SPONSORSHIP AND CENTRAL TRIAL MANAGEMENT FEES POLICY

Document No R&I P02

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
R&I grant development staff; Finance department; Research leads	As required	R&I department

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Summary of changes since the previous version	a) Clarification of roles and responsibilities of staff groups under this policy. b) Updated Sponsorship Fees costing model.

1.0 Executive Summary

All research at the Trust is overseen by the R&I Office. This policy sets out the framework for applying for “Sponsorship Fees” for research studies.

For the ease of researchers, both experienced and novice, the term “Sponsorship Fees” referred to in this policy describes the collective central management costs which should be recouped to facilitate the sponsor (whether the sponsor is the Trust or otherwise) in the execution of their duties as sponsor.

This policy outlines the principles and procedures to be undertaken by the Trust during the grant submission process to ensure that adequate resources are attributed to research studies in order for sponsors to execute their duties.

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2.0 Policy Statement

2.1 This policy outlines the principles and procedures to be undertaken by the Trust during the grant submission process to ensure that adequate resources are attributed to research studies in order for sponsors to execute their duties

3.0 Purpose of the Policy

3.1 To define the circumstances within which the Trust will calculate and apply study specific Sponsorship Fees.

3.2 To define the process for auditing the effectiveness of this policy.

4.0 Scope of the Policy

4.1 This policy applies to:

- **All studies sponsored by the Trust with external funding,** including but not limited to fellowships, staff projects and all other clinical research where a sponsoring organisation is required.
- **All studies where the Trust is delegated specific central trial management activities,** e.g. financial, contract and/or project management activities.
- **All studies where the sponsorship risk proportionate review indicates that the study cannot be delivered in accordance with clinical and research governance without the support of central management activities.**

Where the policy applies, Sponsorship Fees must be requested as part of the grant submission process. There is a recognition that, in theory, a funder may refuse to pay the Sponsorship Fees.

4.2 The following exemptions to this policy apply:

- Student studies, unless the sponsorship risk proportionate review indicates that the scope of the study requires monitoring, e.g. multi-centre, interventional studies etc.
- Low risk studies costed at less than £20,000.
- Studies applying to an Association of Medical Research Charities (AMRC) charity for funding are exempt from the following Sponsorship Fees:

    a) regulatory preparation;

    b) trial fees; and

    c) pharmacovigilance;

  but all other Sponsorship Fees apply.

5.0 Definition of Terms

Term	Definition
Chief Investigator	The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site, as described in the Department of Health *Research Governance Framework for Health & Social Care, 2nd Edition, April 2005*.
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research, as described in the Department of Health *Research Governance Framework for Health & Social Care, 2nd Edition, April 2005.*
Sponsorship Fees	The collective central management costs which should be recouped to facilitate the sponsor (whether the sponsor is the Trust or otherwise) in the execution of their duties as sponsor.

6.0 Roles and Responsibilities

6.1 The Chief Investigator is responsible for**:**

- Notifying R&I as soon as they start thinking about a research proposal.
- Allowing sufficient time for the costing and subsequent approval of all elements of the research proposal.
- Providing sufficient information to allow robust financial review of the final proposal.
- Responding to additional requests for information from R&I pertaining to the final proposal.

6.2 The R&I Office is responsible for:

- Costing and including Sponsorship Fees within research grant applications wherever possible.
- Ensuring that the Sponsorship Fees are appropriately allocated.
- Auditing compliance with this policy.

6.3 The Finance office is responsible:

- Ensuring that costs are allocated to the correct budget code within the appropriate financial year.

7.0 Principles

7.1 All research studies much be costed and resources must be identified.

7.2 Research grants being developed and submitted through the Trust must be reviewed and approved by the R&I Office.

7.3 The R&I Office reserves the right to refuse to review and approve grant costs where the Chief Investigator has given insufficient notice of their intention to submit to permit robust costing and financial planning.

8.0 Procedure

8.1 The Chief Investigator submits a research proposal to the R&I Office for review as early as possible.

8.2 The R&I Office undertakes a risk assessment of the research proposal and identifies risk mitigation plans for the clinical, financial and reputational risks posed by the proposal.

8.3 The R&I Office identifies resources required to mitigate the risk.

8.4 The R&I Office will use a project specific cost tool to allocate Sponsorship Fees against the research proposal that are based around the actual costs required to mitigate the risk. This method allows risk and workload to be accounted for providing actual and justifiable costs. The disadvantages are that it is more complex to apply and therefore more time is needed to include it in grant costings.

8.5 The R&I Office liaises with Chief Investigator to communicate the risk and the mitigation plans and ensure appropriate adaptations, financial or procedural, are made to the research proposal.

8.6 The R&I Office ensures Sponsorship Fees are included in grant submission.

8.7 The above procedure will be adhered to for further amendments to the submitted research proposal, with specific consideration given for the addition of new sites, extended timelines and substantial amendments to study procedures.

9.0 Monitoring Effectiveness

9.1 The below table details the monitoring procedures in order that the Trust can be assured that compliance with a policy is being met.

What will be monitored	**Monitoring/ Audit method**	**Monitoring responsibility *(individual/group / committee)***	**Frequency of monitoring**	**Reporting arrangements *(committee/group the monitoring results are presented to)***	**How will actions be taken to ensure improvements and learning where the monitoring has identified deficiencies**
a) Whether Sponsorship Fees are being applied for in grants submitted, and if not, the reasons why. b) Whether sponsorship costs have been awarded on successful grants.	A report to be run of EDGE data on sponsorship costs and the relevant funding body for the total number of grants: a) that are 'submitted'; and 'successful'; b) where Sponsorship Fees could have been requested; c) where Sponsorship Fees were requested; d) where Sponsorship Fees were fully awarded; e) where Sponsorship Fees were partially awarded; f) where Sponsorship Fees were refused.	Research Operations Manager and Research Development Manager to carry out annual audit.	Annually.	Results of the audit will be reported to R&I Senior Team and the Research & Innovation Group.	We would carry out a project review to identify any issues, develop a plan for improvement and implement any actions, including identifying a rationale for not requested, refused or partially awarded Sponsorship Fees.

10.0 Associated Policies/documents

- R&I P03 Excess Treatment Costs in Research Policy (*currently suspended*).

- Please refer to the North Bristol NHS Trust Standard Operating Procedures: www.nbt.nhs.uk/research

11.0 Reference

- Department of Health *Research Governance Framework for Health & Social Care, 2nd Edition, April 2005* www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962

- Department of Health 2012 '*Attributing the costs of health & social care Research & Development (AcoRD)'* www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133882

- Sponsor Fees: Meeting the costs of undertaking activities to fulfil the role of sponsor for non-commercial NHS research www.rdforum.nhs.uk/content/wp-content/uploads/2014/05/Sponsorfees2010.pdf

- Relevant funder guidelines.

Appendix 1 - Actual Cost Costing Model

Task	Cost	Unit	Basis for cost
Study specific central trial co-ordination and management			
Contract management across sites	£225	per site	2 day Contract Officer
Project Co-ordinator, Band 6 (finance/contracts/vendor management)			Pro-rata based on study complexity
Green light approval - MHRA approved study (site assessment and set up)	£60	per site	2h Clinical Trials Officer (CTO)
Green light approval - non-MHRA study (site assessment and set up)	£30	per site	1h Research Facilitator (RF)
SIV - MHRA approved study	£200	per site	1 day CTO plus travel
SIV - non-MHRA study	£100	per site	1/2 day CTO plus travel
Close out	£100	per site	1/2 day CTO plus travel
Local trial co-ordination and management		project staff	
Regulatory preparation			
Facilitation and delivery team - MHRA approved study	£200	single	Sponsorship review and regulatory submission
Facilitation and delivery team - non-MHRA study	£100	single	Sponsorship review and regulatory submission
Pharmacy technical review	£500	single	
Pharmacy specific sponsorship review	£250	single	
Project staff		as required	
Compliance- MHRA approved study			
Risk-proportionate monitoring	£460	per site per year	2 days CTO or designated monitor
Emergency contact	£60	per site per year	2h CTO
Safety and compliance reporting	£60	per site per year	2h CTO
Compliance - non-MHRA study			
Risk-proportionate monitoring	£230	per site per year	1 day CTO or designated monitor
Emergency contact	£60	per site per year	2h CTO
Safety and compliance reporting	£60	per site per year	2h CTO
Archiving	£152	per box per 10 year period	Iron Mountain
Training	£200	per staff member	GCP and other research training
Trial fees (MHRA, CTA etc.)		as required	
Trial registration fees (ISCRTN etc.)		as required	

Costs should be allocated according to actual planned activity so if monitoring is not required for a study then the cost of monitoring need not be included.