Research Finance – Pre-Award

Introduction

The Pre-Award Research Finance Team is responsible for three main areas of finance in relation to research activity:

- Reviewing and approving applications for grant funding.
- Reviewing and approving trials submitted for confirmation of capacity and capability.
- Reviewing and approving contract amendments.

The main focus of this guidance is on the requirements from a Trial Coordinator during evaluation of studies which are to be submitted to Expert Panel for confirmation of capacity and capability.

Timing

When a study is submitted and validated for R&D review, the R&D finance team may take up to 12 calendar days to review and provide initial comments.
Please ensure you allow for this when planning your submission to Expert Panel.

Check the cost of delivering the trial

Section A – Non-Commercial

Check portfolio status – If a study is put forward as Portfolio adopted, please ensure the portfolio number is provided.
Service Support Costs and in some cases Research Costs (Part B) are funded by NIHR / NHS England where a study is Portfolio adopted.

Validate Service Support and Excess Treatment Costs in line with the AcoRD (Attributing the costs of health and social Research and Development) guidelines. Links to relevant websites and documents are below:

Attributing the costs of health and social care research - GOV.UK (www.gov.uk)

Attributing the costs of Health & Social Care research (AcoRD)

AcoRD - Annex A

The costing tool should reflect all the costs of delivering the research trial, regardless of whether there is funding or not. This enables an informed decision on accepting any trials where it necessary to fund from NuTH resources.
In practice NuTH may decide to undertake a trial where some or all of the costs are not funded fully and some judgement is required on which elements are unfunded as the payment profile in the Trial Agreement may be different to the NuTH costing.

- **Unfunded Research Delivery Team costs**:
  This relates to costs which fall under the research delivery team i.e. research nurse/data manager time, and trial coordination. Where it is identified that these are unfunded, the Delivery Team Lead can authorise the acceptance of these costs, up to a maximum of £3,000.
  If the unfunded costs exceed £3,000 approval from the Clinical Director – Research or Research operations Manager is required.

- **Unfunded Support Department / Research Directorate Costs**:
  The cost of scans, lab tests, pharmacy etc. are borne by the relevant support department, with income from Clinical Trials being allocated to them. Where there is insufficient funding in a trial to cover the cost of these, approval from the relevant support department manager is required for the trial to proceed.
  Where consultant costs are unfunded, approval from the Specialty Clinical Director is required.

- **Unfunded Set up Cost**:
  All clinical trials include some element of setup and coordination costs, including a site file and archiving. The head of the NJRO can accept the costs of archiving as unfunded. All other setup and coordination costs are borne by the Delivery Team, and require approval from the Delivery Team Lead as part of the £3,000 referred to in Unfunded Research Delivery Team costs.

  In some circumstances, unfunded costs may need to be covered from a research holding account.

- **Excess Treatment Costs**
  Where the costing of a trial identifies excess treatment costs, the trial Sponsor should have made arrangements via a SoECAT (Schedule of Events Cost Attribution Tool) submitted to the NIHR for the reimbursement to sites.
  Where this is not included in the Local Information Pack this should be discussed with the Sponsor to identify how these costs will be recovered.

Section B – Commercial

In most cases, Commercial Contracts include prices taken directly from a validated Industry Costing Template. Any variations will be by exception and due to local costs exceeding the national tariffs.

Delivery Teams are required to review the Industry Costing Template from the trial protocol to confirm that the contract value equals or exceeds the cost of delivery, and agree any local variations where appropriate.

Credit Vetting

Where the sponsor is a commercial company, their credit rating should be checked.
The R&D Finance Pre-Award team maintain a list of credit ratings for known sponsors, which is updated and re-issued monthly.
If the sponsor is not included in the list then request a credit vet early in the evaluation stage.
Companies are required to be re-vetted every 3 years as part of our internal policy.
If there are concerns around the commercial company's credit rating, Finance will recommend credit terms for agreement between the Industry Team and Sponsor.

Section C – All Studies

Pharmacy costs need to be verified by Newcastle Hospitals R&D Pharmacy.

Team lead approval needs to be in evidence by way of an email or signature on the Host site Study Capability Form.

Check support department costs with relevant department (e.g. Radiology, Labs, Ophthalmology) – supporting email from the department needs to be provided.

As part of reviewing all contracts / site agreements, whether commercial or non-commercial, we check for terms in the financial appendix which we view as unacceptable (please try to be aware of these before submitting your paperwork for Governance review):

- The financial appendices are required to reflect all aspects of the study funding, including per-patient costs, additional items, other costs, setup fees, and the milestones that trigger payment.
- Payment terms should be no longer than 45 days
- Payment should be quarterly in arrears
- Setup fees should be invoiced on execution of contract
- No retention or holdback of study fees
- Check for a screen fail cap
- Ensure unscheduled visits are paid for
- Travel clause needs to be included, and costs should not be capped.
- Commercial studies – contract needs to match the costing tool
- Check VAT treatment – Some studies need to have VAT included in costing. R&D Pre Award finance can advise.
- Ensure correct contact / invoicing details are included, including a contact email address for invoicing
- The sponsor may require a particular reference to be added to the invoice which identifies this study to the sponsor (for example, some sponsors ask for the protocol number and others ask for the study name)
- Check arrangements for Purchase Order (PO) numbers are properly reflected if these are required

Other R&D Finance Pre-Award Responsibilities

Grant Applications

- review/amendment and final sign off of the NUTH costing tools for grant applications
- review and amendment of application before submission – always if NUTH led (if requested if led by other body)
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Set up (Governance review)

For NUTH Sponsored:

Completion of Financial Appendix for site agreements
Completion of Finance Schedule for Collaboration Agreement
Review and sign off fully completed agreements on contract log

For NUTH hosted:

Commercial - Review clinical trial agreement and costing tools issued by sponsor for sign off on contract log and project register
Non-Commercial - Review site, collaboration agreements and NUTH costing tool for sign off on contract log and project register

Amendments

For NUTH Sponsored:

Prepare financial schedule for amendment and support team to prepare costing tool review and sign off fully completed amendment on contract log

For NUTH hosted:

Review amendment and costing tool and sign off on amendment register
Review and sign off fully completed amendment on contract log

Hand over awarded studies to post award