

Sponsor Fees: Meeting the costs of undertaking activities to fulfil the role of sponsor for non-commercial NHS research

Survey Report

October 2010

Summary

The cost of undertaking activities to fulfil the role of sponsor for non-commercial NHS research is classified as a research cost. In September 2010, 191 NHS R&D Forum members responded to an online survey regarding fees charged. Approximately 30% of NHS/HEI organisations are currently charging fees for undertaking sponsor activities and only 16% do not intend to charge a fee in the future. Detailed fee structures, provided by 16 organisations, showed an average basic fee of £1,000 is charged per study (in some cases per year). A large range of fees are charged depending on type of study e.g. on average organisations charged double the basic fee for sponsorship of Clinical Trials of Investigational Medicinal Products (CTIMPs). With NHS and university budgets under scrutiny there is increasing pressure to ensure all costs for undertaking research related activity are met from an appropriate source. This report raises a number of key issues that warrant further consideration at a national and/or local level - sources of funding, cost versus price and services provided.

Background

The costs of undertaking activities to fulfil the role of sponsor¹ for non-commercial NHS research, although not explicitly referred to in current guidance², are classified as a research cost. Historically, few non-commercial organisations included these costs in grants. However, the landscape has now changed: central R&D Support Funding has been removed; NIHR clinical research network funding supports service support costs of NIHR portfolio studies only; there is increasing financial pressure on NHS trusts and universities to ensure that all funding (clinical and research) is transparent and research costs are all identified and funded appropriately. As a result, the NHS R&D Forum has received increasing requests for guidance on how the costs for sponsorship activities are met and what appropriate fees might be charged.

Method

R&D Forum members were invited to complete an online survey during 7-26th September 2010 in order to collect information on current practice regarding fees charged for sponsor activities (See Appendix 1 for list of questions).

¹ Sponsor as defined by Department of Health (2005). *Research Governance Framework for Health and Social Care*. 2nd edition.

www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Researchgovernance/DH_4002112

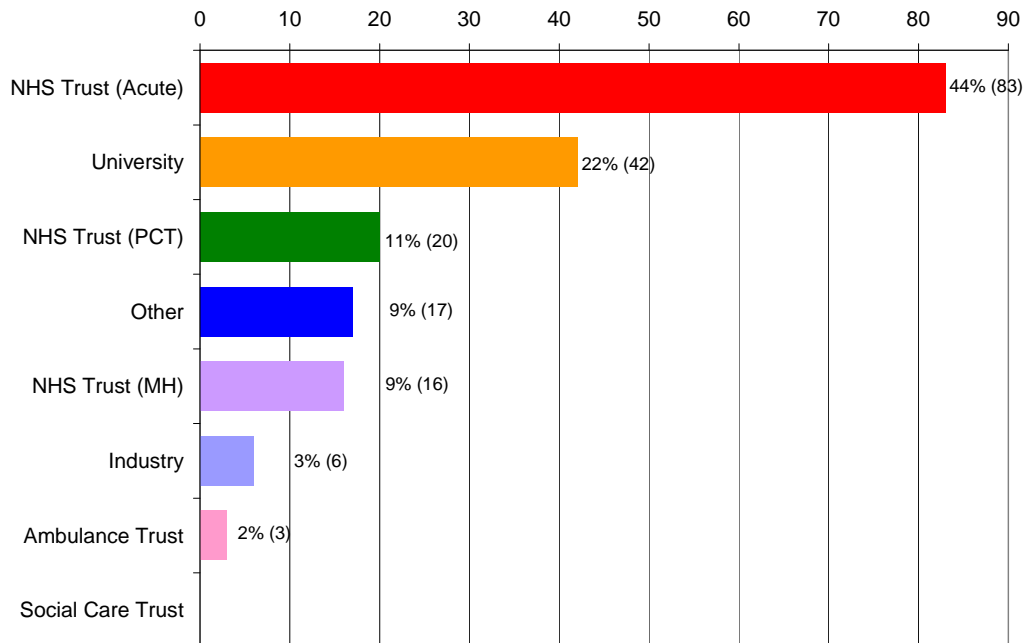
² Department of Health (2005) *Attributing revenue costs of externally funded non-commercial research in the NHS (ARCO)*

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125280

Respondents

191 responses were received, broken down by organisation in Figure 1. Most respondents were from acute trusts or universities. The 'other' category mainly comprised joint NHS/HEI R&D Offices but also included a small number of freelance members.

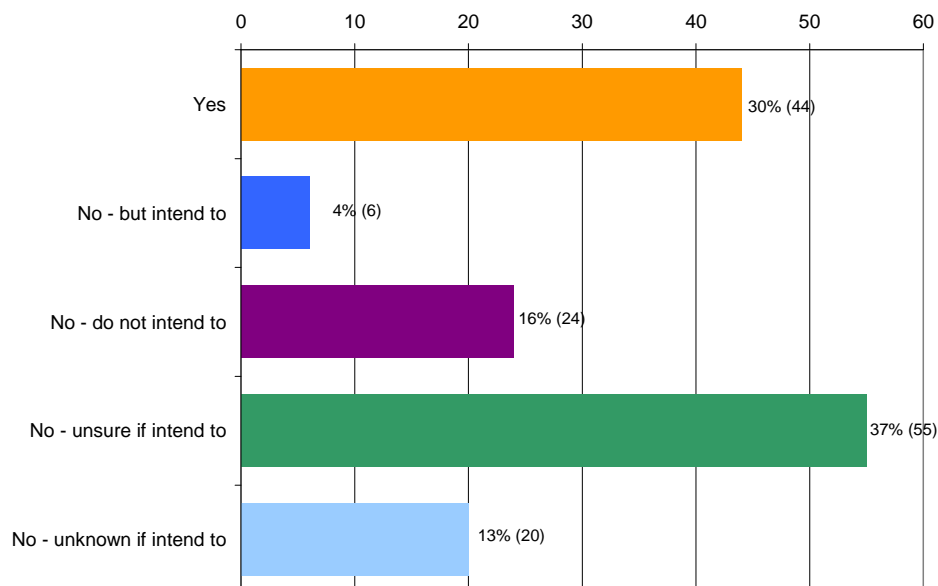
Figure 1: Responses by organisation (n=187)



Results

30% (44/149) of respondents currently (or are about to) charge a fee for sponsor activities. Respondents who do not currently charge a fee were asked if they were likely to charge one in the future - the majority were unsure (Figure 2).

Figure 2: Do you currently (or are about to) charge a fee? (n=149)



Fees charged

Of those that do currently charge a fee, 59% (13/22) charge a one-off fee only, 36% (8/22) charge set-up and annual fees and one commented 'it depends'.

16 respondents provided detailed information on the fees they charge (11 Acute Trusts, 3 PCTs and 2 HEIs). These fees are summarised in Figure 3.

Figure 3: Summary of sponsor fees charged (one-off/set-up) (n=16)

	n	Min	Max	Mean ¹	Median ²
Basic Fee	14	£50	£5,000	£1,329	£1,000
<i>Additional premium charged (on top of basic fee):</i>					
CTIMPs (any)	7	£650	£16,608	£4,608	£1,000
Phase I CTIMPs	3	£750	£950	£867	£900
Student studies (undergrad)	6	£0	£0	£0	£0
Student studies (postgrad)	7	£0	£300	£43	£0
Single centre studies	7	£0	£8,304	£2,001	£300
Multicentre studies	7	£0	£8,304	£2,215	£750
Observational studies	7	£0	£1,000	£257	£150
Interventional studies	7	£0	£8,304	£1,651	£400
Device studies	7	£0	£8,304	£1,651	£400
Questionnaire studies	7	£0	£500	£136	£50
Qualitative studies	7	£0	£500	£114	£0

Note: The fees charged are for sponsor responsibilities only – they do not include other R&D Fees (such for approval or other responsibilities regarding study oversight)

Respondents completed this question to report a variety of fee structures. As a result, it is not appropriate to directly translate Figure 3 into a single overall tariff as the categories are not entirely relative to each other. For example, most did not distinguish between level of student study or phase of CTIMP (many do not sponsor Phase I CTIMPs at all) so this has skewed the relationship between these two groups in Figure 3 above.

Although interpretation of this analysis is complex, some key points can be summarised as follows:

- On average³ organisations charge a basic fee of £1000 to sponsor a study. *However, a large range of fees are charged (£50-£20,000) as one-off or set-up fee depending on the type of study. Some charge a flat rate (same fee for any type of study) and others have a full range of charges for different types of studies*

¹ 'Mean' is the mathematical average of a set of numbers. It is calculated by adding up two or more scores and dividing the total by the number of scores.

² 'Median' is found by arranging all the numbers from lowest value to highest value and picking the middle one. The 'median' is often used in preference to the 'mean', particularly when a distribution is skewed – i.e. there are outliers in the dataset that skew the mean.

³ Median is used in this survey as the preferred statistic for 'average'. The mean is skewed by one respondent charging considerably higher fees (5-10 times) than all the others.

- On average organisations charge double the basic fee for CTIMPs
Although the way fees are charged was different for each organisation it was clear additional fees are charged for CTIMPs/device trials (on average twice the fee than for non-CTIMPs). It was unclear from the responses if fee structures were maximum fees or cumulative (i.e. if fees were added together for multi-centre CTIMPs or if the higher rate is charged where a study met multiple categories) – it is assumed the highest fee (rather than a cumulative fee) would be the most appropriate model.
- In general, organisations charge the lowest (basic or zero) fees for student research, questionnaire and qualitative research
- Only four respondents provided details of the annual fees charged – in two cases these were the same as the set-up fee (therefore the same fee would be charged each year), in the other two the annual fee was 30-60% of the set-up fee.

Sponsor services provided

16 respondents detailed the range of services provided for the fees charged. These are summarised as follows (in order of frequency reported):

- Monitoring / audit including development of monitoring plans, site visits (and associated travel costs), attendance at data monitoring committees
- Contract management including sub-contracts, financial oversight, funder reports
- Site set-up – site files, delegation logs etc
- Pharmacovigilance including safety reporting
- Contribution to sponsor overheads including MHRA GCP inspection fees, environmental monitoring equipment
- Archiving
- Support/advice with regulatory approvals including completion of forms (MHRA, REC)
- Training of study staff (e.g. GCP)
- Advice/Support (24/7, 365 days a year)

Feedback from funders

There is a widespread perception that organisations do not charge fees as funders will not pay them, however this was not supported by responses to this survey. Respondents who charged fees were asked if they had received any feedback from funders when including sponsorship costs in grant applications. 14 provided comments. The majority had received no feedback. For those that had (n=5) the experience was as follows:

“They all accept paying £5k for sponsor fee for non-CTIMP.” (Acute Trust)

“We have had the majority of our fees agreed by the funders” (Acute Trust)

“Generally, not able to claim for this.” (Acute Trust)

“Virtually impossible to cover sponsorship fees from some funders, eg Wellcome Trust.” (University)

“Varied, although (unsurprisingly) the feeling has largely been negative” (PCT)

Funding for sponsor activities in organisations who do not currently charge a fee

Respondents who did not currently charge a fee were asked how they currently fund this activity. Most responded that it was funded as part of the core R&D office and therefore 'funded by the Trust'. Some recognised 'funded by the Trust' meant the activity was actually being funded by Department of Health, CLRN, commercial income, charitable donations or mixture of sources.

A number of respondents commented that this will likely change in the future as Trust budgets are reviewed and there is a pressure to find cost efficiencies. Some respondents commented it is their organisation's policy not to sponsor CTIMPs.

General comments

Respondents were asked for 'any other comments' at the end of the survey. Many commented they would welcome guidance on this issue and support to establish an appropriate fee structure. Examples of other comments are provided below:

"Given sponsor responsibilities for CTIMPS and the current financial/staff climate in both the NHS and University organisations, it may become necessary to implement charges. In addition to sponsorship, it may also be necessary to levy a fee for R&D approval." (University)

"We realised that to fully cost sponsorship would preclude a number of vital clinical trials from occurring. Therefore our fee is considered a contribution towards the overall cost of sponsorship. However, sponsorship is a function that to date has been completely overlooked in terms of support. At present there is no obligation and no incentive for an organisation to act as Sponsor yet without one a study cannot happen." (Acute Trust)

"Charging a sponsorship fee is an additional cost that will further deter clinical research and further adds to the dysfunctional reputation of many NHS R&D Offices." (Mental Health Trust)

"It will be important to standardise sponsor costs for the different types of studies across all NHS trusts to remove the potential for trusts competing for studies based on cost. It will be important to balance recouping true costs of sponsorship and making these transparent with ensuring we don't disincentivise research." (Acute Trust)

Conclusions

A range of fees are currently being charged by organisations to provide sponsor services although on average these are around £1,000 for non-CTIMPs and £2,000 for CTIMPs.

This report intentionally does not propose a specific tariff or guide organisations on what they *should* be charging as the survey raises a number of issues that warrant further consideration locally and/or nationally:

1. Source of funding: If an organisation is to sponsor a study safely (especially a CTIMP) and ensure sponsor responsibilities are undertaken appropriately the organisation should have appropriately resourced systems in place in order to do so. There should be transparency in how this is resourced. Commercial income is helpful to subsidise the system if costs don't cover the fee charged (see point 2 below) but sponsor responsibilities are a research cost. CLRN, NHS patient care and NIHR Flexibility & Sustainability funding should not be used to subsidise sponsor costs.
2. Cost versus price: No assessment has been made in this survey to determine if the fees charged cover the costs of providing such services. Further work to identify the resources necessary to undertake (on average) each sponsor function may be useful.
3. What funders will pay: Fees currently charged likely reflect perceived market conditions. This could be further tested in discussion with funders.
4. Services provided: A range of sponsor services are provided by organisations in this survey. Organisations should make it clear a) what services are provided for any fees charged (by study type); b) which studies they are able to act as sponsor for; c) that fees do not include other R&D Fees (such for R&D approval or other responsibilities regarding study oversight). It is suggested this is also documented in the organisation's Operational Capability Statement (part of the NIHR Research Support Services Framework).

Discussions have been initiated with the Department of Health to consider how the issues raised in this survey might be taken forward.

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Appendix 1: Survey Questions

1. Organisation (NHS Trust/University name)/ email (*text box*)
2. Type of organisation (*tick box*)
 - NHS Trust (PCT)
 - NHS Trust (Mental Health)
 - Ambulance Trust
 - Social Care
 - University
 - Industry
 - Other (please specify)
3. Do you charge a fee for sponsor activities (currently or about to)? (*Yes/No – if yes, skip to Q4*)
IF NO
 - a. How is this work funded currently? (*text box*)
 - b. Do you intend to charge a fee in the future? (*Yes/No*)
Then go to Q11
4. How are your fees structured? (*tick one*)
 - One-off fee only
 - Set up fee and annual fees
 - Other (specify) (*text box*)
5. What is your basic fee (one-off or set-up)? i.e. the minimum you charge. If you charge an annual fee in addition to a set-up fee then this information can be added in following questions
6. Additional premium i.e. £ on top of basic fee (one-off or set-up) for:
Please complete as many lines as relevant depending on your fee structure. It will be assumed for all other studies you charge the basic fee unless specified. For example, a) if you charge a flat rate one-off fee then you would not complete this section b) if the minimum charge above applies only to student studies and all others are charged more, then you would put zero in the student studies line and insert the additional fee charged for all other studies, c) if you only charge extra for CTIMPs then you would only insert a value in this box and leave all others blank as this would indicate the basic fee is charged
 - CTIMPs (any)
 - Phase I CTIMPs
 - Student studies (undergrad)
 - Student studies (postgrad)
 - Single centre studies
 - Multicentre studies
 - Observational studies
 - Interventional studies
 - Device studies
 - Questionnaire studies
 - Qualitative studies
 - Other
7. Annual basic fee (if charged)
8. Additional premium i.e. £ on top of basic annual fee (box for each categories as for Q6)
9. What types of Sponsor services do you provide for these fees? Please give details of what this includes and if different depending on type of study (e.g. frequency of monitoring, type of services) (*text box*)
10. Have you had any feedback from funders when including sponsorship costs in a grant application? (*text box*)
11. Do you have any other comments to make? (*text box*)