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:

We suggest two ways in which the ambitions set out in the "Purpose" section might be better achieved.

First, while acknowledging that the draft Policy is intended to provide high-level principles to achieve compatibility across the UK for the ethics, conduct, and management of research in health and social care, we note that the terminology used throughout the document mentions, variously, 'principles/standards/requirements/best practices/policy'. The different uses are not explained, and the importance of this is more than merely semantic. This can significantly influence the way in which the guidance is interpreted, and can therefore directly impact on whether the overarching purpose is achieved. For example, there is extensive literature on the distinction between principles-based regulation (PBR) and rules-based regulation (RBR), each of which can – variously – use the terminology deployed in the draft policy. For our part, we have written the following elsewhere:

"We envisage PBR as the use of broadly-stated objectives, standards and values by which individuals and institutions should conduct themselves when using data for research purposes. In contrast, rules-based regulation (RBR) relies on compliance with specific rules and gives rise to criticisms of rigidity; where one rule is in conflict with another, there is a lack of flexibility in determining which rule to follow. It is suggested that conflict of rules actually leads to the necessity of additional rules in order to clarify what must be done. Put otherwise, the versatility of rules is limited when the decision-maker is faced with a situation which may not have been anticipated by the drafters and thus no rule has been provided. PBR allows the decision-maker to reflect on broad-based values and commonly-agreed objectives to determine through deliberation and reflection what action best fits in accordance with the particular value(s) advanced, avoiding reliance upon detailed anticipatory drafting for every perceivable situation. In contrast, RBR can overlook the values and objectives of an organisation/background under regulation; it can encourage a tick-box mentality whereby individuals focus on fulfilling a specific task to facilitate compliance rather than thinking about what they are doing and why, cognisant of wider responsibilities. In terms of practice culture, rigid adherence to RBR tends to promote a culture of mere compliance, whereas PBR can foster a culture of reflection and justification. Discretion tends to be reduced or eliminated in the former

and, contrariwise, takes central stage in the latter. This, of course, brings its own challenges...” See: G Laurie and N Sethi, 'Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data' (2013) 4(1) *European Journal of Risk Regulation* 43-57.

We are concerned by the extent to which the deployment of the language of *principles* is, in fact, rule-like. This is re-enforced by the use of terms such as “must” and “should” throughout. Moreover, it is then unclear for the reader how the Principles contrast with “requirements”. See for example the text of para 7.15 which mentions both principles and requirements.

This might raise challenges in terms of promoting a particular type of research culture. As the above quote suggests, unreflexive compliance rather than genuine ethical reflection might result. This said, there are sections where the desire to promote a “research culture” are explicitly mentioned, for example, para 8.13, but even then this could, arguably, include support to identify and work through ethical issues and not merely “encouraging an awareness of research and enabling them to develop skills in research methods”. Indeed, this section is addressed to students, while one would hope and expect that the promoting of an appropriate research culture and suitable ethical reflection would be relevant for all.

Secondly, we suggest that data controllers and tissue bank custodians might merit more direct mention throughout the document. Their attitude towards openness of access to materials is crucial. Moreover, for the last bullet on the “Purpose” list we suggest that (i) avoiding unnecessary duplication of research, and (ii) promoting access to new research-generated data, are also core objectives. See, for example, para 8.2g where the commitment “…to make findings, data and tissue accessible as appropriate after it [the research] has finished” is explicit. This merits mention in the Purposes.

The draft Policy would benefit from a clear Preamble and an explanation of context, in particular why is adopts a principles+actors approach. At present, only para 1.3 in fact sets out the purpose of the policy framework. The other sections provide the context for the policy framework. Accordingly, paras 1.1, 1.2, and 1.4 might serve as a new Preamble or a Context section. Purpose, as expanded in 1.3, could then be a new Part 2.

In sum, we believe that this document would benefit from a preamble/introductory section with all the relevant definitions, clarifications, scope, audience, and an explanation of the principles+actors approach. There would then be a very clear separation after Section 6.

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:

We suggest that more consistent attention could be paid to the specifics of data and tissue research, for example, on the respective roles of anonymisation as a regulatory protective device, as opposed to consent. Moreover, the role of data controllers and tissue collection custodians might be highlighted more clearly. In particular, our previous work on governance of data linkage research has suggested that there are real concerns (and confusion) about who/when the status of "data controller" emerges as a matter of fact and law. This impacts equally on transparency, accountability, and potential legal liability.

Albeit that we accept that a range of risks are in play across different areas of research, a common concern relates to privacy. Accordingly, we would propose two additional "principles". If these are to be drafted in similar language to the current text, then they might be articulated as follows:

- Data controllers should demonstrate their commitment to privacy protection through the development and implementation of appropriate and transparent policies.

- Every effort should be made to consider and minimise risks of identification (or reidentification) to data subjects and their families arising from all aspects of data handling.

These are borrowed from our earlier work on the Scottish Health Informatics Programme (http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf)

If these were to be expressed more as action *guiding* statements, rather than action *determining* statements, then they might appear as:

- The principle of due respect for privacy suggests that best practices involve the transparent demonstration of the existence and effective operation of adequate privacy protection measures, including efforts to minimise risks of identification (or reidentfication) to data subjects and their families arising from all aspects of data handling.

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:

Para 2.2 – how far does this extend to experimental therapies?

Para 2.4 – given that the policy is not to replace existing principles, requirements or standards, perhaps the policy could reiterate the ways in which it: (i) adds value, and (ii) represents a *proportionate* measure [as opposed to yet another set of considerations to take on board]

Para. 4.3 – the laudable aim of promoting "compatibility" between the UK nations is not necessarily the same as delivering "proportionality" for cross-border research. Can anything be said/done to promote this objective and avoid unnecessary duplication of effort/stages of review ? Might the four main audiences of the policy be charged with developing mechanisms of mutual recognition of review?

Part 5 does not contain any processes or procedures for amendment. We assume this is to be a living instrument, open to input from various stakeholders including publics. As such, it is important to demonstrate how evolution and revision will be brought about.

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

☒ Yes ☒ No ☐ Undecided

Please provide details:

See our first comment on the deployment of the language of "Principles". How are these being used and distinguished from "requirements" (where are these in the document), "standards", "best practices" etc ?

There is an unevenness of specificity within the Principles section, as demonstrated in Section 7. For example, *which* ethical principles are being referenced in para 7.3? If the document is determinedly prescriptive, then it is crucial for the reader to know the frame of reference. Para 7.2 is both overly vague and potentially overly prescriptive at the same time. Who is to determine adequate qualification and according to which criteria? As a minimum, a cross-reference to the 'actors' section would assist. Equally, the para seems to suggest that all three criteria must be satisfied, but what happens in the case of a novice researcher? They might have education and training, but arguably not the experience. This could be addressed by text to the effect of, 'as the case may be' or 'as applicable'. Additionally, para 7.7 is an overarching guideline that is expressed at such a level of abstraction as to undermine its value qua guidance. If these provisions are meant to be action guiding, then the reader needs something to which to refer (even if this is further links in an Appendix, stratified according to kinds of research).

Conversely, with para 7.8 we find ourselves with a very specific risk-benefit assessment guidance. This could also have been part of the ethical principles referred to in 7.7, so why is it here? Paras 7.6, 7.7, 7.9 are examples of more procedural guidance, while paras 7.8, 7.11, 7.12 more substantive. We suggest that

these need to be separated, not least because the role of ethical deliberations (and who are the relevant actors) will change. These need to be separated.

The tone of the document could be read as “command and control”. Actors to whom the document is addressed must comply. But, where is the *relationship* between actors and regulators in all of this? Where is the recognition of opportunities for dialogue on genuine ethical dilemmas?

Proportionality in the deployment of the Principles only appears in para 7.15 with respect to how the regulators might react if there is non-compliance. Does the regulator see a role for proportionality in considering the Principles themselves, and if so where and how might the guidance assist?

Para 7.8 is addressed to circumstances before a research project begins. However, one of the major obstacles to timely and effective ethical review is a failure of the part of researchers/sponsors to reflect on – and attempt to address – ethical issues *before* an application is put forward at all. This, we believe, is an essential part of a healthy and responsible research culture. Too many delays arise because of ill-conceived proposals. More can be said (and done) to promote genuine ethical engagement at far earlier stages in the design of research protocols.

Para 7.12 – we suggest revision to “right *to respect for* privacy…” rather than “right to privacy”. The latter appears categoric when this does not reflect the ethical or legal reality.

Para 7.14 – what “information” is being referenced here? Is it research data or participant information? Contrast para 7.16c where it is clear that it refers to information about treatment and care.

Para 7.16d - “duty of care” and Para 8.1 – “communication” – in what ways are these Principles?

Para 8.1 – we suggest that clarity of lines of accountability should also be transparent to the outside world, especially with respect to possible future complaints or queries.

Paras 8.9, 8.20, 8.21, 8.22, 8.25 seem to operate merely descriptively and not in the vein of Principles, traditionally understood.

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

☒ Yes ☐ No ☐ Undecided

Please provide details:

Yes, no further comment.

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 work on administrative data linkage for research suggests that the "culture of caution" is particularly strong within local authorities and related public bodies. More work is needed to demonstrate the value of social care research, to foster confidence in governance mechanisms, and to assist with appropriate ethical reflection and review. Too often, the view is put that a lack of a lawful basis for sharing is a reason not to share or allow access, when this might not be the case. A clear identification of what is permissible (as opposed to merely perceived) is crucial. We have developed a decision-making matrix to assist in the public sector in identifying which kinds of obstacle are being faced. This might be useful. See further p.9 of this SSRN paper here:
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2487971

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:

See comments above about the importance of careful ethical preparation *before* submitting for formal ethical review. Robust and timely ethical review is co-produced.

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:

Yes, no further comment.

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:

We wonder where is their role is promoting optimal accessibility to novel research data. This might, however, be too far-reaching for the current document.

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:

See reply to Question 7.

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:

Yes, no further comment.

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:

Yes, no further comment.

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:

This section is purely description. It does not offer guidance for the reader on how to work with regulators or to navigate their procedures or working arrangements. The further links do not obviously help in this regard. Has the HRA considered linking with guidance from the ESRC on ethics review for social science research? This is currently under review.

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:

See answer to Question 7. Furthermore, while open reporting is important, what are employers then expected to do, especially regarding their relationship with other parties and the four principal research oversight entities in the UK?

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:

Yes, no further comment.

16. Do you think the policy framework will help make the UK a better place to do research?

☒ Yes ☐ No ☐ Undecided

Please provide details:

Yes, so long as its added value and proportionate benefit can be clearly communicate. More could be done to clarify and promote a health research culture, which goes beyond “though shall” pronouncements, and which encourages reflection on ethical issues.

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

☐ Yes ☐ No ☐ Undecided

Please provide details:

See above.

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:

We are wary of a metrics-driven approach when the core concern is a genuinely reflective culture of appropriate ethical deliberation.

19. Do you have any other comments?

Our main points are made above.

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: Graeme Laurie
Email: Graeme.Laurie@ed.ac.uk

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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.