
Summary

- The Academy of Medical Sciences welcomes the opportunity to respond to the Health Research Authority's (HRA) draft UK policy framework for health and social care research. We are highly supportive of the HRA's efforts to streamline the regulation and governance of health research and welcome the development of a single framework to coordinate health and social care research across the UK.
- We reiterate our previous recommendation that the legal status of the document is more clearly communicated and that it is framed as a minimum set of standards.¹ More generally, it is important to note that key points in the framework should feature prominently in the main body of text to ensure that they are not 'lost' within the guidance.
- It would be helpful to provide further clarity, in some areas, on how organisations must comply with the framework, including what this might represent in practice.
- We believe that there remains a need to further highlight the overriding responsibility of all stakeholders, including the NHS, to promote research in the UK.
- We recommend that the document references the use of routine health records, as well as considering the increasing variety of sources of research data which will need to be accommodated within this framework.
- Again, we would welcome further information on how the framework will be evaluated and compliance monitored.

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.

The Academy welcomes the opportunity to comment on the UK policy framework for health and social care research and this response is formed from the views of the Academy's Fellows and further experts, many of whom have extensive experience of conducting healthcare research in the UK.

Overview

As outlined in our previous response, we strongly support the principles within the policy framework and the coordinated approach to harmonise and simplify the regulatory and governance processes for health research across the UK.¹ We welcome the emphasis on research as a core function of health and social care, and that conducting research should be simple with quick

¹ Academy of Medical Sciences (2015). Initial comments on the Health Research Authority draft UK policy framework for health and social care research. <http://www.acmedsci.ac.uk/download.php?f=file&i=31338>

decisions and where possible, minimal duplication of effort. With its focus on the involvement of patients in health research, this framework has the potential to significantly contribute towards a new social contract for research, and we hope that the HRA will consider the Academy's work in this area.²

We are pleased that a number of points from our response to the first draft have been taken into account, and are strongly supportive of the recognition within the document that proportionality, transparency and streamlining of processes are key. However, there are still some important areas that we think need to be addressed further.

Within our response to the first draft, we highlighted the need for **further clarification on the legal status of the document**, as well as **framing the document as a minimum level of requirements**. We believe that this still needs to be more clearly communicated within the current draft. In general, it should be noted that key points included within the glossary or footnotes should feature more prominently within the body of text. For example, the definitions of 'must' and 'should'.

It would be useful to provide further clarity in some places on **how organisations must comply with the framework**, including what this might represent in practice and the operational arrangements. For example, further information could be provided on the requirements for organisations to work together to avoid duplication in local research governance. Whilst it is necessary that the document remains high level, those to whom it applies may benefit from a more prescriptive approach in some areas and this could be covered in more detail within the associated guidance documents. Again, we recommend that the framework more strongly **emphasise the overriding responsibility of all stakeholders, including all health providers whether NHS or the private sector, to promote research in the UK**.

There is still an absence of **references to the use of routine health records for research**, which would help to facilitate access to such records given the delays and difficulties with access that are currently experienced by some researchers. It may be helpful here to map the responsibilities of the relevant bodies involved such as the Health and Social Care Information Centre. We also encourage the HRA to consider the increasing variety of research data sources (e.g. social media) – as explored at the Academy workshop on 'Real world evidence' – where it could be difficult to apply the conventional guidance in the document.³ The framework should be sufficiently adaptable to accommodate such new forms of information.

Finally, it is important to understand **how the framework will be evaluated and compliance monitored**, and we look forward to further communication on this as ensuring successful implementation of the high level framework in practice will be the next key step to overcoming barriers to health research. To achieve compliance, expectations should be clearly outlined within the framework, and whilst there is some information on these expectations within the document (e.g. 9.8) it would be helpful if they featured more clearly within the text.

Our detailed comments are annexed.

² Academy of Medical Sciences (2015). *Exploring a new social contract for medical innovation*. <http://www.acmedsci.ac.uk/download.php?f=file&i=33011>

³ Academy of Medical Sciences (2016). *'Real world evidence' workshop report*. <http://www.acmedsci.ac.uk/viewFile/56cab22108cf9.pdf>

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Annex 1 – Detailed comments

1. Context

1.1 The framework should reflect that research is also important for evaluating existing treatments where further evidence on their effects is required, as well as for evaluation of new treatments. Therefore we suggest that the second bullet point is amended to '*Both for new and (where reliable evidence about their effects is absent) existing treatments, and for care and other services, there should be a rigorous process of evaluation by ethical and scientifically sound research for the benefit of patients, service users and the public*'. The framework should be amended throughout to remove any implication that research is only relevant for new treatments.

Additionally, we welcome the reference to the importance of data transparency and the need for clinical data to be made available for future research, subject to appropriate safeguards and approval processes. The importance of data transparency should feature more prominently within the rest of the draft framework.

In the 'Context' section, it may be helpful to reference the updated NHS Constitution, which underlines the importance of research in providing the highest quality care.⁴

3. Scope

3.2 It would be useful to provide further clarity and guidance on the distinction between research and audit. For example, evaluating the effectiveness of some services may not be possible until they are implemented, such as population screening, and this could be misinterpreted as audit.

Additionally, footnotes 7 and 9 appear to contradict each other, where footnote 9 states that research only includes service evaluations '*that are designed to produce generalisable findings*', but footnote 7 ascertains that the generalisability cannot always be judged from the outset.

3.4 It might be helpful for footnote 11 to instead reference a 'Resources' page on the HRA website with publications on good research practice. This would ensure that those suggested do not become out of date and prevent any potential confusion around the selective referencing of publications.

5. UK-wide responsibilities

5.3 With regards to footnote 18, it would be beneficial if the guidance addressed research on children's social care services/data sources. If there are legal reasons for this exclusion then these may need to be re-considered as it is important to establish ethical guidance for this sensitive area of research.

6. Development, status and maintenance

6.2 As highlighted in our previous response, there is a need for further clarification on the legal status of the document, particularly with regards to the devolved administrations where it is not apparent if they are *legally* expected to comply with the guidance. Communicating the legal positioning of the framework through defining 'must' in the glossary at the end of the document is

⁴ Department of Health (2012). *The NHS Constitution for England (Updated October 2015)*. <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

not sufficiently clear and instead, the legal status should be explicitly stated within the body of the guidance.

Similarly, we are pleased that our comments around framing the document as a minimum set of standards for the conduct of research in the UK have been addressed to some extent through defining 'should' in the glossary as: 'We use 'should' for expectations we regard as minimum good practice, but for which there is no specific legal requirement'. However, again, it would be clearer to state this within the body of text, and to more explicitly frame the *whole* document as a minimum set of standards.

It would be helpful to clarify whether the guidance applies to data held by government departments relevant to social care, for example, data on benefits from the Department of Work and Pensions.

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

8.11 The potential issues around making information on findings available need to be more nuanced and this should be considered throughout the document. The text should consider that some types of information disclosure could be deemed harmful and/or unexpected for the participant, as identified in the 2012 report and later framework developed by the Wellcome Trust and Medical Research Council.^{5,6}

8.12 As highlighted in our previous response, there remains a need to widen the definition of participants to include those such as children who may not be able to give consent. It would be helpful to provide greater clarity on principles for enduring consent as well as re-consent, taking into consideration a proportional approach. For example, when contacting those participants for re-consent who previously participated in a study as children, they may be unaware of this participation and their contact details may be outdated. This could result in a high non-response rate and thus researchers being prevented from utilising participant information under Section 251 of the NHS Act 2006.

9. Principles that apply to individuals and organisations

Chief investigators

9.2a Further clarity and detail is needed on 'Taking account of developments while the research is ongoing'.

9.2b It is not always feasible to obtain independent expert review for smaller projects such as undergraduate projects, and so the text should be amended or removed to reflect this.

9.2h See 8.11.

⁵ Wellcome Trust, Opinion Leader, Medical Research Council (2012). *Assessing Public Attitudes to Health Related Findings in Research*. http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtvm055196.pdf

⁶ Wellcome Trust, Medical Research Council (2014). *Framework on the feedback of health-related findings in research*. http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtp056059.pdf

Research teams

9.7a The provision of this level of information could be difficult and/or inappropriate for certain groups of participants, and result in an unnecessary burden of information, conflicting with 9.8 which states that *'proportionality should be applied to the provision of information'*. We suggest that a statement should be included to confirm that if this is not deemed appropriate, the course of action should be fully justified and be acceptable to the appropriate bodies.

9.8 As outlined in our previous response, we are highly supportive of the emphasis on proportionality in the provision of information to research participants, and this is consistent with the recommendations in our 2011 report on the regulation and governance of health research.⁷

Whilst we strongly welcome the principle that the level of information provided should reflect the possible risks of the study with lower risk research associated with less documentation, in line with comments on 9.7a, we also do not want to increase unnecessary burdens of information that may actually lessen and/or dilute participant understanding. Thus we suggest emphasising that the objective of participant information is not the *volume* of information provided, but rather the knowledge gained by the potential participant on what taking part involves. Otherwise, this statement could contribute towards increasingly lengthy participant information sheets, which may not be fully read and so could lessen participant understanding.

Funders

9.9a We are concerned by the statement around *'involving patients, service users and the public effectively in funding decisions'*. We are supportive of the involvement of these groups where appropriate, however, the extent and nature of the involvement will likely vary and we believe that the funder should decide their *appropriate* involvement. Therefore the text should be amended to reflect this.

9.9b In some cases, it may be difficult for funders to be able to assess that *'costs to the health and social care system are not disproportionate compared to research costs'*. This responsibility should lie with the researcher, employer and sponsor, although funders can also play a role in encouraging this.

9.9e We are supportive of encouraging chief investigators to make *'accurate findings, data and tissue accessible, as appropriate'* but it should be noted that this could have significant implications for costings for chief investigators, for example, around the funding of longer term availability of tissues. This would likely lead to a review of the necessary resources for structures that host tissue banks and datasets.

Sponsors

9.10d *'Ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable'* may be beyond the capabilities of university research offices and could create difficulties if there are multiple bodies with different perspectives scrutinising research in this way.

9.10f See above.

⁷ Academy of Medical Sciences (2011). *Regulation and governance of health research*. <http://www.acmedsci.ac.uk/download.php?f=file&i=13646>

Research sites

9.15 Again, reiterating our previous response, we strongly support the HRA's efforts to reduce duplication of work between research sites, ethics committees and other approval bodies.

9.16b It would be useful to provide further information on intentions to set timelines that research ethics councils and research sites (including data holders) can be held to, thereby ensuring that the response is timely as described.

Health and social care providers

9.22b We welcome the additional point in the new draft which outlines that health and social care providers are expected to be '*promoting opportunities to take part in health and social care research*'. However, we recommend that the framework more strongly highlights that *all* stakeholders such as researchers and research funders, not only providers, have a responsibility to do this, and that this expectation is outlined at the start of the document to underline its importance.