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:

Specific comment – suggest second bullet point says, for example, timely and consistent rather than quick and predictable.

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:

It is not always clear how this will work within the Devolved Administrations where the HRA does not apply. The operational arrangements must be compatible UK wide. A flowchart would be a good way to portray the links. The level of detail in the policy framework is, in places, too high level and open to interpretation which subsequently may lead to inconsistencies across the UK.

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:

Shared care and continuing care sites and responsibilities are not covered.

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:

7.16 e 'Information about the findings of the research should be provided to those who took part in it' This should be qualified with if the participant wishes to be informed if it means contacted directly. For large studies it is a huge undertaking to contact participants individually and it raises the issue of checking participants have not moved and are not deceased. It is unclear when participants should be informed especially for studies that are in long term follow up. This needs clarification and recognition of logistical demands

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:

Not clear what differences apply to social care research. It needs to be more explicit and not just be blanket statements.

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:

This sections details what the CI is responsible for submitting for review but does not document that they must get the relevant approvals.
Does the CI not have a responsibility to ensure no activity takes place until relevant approvals including sponsor and R&D are in place.
Says that no student at any level can be a CI (8.3) - is this realistic? Why can't a student be a CI for a low risk study with appropriate supervision? Especially if the student is an experienced professional undertaking an educational qualification as part of their professional development.

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:

The CI is part of the research team and therefore also has these responsibilities.
Again not clear that research should not start until approvals are in place.
Section 8.7 a and c both these statements include 'normally' would it be worth saying it must follow what is documented in the approved protocol.
Consent must be informed and perhaps this should be included

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:

Not sure about a funder requiring that a sponsor is in place. Practically this works the other way where the sponsor ensures there is funding in place.

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:

8.10 e how does R&D / HRA approval fit in? This is not very clear in this process, perhaps an annotated flow chart might help.

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:

Research sites could be within universities and this does not seem to be taken into account. The document does not portray full understanding about the variety of sites, also not clear for other care providers e.g. council
8.17 b ensuring research is conducted and managed – not sure how a site can do this as a body? Does sponsor not retain responsibility and delegate as required?
8.18 when agreeing to participate in research the site must also take funding into consideration
8.19 poor intelligence is not a good explanation
8.19 c implies that the sponsor is driving this but if genuine issues then these need to be addressed

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:

Sponsor and the NHS organisations should be included as they retain their responsibility and may investigate.

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:

Worth noting that where university employed there may still be clinical responsibility within the NHS. The document may need to recognise dual employment more clearly.

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:

As some aspects are open to interpretation it may lead to differences in practice. The underlying operational guidance will be key.
Is better than the existing framework as it is shorter and clearer. If the previous issues could be cleared up then yes it will make research in the UK easier.

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?

The definition of research in 2.2 is confused by the term generalisable and/or transferable. It is key that the remit of the document is clearly and consistently interpreted. Footnote 4 is concerning as if it is not known if the findings will be generalisable before completion can research take place without appropriate governance and approvals. Footnote 5 seems to accept poor quality research when surely this should not be taking place?
Section 4.2 – would recommend removing links to previous RGF as danger that they are used without realising they have been superceded.
Section 6.1 – are the executive summaries available for comment? It is key that these highlight the correct sections.
A definitions sections would be useful, especially for new researchers.
A diagram or flow chart may be useful to explain links between bodies/ organisations etc

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 Joanne Rodger
Email: joanne.rodger@nhs.net

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).

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