COMMERCIAL RESEARCH POLICY

Document No R&I P01

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 department; Clinical researchers; Finance department	Monthly	Division management teams

Main Author(s):	Rebecca Smith, Deputy Director of Research; Helen Lewis-White, Research Operations Manager
Consultation:	Research & Innovation Senior Team
Ratifying Committee:	Research & Innovation Group
Executive Lead:	Chris Burton, Medical Director
Date of Approval:	September 2018
Next Review Due:	September 2020
Version:	4.0
KEYWORDS:	commercial, research

Summary of changes since the previous version	1) Policy updated to clarify that the current national commercial costing template set up fee will be charged (altered from a set amount as this figure changes annually) 2) Updated reference to the current regulations

1.0 Executive Summary

All research at the Trust is overseen by the R&I Office. This policy sets out the framework for conducting commercially sponsored research at North Bristol NHS Trust including:

- Commercial research will be formally contracted to ensure legal and financial implications of the study are addressed.
- Income will be allocated against defined criteria.
- The study will meet national regulations and R&I will issue confirmation of Trust capability and capacity to deliver the study.

Contents

2.0 Policy Statement

2.1 It is the policy of the Trust that all commercial research is appropriately set-up, negotiated, funded and conducted.

3.0 Purpose of the Policy

3.1 This policy sets out the procedural framework for conducting commercial research within North Bristol NHS Trust (the Trust).

4.0 Scope of the Policy

4.1 This policy applies to all commercially sponsored research hosted by the Trust, undertaken by Trust Staff, incurring costs for the Trust or utilising Trust resources (ie it also applies to individuals appointed on honorary contracts with the Trust. Individuals appointed to an honorary contract will be required to give their agreement to abide by the terms of this policy).

4.2 In 1999 NHS Accounting Regulations on charitable funds changed – preventing Trusts from handling commercial research through charitable funds:

> 'When a drug company contracts with a researcher to undertake a clinical trial on its behalf, the contract, which is made between the researcher and the drug company, invariably makes it clear that the results are owned by the drug company. Therefore, even if in due course the results are made available to the public, it is the drug company that receives the results first in order to see if they are capable of being exploited commercially. This is therefore a business service undertaken by the researcher or by the NHS trust (depending on who signed the contract) and not a charitable activity.'

4.3 In accordance with the requirements of the NHS Finance Manual and Health Service Guidelines (HSG 97-32), NHS Trusts are expected to recover all costs of commercial research and development from the company concerned.

4.4 In November 2017 the HRA published the UK Policy Framework for Health and Social Care Research[1] (replacing the second edition of the 'Research Governance Framework for Health and Social Care'). This document defines the responsibilities of investigators, sponsors and Trusts.

4.5 Finally, the UK legislation on the Medicines for human use (Clinical Trials) enacting the European Directive on Clinical Trials, lays down certain legal requirements and restrictions for the conduct of such trials.

4.6 The Trust is the legal body with whom all contracts/agreements must be made. Failure to comply with this places both the Trust and the researcher at risk where legal liability is concerned.

5.0 Definition of Terms

5.1 "Commercial research" is defined as research that is funded and sponsored by a

[1] www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/

commercial organisation.

5.2 The company will design the protocol and own the results and intellectual property rights arising from the research. In general, this research is clinical trials that contribute to the development and/or licensing of a medicinal product or a medical device but may also include post-marketing surveillance studies.

5.3 Research that is funded by a commercial company but where the Trust or another non-commercial organisation retains the intellectual property rights and/or is the sponsor of the study is not covered by this policy. This type of research is known as 'non-commercial research funded by industry' and therefore normal R&I non-commercial research procedures apply.

6.0 Roles and Responsibilities

6.1 R&I will oversee the process of agreeing the costs and contract set out within this policy and for ensuring that income is allocated as per this policy

6.2 Researchers will work with R&I to enable the policy to be adhered to for all commercially sponsored research studies

6.3 Finance or a designated research staff will invoice and allocate income as per the policy. Finance will also ensure that commercial income is placed in a cost centre for that study and that the income is carried forward for continuing studies.

6.4 Division management teams will ensure that any research supporting programmed activity (SPA) allocations to clinicians for delivery of commercial research are funded from the PI income

7.0 Procedure

7.1 For commercial clinical research, the R&I Office facilitate research on behalf of the Trust Board, with a specific role to undertake the following:

- Perform a legal assessment of the contract to minimise risk (negotiation of the clinical trial agreement).
- Determine the price to be charged for each individual trial to ensure ALL costs are covered and overheads are recovered in line with government policy.
- Provide a project management service for investigators to facilitate and co-ordinate interaction between the company and the Trust in order to smooth the progress of trials through the contracting and trial set-up process.

7.2 The earlier the R&I Office is involved in the process of setting up a commercial clinical trial the better. The local investigator will refer the company to the R&I Office at the earliest opportunity.

7.3 **NHS Confirmation of Capability and Capacity**

7.3.1 Trust R&I confirmation will be given providing that:

- A Clinical Trial Agreement has been signed off by the company and the Deputy Director of Research or their deputy or Chief Executive.
- Health Research Authority (HRA) approval has been granted, signifying that all regulatory checks are complete and the R&I Office has received a copy of the HRA application and approval (all parts) enabling the study to be registered in the usual way.
- All support services required for the study have agreed their involvement.

7.4 **Negotiation of the Clinical Trial Agreement**

7.4.1 The R&I Office will negotiate the Clinical Trial Agreement on behalf of the Trust to ensure that the legal and financial implications are properly addressed in the final contract.

7.4.2 For commercial trials commercial organisations will be requested to use the current National Institute of Health Research (NIHR) model agreements which have been endorsed by the Department of Health.

7.4.3 The R&I Office will check the agreement terms are appropriate through comparison with the model Clinical Trial Agreement, confirm the financial schedule (see paragraph 7.4.6 below) and obtain relevant signatures.

7.4.4 Where the commercial organisation does not agree to use the model Clinical Trial Agreement (or other agreed template), in addition, the R&I Office may request further legal review, the costs of which will be expected to be met by the commercial organisation.

7.4.5 The R&I Office will liaise with the relevant Clinical Support departments (eg Pharmacy) to agree costs, the feasibility of the study and the departments' agreement to support the trial. In line with the guidance on the use of the NIHR model agreements, a separate agreement (eg with Pharmacy) is discouraged.

7.4.6 A non-returnable set-up fee, as detailed in the current National Institute for Health Research Comprehensive Research Network Coordinating Centre (NIHR CRN CC)'s Industry Costings Template, will be charged by the R&I Office to the commercial organisation for this process.

7.4.7 Set up fees charged by other departments will be included in the financial schedule where appropriate. It is the responsibility of the relevant department to ensure that any set up fee required is notified to the R&I Office and included in the Clinical Trial Agreement.

7.5 **Costing Commercial Research**

7.5.1 For NIHR CRN adopted Industry studies the commercial company will agree an initial costing using the National Institute for Health Research Comprehensive Research Network Coordinating Centre (NIHR CRN CC)'s Industry Costings Template. The R&I Office will agree with the Principal

Investigator and any affected Support departments the costing for the study. The Finance Department will provide support to the R&I Office as necessary.

7.5.2 The template uses an overhead rate of 70% on all direct costs and a "Capacity Building" charge of 20% on all direct costs (see Appendix 1). The overhead will be top sliced to fund the Trust's average overhead rate of 29%. The remaining overhead, 41%, is to be allocated to the relevant cost centre for the trial and managed by the Principal Investigator.

7.5.3 For Industry studies which are not adopted by NIHR CRN, the Industry Costings Template will still be downloaded and used to agree the costing for the study.

7.5.4 Where a study is locally costed and found to cost more than the fees offered by the company, if the Principal Investigator wishes to proceed, one or all of the following steps will be taken:

- The company costing (if available) will be compared with the local costing and difference identified and discussed with the Principal Investigator. Where the local costing is agreed to be too high this will be amended.
- The R&I Office may approach the company to enquire if further funding can be secured.
- The Principal Investigator may forego all or part of their overhead fee to cover the remaining costs

7.5.5 Once these steps have been completed, affordability will be re-examined.

7.6 **Income Generated**

7.6.1 Invoices will be raised according to the financial schedule agreed within the contract.

7.6.2 The Finance Department will maintain a separate cost centre for each trial and will ensure the carry forward of income on all continuing trials.

7.6.3 The 20% Capacity Building income will be transferred to a central budget, administered by the budget holder for the R&I Office. The funding collected is to be used to provide capacity for research across the Trust.

7.6.4 Elements of the Per Patient Fee attributed to the Principal Investigator's own time will be remitted to the trial cost centre. This approach is used to provide enhanced incentive to researchers to undertake studies. Further elements of the Per Patient Fee undertaken by doctors in training will be treated in the same manner as the Principal Investigator's own time.

7.6.5 The income for other staff will be allocated to the cost centre that funds their

time. If the trial cost centre funds the time, then the relevant element of the Per Patient Fee will be remitted there. However, if, for example, a nurse funded from the Research Infrastructure budget is costed to the commercial trial, the funding attributable to that nurse's time will be remitted to the Research Infrastructure budget. The principle of this approach is that the department that pays for the staff will be reimbursed for the time of their staff. It is hoped that this method will encourage departments to provide staff to trials.

7.6.6 Any investigations carried out by Support Departments will be remitted to those departments according to the charges agreed. Pharmacy charges are on a separate sheet in the Industry Costings Template and will be remitted on the basis agreed to the Pharmacy department's budget.

7.6.7 A financial reconciliation will be completed by the R&I Office, research staff and Research Costing Accountant which identifies the study specific income flow. A copy of the reconciliation will be available for the research team. It is the responsibility of the Principal Investigator to monitor the expected income, recruitment, follow-up visits etc, and liaise with the R&I office, Research Costing Accountant or designated research invoicing staff.

7.6.8 The final balance, including the 41% overhead fee collected by the Principal Investigator is available for use by the Principal Investigator once the study has closed and all payments have been made. Unless otherwise agreed by the R&I Office, no expenditure other than scheduled payments will be permitted until the final balance has been calculated. Appropriate use of the final balance includes funding non-commercial research, attendance at training and conference events, funding research sessions or backfill and purchase of research equipment.

7.6.9 Once the final balance for the study has been calculated the PI will be required to submit a spending plan for the income within the cost centre.

8.0 Monitoring Effectiveness

8.1 The below table details the monitoring procedures in order that NBT 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**
Income and allocation of income generated from commercially sponsored research	An annual financial audit of commercial research income will be completed, by cross-checking data from the financial report against the study information in the EDGE database.	Research Operations Manager to carry out financial audit of commercial study activity	Annually	Results of the audit will be reported on an annual basis to R&I Senior Team and Research & Innovation Group	R&I senior team will ensure that SOPs are updated where deficiencies occur
Allocation of SPA using commercial research income	Requests for research SPA are made via R&I annually. R&I will audit financial income for that consultant to confirm that a SPA is justified and that there is sufficient income to fund it	Director and Deputy Director of Research to confirm that criteria for allocation of a research SPA are met	Annually	Results of the audit will be reported to Division management teams and the Deputy Medical Director	R&I senior team will ensure that the policy is updated where deficiencies occur and provide training and communications around the policy

9.0 Associated Policies/documents

9.1 Allocation of research supporting programmed activity (SPA) time for NHS consultants at North Bristol NHS Trust guidance document.

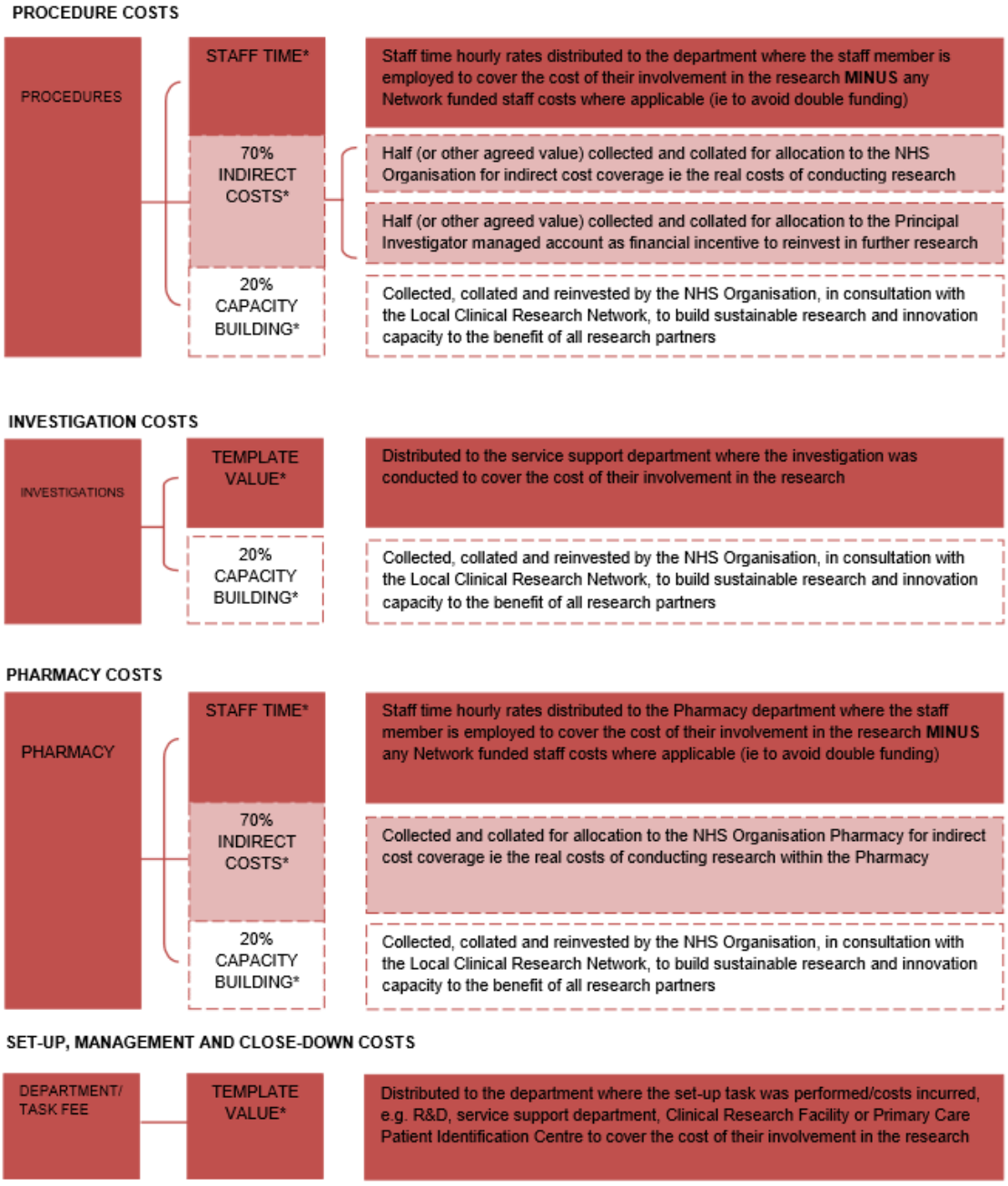
10.0 References

- Research Governance Framework for Health and Social Care, second edition, 2005
  www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/

Appendix 1 - The NIHR CRN CC Industry Costing Template[2]

The Total per Patient Fee represents 190% and is split as follows:

*All values inclusive of the relevant Market Forced Factor uplift for the NHS Organisation



[2] www.crn.nihr.ac.uk/wp-content/uploads/Industry/LCRN%20Guidance%20S12%20-%20Income%20Distirbution%20Model%20Guidance%20v2.0.pdf