**Call for comments on the report: A preliminary exploration of the perceived risks and barriers to organisations conducting research**

As part of the work to underpin the development of a replacement for the Research Governance Framework (RGF) when the HRA becomes a Non Departmental Public Body (as part of the Care Act 2014), the HRA sought comment on a [report](http://www.hra.nhs.uk/wp-content/uploads/2014/05/Perceptions-of-risk-report-v1.3.pdf) which highlights findings from a preliminary exploration of the perceived risks and barriers to organisations conducting research.

The project deliberately selected a small number of participants as a scoping exercise to expose perceptions of risk which deter organisations from being more research active, with the intention of identifying themes that could be tested more broadly. The purpose of the call for comments was to determine whether the views expressed by the project participants were corroborated by a wider and more diverse community.

Some respondents commented on the small number of people invited to review the document, perhaps not being aware that this formed part of a planned broadening of the conversation with a more diverse audience. Some respondents commented on an absence of reference to social care research and student research: these topics form part of separate projects and the comments received on these areas have therefore been used separately to inform those activities.

**Recommendations from the report**

There was strong support from respondents for the recommendations made by the project participants (http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/replacing-research-governance-framework/risks-research-perceived-risks-research/):

***1)         Clarify the Purpose of the Research Governance Framework***

*Using standardised terminology to ensure relevance across stakeholders, the role of the RGF in setting out unambiguous principles should be articulated clearly. This should leave no scope for interpretation as a set of standards for local application to research. The RGF’s scope, including its limitations, should be clear.*

***2)         Define Principles for Interface Management Between Stakeholders***

*The central role of collaboration within a research project should be described. Learning derived from the case study, and participant interviews, suggests clear, upfront agreement of principles and procedures for each project to be essential to the effective conduct and success of a study as well as mitigating some risks.*

***3)         Make the Quality Research Culture Explicit and Relevant to all Stakeholders***

*Principles of good practice should be explicit, not implied, and should clearly apply to all parties. Systems should enable the identification of failures or breaches and place responsibility with the relevant party. Effective calculation of costs and financial management are critical, as financial probity and value for money can be construed as indicators of quality.*

***4)         Focus on Learning and Sharing Good Practice***

*Current arrangements for learning are, on the whole, based on informal networks. A greater emphasis is required on identification and implementation of lessons learnt from experience, including incorporating this into training and personal development. Consideration should be given to mechanisms for future updates of the replacement of the RGF, learning from experience.*

The HRA will consider this feedback in drafting the replacement to the Research Governance Framework.

**Responses to the report**

In addition to commenting on the recommendations of the project report, respondents reinforced many of the points raised in the report, and identified additional concerns.

* There was agreement between respondents that research governance is interpreted in terms of processes rather than being a set of principles upon which to base judgements. However, it was noted that the framework lacks operational detail. This has evidently led to uncertainty about the application of proportionality to the principles. The result has been that there has been a tendency to apply the requirements set out in clinical trials regulations to all research, because of the level of detailed operational arrangements set out in the regulation and the fear of inspection of clinical trials of investigational medicinal products. The issue is not therefore that the RGF itself necessarily lacks proportionality but the lack of operational clarity across all types of research has caused disproportionate activities. In contrast, some respondents noted that researchers not undertaking clinical trials adopted an excessively lax attitude due to the absence of inspection.
* The RGF places an emphasis on the responsibilities and accountability of the various parties in research. In some organisations, a perception of insufficient resources to meet the requirements has resulted in delegation of responsibilities and actions to individual clinical researchers. This has increased the sense of burden felt by researchers.
* It was noted that the history of the RGF as arising from failures in research quality had created a sense that implementation of bureaucracy was required to avoid risks of future failures. These failures are often alluded to in training, thus reinforcing the notion of research being risky.
* Although allocation of responsibilities is a key feature of research governance, the RGF does not provide clarity about the allocation of liability when problems arise. Respondents felt that this has led to a tendency to incorrectly assume liabilities will apply, leading to behaviours to avoid such liabilities. Ironically, the double-checking and excessive bureaucracy that result from these misconceptions can in fact create liabilities where none existed.
* The emphasis on allocation of responsibilities has resulted in increasing difficulties as the organisational landscape has become more complex, particularly outside acute healthcare.
* Finance, reputation, contracting and capacity are the key perceived risks of research. However the perceptions of these risks or their impact are varied across organisations due to different contexts, size and organisational factors. This leads to some of the variation between organisations that causes so much difficulty for researchers. It was noted that where the organisational culture does not support research, research is particularly viewed as a risk for information governance compliance. Undertaking research in such organisations is frequently beset by problems with information systems, HR planning and resource allocation.
* There were suggestions from some respondents that some of the complexities arise from research being managed separately from mainstream NHS management. This separation arises from a range of reasons: research has different finance flows, there are specific legal and regulatory requirements for research, and the project-based nature of research demands individualised management arrangements.
* There was strong support for the need to re-balance the emphasis of oversight across the whole life-cycle of research project not just start. It was noted by some respondents that current financial allocations had led in some areas to an inappropriate focus on up front approvals that were separated from mainstream NHS activity. Funding flows should reinforce a holistic approach to the management of research.
* There were some comments about terminology. It was acknowledged by respondents that ‘governance’ has acquired negative connotations in relation to research but is also a well-established term across all aspects of the public sector. Frequent confusion between Good Clinical Practice and research governance was reported.

The HRA will consider this feedback in drafting the replacement to the Research Governance Framework.

**Proposals from respondents:**

Respondents made a number of suggestions, some of which were more general proposals for the replacement to the RGF rather than applying specifically to the issues relating to perceptions of risk.

* The replacement should be clear about its objectives, and should be evaluated as to whether it is meeting its objectives.
* The new framework should recognise the varying infrastructure and settings of research in health and social care with increasingly diverse providers or care and services.
* In recognition of the increasingly diverse settings for research, the framework should set out expectations about the level of seniority required of local staff supporting a quality research culture and the requirement for sufficient capacity and capability to do this at an organisational level.
* The framework should be accompanied by appropriate levels of clarity about operational aspects of acceptable practice to avoid ‘gold plating’.
* The term ‘GCP’ is confusing as it is used broadly across the research community but is only defined in relation to clinical trials. ‘Good Research Practice’ should be used instead.
* Training should be relevant and tailored rather than ‘one size fits all’.
* The importance of sharing experiences and learning lessons about the management and oversight of research were stressed.
* To introduce proportionality to document-based compliance systems, approvals should set out the scope of delegated permissions to the sponsor for certain adjustments or amendments within the scope of the approved activities.
* Where ‘governance’ is focussed entirely on up front approval the arrangements should be modified to ensure ongoing support to a quality research culture and management across the life cycle of research. Funding allocations should support these models.

The HRA will consider this feedback in drafting the replacement to the Research Governance Framework.

**Next steps:**

The HRA will continue conversations on these topics as part of its engagement with the research community. In particular collaborative work with the NHS and the NIHR Clinical Research Network during the implementation of HRA Approval will provide further opportunities to introduce and explore these issues further.

The HRA will consider the above recommendations and comments made by the community in its drafting of a replacement to the RGF. It is envisaged that a formal consultation of the new framework will take place early in 2015.

**Respondents**

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| Abertawe Bro Morgannwg UniversityHealth Board |
| Barnet and Chase Farm Hospitals NHS Trust |
| Birmingham and Solihull Mental Health NHS Foundation Trust |
| The Belfast Health and Social Care Trust |
| Canterbury Christ Church University |
| Central Manchester University Hospitals NHS Foundation Trust |
| The National Institute of Health Research Guy's and St Thomas', King's College London Biomedical Research Centre |
| Imperial College |
| James Lind Initiative |
| NHS R&D Forum |
| Noclor Research Support Services |
| Oxford University Hospitals NHS Trust |
| Sheffield Teaching Hospital NHS Trust |
| Social Care Workforce Research Unit |
| Social Service Research Group |
| University of Cambridge School of Clinical Medicine |
| The National Institute of Health Research Collaboration for Leadership in Applied Health Research and Care North West Coast University of Liverpool |
| York Teaching Hospital NHS Foundation Trust |
| Other individuals |