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:

Generally the "Purpose" section is well-written and comprehensive in relation to the various processes that must be considered when undertaking research in health and social care. However, the MSC believes that further detail is required as to how proportionality of approach can be achieved, especially given that the majority of the research undertaken is not as complex as a trial (e.g. small samples being taken for in vitro research). There is no reference to processes that should be adopted in these circumstances, the implication being that all steps must still be covered as for a full trial. This creates difficulty if bodies are expected to comply with the guidance in order to hold an NIHR contract. A framework which specifically splits out the requirements in a proportional way depending on the type of research is essential if the efficiency of process is to be enhanced.
In section 1.2 it is the view of MSC that there is now abundant evidence linking participation in research – at both an individual and Institutional levels – to enhanced patient outcome. The section "may be higher" can be strengthened accordingly.
There is also concern that "time" is not addressed. Whilst the document references the need for expediency in places, the evidence base points to research activity overall being of "low risk" – certainly less than conventional clinical practice, with, conversely, reports of patients dying because of delays in the regulatory pathway. The paper might be worded with a greater pressure on each part of the operational pathway once ethics is in place – with the default being acceptance and onward progress rather than a "hurdle". This is particularly relevant for "multi-site" approvals (see below).

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:

Overall the document provides sufficient detail to allow implementation. Any concerns, as highlighted above, are around a prescriptive document not allowing local flexibility.

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:

In general the content of the document is suitable, although the development of an overly bureaucratic regulatory system must be avoided. The role of medical education research not undertaken for the primary purpose of developing the researcher's education skills remains unclear (i.e. research undertaken by experienced researchers where students are the subjects to explore educational and related interventions). It may be beneficial to confirm whether this would fall within the definition of research offered in paragraph 2.2.

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

☒ Yes ☒ No ☐ Undecided

Please provide details:

Overall we agree with the principles stated with the following caveats:

- 7.10 Should researchers be required to make information about all research projects publicly available? This should not apply to those smaller scale projects that are undertaken. A potential re-wording could be "should be made publicly available/accessible.
- 7.11 The principles outlined in this statement are correct, although there must be provision for circumstances where samples are taken from patients without consent (e.g. pandemic situations) or where they are unable to give consent (e.g. they are unconscious) Retrospective consent would be sought in these instances.
- 7.13 The use of the term 'any liability' should be altered to reflect the fact that the NHS will only cover for non-negligent harm.

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

☐ Yes ☒ No ☐ Undecided

Please provide details:

Item 7.16e should be amended since research participants often do not want to receive findings of research that they had taken part in. A more suitable form of words would be "….should be accessible/available to…"

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:

Social care research is appropriately addressed even though there is no specific section on this area.

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:

Overall the responsibilities are suitable with the following amendment:

- 8.2 a. should include the management of a research project along with design, registration and conduct.
- 8.2 c. The proportionality of the requirement for independent expert review for those smaller studies should be considered. The effect on systems could be considerable.

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:

The requirement for proportionality (8.8) should be expanded as described above. Researchers should be encouraged, and supported through the relevant bodies/associated processes to make all participant information as short as possible.

The section gives little reassurance that the current and significant delays in multi-site sign off will be significantly improved. Section 8.18 needs more rigour to address this. It is unclear in what scenarios any research team would wish to question ethics or approval bodies' authority. Rather any NHS organisation be it a Foundation Trust

or not hosting a PI/ Co-PI and a research team should be duty bound to accept prior approvals in a time-limited (or at least time-guided) fashion.

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:

The requirement for assessment of scientific quality of the research proposed by the funder is not required if a corresponding sponsor responsibility exists to ensure that the proposal or protocol satisfies an independent expert review.

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:

Overall the responsibilities are acceptable with the following caveats:

- 8.10. d. We agree with the need for appropriate peer review, however, potential confusion with funders' identified responsibilities as stated should be resolved.
- 8.12 We feel that the responsibility for sponsorship for educational research should not lie with the student's employing organisation but the supervisor's. This is often the same but appropriate weight should be given to the supervisor's role.
- 8.13 is a particularly welcome inclusion given the difficulty in enabling students to undertake applied health research. The ability of universities to enable their undergraduates to undertake this type of research in recent years has been curtailed. Establishing an in-house culture of research in professional education offers an alternate platform for undergraduates to develop research skills in the applied health arena.
- In order to ensure participant safety it would be beneficial to explicitly identify which body is responsible for the DMEC/trial steering committee. This refers to who must ensure appropriate insurance rather than just who is responsible. With increasingly complex studies experts are engaged from around the world requiring personal insurance to act in this capacity. An increasing amount of effort is expended attempting to identify responsibility for providing this level of insurance cover. It would appear appropriate to identify the sponsor as responsible given that they ensure patient safety and data validity for the project as a whole

- Clinical academics undertaking research can be employed variably across University or NHS. Local joint research offices are in place across many partnerships – under such robust models the Sponsor is often not the employer of the Chief Investigator.

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:

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:

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:

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:

Any subsequent implementation plan derived from this policy has the potential to make the UK a better place to do research, as long as the concept of proportionality is kept to the fore, helping to streamline the overall process.

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

☒ Yes ☐ No ☐ Undecided

Please provide details:

The introduction of an overly prescriptive implementation plan should be discouraged.

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:

Appropriate monitoring of study set-up times would ensure that "applying to do research is simple and getting a decision is quick and predictable".

19. Do you have any other comments?

Research needs to be seen as mainstream NHS activity. The NHS England mandate is for every NHS patient to be engaged within research and an appropriate risk – benefit approach is now essential if we are to drive this forward. An "opt-out" attitude to the regulatory process should be encouraged in many domains with increased pressure at all levels to accelerate the pathway.

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:Katie Petty-Saphon
Email:katie.petty-saphon@medschools.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.