NHS
Health Research Authority

Consultation:

HRA and Research Sponsor Responsibilities

January 2014

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1) Background

The Research Governance Framework for Health & Social Care (RGF, 2005) outlines the responsibilities sponsors have for quality around the conduct and delivery of research. The recent publication of The Concordat to Support Research Integrity (Universities UK, 2012) seeks to provide a comprehensive national framework across all subject areas for good research conduct and its governance. In spite of the presence of such documents aimed at supporting the integrity of research and other related documents, concerns are still being raised by organisations which host and regulate research around the variability of

- understanding of sponsors' responsibilities across all parties
- how sponsors address their responsibilities
- transparency of what sponsorship entails -what researchers may expect of the sponsor and *vice-versa*
- understanding of which organisations are suitable to sponsor what type of research.

The HRA has identified that these issues are not only a concern in themselves, but can be the root cause of delays in the approvals process and of subsequent difficulties in conducting and completing studies. Examples of what was considered by respondents to be examples of good sponsorship have been shared with the HRA.

The HRA has set out an ambitious programme of work to make it easier to do good quality research in the UK. The HRA leads some of the work in identifying and implementing improvements, continuing to work effectively in collaboration with key stakeholders. Other areas may require the HRA to identify issues and options for solutions, but implementation may not sit with the HRA alone.

The work has been managed through HRA project teams, included seconded staff, or current established groups as agreed by the HRA Collaboration and Development Steering Group, established in November 2012.

The Sponsor Responsibilities project undertook a scoping exercise between Feb 2013 (at the HRA Stakeholder event) and November 2013. Earlier reports from the project outlining different possible approaches to supporting this work were considered by the HRA Collaboration and Development Steering Group. This group has strategic overview of this project amongst other Collaboration and Development projects, and includes representatives of industry sponsors, Higher Education Institutions and NHS organisations, as well as funders of research. The project was also discussed by the United Kingdom Research Ethics Development Group, which represents the Operational Management of RECs in each of the Four Nations.

Highlighted problems were:

- Authorisation of IRAS applications by sponsors without adequately scrutinising what was being authorised. In particular, it was reported that Sponsor Authorisation was sometimes given to applications where the level of scientific critique was not explicit, was felt by REC or R&D to be insufficient based on the information provided, or was simply not addressed at all in the application. Intervention from R&D offices or RECs to try and resolve the issues, or clarify peer review subsequently introduced delays.
- Conversely the opposite of the above also occurred - serious delays to study start up were experienced when it took a significant amount of time (sometimes months) for sponsors to sign off R&D and REC applications. In many circumstances this could be

ascribed to the Sponsor's diligence in undertaking their responsibilities, but researchers did not appreciate the sponsor's role and were often frustrated as a result.

- Irrespective of the time taken to sign off applications, it has been reported that there is often no transparency around the sponsor's oversight of the project.
- Reports from NHS R&D offices suggest that there are cases when sponsors sign the authorisation, receive the grant, and then do nothing further to oversee the conduct, progress, completion and reporting aspects of a study. The HRA expects, as a minimum, that researchers and sponsors ensure registration of research, including publication of summary results, on a suitable publicly-accessible register (see http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/publication-and-dissemination/).
- Some investigators feel that they are delegated excessive responsibilities and are not adequately supported or resourced to meet expectations.
- NHS hosts report a lack of communication or shared understanding in relation to the expectations of some sponsors of what they will be responsible for.
- The applicant completing IRAS is often the Chief Investigator or a deputy, who may not consult the sponsor about the questions relating to sponsorship, or provide clarity about the allocation of responsibilities. Where this is done and information is incomplete or requires further clarification, it can create delays during validation or review of REC or R&D applications.
- Students, particularly below Doctoral level, were often unclear about their institution's responsibilities to them in relation to research (and "what does the sponsor actually do") above and beyond the institutions' responsibility to them as a student

2) Improvement measures

The HRA has observed that researchers, as well as REC and R&D offices, would benefit greatly from assurance that sponsoring organisations understand their role and responsibilities, and have the necessary systems and processes in place in order to support and promote high quality research. The HRA has a remit to enable public and patient confidence in research. Sponsors that are able to demonstrate appreciation of their responsibilities in relation to research contribute to patient and public confidence in research.

The Sponsor Responsibilities project team (convened April 2013) and the wider HRA Collaboration and Development Steering Group have explored and consulted with Sponsor representatives on a number of approaches to maximise assurance and build confidence around Sponsor Responsibilities. These were undertaken mindful of constraints and other potential developments. Just as importantly, there was recognition of the need to avoid overburdening the research community, and to ensure that the work which goes in to providing assurances is proportionate to the benefit derived.

As a result of this work, HRA has agreed to:

- publish its expectations around Sponsor Responsibilities (see Appendix 1) , in its capacity as the organisation responsible for NHS Research Ethics Committees and the Confidentiality Advisory Group (CAG).
- consult with sponsors and other stakeholders on the use of a Declaration for sponsors to show how those responsibilities are met

3) Scope

a) The HRA

The HRA has initiated this project in its capacity as the organisation that (in England) is responsible for ethical review of health research, and approves requests for research under s251 through the Confidentiality Advisory Group (CAG). HRA therefore requires appropriate levels of assurance with regard to the suitability of sponsorship arrangements for studies it reviews, in areas of sponsor responsibilities where HRA may require such assurances.

However, this work also addresses HRA's mandate to streamline the regulation of research, and to facilitate discussions between stakeholders to this end. Stakeholder agreement on a prospective way for information on Sponsorship Arrangements to be uniformly recorded and made available, could increase the streamlining of research processes as this can be made available to all stakeholders without the need for repeated requests.

The HRA is a Special Health Authority in England, although ethics committee review is provided within a UK-wide framework. There is a commitment across the four countries to coordinate activity across the regulation and governance of research, recognising that whilst there may be good reason for differences there must be a clear joined up overall framework. HRA chairs the UK Ethics Committee Authority (established under the Medicines for Human Use Regulations) and the Four Nations Group (with policy oversight of UK-wide REC systems).

This consultation is initiated by the HRA in England. It is anticipated that the report from this consultation will be presented to the UK-wide HRA Collaboration and Development Steering Group, HRA Board, and the Four Nations Group. Any future policy decision following this consultation will be made in the context of a UK-wide framework for ethics review and will have regard to the compatibility of regulation and governance systems across the UK.

b) Responding to the consultation

i) The HRA seeks comment on the draft "**HRA Self Declaration for Sponsors v2 Consultation "(Appendix 2)**. It is suggested that this is considered in conjunction with HRA's expectations of sponsors (as set out in Appendix 1).

ii) The consultation period ends on **28th February 2014**.

iii) Responses should be sent to **hrasponsorship.consultation@nhs.net**

iv) Responses are welcomed from any individual or organisation with an interest in the role of the sponsor. This may include:
Members of the public, or patient groups; commercial and non-commercial sponsors; researchers (including students); Supervisors; NHS R&D staff; HEI research management staff ; funders; professional and research regulatory bodies.

v) In considering this approach, and the template document, HRA suggests that you take account of a number of issues, although you are encouraged to comment as broadly as you feel useful:

- It is suggested that Sponsor Declarations should be made publicly available, in the case of HEIs to their staff and students, for NHS sponsors, to their staff and patients. This may also benefit sponsors from outside the UK in establishing who to approach in the UK.
- Whilst both the RGF (2005) and Concordat (2012) outline responsibilities, the aim of the Declaration is to be a statement of how these responsibilities are met. Thus, declarations of this kind may be viewed as complementary to these frameworks, rather than duplication.
- The HRA recognises that the requirement for the declaration may be perceived as an additional requirement and therefore a burden or additional layer, however the problems identified through lack of clarity on the roles and responsibilities of sponsors is significant and this is proposed as a solution. Ideas are also invited on potential alternatives as part of this consultation.
- Whilst completion of a template such as this presents an additional task, consideration has been given to making this acceptable in proportion to the benefit derived in terms of assurance and transparency. Members of the project team have suggested that clear representation of the work entailed in sponsorship of research is a positive way in which research management and support departments can justify the resources expended and demonstrate the contribution to high quality research. The project team has also recognised that this template provides a way for institutions to compare themselves with others, and may be less onerous than some current methods of demonstrating compliance.
- Sponsors already provide HRA with written confirmation of the organisations' authorised signatories for REC applications as and when these change. Where this information is not forthcoming, it can delay validation of applications. It is suggested that the Declaration is used to publicly confirm the authorised signatory. In addition to sponsors publishing the declaration on their own websites, the HRA would envisage a central repository of submitted declarations in an appropriate location on its website. This could assist in core sponsorship information being consistently and clearly available to the research community and the public and reduce delays to permissions with information being immediately available to R&D and RECs in particular.
- The completion and publication of a Sponsor Declaration may be a factor in assisting funders in their decisions regarding the suitability of a particular sponsor for a specific study, or study type. Comments are welcome from any party relating to the usefulness of the declaration in this regard, or whether the declaration might be revised to this end, if a contributing factor.

c) Close of Consultation

Responses to the consultation will be collated and analysed by the HRA Collaboration and Development management group in consultation with external stakeholders. Resulting recommendations will be communicated on the HRA website and directly to respondents.