Health Research Authority: UK policy framework for health and social care research consultation

Response by the Wellcome Trust - March 2016

Key Points

- We continue to support the high-level approach of the framework, but the language must be clearer and more accessible to enable the framework to fulfil its purpose.

- The principles for regulators must have equivalent status to those for other stakeholders. These should clearly set out the regulators’ roles in coordination, standardisation, and ensuring proportionality, as well as their responsibilities and liability.

- We encourage patient participation throughout research and were pleased to see this reflected in the framework. We suggest broadening this point to include a wider range of approaches to involve patients in research, which will enable funders to fulfil this responsibility in a way that is effective and practical.

Introduction

1. The Wellcome Trust is a global charitable foundation dedicated to improving health. In 2014-2015, our grant funding and direct charitable expenditure was £886 million, the vast majority of which was spent in the UK. Our breadth of support includes public engagement, education and the application of research.

2. We are pleased to respond to the consultation on the UK policy framework for health and social care research. We feel the new document goes a long way towards addressing some of the issues in the Research Governance Framework for Health and Social Care (RGF), particularly the avoidance of duplication and delays. We thank the HRA for considering and incorporating stakeholders’ comments on the earlier draft framework. Our response focuses on comments specific to this new draft and areas where we consider further work is needed.

Do you think the policy framework will help make the UK a better place to do research? Does the policy framework place sufficient emphasis on a proportionate approach to the conduct and management of research?

3. We would like to reiterate our support for the ambitious commitments set out under ‘Purpose’. These recognise the importance of risk proportionality and avoiding the financial and opportunity costs associated with delays to research. The framework has an important role to play – alongside practical changes such as HRA single approval – in addressing the lack of balance that has persisted in the UK regulatory and governance system.

Is the level of detail in the policy framework sufficient for it to be implemented? If not, how could this be improved?

4. An appropriate level of detail is provided in the draft framework to establish over-arching principles and objectives. We continue to support the high-level approach of the framework, but believe that the framework would benefit from structural changes and the use of clearer language. We also recognise that further detail on processes, including plans for evaluation and review, will be needed to support implementation and this supporting documentation should be available in a single location to facilitate this.
5. We welcome the classification of legal obligations using “must”, as recommended in Wellcome's previous submission. However, the definitions of “must” and “should” are found at the end of the document in the glossary. We recommend these are moved into the “Scope” so that the distinction is understood from the start. These terms should also be used consistently throughout to remove ambiguity. For example, the legal status of the statement that “all healthcare research will have a sponsor” in 9.10 is unclear and should be reworded.

6. The language of the previous draft was mostly appropriate and clear. However, we are concerned that this has been lost. Some sections have become particularly lengthy and challenging, and use inappropriate legal jargon. Critical information must be included in the main body of the frameworks and footnotes used only for supplementary information or links to more detail. Cross referencing should also be used throughout. These points should be addressed throughout the framework, including for the following specific examples:
   - The use of legal language such as “with due regard to” in 2.2 and “must have regard” in 6.2.
   - 9.15 is a critical aspect of the framework – ensuring approval processes are not duplicated across different localities – but it uses long, inaccessible sentences and unclear language.
   - The responsibilities for making research information available are set out in 9.2.g. and footnote 21 and should be cross referenced when referred to in later sections. On first reading, we missed important information in footnote 21 that describe the mechanisms for making research information available.
   - Footnote 19 summarises 6.2 in clearer language than is used in the body of the text.

7. It is helpful for the footnotes to refer to relevant guidance where more detail is available and for these links to be as comprehensive as possible, for example including a reference to Department of Health cost attribution guidance at relevant points, such as 9.9.b. It is also important that references to guidance are up to date and accurate for the framework to be authoritative. For example, it would be more appropriate to refer to MHRA’s good clinical practice guidelines in footnote 11 rather than International Conference on Harmonization guidelines, which are not a legal requirement in the UK for clinical trials of investigational medicinal products.

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

8. We would like to see the point in 9.16.g. on responsibility for “quick co-operation among relevant parties” in cases of urgent need or a small window of opportunity moved to the section on principles that apply to all. This is not the sole responsibility of research sites and cannot be achieved unless all stakeholders cooperate.

Do you agree with the responsibilities stated for chief investigators?

9. The section relating to students has been expanded in this draft and is difficult to find. We suggest point 9.3 is moved into a new, separate section of requirements for supervisors as it is more intuitive that they are responsible for the involvement of students in research, rather than Chief Investigators. It must also be made clear that these responsibilities refer to PhD students as well as undergraduates.

Do you agree with the responsibilities stated for research teams?

10. Research teams are required to “demonstrate their suitability to conduct research”, but it is not clear who they need to demonstrate this to. The requirement for Chief...
Investigators in 9.2.d. is more appropriate and should adequately ensure teams are suitable and qualified, so we suggest 9.6.a. and 9.6.b. are removed.

Do you agree with the responsibilities stated for funders?

11. 9.9.a. states that funders should involve "patients, service users and the public effectively in funding decisions". While patient involvement can improve research outcomes, there are many ways of achieving this. For example, involving patients in priority setting and research design, and engaging patients and the public with research policy and outcomes, as well as engagement in funding decisions. Wellcome makes awards based on scientific merit, feasibility and benefit to health. Our breadth would make engaging patient groups for each disease area in our funding decisions impractical or, in some cases, impossible. We encourage patient participation throughout research and therefore suggest this clause is broadened to “funders should encourage the appropriate involvement of patients, service users and the public in the development and prioritisation of research questions....”, or modified to reflect 8.4. This will provide flexibility to enable funders to fulfil this responsibility in a way that is effective and practical.

12. 9.9.c. requires funders to consider "whether the research is really achievable within the setting as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health and social care". In our previous submission, we outline our concerns regarding this requirement. Funders will consider whether the environment would enable high quality research to be carried out. However, we are not in a position, nor do we have adequate information, to consider the impact on care provision. This responsibility should therefore be removed. We consider that it should be the responsibility of the care provider to determine if a study would adversely affect the quality of care provision.

13. 9.9.d. has been altered from “requiring that a sponsor is in place before the research begins” to “making funding conditional on a sponsor and on relevant approvals being in place before the research begins.” In some cases, Wellcome provides small amounts of money before full grants are made available to support study set up. We suggest that 9.9.d. is removed or amended to “requiring all relevant approvals to be in place before the study starts”. This approach would be more consistent with current good practice among many funders, which has recently been reviewed and discussed by the HRA Collaboration and Development Forum.

Do you agree with the responsibilities stated for regulators?

14. We are concerned that the responsibilities of the regulators are limited compared to those set out for others in the framework. As we noted in our previous submission, this section should be revised to set out the regulators’ specific responsibilities. We have suggested an approach in Box 1. The framework will only be effective if there is reciprocity between different stakeholders’ responsibilities and it is therefore essential that there is greater clarity and assurance on regulators’ roles. The layout should also reflect the format of other sections to demonstrate their equal footing.

15. For the framework to be effective, all stakeholders must trust the regulators to make accurate, informed and fair decisions. If the regulators are not held responsible for their decisions, individual stakeholders may feel compelled to conduct their own assessment. 9.18 sets out the HRA’s responsibility, but the liability of the regulators is not described in plain English. This must be addressed to give stakeholders the confidence in the framework that is fundamental to its success.
Box 1: Proposed wording to include in “Regulators” section

9.18 Regulators are statutory bodies that oversee particular activities according to their functions, which are set out in legislation. There are a number of regulators in the UK with a remit for activities related to health and social care research (the HRA) or to health research only (the MHRA, the HFEA and the Human Tissue Authority).

a) The HRA, MHRA, HFEA, and the Administration of Radioactive Substances Advisory Committee all have a role in cooperating with each other to approve research. This is underpinned by ‘memoranda of understanding’ between these bodies which set out: how they work together to improve and simplify the regulatory environment; and other agreements which arrange for one body to perform functions on behalf of others.

b) The HRA and the Devolved Administrations work together to co-ordinate and standardise the regulation of health and social care research.

9.19 The HRA has a specific role to ensure the following:

a) The regulation of health and social care research is proportionate, so that research that is clearly lower-risk gets processed accordingly.

b) Guidance for researchers is provided by the HRA on behalf of the Devolved Administrations for UK-wide use.

c) Applications to all the key research approval bodies are made through a single UK-wide Integrated Research Application System provided by the HRA.

d) The framework and supporting documentation are provided in one, easily accessible location.

e) Responses are standardised and predictable.

f) That HRA takes responsibility and liability for approvals where checks have been carried out only by the HRA and not by other organisations.