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** ○ Undecided

Please provide details:

The UK position is not yet clear particularly with respect to the HRA. In addition to the HRA references in section 3, the equivalent for the Devolved Administrations should be given. In terms of non-compliance (Principles 7.15) there is no mention of the employing institution.

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:

It is not clear how this policy will interface with the new UP portal and single application process to be introduced following the new EU Directive on clinical trials of medical products.

Quality is not covered adequately.

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

● **Yes** ○ No ○ Undecided

Please provide details:

But adequate funding of studies should be included as a core principle.

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:

Clarity re role of NHS ethics and composition of ethics committees and review of social care research would be helpful.

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:

Should be explicit that the CI must ensure that regulatory approval is in place prior to study initiation. It is preferable for a proposal or grant application to be converted into a study specific protocol for the clinical study. Protocol would be the preferred choice of word.

Registration applies to CTIMPs only. What does this mean for non-CTIMPs?

Information to participants about study results is usually covered in IRAS and depending on the study, different approaches may be taken. Individual participant feedback would often not be the preferred approach.

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:

Again protocol much preferred to proposal

8.7a – Would be preferable to give exceptions e.g. in a footnote, and the term 'normally 'removed.

Section 8.8 would be better if provided as a footnote in the CI section.

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:

8.9b It should be a responsibility of funder to ensure that costs are attributed properly.

Important to ensure funders have quality systems in place to both assess the scientific quality of the research as well as the transparency of the review process.

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:

Not necessary to state who can be a Sponsor (remove second sentence) Close down and archiving of trials should be included. 8.11 Medical devices, GMO, ATIMPs broader than IMP; diagnostics – legislation not captured. Only refers to CTIMPs. 8.12 Sponsorship decisions are more usually made depending on the study participants (e.g. patients v healthy volunteers) rather than student's employer. 8.14 welcomed

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:

This section is repetitive and could be condensed.

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:

For HRA responsibility has been replaced by purpose.

Good to understand the quality assurance of HRA approval and indemnity.

HTA is not mentioned.

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:

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:

It would be useful if the document was less high level and more specific in some places. There is not enough reference to directives and specific legislation in place as well as new directives coming into place.

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**
- ( ) 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: Dr Roma Armstrong
Email: Roma.Armstrong@ggc.scot.nhs.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