North Bristol NHS Trust

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

Main Author(s):	Helen Lewis-White, Research Operations Manager Rebecca Coad, Research Development Manager
Consultation:	Research & Innovation Senior Team
Approving Committee (and sub-group if relevant):	Research & Innovation Group
Executive Lead:	Tim Whittlestone, Medical Director
Date of Approval:	06 September 2021
Next Review Due:	01 June 2024
Version:	4.1
KEYWORDS:	sponsor, monitor, grant, costs

Summary of changes since the previous version	Appendix 1: Actual Cost Costing Model updated

COMMITTEE DECISION FORM

To be completed as appropriate and returned to author after the Committee meeting

Committee:	Research & Innovation Group
Committee Chair and title:	Tim Whittlestone, Medical Director
Document name:	Sponsorship and Central Trial Management Fees Policy
Lead Author/ Clinician:	Helen Lewis-White
Specialty/ Division/ Trust-wide:	Research & Innovation, Strategy & Transformation
Committee meeting date at which the document was discussed:	06 September 2021

DECISION (please tick appropriate box)

Approved	X
Approved subject to following minor amendments being made:	
Not approved, Amendments required by the author – Chair to be sent amended document – approval will be given when changes are made	
Not approved, Amendments or rewrite required by the author before resubmission to the next Committee meeting	
The Committee made the following comments and required these amendments:	
For further discussion please contact:	

1. Executive summary

All research at the Trust is overseen by the Research and Innovation (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 researchers during the grant submission and financial reconciliation process to ensure that adequate resources are attributed to research studies in order for sponsors to execute their duties.

Contents

2. Policy statement

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

3. 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. Scope of the policy

4.1. This policy applies to:

- All studies sponsored by the Trust with external funding, including but not limited to clinical trials, 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, pharmacovigilance, reporting 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. Where a funder refuses to pay for central management activities (sponsorship fees) the Trust will review the deliverability of the study and make a proportionate decision.

4.2. The following exemptions to this policy apply:

- 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. Definition of terms

Term	Definition
Chief Investigator (CI)	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 UK Policy Framework for Health and Social Care Research. The CI will hold a substantive or honorary contract with the Trust to be eligible for the Trust to act as sponsor.
Sponsor	The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the Chief Investigator in the case of non-commercial research, as described in the UK Policy Framework for Health and Social Care Research.
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. Roles and responsibilities

6.1. The Chief Investigator is responsible for:

- Notifying R&I about developing a research idea so that R&I help shape the proposal.
- Providing a project outline to allow an assessment of the risks and challenges the study may need to manage.
- 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.
- Ensuring adherence to all relevant SOPs and policies when submitting any research grant proposals

6.2. The R&I Office is responsible for:

- Undertaking an assessment of the risks and challenges the study may need to manage.
- Costing and including Sponsorship Fees within research grant applications.
- 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. Principles

7.1. All research trials and research grants must 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. Procedure

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

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

8.3. The R&I Office will identify resources required to mitigate the risks.

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. Monitoring effectiveness

9.1. The below table details the monitoring procedures in order that NBT can be assured that compliance with a policy is being met. It identifies both the processes for monitoring compliance and the actions to be taken where deficiencies and non-compliance are identified. This table must be completed in all policies

9.2. This section describes how the implementation of the policy will be monitored. Audit activity should form part of all policy monitoring; therefore an audit tool/checklist must be appended (or reference made to a national audit the Trust participates in on a regular basis). The below table should be populated with the key areas currently being monitored in addition to any monitoring criteria as required by regulators such as the CQC. This table can be extended as required.

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. Associated policies/procedures/guidelines/documents

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

11. References

- UK Policy Framework for Health and Social Care Research www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

- 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

Where a trial or observational study is embedded within a larger programme of work, the costs should only be applied for the duration of the trial/study not the duration of the whole programme of work.

Task	Cost	Unit	Basis for cost
Study specific central trial co-ordination and management			
Contract management across sites	£360	per study	2-day Contract Officer
Project Co-ordinator, Band 6 (finance/contracts/vendor management)			Pro-rata based on study complexity
Green light approval – Interventional Trials (site assessment and set up)	£48	per site	2-hour Clinical Trials Officer (CTO)
Green light approval - Observational studies (site assessment and set up)	£20	per site	1-hour Research Facilitator (RF)
SIV – Interventional Trials oversight and sign off (with Trials Unit undertaking SIV)	£180	per study	1-day CTO excl. travel
SIV – Interventional Trial (without Trials Unit undertaking SIV)	£180	per site	1-day CTO excl. travel
SIV – Observational studies (would normally exclude survey/qualitative studies)	£90	per site	1/2-day CTO excl. travel
Close out - Observational exclusion as above (with Trials Unit)	£90	per study	1/2-day CTO excl. travel
Close out - Observational exclusion as above (without Trials Unit)	£90	per site	1/2-day CTO excl. travel
Local trial co-ordination and management		project staff	
Regulatory preparation			
Initial HRA review and risk assessment (multi-centre), feedback and submission review for compliance	£862	single	1-day risk assessment and updates. 3-day assessments, feedback, regulatory compliance CTO. 1/2-day Clinical Trials Manager (CTM) and 1-hour senior oversight
Initial HRA review and risk assessment (single centre), feedback and submission review for compliance	£720	single	1-day risk assessment and updates. 3-day assessments, feedback, regulatory compliance CTO
Non-substantial amendment review and compliance checks / assurance (x2)	£120	per year	2.5-hour CTO (x 2)
Substantial amendment review and compliance checks / assurance	£84	per year	3.5-hour CTO
N.B For platform studies where the intention is to use substantial amendment to adapt the study prospectively	£420	per year	3.5-hour CTO (x 5)
Project staff		as required	
Compliance- Interventional Trials			
Risk-proportionate monitoring oversight and sign off (with Trial Unit undertaking monitoring)	£48	per site per year	2-hour CTO or designated monitor
	£180	per study	1-day CTO or designated monitor excl. travel
Risk-proportionate monitoring (without Trial Unit undertaking monitoring)	£360	per site per year	2-days CTO or designated monitor
Emergency contact	£48	per site per year	2-hour CTO

Safety and compliance reporting	£48	per site per year	2-hour CTO
Trial progress meetings	£290	Per year	2-hour CTO (6 per year)
Annual Reports reviews	£96	Per year	4-hour CTO
Final report review, publication reviews, media reviews	£260	One off	1-day CTO, 2-hour Senior Manager
Compliance – Observational Studies			
Risk-proportionate monitoring oversight and sign off (with other Party undertaking monitoring) - would normally exclude survey/qualitative studies	£24	per site per year	1-hour CTO or designated monitor
	£180	per study	1-day CTO or designated monitor
Risk-proportionate monitoring (without other Party undertaking monitoring) - would normally exclude survey/qualitative studies	£180	per site per year	1-day CTO or designated monitor
Study progress meetings	£48	per year	2-hour CTO
Archiving	£152	per box per 5-year period	Iron Mountain
Trial fees (MHRA, CTA etc.)		as required	Included in grant costing
Trial registration fees (ISCRTN etc.)	£272	as required	Include if not portfolio eligible and/or non-interventional
Fees external to R&I			
NBT IG / AI / Specialist technical review	£500	Single	
HRA Pharmacy technical review	£500	Single	
NBT Pharmacy specific sponsorship review	£250	Single	
HRA, or self-led, Radiology technical review	£500	Per radiology type	