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 xNo ☐ Undecided

Please provide details:

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 x No ☐ Undecided

Please provide details:

The document outlines broad principles. Appropriately the document provides little operational guidance. However, the content is therefore open to different interpretations and potentially differing approaches to implementation.

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?

X Yes ☐ No ☐ Undecided

Please specify:

How the additional step of approval by the HRA will add value or speed up processes.

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

X 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:

Our experience lies mainly within the healthcare sector and therefore we are not best positioned to comment on this section.

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

☒ Yes ☐ No ☐ Undecided

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

In general we are supportive. However, point 8.3 would benefit from further clarification of the term ‘student’. The important aspect of being a CI is whether the individual has the appropriate level of competence to assume the role of CI. To a degree, it is irrelevant whether someone is studying or not. For example, an experienced CI may also be a student and undertaking a Masters degree. Indeed, subscript 14 (page 8) does not include master level students with appropriate experience/competence as exceptions.

8. Do you agree with the 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 the 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 the responsibilities stated for sponsors?

☒ Yes ☐ No ☐ Undecided

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

We welcome the increased clarification of the roles and responsibilities of HEIs.
8.14 Could there be clarification regarding 'batch' application? e.g. footnotes or examples would be helpful.
8.16 We welcome this point.

There is no reference in this document to the requirement for a UK- based sponsor's representative for non-CTIMP studies sponsored out-with the UK. Is this intentional?

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

☐ Yes ☒ No ☐ Undecided

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

8.18 & 8.19. We do not agree with the lack of ability to repeat checks made by ethics committees or other approval bodies. We have experienced situations where there have been issues with decisions made by such parties. We do not agree that liability can be assumed by the HRA particularly in respect of data control. In addition, this would not address any reputational risk and patient safety issues associated with incorrect decisions approved elsewhere.
8.19d. This section needs refinement and could be better phrased. There are issues with the practicalities of the processes (e.g. contracting, the research passport and HR processes).

12. Do you agree with the 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 the responsibilities stated for regulators?

☐ Yes ☐ No ☒Undecided

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

We would welcome clarity on the roles and responsibilities of the regulatory authorities and that of the HRA. Although headed regulators, it predominantly talks about HRA and only mentions some (but not all) regulators in passing. It is unclear how the responsibilities of the HRA align within the devolved nations and clarification within this UK wide document would be welcome.

14. Do you agree with the responsibilities stated for employers?

☒ Yes ☐ No ☐ Undecided

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

This is a helpful section.

15. Do you agree with the 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:

This policy is not currently UK wide and there are concerns.

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

☒ Yes ☐ No ☐ Undecided

Please provide details:

See earlier comments.

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:

The Academy of Medical Sciences encourages effective dialogue with the research community and public involvement to ascertain opinion. Such an approach with investigators, service users and commerce could be used to help evaluate the effectiveness of the policy and whether there has been an improvement to stakeholder experience of the research process. It has yet to be determined whether the involvement of an additional layer of regulation by HRA will be helpful in achieving the ambitions set out in the 'Purpose' section and addressing concerns of those affected.

19. Do you have any other comments?

No.

About you

Where are you based?

☐ **England** ☐ **Wales** x **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**

☐ **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:

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:
Email:

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.