HRA Sponsorship Responsibilities

Report on Consultation. March 2014

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. Early scoping work by the HRA identified significant variation in:

- 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 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. 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 on its inception in November 2012.

The Sponsor Responsibilities project, managed by seconded staff from across organisations including NHS sponsors and sites, 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.

In January the project moved to its next stage: an open consultation on a simple mechanism for the consideration, recording and publication of information on how sponsors address their responsibilities. This has come from reported and perceived concerns of a lack of consistency and quality in how these are met, particularly in these areas:

- supervision of students undertaking research;
- the assessment and approval of level of peer review;
- over-delegation by sponsors to CIs;
- confirmation of systems in place for handling serious breaches or fraud and misconduct.

The consultation, whilst suggesting one possible approach to improvement in consistency across sponsors in England, sought to engage with sponsors and stimulate further discussion to enhance understanding of the issues.

The first part of this stage of the project was the HRA's publication on its website of a statement of our expectations of sponsors. In conjunction with this statement, following discussion with a sample of sponsors in England, a simple tool for sponsors was suggested as a possible approach to facilitate the consideration, assurance and publication of how it meets its obligations. The consultation documents had been considered by the HRA Collaboration and Development Steering Group, and discussions were held out of session with Devolved Administration representatives. The consultation closed on 28 February following a period of nearly eight weeks.

1) Responding Organisations:

Responses were invited from across England, particularly from researchers, sponsors of research and the public. Notification of the consultation was made on the HRA Website; through HRA Newsletters; via Management and Steering groups for cascade; direct notification of correspondents with HRA Queries Line Collaboration programme. 24 responses were received from:

- The R&D Forum
- A group response from NHS R&D in the South West of England
- 7 Universities
- 11 NHS organisations
- The Institute of Cancer Research
- The Wellcome trust
- Cancer Research UK
- The Association of Medical Research Charities.

(See Appendix A for full list or respondents)

2) Comments on the Self-Declaration model:

On the whole the suggested approach was well-received for its proportionality; clarity of information to be provided and, most resoundingly as an opportunity to encourage sponsors to reflect. Felt to be less clear were the purposes of the form in terms of what is would achieve beyond self-reflection; where it would be shared ; how comparisons would be drawn, by whom and to what effect. Indeed one respondent felt that the proposed model did not go far enough in providing assurances to be made publicly available unless the HRA were to undertake some kind of quality check on sponsors which is beyond its remit. However, the same respondent suggested a two-tier approach either "side" of a declaration might be beneficial - at the "lower" level, though possibly still making impact, provision of accredited sponsor training and publication of those who had undertaken such training.

Of those more supportive of the proposed approach, a common theme was that it firmly frames the sponsor responsibilities as an institutional matter, of the highest importance, whereas the repetitive nature of the IRAS declaration might diminish this. Where an institutional, rather than study-based approach to sponsorship would be employed, it would require the institution to set out prospectively how risk-adapted procedures meet their responsibilities. Some respondents felt this to be proportionate and manageable; and although some felt it to be unwieldy and resource-heavy with relatively little in return. However, in any case most suggested refinements to the form such as the additions of extra categories or indicated that the content of the tool was appropriate. However, it was felt that some of the wording was too conducive to subjective judgment.

Very little comment was made on how useful the approach might be to the public, researchers themselves, or the, or the impact upon them. The responses tending to be inwardly-focused on the organisation and, reasonably, benefit accrued thereto. However, some comment was made welcoming the aspect of making information available on the internet, as it gave UK sponsors an opportunity to promote not only their own institutions, but also research in the UK more generally.

3) General comments from responses

a) Issues from NHS as hosts:

- It was acknowledged that organisations are not always able to discharge their responsibilities fully due to a lack of capacity and experience, and so articulating the work involved in sponsorship of research may help organisations to better recover the costs, and ultimately build up their expertise. In this regard the systematic nature of a standard tool could be useful.
- A further issue for NHS sites was highlighted that the capacity of some sponsors to undertake ongoing monitoring of the research, which can have an effect on sites.
- It was suggested that non-commercial sponsors may benefit from greater support to fulfil their role. This support could be training; a "how-to" toolkit; in some cases, communication directly with sponsors by funding bodies which usually deal directly with investigators.
- Disproportionate NHS R&D time is spent on clinical MScs where universities will not sponsor their own student research – greater understanding and commitment to co-sponsorship should be promoted and might be assisted by such a system of self-declaration.

b) NHS as sponsors:

- NHS sites can experience difficulty accessing peer review to an acceptable level.
- Some NHS organisations report difficulty in registering of studies on an appropriate database.
- Funding bodies were perceived by some to tend to deal with sponsors only in relation to finance, and not to recognise the role sponsors should have in quality assuring and overseeing the research. They generally do not recognise the costs associated with work necessary to meet the responsibilities of sponsorship and rarely allow these costs to be included in grant applications.

c) Universities

- As might be expected, some respondents welcomed the consultation more than others. Although agreeing with the principles and committed to responsible sponsorship the universities which responded generally supported a proportionate approach, adapted to risk not necessarily expanding upon what this might entail, apart from suggestion of tiered approach starting with training.
- Some universities reported that an institutional assurance of sponsor responsibilities would be impractical as these were devolved to individual Schools

- Benefits of joint offices were extolled, with the challenges also entailed, and the practice of sponsorship committees (or sub committees) maintaining oversight was referenced.
- Universities did not perceive any problems in communication with host NHS sites as affecting the fulfilment of responsibilities

d) Funders

- Attempts to improve assurances relating to sponsorship are welcomed, and may be beneficial for purposes of due diligence.
- As with sponsors, funders were are keen that any approach used should be proportionate. Generally, the suggested approach was thought to be proportionate.
- AMRC membership was supportive of a voluntary, flexible approach which balanced the management of risk in research, and risk of mismanagement of funded studies, with appropriate, proportionate standards for sponsors.
- Other than general reference to due diligence, and improved public confidence, no further specific mention was made of funder interest in sponsorship competence, although AMRC did suggest its members would be willing to reference an assurance scheme in its application. This resonates with a NHS suggestion that funders tend to deal directly with investigators to the exclusion of sponsors. NIHR view would also be beneficial.

4) Observations

It was not perceived that the proposed template adequately facilitated the capturing of the extent and arrangements for delegation of responsibilities by sponsors, to appropriate persons or organisations.

No responses were received from commercial funders, though ABPI representatives on HRA Collaboration and Development Steering Group were broadly supportive of the approach as a next step in facilitating improvement in this area.

Further work appears to be needed to arrive at a common understanding across sponsors of what improvement looks like. It was commonly suggested amongst respondents that subjective terms in the draft declaration tool such as “proportionate”; “appropriate” were not clear enough, though a proportionate approach was almost unanimously endorsed.

5) Additional or alternative measures

Whilst broadly welcoming this type of approach, in that it is voluntary and was generally viewed as proportionate, respondents suggested some specific other approaches for consideration:

- Training and awareness of sponsor responsibilities to an accredited level

- A “How-To” toolkit for sponsors
- Increased approach from funders to communication with sponsors, and clarity over funder interest in assurances around suitability of sponsors
- A strictly defined reporting mechanism for legitimate concerns about sponsor activity, agreed by stakeholders, and with clear system to target support and action where it is needed.
- Respondents asked that any system of assessing and recording matters relating to sponsor responsibilities be clear in its definitions and parameters, avoiding such openness to interpretation of standards expected as to become meaningless as an assurance. However, it should be noted that simultaneously, respondents requested that such a system be flexible enough to recognise and accommodate risk and proportionality, and different imperatives upon different types of sponsor and stakeholder, as well as the common ground in expectations.

Appendix A : Respondents to the HRA Consultation on Sponsor Responsibilities

NHS/R&D:

Cambridgeshire and Peterborough CCG

The Christie NHS foundation Trust, Manchester

County Durham & Tees Valley CLRN

Great Ormond Street Hospital foundation Trust/ Institute of Child Health Joint Research Office

Manchester Biomedical Research Centre, Central Manchester University Hospitals NHS Foundation Trust

Norfolk & Suffolk Primary & Community Care Research Office

North Bristol NHS Trust

Northern Devon NHS Trust R&D (on behalf of South West NHS R&D)

R&D Forum

Salford Royal NHS Foundation Trust

University Hospitals Birmingham NHS Foundation Trust

University Hospitals Bristol NHS Foundation Trust

UCLH Joint Research Office

Universities:

Birmingham

Bristol

Cambridge

Cardiff

Keele

Liverpool Joint Research Office

Sheffield

Sussex

Other respondents:

Association of Medical Research Charities

Cancer Research UK

Institute of Cancer Research

Wellcome Trust