

Initial comments on the Health Research Authority draft UK policy framework for health and social care research

Summary

- The Academy of Medical Sciences welcomes the opportunity to provide initial comments on the Health Research Authority's (HRA) draft UK policy framework for health and social care research. We are very supportive of the HRA's efforts to streamline the regulation and governance of health research and welcome the development of a single policy framework for health and social care research.
- We firmly support the high-level principles set out in the policy framework and the majority of our comments aim to fine-tune rather than substantially amend the existing draft. However, we make a small number of more substantive points for consideration.
- We would welcome clarification on the legal status of the document. We would encourage the HRA to more clearly frame this document as a minimum set of standards for the conduct of health research in the UK, compliance with which will ensure that all relevant legal requirements are being met. We also recommend that the framework more strongly emphasises the overriding responsibility of all stakeholders to promote research in the NHS.
- We suggest that consideration be given to include a section on the role of research participants, including patients, carers and other volunteers.
- A section on the use of routine health records for research may also be a helpful addition, given that researchers are currently experiencing significant delays in accessing such records.
- We recommend that further information on UK research and governance processes – including HRA approval – be included within, or closely linked to, the final version of this framework.
- We would welcome more information about how the framework will be evaluated and compliance with its principles monitored over the coming months and years.

Introduction

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship comprises some of the UK's foremost experts in medical science, drawn from a diverse range of research areas, from basic research, through clinical application, to commercialisation and healthcare delivery.

We welcome the opportunity to provide initial comments on this draft policy framework and look forward to remaining engaged as this document evolves. Our initial response is based on the views of our Fellows and other experts, many of whom have significant experience of conducting health research. It has also been informed by our 2011 report on the regulation and governance of health research¹ and the output of a 2014 discussion between Academy Fellows and the HRA.²

¹ <http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf>

² <http://www.acmedsci.ac.uk/viewFile/54760c6a39bcc.pdf>

Overview

We firmly support the high-level principles set out in the policy framework and the majority of our comments aim to fine-tune rather than substantially amend the existing draft. However, we offer a small number of more substantive points for consideration.

We strongly support the HRA's work in providing guidance on principles of good research practice in England and welcome the development of a document that attempts to consolidate policy for the whole of the UK. We believe that such a framework has the potential to add significant value; as the legislative differences highlighted in the document's appendix demonstrate, navigating the legal landscape with confidence can be extremely difficult for researchers. Nevertheless, **we believe that the legal status of the document could be clarified**. Paragraph 5.2 describes the framework as 'guidance with which NHS trusts and local authorities in England are legally expected to comply'. However, this does not make clear its legal position in relation to other groups (for example, clinical commissioning groups, sponsors and funders). We are also unclear about the document's legal status in the devolved nations. We recommend that further clarification be offered in the document's initial paragraphs to ensure that users understand its legal implications and give it due weight. **We encourage the HRA to more clearly frame this document as a minimum set of standards for the conduct of health research in the UK, compliance with which will ensure that all relevant legal requirements are being met.**

Both the Health and Social Care Act 2012 and the Care Act 2014 draw attention to the importance of health research and place a legal duty on its promotion. However, we believe that cultural change is still required to embed health research within the NHS as a core function, to foster a more facilitative approach to research governance and to promote public and patient engagement in research.³ We recommend that the framework more strongly **emphasise the overriding responsibility of all stakeholders to promote research in the NHS**.

The framework very helpfully defines the responsibilities of the various stakeholders involved in the conduct and management of research. However, **there is currently little mention of the role of research participants themselves**, including patients, carers and other volunteers. This may be a deliberate decision and we understand that a 'lay' version of this document will be made available. However, we suggest that greater focus be given to the notion of research as a patient-centred activity and that consideration be given to including a section on the roles and responsibilities of participating individuals and groups. We also **note the absence of a section on the use of routine health records for research**. This may be a helpful addition, given that researchers are currently experiencing significant delays in accessing such records. The HRA can play a central role in facilitating more widespread access to routine health records for research. We note that the draft framework makes no mention of progress towards a single HRA approval process for research conducted in the NHS in England. This is understandable given the timing of this consultation. However, we would recommend that **further information on UK research and governance processes – including HRA approval – be included** within, or closely linked to, later versions of this framework.

The degree to which the framework is consistently operationalised in different parts of the UK will be critical to achieving its intent. We therefore look forward to hearing more about **how the framework will be evaluated and compliance with its principles monitored** in the future.

³ <http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf>

Detailed comments

1. Purpose

1.1 'Applying to do research is simple and getting a decision is quick and predictable'. We would question whether 'predictable' is the right word; the decision-making process could be predictably poor, for example. We would suggest: 'Applying to do research is simple and the decision-making process is quick and consistently effective'.

1.2 We suggest that sentence four is amended to 'Research involves staff in our universities, hospitals, social services, primary care and elsewhere in something that develops their skills', in order to better reflect the diversity of places in which research occurs.

1.4 We suggest that the last sentence be amended to 'This will achieve compatibility across the UK for the ethical standards, conduct and management of research in health and social care'.

2. Scope

2.1 Increasingly, many patients are based in the community rather than in hospitals or social care and receive treatment from medical professionals outside the scope of the four UK health departments; for example, in addiction centres and sexual health clinics. We suggest that the document further clarify whether research carried out in these locations falls under the purview of the framework, particularly in the context of footnotes 2 and 11.

We also suggest that the second sentence be amended to: 'This applies to research that care users take part in, either directly (e.g. research involving a treatment, investigation or an interview)'.

2.2 'It also includes projects that aim to generate hypotheses (e.g. pilot studies) and projects whose primary purpose is educational to the researcher, either in acquiring research skills or in obtaining an educational qualification.' Pilot studies are carried out not only to generate hypotheses but primarily to test feasibility of larger studies. The definition of research should include projects that aim to perform the latter. In addition, it would be helpful to clarify that 'obtaining any educational qualification' refers to any educational qualification involving research.

2.2 footnote 6 We would welcome clarification on whether this exception refers only to service evaluation or also to audit and market research.

2.3 It may be helpful to provide an example of the type of "local controls" that might exist.

5. Development, status and maintenance

5.2 It may be helpful to include in a footnote the precise clause of the Care Act 2014 which gives this document legal status. It is also not clear whether researchers in the devolved administrations are 'legally expected' to comply with the guidance in the same way the researchers in England are.

7. Principles that apply to all health and social care research

7.2 It is not clear what "qualified by education" means in practice. For example, should a highly trained and experienced nurse be prevented from participating in research on the grounds of educational achievement? We suggest: 'All the people involved in conducting a research project must be competent and qualified by education, training and/or experience to perform their tasks'.

7.5 We suggest an amendment to paragraph 7.5: 'Research must be designed, reviewed, managed, undertaken and made public in a way that ensures integrity, quality, transparency and compliance with relevant ethical standards'.

7.6 'The research proposal or protocol must include any specified information.' It is not clear what is meant by 'any specified information'.

7.6 footnote 12 We do not think it is helpful to use the terms 'research proposal' and 'protocol' interchangeably. The former is usually the basis of a funding application and is much less specific about the practical details of a research study than the latter.

7.7 A footnote note on what might be included in "relevant guidance" would be helpful.

7.10 We question whether there are research projects where providing public information before the start of the project might invalidate them – certain psychological experiments, for example. Consideration should also be given to additional controls required for so-called 'dual use' research, such as work in the CBRN (chemical, biological, radiological, and nuclear) field. We suggest: '*Information about research projects should normally be made publicly available, before they start, unless exceptional circumstances prevent this. Their findings must be made accessible in an appropriate form after they have finished.*' A footnote could be included to provide examples of the types of circumstances exempted from this requirement.

7.11 The reference to research participants does not cover participants whose consent is given by others, such as infants, young children, or those who are not mentally competent. It is also unclear whether the continued use of data for which consent is given by parents on behalf of minors (e.g. paediatric neuro-imaging data), requires re-consent once the minors reach adulthood.

7.13 We suggest: '*Adequate provision must be made for insurance or indemnity to cover any liability which may arise in relation to the design, management or conduct of the research project*'.

7.16 (e) The Academy strongly supports efforts to increase transparency around the existence, methods and results of clinical and health research. However, it should be noted that some participants may not wish to receive the results of the research that they were involved in. In addition, information about findings cannot always be provided directly to all those who took part, if there is no direct communication between the researcher and the participants. We suggest: '*Information about the findings of the research should be made available to those who took part, should they wish to access it and where participants are known*'.

8. Principles that apply to individuals and organisations

8.2 (e) See 7.2 above. We suggest: '*ensuring that they and the research team they lead are competent and are qualified by education, training and/or experience to discharge their roles in the study*'.

8.2 (h) See 7.16e above. We suggest: '*making information about the findings of the research available to participants, should they wish to access it*'.

8.3 We consider it important that students are not discouraged from undertaking research involving direct contact with patients.⁴ We agree that '*Students should not normally take the role*

⁴ <http://www.acmedsci.ac.uk/viewFile/535a4e28c203f.pdf>

of chief investigator at any level of study' but seek clarification on whether registrars and F1/F2 doctors can take on this role. Also, 8.15 refers to 'undergraduate students leading individual research projects in isolation'. Statements 8.3 and 8.15 seem to be contradictory and we seek clarification on this.

8.6 This broad definition of the 'research team' may be problematic given 7.2 and 8.2e, which suggests that all members of the research team should be 'competent and qualified by education, training and/or experience' (our suggested amendment). Students, care users and members of the public, for example, may not meet these requirements. We would also challenge the implication that these groups are responsible for 'conducting the research to the agreed research proposal or protocol, in accordance with legal requirements, guidance and accepted standards of good practice', as suggested by 8.6a. We suggest that the 'research team' be more narrowly and precisely defined.

8.6 (b) We suggest: '*providing accurate and accessible information for participants*'.

8.7 We believe that the framework could be clearer about circumstances in which individual consent may not be required, due to either proportionality or patient interest. For example, guidance on the precise consent requirements for non-interventional studies such as questionnaires and greater recognition of circumstances in which written consent may not be possible or appropriate, such as in emergency medical situations, may be helpful. We have previously suggested that an alternative option to obtaining written consent would be to obtain verbal consent prior to intervention, with witnessed assessment of understanding through three simple questions. Follow-up written consent could be then obtained when possible.⁵

8.7 (c) We encourage the development of means to capture consent electronically, and to move away from storing consent documents in institutional study-site file folders, so they can be easily accessible to other researchers or auditors. We would also highlight that there may be situations in which the requirement for consent to be available for inspection may conflict with assurances of participant confidentiality.

8.8 We strongly support the policy framework's focus on the application of proportionality to the provision of information to potential research participants. This is consistent with recommendations made in our 2011 report on the regulation and governance of health research.⁶ We agree that valuable, lower risk research should involve a lighter burden of documentation than intrusive research involving novel interventions.

However, risk is a function of both magnitude and uncertainty. We therefore suggest a slight amendment to the second sentence to more explicitly recognise the need to consider uncertainty alongside the expected outcomes: '*The more research deviates from established practice or otherwise detrimentally affects the balance between potential risks and benefits, the greater the amount of information that needs to be provided to potential participants.*'

8.9 (a) We understand that funders are not always closely involved in directly assessing the quality of the research that they are supporting and may not always have the expertise to do so. Under circumstances where funding organisations lack in-house expertise, research proposals are assessed by external experts and many funders use external peer reviewers. Hence, it may be

⁵ <http://www.acmedsci.ac.uk/viewFile/5476011fc9b91.pdf>

⁶ <http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf>

more appropriate for funders to simply ensure that such an assessment has taken place. We suggest: '*The funder is responsible for ensuring that the scientific quality of the research as proposed has been assessed*'.

8.9 (b) '*Championing the value of research to health and social care*' is an overarching responsibility shared amongst all those involved in research, not just funders. We recommend that this be made more explicit throughout the document.

The responsibilities of funders should also extend to ensuring compliance with relevant research standards and publication of research findings.

8.9 (d) Thought needs to be given to the resources required to achieve this principle. It could be quite bureaucratic for non-commercial funders such as small patient-led charities to identify whether Principal Investigators have ensured that a sponsor is in place prior to commencing research.

8.10 The wording of this paragraph should be amended to reflect the fact that many clinical academics hold only honorary contracts with the NHS organisation sponsoring the study.

8.10 (f) See 7.10 above.

8.13 We welcome the HRA's recognition that undergraduate students should be encouraged to become more research aware and develop skills in research methods.⁷ It is essential to foster a research culture in all clinicians entering the NHS, not just those with an interest in pursuing a career in academic medicine. The Academy is active in encouraging undergraduate participation in research, through our INSPIRE program⁸ and other careers policy projects.

8.14 We support the need for expedited, proportionate review of projects with no material ethical issues. The sponsor should be responsible for supporting academic staff in making single 'batch' applications for ethical review on behalf of a number of different students.

8.15 Undergraduate students should not be discouraged from taking part in research that involves direct contact with care users under appropriate supervision. However, we agree that supervisors should be responsible for ensuring that proposals are of sufficient quality, and that risk mitigation and control have been considered, before submission for review⁹. See also 8.3 – we seek clarification on what is meant by '*students leading individual research projects*'.

8.17 We understand that the term 'research site' actually refers to the organisation responsible for the location where research is taking place, rather than the location itself. If so, this should be made clearer.

8.18 We strongly support the framework's recognition of the need to prevent research sites from duplicating or repeating checks undertaken by research ethics committees and other approval bodies.

⁷ <http://www.acmedsci.ac.uk/snip/uploads/534f94eed1847.pdf>

⁸ <http://www.acmedsci.ac.uk/careers/mentoring-and-careers/INSPIRE/about-INSPIRE/>

⁹ <http://www.acmedsci.ac.uk/viewFile/535a4e28c203f.pdf>

8.19 (d) *'Decisions about researchers' suitability must not be based on inappropriate HR processes.'* It is unclear what 'inappropriate HR processes' are being referred to in this case. This needs to be clarified in order to ensure that this principle is put into practice.

8.24 We support the emphasis on encouraging incident reporting. Safety reporting can, unquestionably, protect participants. We strongly agree that it is essential to foster a culture of open and honest reporting, with a focus on improvement rather than blame.

This response was prepared by Dr Mehwaesh Islam (Policy Officer) and was informed by the Academy's Fellows and others experts. For further information, please contact Victoria Charlton (victoria.charlton@acmedsci.ac.uk; +44(0)20 3176 2168)

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