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

Please send your comments to resgovfram@scotland.gsi.gov.uk 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:
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 ৷ Undecided
Please provide details:
The framework provides a concise version of the previous guidance available to researchers. However, the framework provides little detail as to how the operational arrangements might be put into place. The University of Stirling would recommend that once the operational arrangements are embedded, an appendix is added to the Framework that directs researchers to further guidance.
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:
The policy framework sets out with good intentions the desire to ensure that applying to do research is simple and getting a decision is quick and predictable. While work to streamline the process has been evident, there is an awareness that academics can still struggle with slow or incomplete responses from sites causing a delay in

applications or the start of the research.

4. Do you think the principles that apply to all health and social care research are right?
□ Yes □ No ⋈ Undecided
Please provide details:
The University of Stirling supports the principle that information about research projects should be made publicly available. However, making this information public before the start of the research could be challenging and, therefore, the University would recommend that caveats be added that state that under certain circumstances, dependent on the sensitive and competitive nature of the research, information is not required to be shared in advance in order not to compromise the study.
5. Do you think the principles that apply to interventional health and social care research are right?
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:
The University of Stirling supports the way in which the framework addresses the needs of social care research. However, it is felt that this simplified approach does not necessarily reflect the complex nature of social care research given the differences in the potential stakeholders involved, as well as the range of academic disciplines covered.
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:

8. Do you agree with the responsibilities stated for research teams?
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?
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?
Are there any responsibilities that you think should be added or removed? Please provide details:

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

Are there any responsibilities that you think should be added or removed? Please provide details:
The University of Stirling supports the responsibilities stated for research sites. However, the University would like to reiterate that the experience of our academics has been that responses from research sites can be slow and incomplete and multisite working is complex with multiple permissions being required.
12. Do you agree with the responsibilities stated for professional bodies?
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?
Are there any responsibilities that you think should be added or removed? Please provide details:
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:

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: Further details on operational implementation would facilitate the identification of appropriate measurements and indicators. 19. Do you have any other comments? None **About you** Where are you based? Scotland **☐** Northern Ireland □ England ☐ Wales ☐ 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.
\Box 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: Rachel Beaton

Email: rachel.beaton@stir.ac.uk

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.