Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust

Research & Development

R&D POLICY:

COMMERCIAL RESEARCH

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Document Audit Trail

Version	Date	Author; name & title	Key Changes

R&D POLICY: COMMERCIAL RESEARCH

1. Introduction

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

2. Purpose of this Policy

2.1 This policy sets out the procedural framework for conducting commercial research within Royal National Hospital for Rheumatic Diseases NHS Foundation Trust (The Trust).

3. Scope of the Policy

3.1 This policy applies to all commercially contracted 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 or given Letters of Access with the Trust. Individuals appointed to an honorary contract will be required to give their agreement to abide by the terms of this policy).

3.2 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.*'

3.3 In March 2000 the government published the document 'Research and Development for a First Class Service'. This states that NHS Trust must recover the FULL costs of commercial research from industry:

> *'Industry is the largest funder of health-related R&D in the UK. Much of the R&D funded by industry is undertaken in commercial facilities, but much also involves the universities and the NHS. Government policy is that industry should meet the **full** costs of work that the NHS undertakes for industry under contract.'*

3.4 In February 2001 the government published the document 'Research Governance Framework for Health and Social Care'. This document defines the

responsibilities of investigators, sponsors and Trusts. The responsibilities of the organisation providing care (the Trust) are:

> *'The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.*
>
> *The organisation demonstrates financial probity and compliance with the law and rules laid down by H M Treasury.'*

3.5 2011 – NIHR issues issued guidance for all commercially funded studies which are registered on the NIHR Portfolio; 'Income Distribution from NIHR CRN Industry Portfolio studies'

This states that staff funded by the CLRN and working on commercial studies should have their time repaid to the CLRN. Following this the WCLRN Board agreed on 2nd June 2011 that such income should remain in the host Trust but a clear policy outlining how the income is used in line with the NIHR guidance must be in place.

3.6 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.

3.7 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.

4. Definition of terms

4.1 Commercial research is defined as research that is funded and sponsored by a commercial organisation.

4.2 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.

4.3 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' or Non-industry sponsored studies and therefore normal R&D non-commercial research policies and procedures apply.

5. Duties within the organisation

5.1 For commercial clinical research, the R&D Office facilitates the 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 approval process.

5.2 The earlier the R&D 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&D Office at the earliest opportunity.

NHS Permission (R&D Approval)

5.3. Trust R&D Approval will be given providing that:

- A Clinical Trial Agreement has been signed off by the Company, the Investigator and the Director of Finance. If a separate form of indemnity is used sign off is required by the Chief Executive (plus the medical director (or Chief Executive).
- A favourable opinion from the appropriate NHS Research Ethics Committee has been obtained (MREC/LREC) and the R&D Office has received a copy of the REC approval letter enabling the study to be registered in the usual way.
- A Site Specific Information form, R&D form (IRAS) and RNHRD Data Protection form (all with applicable signatures) have been completed and submitted with all relevant study documentation eg protocol, patient information sheet, consent forms, GP letters etc.
- All RNHRD/Royal United Hospital and Bath Institute for Rheumatic Diseases (BIRD)support services required for the study have agreed their involvement.
- All governance checks have been completed.

Negotiation of the Clinical Trial Agreement

5.4 The R&D 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.

5.5 For commercial trials of a medicinal product, commercial organisations will be requested to use the model Bi-partite or Tri-partite Clinical Trial Agreement approved by the British Pharmaceutical Industry and the NHS (2002). For other trials (e.g. of medical devices) the model Clinical Trial Agreement for Devices should be used.

5.6 The R&D Office will check the agreement terms are appropriate through comparison with the model Clinical Trial Agreement, confirm the financial schedule (see 5.9) and obtain relevant signatures.

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

5.8 The R&D Office will check that the relevant Clinical Support departments (eg radiology, RUH Pharmacy, Imaging and Pathology/Biochemistry/Haematology and BIRD) have been notified by the Principal Investigator or commercial company and have agreed to support the trial. In line with the guidance on the use of the model Clinical Trial Agreement, a separate agreement (eg with Pharmacy) is discouraged but a letter outlining the service to be provided and the payment timescales and terms will be issued.

5.9 A non-returnable set-up fee of at least £756 plus VAT will be charged by the R&D Office to the commercial organisation for this process (paid by cheque, sent with final agreements for signature). Set up fees to cover time spent on study set up by PI/SI/research nurse/therapist and specific fees charged by other support departments will be included in the financial schedule where appropriate.

Costing commercial research

5.10 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&D 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&D Office as necessary and contract will be signed off by the Financial Director.

Income generated

5.11 The template uses an overhead rate of 70% on all direct costs and a "Capacity Building" charge of 20% on all salary costs (see appendix 1). The overhead will be top sliced to fund the Trust's overheads at 30%. This rate will be the budget for capital charges, facilities and corporate departments eg HR finance, IT etc as a proportion of the total direct costs. Of the remaining overhead, 30%, is to be allocated to the relevant cost centre for the trial and managed by the Principal Investigator and 10% towards the R&D office for ongoing support of the trial.

5.12 The 20% Capacity Building income will be transferred to a central Capacity Building Fund, administered by the budget holder for the R&D office in discussion with PI's and the Trust's Financial Director. The funding collected is to be allocated to support research.

This may include, new posts to support research eg. database support, clinical trials co-ordinator etc. not funded from elsewhere and on an annual basis ~~through a "Small Grants' Scheme"~~ by the Clinical Studies Management Group ~~calls as agreed~~ and agreed by the Research ~~Committe~~Committeee, ~~and as necessary to fully utilise funds accumulated. These small grants will be accessible to any staff who have been involved in the conduct of the commercially funded trials.~~

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

5.14 Elements of the Per Patient Fee attributed to the Principal Investigator's own time will also 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 dependant on the employment contract of the SI and source of salary. This reflects their need to undertake or contribute to some research as part of their educational experience. This time is already funded by the ~~PGMDE funding stream within MPET levy~~ Postgraduate Deanery funding stream within the Multi-professional Education and Training (MPET) levy. Where SI's are funded from other sources the time spent on commercial trials may be reimbursed to the cost centre that funds their salary.

5.15 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 R&D budget is costed to the Commercial Trial, the funding attributable to that nurse's time will be remitted to the R&D 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.

5.16 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 RUH Pharmacy department's budget. Direct costs charged by other external organisations will also be passed on direct through the trial cost centre account.

6. Method of monitoring/audit

6.1 The R&D Committee will receive regular information about the commercial activity within the Trust including the amount and distribution of the Capacity Building Fund.

7. Consultation

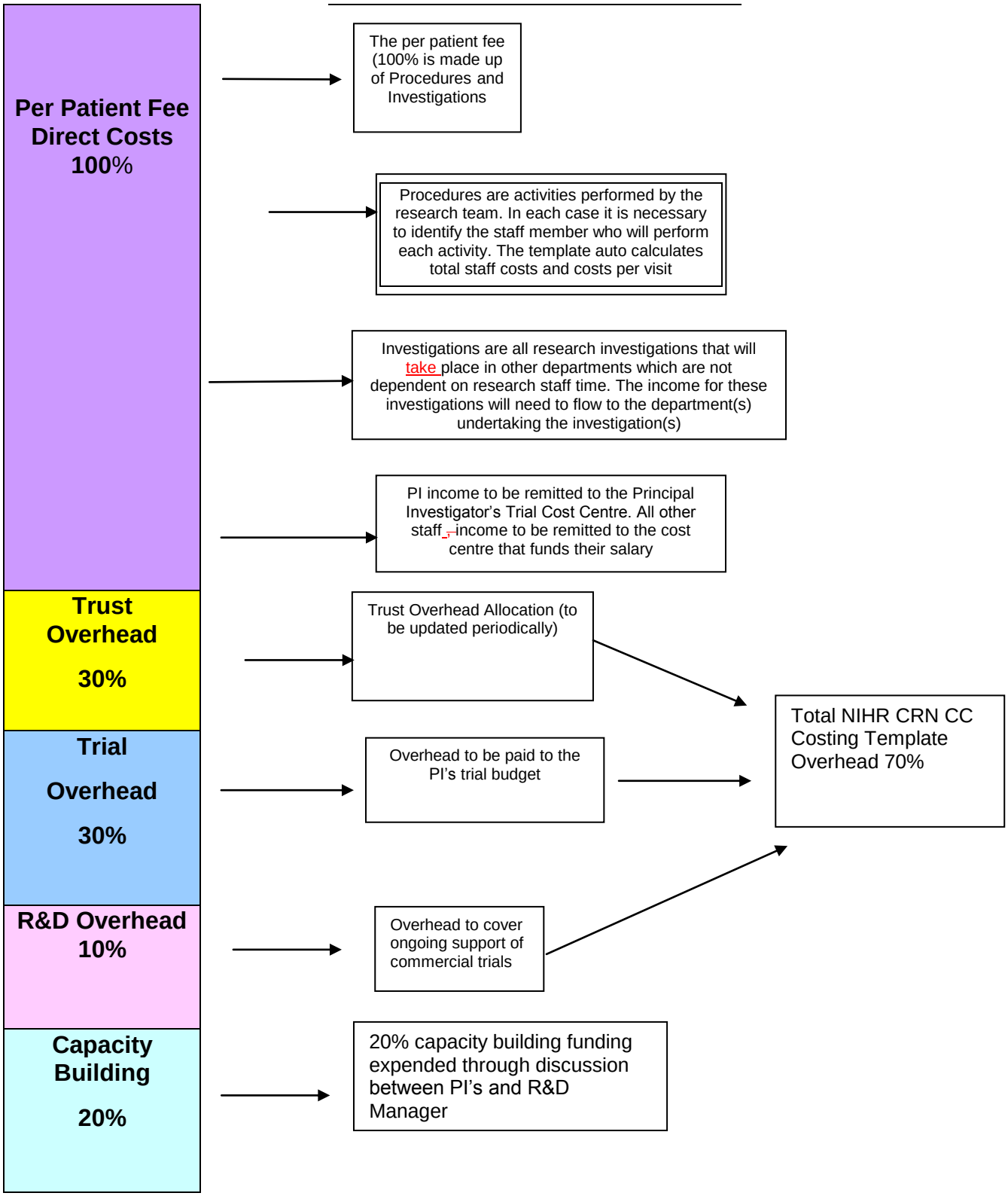
7.1 The Trust's Clinical Studies Management Group, current commercial research project PI's and the Research Committee have been consulted on the development of this policy.

8. References

- Framework for Research Governance in Health & Social Care (Department of Health, 2001) http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance.htm
- Research & Development for a first class service (March 2002) Department of Health http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005946&chk=BXEYyP
- NHS Accounting Regulations (1999) http://tap.ccta.gov.uk/doh/finman.nsf/
- Model Clinical Trial Agreement (ABPI/NHS) and associated guidance http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/PharmaceuticalCompetitivenessTaskforce/fs/en?CONTENT_ID=4002073&chk=V7tQCU
- National Industry Costing template http://www.ukcrn.org.uk/index/industry/costing

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

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



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