The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Finance Information Requirements for Raising an Invoice

Contents:

Introduction

This guidance document is intended to be used by research delivery teams who have responsibility for advising finance to raise an official Trust invoice to an external organisation in relation to work undertaken for clinical trials or research study.

This document provides a comprehensive overview of the detailed information required by the finance team in order to efficiently and effectively process those requests. The Financial Management Research Finance team will produce a Trust Notification of Debt (NoD) which is forwarded to the Trust Accounts Receivable Finance Team who produces the official Trust Invoice to be sent to the external organisation.

All work undertaken by Research Delivery teams is as detailed in the contractual agreement with the Trust. There are two standard agreements, either between Trust and Sponsor or a tripartite agreement between Trust, Sponsor and Contract Research Organisation (CRO), if Sponsor has delegated management of the trial. The external organisation (Sponsor or CRO) has no obligation to pay for anything not identified in the fully executed contract.

Commercial Studies

Commercial studies should be costed using the NIHR commercial interactive costing template for secondary care; this is used as the basis of negotiation between the Trust Research Delivery Team and Sponsor/CRO to determine the final price relating to the clinical trial.

The information contained on the template should then be incorporated into the model Clinical Trial Agreement (mCTA) supplied by Sponsor for the trial. All information detailed in the contract must agree with that detailed in the costing template which has been agreed between Research Delivery Team and Sponsor for the trial. Sponsors/CRO's generally will not pay any invoices relating to a trial until they have verified the data, we therefore do not raise any invoices until data verification has taken place.

Costs are split into 4 categories on the Industry Costing Template

a. Set-up & other costs
b. Patient visits
c. Additional itemised costs
d. Pharmacy

Set-up costs

On notification of confirmation of capacity and capability by the Newcastle Joint Research Office the finance team receive a copy of the relevant contract. The finance team will at this point set-up the financial cost centre in the Trusts financial accounting system and arrange for an invoice to be raised for all set-up costs identified in the contract. There is no requirement on Research Delivery teams to advise the finance team of anything relating to set up fees to be invoiced unless the contract includes a set up fee based on an hourly rate that is dependent on the number of hours incurred ,for example site initiation.

Pharmacy

The Trust Clinical Trials pharmacy team are responsible for sending information relating to pharmacy costs in contracts to accounts receivable department. There is no requirement on Research Delivery teams to advise the finance team of anything relating to pharmacy to be invoiced.

Patient Visits/ Additional itemised items and all other costs

Sponsors/CRO's vary in the sophistication of their verification data capture and this results in various potential ways of informing the finance team to raise invoices.

Some Sponsors/CRO's following verification visits produce reports itemising detail of invoices to be raised. It should be noted that sponsors vary in what they include in these reports, from purely identifying the per patient visit costs to inclusion of additional itemised costs and potentially all costs identified in the contract.

If the Sponsor/CRO report encompasses all costs, once the Research Delivery Team has agreed the report is correct, the Report should be emailed ASAP to:

researchfinance@nhs.net

With the following detail in the e-mail subject header:

(Action to raise NoD) Cost Centre Number – R&D number – Team number

The request must contain the following details:

1. R&D Number

2. Cost Centre Reference
3. Principle Investigator
4. Sponsor/CRO to be invoiced
5. Protocol Number
6. Requested by – name
7. Sponsor/CRO verification date
8. Purchase Order number if applicable
9. E mail invoice to details (as per the contract)
10. Copy invoice e mail internally to details

Details of costs not contained in a report from Sponsor /CRO and for organisations that do not produce such reports details for invoicing should be notified to the finance team as described below.

Only once patient visits have been verified and agreed by Sponsor/CRO details should the finance team be notified to raise invoice by the completion of Backing for Invoices Template (NJRO-GEN-T-027).

This standard excel file has 4 tabs to complete and a finance summary tab for use by finance department:

1. Patient Visits
2. Additional Itemised Costs
3. Other Costs
4. Patient travel and compensation

This file can be modified to remove unnecessary tabs if Sponsor/CRO includes those details in reports for invoicing purposes as described above.

It is recommended that Teams complete and save using a standard naming convention.

A file relating to each monitoring visit once Sponsor/CRO has validated the data should be emailed ASAP to:

researchfinance@nhs.net

With the following detail in the e-mail subject header:

(Action to raise NoD) Cost Centre Number – R&D number – Team number

There is no requirement for any detail to be put into the body of the e mail as all relevant information required by the Finance team is incorporated into the excel file.

Non-Commercial Hosted Studies

Non-Commercial studies should be costed using the Trust costing template, this is used to inform Trust Research Delivery Teams of the cost of undertaking the study. The costing tool is used as a comparator against the Sponsor's documentation submitted to HRA, detailing payments that would be received if we accepted the offer to be an NHS recruiting site.

For information, if a template indicates that the Trust can undertake the study at a cost less than payment offered which is a rare occurrence, income surplus over expenditure is retained in the study account and transferred to relevant holding account on the instruction of the Principle Investigator (PI).

If the NUTH costing template identifies that the payment offered for the study is insufficient to cover expenditure, then the capacity and capability form requires e-mail confirmation as to relevant authorisation to absorb costs.

The information contained on the template is used for relevant research cost attribution and this is undertaken by the finance team.

Upon notification of confirmation of capacity and capability by the Newcastle Joint Research Office the finance team receive a copy of the relevant contract. The finance team will, at this point, set up the financial cost centre in the Trusts financial accounting system and arrange for an invoice to be raised for all set-up costs identified in the contract. There is no requirement on Research Delivery teams to advise the finance team of anything relating to set up fees to be invoiced unless the contract includes a setup fee based on an hourly rate that is dependent on the number of hours incurred for example site initiation

Pharmacy

The Trust Clinical Trials pharmacy team are responsible for all information relating to pharmacy costs in contracts to accounts receivable department. There is no requirement on Research Delivery teams to advise the finance team of anything relating to pharmacy to be invoiced.

Patient Visits and Additional itemised items

Details of income due relating to per patient visit and any other identified income in addition to a per patient visit is detailed in either the model agreement for non-commercial research in the Health Service (commonly known as a site agreement) or on the HRA schedule of events where the monetary value is less than £10,000 income per study and it isn't a clinical trial. Both of those documents should indicate how funding flows from funder to us as a research site.

Site agreements generally detail per patient fee and the frequency and information requirements for invoicing. For example, if a contract states quarterly invoicing we would expect the research delivery team to use the standard Backing for Invoices Template (NJRO-GEN-T-027) as notification to raise an invoice.

This standard excel file has 4 tabs for completion and a summary finance tab for use by finance:

1. Patient Visits
2. Additional Itemised Costs
3. Other Costs
4. Patient travel and compensation

It is recommended that Teams complete and save using a standard naming convention.

A file relating to each request should be emailed ASAP after the time period specified in the contract to:

researchfinance@nhs.net

With the following detail in the e-mail subject header:

(Action to raise NoD) Cost Centre Number – R&D number – Team number

There is no requirement for any detail to be put into the body of the e mail as all relevant information required by the Finance team is incorporated into the excel file.

Investigator Led Studies

Investigator Led Studies are those where a Trust Investigator has the research idea but funding is provided by a commercial company. These should be costed using the Trust costing template and all costs identified as research costs to be used to negotiate funding from the commercial company.

Details of income due relating to these studies are contained within a contract generally supplied by the funder. The contract should also indicate how funding flows from funder to the Trust.

We would expect the research delivery team to use the standard Backing for Invoices Template (NJRO-GEN-T-027) as notification to raise relevant invoices in line with details in the agreement.

This standard excel file has 4 tabs:

1. Patient Visits

2. Additional Itemised Costs

3. Other Costs

4. Patient travel and compensation

If payment is related to milestones, then use of tab three “other costs” should provide detail of the milestone as per the contract.

It is recommended that Teams complete and save using a standard naming convention.

A file relating to each request should be emailed ASAP after the time period specified in the contract to:

researchfinance@nhs.net

With the following detail in the e-mail subject header:

(Action to raise NoD) Cost Centre Number – R&D number – Team number

There is no requirement for any detail to be put into the body of the e mail as all relevant information required by the Finance team is incorporated into the excel file.