NIHR | Clinical Research Network East Midlands

Standard Operating Procedure and Guidance

CRN Portfolio Commercial Contract Research Income

v.1.0 June 2019

Host Organisation: University Hospitals of Leicester NHS Trust

SOP for CRN Portfolio Commercial Contract Research

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NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

SOP for CRN Portfolio Commercial Contract Research

CONTENTS

1. INTRODUCTION

1.1 PURPOSE

In accordance with section C.3.1.13. of the NIHR CRN Performance and Operating Framework 2019/20 V1.0, the LCRN Host Organisation must obtain assurance from the Host and LCRN Partner organisations that NIHR funding is not used to subsidise commercial research.

As per Control CF1 of the LCRN Minimum Financial Controls (V4.0 Jan 2019), the LCRN Host Organisation must have a formal written Standard Operating Procedure (SOP) in relation to CRN Portfolio Commercial Contract Research that Partners must adhere to if they undertake CRN Portfolio Commercial Contract Research.

This SOP provides guidance and outlines the step-by-step process in relation to income generated from NIHR CRN portfolio commercial contract research. It will help to ensure that within the Clinical Research Network East Midlands (CRN EM) commercial research income from portfolio research is managed to the highest professional standards. It includes:

- Clearly defined responsibilities for dealing with commercial income
- Guidance on dealing with commercial income

This SOP applies to all Partner Organisations conducting commercial research within the region.

1.2 OVERVIEW

The Department of Health and Social Care (DHSC) considers the support and delivery of commercial industry-funded and sponsored research to be a priority. Therefore, it is crucial that all stakeholders are sufficiently incentivised to participate in commercial industry-sponsored research. It is important that investigators are incentivised to carry out commercial research, but this should be balanced with the requirements of the Organisation and NIHR CRN to recover their costs, where appropriate.

Income from commercial industry-sponsored research on the NIHR CRN Portfolio has historically been managed in a wide variety of ways. There is, however, a national expectation that appropriate local systems are in place to allow funding flows from NIHR CRN Portfolio commercial research to support investigator incentives and the local infrastructure provided by Local CRNs. (Local CRN Guidance Suite; Income Distribution from NIHR CRN Industry Portfolio Studies V4.0 January 2017)

The NIHR CRN released the first Industry Costing Template in May 2008, which continues to evolve and was most recently released as the Interactive Costing Tool based within CPMS (Central Portfolio Management System). The costing tool has provided companies and NHS Organisations with a single consistent approach to calculating commercial trial costs which is both clear and transparent for negotiating and establishing a price for research within the NHS.

In relation to commercial income there is a requirement to ensure that any NIHR funded costs incurred by the LCRN Host or Partner Organisations (POs), when performing commercial research, are identified, recovered from the commercial Sponsor where applicable and redistributed appropriately within the organisation. Specifically, the LCRN Minimum Controls requires documentary evidence to show POs have a clear governance framework to ensure:

- Commercial research is remunerated in an appropriate, transparent and sufficient manner to allow actual costs of research to be covered and also to ensure organisations are able to build capacity for future research
- There are clear, documented processes within each organisation for the costing of contracts, subsequent invoicing and credit control of such contracts
- There are clear lines of accountability within each organisation around the management and subsequent use of this income, including assurances around CRN income not funding commercial activity.

1.3 BACKGROUND

The CRN East Midlands are keen to move to a more transparent approach whereby we are able to receive regular assurance from partners, that commercial income is being utilised in line with the principles of this SOP. **This SOP sets out 'where' income can be distributed but does not detail exactly 'how', although some examples are provided for guidance.**

Our ambition is to see transparent processes across the East Midlands, which reimburse and reward all stakeholders involved in commercial portfolio research thus supporting the local performance measure of increasing the number of commercial studies in the region. In so doing, this should enable the CRN East Midlands to demonstrate that the NIHR Income Distribution Principles of Good Practice as detailed below (Income Distribution from NIHR CRN Industry Portfolio Studies V4.0 January 2017 p8) are being adhered to at a local level

1.4 NIHR INDUSTRY COSTING TEMPLATE/INTERACTIVE COSTING TOOL (ICT)

The NIHR ICT provides a clear methodology to calculate consistent and transparent prices associated with commercial contract studies to support the Life-Sciences Industry and the NHS. It is mandated to use the standard costing methodology for cost calculation for Industry studies (fully sponsored and fully funded by a commercial company) as detailed in the National Directive on Commercial Contract Research Studies v1.0 26 September 2018.

The ICT supports the full reimbursement for activities associated with industry studies (in accordance with the Health Service Guidelines [HSG] 97-32 detailing the 'Responsibilities for meeting patient care costs associated with research and development in the NHS') while providing clear expectations for Industry. The ICT automatically calculates the full cost of the study and price charged to the commercial sponsor. The template has historically been accepted by partner organisations (Category A, and in many cases other partners operating under Partner B and C contracts) across the East Midlands.

Further information and support regarding the ICT and the development of its cost

structure and values are available on the NIHR CRN Industry website at: www.supportmystudy.nihr.ac.uk. The CRN East Midlands central team offers regular workshops that provide an introduction to the ICT and give an insight into the process, attendance is recommended to finance staff and any other staff involved in costing commercial research studies.

At present, the ICT provided by the sponsor is intended as a starting point for negotiation and is subject to local review prior to finalisation at each PO, work is currently ongoing to move towards the introduction of a single contract value review process, thus SOP will be further updated in due course. The elements that make up the template are detailed below:

Direct costs NHS Staff Time The fee the sponsor pay to cover the cost of the research team's involvement.

Investigation costs NHS direct costs for investigations

Indirect Costs An automatic 70% indirect cost is added to the staff costs only. These indirect costs include physical aspects such as heating, lighting, building maintenance and security, as well as the support functions required to deliver a clinical trial such as finance, general administration, human resources, information systems and corporate management.

Capacity Building A capacity building rate of 20%, is added to both direct staff time costs and investigations. This should be considered as 'system optimisation' which is designed to build sustainable research and innovation capacity to the benefit of all research partners.

Market Forces Factor NHS England, commissioned by the Department of Health, annually publishes a Market Forces Factor tariff via the group 'Monitor' as part of the National Tariff. This factor provides an adjustment value to accommodate the unavoidable cost differences of providing healthcare across the country; this is incorporated into the costing template.

Pharmacy costs Pharmacy costs are calculated separately and not included in the per patient budget. These costs reflect the work involved in the set-up, maintenance and close-down of the study for the pharmacy department, which is not directly dependent on the number of patients.

Set-up and Other trial related costs The pre-trial and ongoing related study costs are managed through the use of set-up fees and separate costs which are assigned to the relevant department. The ICT uses recommended fees based on national averages to provide a list of potentially applicable fees depending on the study requirements.

Once the ICT has been applied to a study, a per patient budget is generated which has all these various costs built in, along with the one-off fees. At this stage the organisation is aware of all the potential income and should be considering how this will be distributed.

2. PROCEDURE PROCESS

2.1 CONTRACTING AND INCOME COLLECTION

It is important that CRN partner organisations have clearly documented processes for effective contract negotiation and subsequent trial management and income collection from commercial sponsors. As a minimum, partner organisations should have in place processes and responsibilities for:

- Liaising with the Sponsor or Clinical Research Organisation regarding any new commercial trial proposal and subsequent negotiations
- Quantification and agreement of the detailed work required to complete a commercial trial, including staff time, interventions and tests required
- Obtaining agreement from relevant support departments such as R&D, pharmacy and pathology
- Ensuring Principal Investigator oversight throughout the process
- Obtaining R&D/I confirmation of capability and capacity (Post HRA Approval)
- Obtaining financial approval prior to contract signature
- Contract signature and record keeping
- Invoicing and Credit Control
- Monitoring and reporting activity
- Income distribution in accordance with organisational policy
- Contract Amendments

As part of the Partner Finance Health Checks that the CRN EM perform with Partner Organisations to review the financial procedures a request will be made for a copy of the commercial income policy (Appendix 1 extract), and assurance around this income

2.2 INCOME DISTRIBUTION APPROACH

Feedback to date has shown an income distribution model is most effective when all income values are transparent to all departments involved through good local accounting allocations, clear distribution rule application and central Organisation oversight (such as by the R&D/I Department). While income is distributed back to individual departments to support engagement in commercial research, the use of this income should be managed and monitored through spending plans which are reviewed and approved centrally by the Organisation. The elements outlined above, which relate to the way the budget for a commercial study is derived, are now considered with respect to income distribution, once received.

Direct costs - (NHS) Staff Time
Direct costs for staff time should be reimbursed to the staff member's department. For commercial studies involving University staff, agreement should be in place between the relevant NHS Organisation and University to agree suitable distribution of the Staff Time costs or the mechanism to be applied to accommodate alternative cost approaches, employed to compensate for the work performed.

Where a post is CRN funded and the person works on a commercial study, if commercial income is received in that year it needs to reimburse the costs of that person, thus freeing up some CRN money and that is re-invested in portfolio research in a well identified way, and in dialogue with the relevant Senior Team Link (STL) for the organisation .
This should be clearly identified in the monthly monitoring returns submitted to the CRN.

Should a member of the CRN East Midland flexible Research Support Team (RST) be deployed to work on a commercially funded study there will be a separate mechanism to manage this which is considered prior to the resource being placed, with clear reimbursement required:

- Joint agreement of actual activities and time required by RST staff
- Update the costing distribution process and provide confirmation back on agreed invoicing/cost recovery process
- A Purchase Order is created by the CRN Finance Team and sent for approval to PO for payment
- Should a CRN flexible member of staff start to support an already active Commercial study, we would then create a CRN income line in the Host ledger to ensure the money followed the activity and support given

Investigation costs
The funding for the investigations (e.g. scans, pathology tests etc.) should go directly to the appropriate support department to cover the actual costs. In some cases these costs may go to a non-NHS provider, if this has been expressly agreed for the provision of their services.

Indirect Costs
The distribution of the indirect cost element varies between Organisations. We recommend dividing this between the NHS Organisation and the Investigator/Research team. The level of this division should be locally agreed, but an example might be 50% paid direct to the Trust to cover corporate and R&D/I costs and 50% to the Investigator's own account held either in their own department or managed by R&D/I, which should be ring fenced to be used for developing further research.

Capacity Building
The intended use of the Capacity Building element within the (NHS) organisation should be clearly documented to support and evidence its reinvestment in research. It is recommended that the Organisations involve the Local CRN in defining the application of this element; this will form part of the discussion within the budget review meeting for each PO.

Pharmacy costs
The funding attributed to pharmacy will return in full to the pharmacy department to cover their actual costs

Set-up and Other trial related costs
It is recommended that POs adhere to the costs provided. The R&D/I management fee will flow to the R&D/I department with other costs being allocated to the appropriate cost

centre where the activity occurs; typically, the Site initiation fee allocated to the research team and the support department set-up fee to the support department.

University Staff
The NHS Organisation and the University should establish arrangements within their local Memorandum of Understanding or service level agreements to recover costs incurred through the involvement in commercial contract studies, which may also include honorary employment contracts where appropriate. The University cost recovered should not exceed those agreed by the NHS Organisation with the Sponsor for the University staff or indeed facilities.

Clinical Research Facilities and resources
CRFs and other NIHR infrastructure units are key assets in the clinical research environment. If any activity or review is led by the CRF then the money should flow through to these units and departments where and when the activity has occurred. This should be agreed locally between the CRF and the R&D departments during set-up and should not impact on the Sponsor discussions.

Independent Sector Healthcare Providers
If any activity or review is led by an independent (non-NHS) organisation then the money should flow through to where the activity has occurred, this should not impact on the Sponsor discussions.

Ensuring cost recovery for study activity
The following proposed mechanisms are suggested to support the full reimbursement of the NHS for activities associated with industry studies (in accordance with the requirements of the NHS Finance Manual and the Health Service Guidelines [HSG] 97-32):

- The Open Data Platform provides partner organisations with the opportunity to produce a list of all the commercial contract research studies that have recruited and closed within the last financial year to support ensuring that an invoice has been raised to reflect the activity.
- It is the role of the PO to monitor invoicing and spend within its organisation and to ensure there are robust internal processes agreed between their Finance and Study teams to execute invoicing in a timely manner. The study contract should clearly state when invoices are raised, we suggest monitoring visits be used as a trigger to support internal invoicing processes.
- If a trial is not monitored for 3 months the CRA is contacted with a list of all visits completed in line with the dates/milestones within the Contract

2.3 LOCAL PROCESS FOR ASSURANCE

To ensure that the above expectations are met, CRN East Midlands has several processes in place, including financial monitoring, annual statements of expenditure and local finance health-checks. This is detailed further in the CRN East Midlands Standard Operating Procedure for the Monitoring of Partner organisations.

Each Partner Organisation has completed a health check questionnaire (Appendix 1) which sought to identify processes in place to manage commercially funded research fund management. Prior to the health check visit, evidence is requested to provide assurance that CRN funding is used according the ACoRD principles and any commercial income is appropriately managed. During the health check visit, there is a discussion regarding commercial study income and how this is managed - this is documented in the feedback for the health check along with any recommendations.

Should any concerns be raised during a health check then this would be followed up to ensure that any actions or recommendations have been implemented until satisfied that contractual obligations are being adhered to.

Appendix 1

3.1 Finance Health Check Questionnaire (September 2017) Commercial Income Exert

CRN EAST MIDLANDS
Partner Financial Health Check
Pre Visit Questionnaire

To be completed and returned to CRN East Midlands by XXX. Please email the completed return to Rachel Webb, Project Support Officer via: rachel.webb@nihr.ac.uk

Background
CRN East Midlands is contracted by the Department of Health (DoH) to undertake timely and accurate budgetary monitoring and reporting on funds paid directly to Partner Organisations. Additionally, CRN East Midlands is required to provide sufficient assurance that NIHR CRN funding is used only on eligible CRN activity, in accordance with DoH funding agreement terms. CRN East Midlands gains this assurance through a range of mechanisms of which the Financial Health Check visits to Partner Organisations is one. This Pre Visit Questionnaire forms the first stage of the Financial Health Check visits.

Please complete the questionnaire below. At present we are not requesting evidence, however if your organisation is selected for a visit, we will be in contact with you nearer the time to request this. We would therefore recommend that you give some thought to the evidence which could be provided at that stage, and include in these sections the evidence you would provide in response to the various aspects of the financial health check

Questionnaire

Ref	Question	Evidence to be provided before Visit	Partner response/ commentary
	Commercial Income		
	What is the current process by which the Partner Organisation ensures that industry sponsored contract research is conducted in accordance with NHS guidelines?		

	Has the Partner Organisations adopted income distribution models (e.g. based on the CRNCC guidance on Industry Income Distribution, or the guidance provided by the CRN)? If so, please can the model be briefly described?		
	How does the Partner Organisation ensure that CRN income, funded staff etc. are not subsidising commercial studies?		