational arrangements that reflect and embed the principles it sets out (e.g. in England, guidance for HRA Approval, which will be made available later). Is the level of detail in the policy framework sufficient for it to be implemented? If not, how could this be rectified?

Yes No Undecided

Please provide details:

3. Are there any issues (e.g. obstacles to research) that the policy framework does not address? If so, what are they and how could they be addressed?

Yes No Undecided

Please specify:

4. Do you think the principles that apply to all health and social care research are right?

Yes No Undecided

Please provide details:

5. Do you think the principles that apply to interventional health and social care research are right?

Yes No Undecided

Please provide details:

6. Do you think the policy framework adequately addresses the needs of social care research? If not, what needs to be covered?

Yes No Undecided

Please provide details:

7. Do you agree with responsibilities stated for chief investigators?

- Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

8. Do you agree with responsibilities stated for research teams?

- Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

9. Do you agree with responsibilities stated for funders?

- Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

10. Do you agree with responsibilities stated for sponsors?

Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

11. Do you agree with responsibilities stated for research sites?

Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

12. Do you agree with responsibilities stated for professional bodies?

Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

13. Do you agree with responsibilities stated for regulators?

Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

14. Do you agree with responsibilities stated for employers?

- Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

Our report [Children and clinical research: ethical issues](#) (published 14th May 2015) looks specifically at the ethical issues of involving children in research and the roles and responsibilities of researchers in developing and reviewing research with children and young people.

When reviewing research protocols, RECs should have in view both their ‘protective’ and ‘facilitative’ roles. Consideration of the potential risks and burdens of the research *must* certainly play a central part in the ethical review of any research protocol, but at the same time the potential value of the research should not be overlooked.

In order for RECs to be well placed to make these (sometimes very finely balanced) decisions as to whether, in a particular case, the burdens and risks presented by a study protocol can ethically be justified, it is essential for them to have access to appropriate expertise. (paragraph 5.23).

We recommend that, whenever research ethics committees consider protocols relating to research with children, they should always ensure that they have timely access to expert advice from the relevant area of children’s and young people’s healthcare. Such expertise may need to be obtained through an external adviser co-opted for the particular decision.

However, the Working Party was struck by the difficulties that health professionals and others engaged in research sometimes appear to encounter in convincing their employers that the time required to serve as a REC member is time well-spent (paragraph 5.25).

In our report, we therefore recommend that **that the UK Departments of Health, NHS Employers, Universities UK and the Health Research Authority should jointly consider what steps they can take to protect the professional time needed for research ethics committees to work effectively.**

We further recommend that the Royal Colleges and professional bodies concerned with children’s and young people’s health should make their commitment to evidence-based care clear by reinforcing the professional responsibilities of their members to contribute to the ethical review of research over their professional

lifetime. For example, involvement of some form in a research ethics committee (including in an *ad hoc* advisory role) could be encouraged as part of continuing professional development schemes. A number of rotational posts for trainees working in different areas of children's and young people's healthcare could be linked with their local research ethics committees.

15. Do you agree with responsibilities stated for health and social care providers?

- Yes No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

16. Do you think the policy framework will help make the UK a better place to do research?

- Yes No Undecided

Please provide details:

17. Is there anything more it could say in order to achieve this?

- Yes No Undecided

Please provide details:

18. Do you have any suggestions about how to measure the policy framework’s contribution to achievement of the ambitions set out in the “Purpose” section?

Please provide details:

19. Do you have any other comments?

About you

Where are you based?

- England Wales Scotland Northern Ireland
- Crown Dependency EU outside UK Outside EU Please specify:

What will we do with your response?

The HRA has a commitment to transparency. We will analyse the comments we receive, and publish a report on our website which summarises them and explains how we will address the themes raised. We will use the comments received to inform the next version of the policy document which will be sent out as part of a formal consultation later in the year.

Organisational responses: In the interest of transparency, all comments made on behalf of an organisation may normally be published and attributed unless an explanation is provided with your response as to why you consider the information should not be. (Please note the Confidentiality of Information section below.).

Individual responses: We will aim to summarise individual responses in such a way that does not identify individual respondents unless we have your permission to identify you.

If we receive comments without this form we will adopt the position that organisational responses are attributed and individual responses anonymised.

Are you responding in an organisational or personal capacity?

- Organisational – responding as the Nuffield Council on Bioethics**
- Individual**

If you are replying in an organisational capacity, please note that your response may be published and quoted in the final report.

- If you do not wish your organisational response, and any quotes used from it, to be identified in any report on this call for comments and any future HRA publications, or published once the comments period has ended, please explain why below:

Our report, *Children and clinical research: ethical issues*, which is quoted in this response, is under embargo to Thursday 14th May. It was agreed over email with Bill Davidson (29th April) that our response to this consultation would therefore not be published until after 14th May 2015.

Individual responses

I am responding primarily as a:

- Researcher/research team member
- Research support staff
- Member of the public
- Patient
- REC member
- HRA staff
- NHS/Social Care/HSC R&D management community
- Other NHS/Social Care/HSC staff
- Industry (mainly or only phase I)
- Industry (other)
- Regulatory body
- Academic
- Other

Please write in below:

- I am willing for my response, and any quotes used from it, to be made identifiable in the report on this call for comments and any future HRA

publications.

I do not wish my response, or any quotes used from it, to be identified in the report on this call for comments, future HRA publications, or published once the comments period has ended.

All responses

I am willing to be contacted by the HRA for further information in relation to this call for comments or future consultations.

If you have checked the box above please provide your contact details below. By providing these contact details, you are giving your consent for a member of HRA staff to contact you about calls for comments and consultations. The HRA takes data protection very seriously. We promise we will not pass your details on to any other organisations or use them for any other purposes.

Contact name: **Seil Collins**

Email: **bioethics@nuffieldbioethics.org**

Confidentiality of information

The HRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties without your permission or unless required by law.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the HRA.