NHS
Research and Development Forum

RESPONSE TO HRA CONSULTATION (FINAL v.1.0)
11th July 2014

- **A PRELIMINARY EXPLORATION OF THE PERCEIVED RISKS AND BARRIERS TO ORGANISATIONS CONDUCTING RESEARCH**

- **A REVIEW OF SERIOUS ADVERSE EVENTS IN RESEARCH, EVIDENCED FROM BREACH NOTIFICATIONS**

1. INTRODUCTION

- "As part of the work to replace the Research Governance Framework (RGF) when the HRA becomes a Non Departmental Public Body (NDPB), the HRA and Devolved Administrations have committed not to just update the Research Governance Framework as a document, but to fundamentally review the whole framework with an ambition to have a single framework for research across the UK.

- The HRA intends to have a high-level set of principles for good research ready for consultation upon becoming a NDPB. To support this programme of work, a number of reports have been, or are in the process of being, developed, ahead of the full consultation.

- The HRA are seeking comment on two projects on the risks associated with research." *Taken directly from the HRA website*

- The following link takes you to their website where information on each of these projects can be accessed. http://www.hra.nhs.uk/about-the-hra/consultations-calls/risks-research/

2. METHOD

- The project reports were circulated to the Research Strategy, Research Management and Primary Care Forum working group members. Responses to the papers were all received by email correspondence and formulated into a response, which was then re-circulated for review and comment.

- This response aims to provide constructive feedback and to start a conversation around the new Research Governance Framework

- This response takes each paper in turn and aims to address any specific requests for information or opinion as well as a review of the consultation or paper itself.

3. FORUM RESPONSE:

3.1. A Preliminary Exploration of the Perceived Risks and Barriers to Organisations Conducting Research, (*Version 1.3 20th March 2014)*

- The groups understand that that aim of the project itself was to start to review the principles upon which the Research Governance Framework (RGF) is based, with the aim of the consultation exercise to gain insight from the R&D community on the following specific areas which we have answered in turn:

  - *How the RGF contributes to the delivery of good quality research plus perceptions of risk or barriers that are deterring them from being more research active.*

  - *Which principles of Research Governance encourage research and which ones disrupt it?*

  - *What are enablers of good practice – are they practice based or explicit requirements?*

3.1.1. How the RGF contributes to the delivery of good quality research plus perceptions of risk or barriers that are deterring them from being more research active.

- The RGF explicitly promotes a quality research culture and sets out responsibilities for all those involved in research. This makes clear that all parties have responsibilities and that research is a collaborative enterprise.

- There is general agreement that the Framework itself may not be used directly so much these days as the principles are now more embedded into practice than they were when it was first launched. The Framework itself was not intended to be a pragmatic operational "tool", although the national tools that now exist are too focussed on the approval stages.

- There is a general feeling amongst the R&D management community that governance is perceived by others to be negative, overly onerous, and a block to faster easier clinical research. The question about the perception of risk is suggestive of this also however the groups generally agree that risk and risk perceptions should be explored further.

- The RGF contributes to the delivery of good quality research by:

    - Stipulating that all research must have a Sponsor with responsibility for quality and oversight, including non-portfolio research.

    - It defines research and provides a standard reference point and expectation that research means quality and that research studies must be managed/signed off/governed/overseen to ensure the ethical, safe, legally compliant, quality data that is disseminated for the greater good.

    - It embraces more than the project-specific and sets the expectation for culture change at organisational and community level. It is therefore broader than GCP as a framework.

    - Research management or governance embraces organisational responsibilities for finance for example, that reach beyond the project-level and the working groups made clear that they agreed the process for recovering and financing research including non-portfolio studies, could be onerous and difficult with particular reference to Primary Care.

    - The financing and loss of expertise in Research Management has been a particular issue for primary care and also where there are more complex relationships. For example where health and alcohol/ substance misuse services are provided by providers from NHS Trusts, third sector, primary care etc. to people in prisons and other CJS settings including community services, working out to whom the participants "belong" in research governance terms can be complicated and stifle the 'proper' research which is badly needed.

    - Different interpretations of funding and support by different CRNS was agreed to be an issue. Solutions and support for the management Excess Treatment costs is also extremely variable as the Forum have made reference to before *(see our response to the NHS England draft research strategy consultation).*

    - The re-organisation of Primary care has destabilised systems that were previously in place and there is a need for national guidance on what should be provided or supported

    - The RGF originally included social care, which is critical and the groups feel strongly that the new RGF must ensure it is broad enough to cope with the emerging and changing landscape.

- It originally put research **and** quality on the agenda and created a duty on organisations to deliver.

- The groups generally agree that risk management and risk assessment are separately related things and should both be embraced within the revised framework.

3.1.2. Which principles of Research Governance encourage research and which ones disrupt it?

*The groups felt that **Research Governance encourages:***

- Responsibility and accountability for research.

- Quality and (if delivered well and appropriately) public confidence. It doesn't take much media coverage to influence the public perception and confidence in researchers (see recent commentary of Facebook "research" in the media and also the handling of care.data. http://www.theguardian.com/technology/2014/jun/29/facebook-users-emotions-news-feeds However it is a fine line to tread, as by overly promoting the RGF to exist as a result of the few bad headlines, it perpetuates the myth that researchers might generally be inclined to do things that they shouldn't be doing, which is not the case.

- It promotes the notion of a quality research culture and what this means, namely **leadership and an organisational culture that promotes research, and research that is ethical, high quality research that will inform practice.** This embraces more than the general perception of governance today.

- There is a feeling that the current emphasis is generally on governance being about the governance "checks" and not about the general environment, quality processes, or the pulling through of studies as these tend to be thought of as a separate domain of the overall research agenda. The "Faster, easier clinical research" strap line, doesn't mention quality research, or quality care being a part of research culture and evidence into practice.

- Research Governance can encourage negativity in some clinical and research staff so there is something about the perception of governance that needs re-selling or re-branding. However the groups feel we should be mindful of removing the term governance altogether as the concept of governance is well embedded and used throughout the NHS – (Information Governance for example), and it provides a reference point for good practice.

- It is an opportunity to be clear that even with the HRA single assessment and approval there remain responsibilities at site level and across all the organisational relationships.

The groups felt that ***Research Governance <u>disrupts:</u>***

- Disruption caused may be around the perceptions of governance itself and because the framework, or rather the interpretations of the principles of the framework, are not risk-adapted. Whereas this in theory allows for flexibility, the lack of instruction and detail means there is not a consistent ability to clearly distinguish what is expected and so there is a tendency towards the industry standards of GCP for CTIMPS, at a study level. The CSP checks are one way of interpreting and practically delivering the framework but these stop at permissions and amendments and in themselves may be overly onerous in places (everything recorded and referenced etc at site level).

- Grey areas around research definition may allow low risk studies to potentially be pushed into service evaluation if the systems for requiring a sponsor, peer review, funding and a detailed protocol for example, are seen to be onerous and vice versa (where organisations are concerned about the risks or governance of a service evaluation and subsequently pushing it into being research).

- The concept of Governance, by definition, includes accountability and it maybe that this accountability creates a level of risk perception that is potentially disruptive. The original framework was presented at a time when there was poor governance and high impact stories in the media (many research managers have given presentations with these stories at the reasons for the framework existing.) This reference point still exists and coupled with the emphasis on organisational accountability without any proportion, context, or examples of practice may result in organisations accepting this as a burden in a disproportionate way. This does not however mean that the concept of the framework is wrong, disruptive, built on falsely perceived risk, or that the principles are out of touch, but maybe some clarity is required around what the implications might look like and how organisations with responsibilities can be diligent, without applying one size to everything.

- The Forum whole heartedly endorses the concept of sharing lessons learned and communities of practice etc., as we aim to provide a means by which individuals can share opportunities, lessons, best practice and resource.

- The drive for “pragmatic and proportionate” RM&G still exists but again tends to focus on set up, approvals and permissions. This may be short

sighted because it creates an emphasis and 'machine' around the approvals, which is divorced from the overall general management of research and means communication can become disrupted and stilted.

- Lessons learned, sharing of good practice, and allowing proportionate and pragmatic methods for implementing the principles of the research governance framework should better encourage research for quality and quality research.

- There is a notion of research being separate from main stream management, that possibly creates a conflict with the overall strategy to promote and engage everyone to do research and although everyone has responsibilities in the framework the financing etc is still considered to be separate from patient care. Maybe this is something for review or for maintaining but there is something about the governance sitting "aside" from organisations and this was touched on in the document with regards to RM&G staff needing to be more embedded into the NHS.

- Applying the concepts to a new emerging cross organisational landscape presents challenges for the management and governance of research in its traditional form. This should really be addressed in any new framework to prevent potential disruption as teams are unclear what to do.

3.1.3. What are enablers of good practice – are they practice based or explicit requirements?

- Clarity of expectation enables best practice. To be clear what is required with evidence of how to achieve it in practice. The Forum hopes to help provide some of this "how to", to clarify practice based standards but there is also a need for explicit national standards and the Framework could set out risk-adapted expectations.

- Context through guidance and clear examples to show what is considered acceptable practice.

- Open access and Forums provide excellent opportunity for sharing experience, expertise, working tools and lessons learned.

- Defining where there are risks, what these risks are in terms of where the impact might lie (either to the organisation, to the sponsor, to study delivery, to quality, to safety or to the patient experience?)

3.1.4. General feedback on the Perceived Risks Paper

- There was some concern amongst the group with regards to the scope of the project and the number of respondents from similar organisations or with good links to the HRA, (three organisations had two interviewees each out of ten respondents). There was no detail on the case study and or any information on the author and we suggest the case study is appended to the report. There was also some scepticism around the validity of the project methods in their ability to elucidate views and thoughts on the riskiness of research to assess perceptions of risk.

- The groups nevertheless agreed with the resulting recommendations but suggested the purpose of the framework should be agreed first and as a priority to enable the rest to follow.

- The Forum feels it is ideally placed to feed into this work and should very much hope to be part of the re-writing exercise. It was an explicit request from the groups and a strongly held view that the Forum should take part in discussions around a re-write. It was also a strongly held view that the new document embraces the changing landscape for health care.

- In summary the groups felt there is a need to accept and promote that enabling and ensuring quality includes good management that is more than the governance checks, and that the concept of governance as an approval does not help with the perception that RG disrupts by creating a "perceived" risk.

- "R&D" should be supported and enabled to be integrated, and considered as facilitator of quality and improvement which is part of a governance framework that promotes research and a quality research culture. Improving the dialogue and ensuring better integration of research with the rest of the health care should be promoted to ensure that R&D teams are not working in isolation of the whole health community, and dealing with some difficult problems without a benchmark or reference point, such that they become risk adverse, risk-takers, or perceived to be a block. There are very good examples of excellent integration existing already in many places, but this can be limited where there is poor resource or very removed models of R&D support based around permissions.

3.2. A Review of Adverse Events in Research, Evidenced from Breach Notifications

- The Forum understands that "the purpose of the document is to highlight the types of issues that do occur, look at the themes and trends which have been identified and to share learning more widely" *(p3)*. The Forum therefore comments with this purpose in mind, and aims to offer constructive insight into the system with particular regard to the new Research Governance Framework and perceptions of research risk.

- Our comments are largely focussed on use of language and clarity of statements and definition, rather than the project itself and the Forum is extremely supportive of sharing examples of breaches, so that lessons can be learned.

- It is felt that the aims of the project were met in principle but it was noted that the aims were not accurately reflected in the title i.e., the aim was not to identify adverse *events* from the reporting process (as stated in the title); understanding that adverse events (generally defined as an untoward medical occurrence) are different from an (adverse) "impact" on participants, researchers, sponsors and that the breach may result in an adverse event but also a near miss or other non-medical incident.

  NB: The current draft of the Research Governance Framework does not clearly distinguish between incidents, SAEs and safety *monitoring* procedures, breaches and deviations etc, which may have led to some confusion and could be rectified/ made clearer in the new version.

- The introduction begins by asserting that all breaches are reported for all studies. It is subsequently stated (*right hand box, p1*) that reporting is considered necessary for breaches that are serious. Other non-serious breaches are defined in the document as only protocol violations.

- We understand that all serious breaches must be reported, that all "non-serious" breaches can be protocol violations (but may also be a minor breach of GCP, written instructions and applicable regulations), and that there could be a further category of minor deviation, which is more likely to be, for example, a patient who has missed a visit or not completed a data collection tool (these need not be reported to REC)

- The lack of reporting in non-CTIMPS was considered likely as there is a general lack of clarity in this area as referenced in the report. It would have been useful to quote the specific NRES requirements, or SOP reference that stipulates all breach reporting is required for all REC approved studies.

NB: when the group looked for a reference to substantiate the statement it was not clearly found; to our knowledge it is not in the non-CTIMP conditions of approval or on the HRA website and this could be added, plus the NRES SOPS 5.1, p145 states *"A serious breach of the protocol or GCP resulting from error or misconduct must be reported."* There is therefore a need and opportunity for further clarification.

- It is suggested that a simple grid or table with terms, definitions and reporting requirements would be useful rather than lots of text and would help to provide a national standard. Further clarity around these definitions would be gratefully received in the revised Research Governance Framework and (it is suggested) should be linked with definitions in the MHRA grey guide and other accepted literature wherever possible.

- As there is a general understanding that GCP training is not always required for non-CTIMPS it should be made clear that a breach of GCP nevertheless applies to non-CTIMPS (if this is indeed the definition of a breach) OR there should be an explanation/definition as to what the "equivalent" standards for a non-CTIMP are.

- *Section 5 Impact of Breaches (p15)*: We were uncertain that the impacts on study participants identified through the reported breaches were categorised to be low as reported by the research team at the time of the breach or whether they were categorised as such by the author. This could be explained or justified further (i.e. low risk because not a safety issue for the study participants themselves) or developed into a piece of work that might be conducted, namely 'what do patients and the public perceive to be high, medium and low risk of the impacts of reported breaches? The Forum agrees that there may be a big impact on data quality and integrity (which could have a longer term impact for patients), and also waste.

- It is not clear that it can be reasonably extrapolated from this work that research is not 'risky' (or should not be considered to be risky) and suggest that this might more accurately be interpreted as follows: "the nature of reported breaches shows us that a breach of protocol or GCP, does not pose much of an immediate risk in terms of its safety impact on the patients who have participated (as above) AND/OR that if research is conducted and well managed with all appropriate controls and measures in place (as defined in the protocol and to standards of GCP) our evidence shows us that these are rarely breached and therefore research *in practice* is not very risky?

- *4.1.4. (p 12)* a SUSAR is defined incorrectly as a "*Sudden* Unexpected Serious Adverse Reaction and should be changed to be a *Suspected* Unexpected Serious Adverse Reaction. Again accuracy of definition is particularly important in this area and for the RGF re-write, to ensure that hosts and Sponsors are all explicitly clear of their roles and responsibilities for safety and compliance reporting and monitoring.

- In conclusion the Forum welcomes the key recommendations and the main messages of shared lessons learned and improved communication between the research communities.

- The Forum working groups believe there are opportunities to provide further clarity in the next version of the research governance framework with regards to breach and safety reporting, and that any future documents should be particularly mindful of definition and differences in interpretation.

FORUM CONTRIBUTORS

- **Research Strategy Working Group**

- **Primary Care Working Group**

- **Research Management Working Group**