

**STANDARD OPERATING PROCEDURE**

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## 1. Document History

<b>Version Number</b>	<b>Issue Date</b>	<b>Reason for Change</b>
1	15 <sup>th</sup> May 2014	Original SOP.

## 2. Introduction

Funding bodies support 'high impact' applications which contribute to and benefit participants, society, the National Health Service (NHS), health services, academia and the economy. Research applications are meticulously evaluated, by independent peer review, to ensure that only the most outstanding proposals are funded.

As a major public sector organisation within the NHS, Nottingham University Hospitals NHS Trust (NUH) is publicly accountable for all resource use. Research conducted within the Trust therefore needs to be fully costed with clear accountability of all funds spent. Funding bodies require precise milestones, deliverables and financial reports on how the awards are spent. Underperformance and failing to deliver key milestones may result in funding bodies reclaiming the award. NUH Research and Innovation (R&I) is responsible for the processing of all externally-funded research grant applications and awards received by the Trust. In order to do this the Trust requires all applications made to funding bodies to be checked and endorsed by R&I on behalf of the Trust before the application is submitted. This is done to ensure that the funds requested are sufficient to cover the research being undertaken.

## 3. Purpose and Scope

This standard operating procedure (SOP) applies to any research study grant funding which will require access to NUH participants, facilities or staff. NUH R&I is responsible for all contracted externally funded research grants and awards. R&I offer assistance and guidance in formulating the research grant applications being submitted and ensure financial probity of the application and to ensure successful delivery of the research award.

## 4. Responsibilities

### Head of Research Awards

Has overall responsibility for the research awards process, the strategy and practices from first notification or intention to apply from the Lead Applicant through to closure and final reporting of the Research Award.

### R&I Pre-Award Manager

Coordinates all grant applications and acts as the primary point of contact for all applicants. An email inbox [researchgrantapplications@nuh.nhs.uk](mailto:researchgrantapplications@nuh.nhs.uk) will be regularly checked by the pre-award team and appropriate actions taken.

### Lead Grant Applicant

For all research grants involving NUH participants, facilities or staff it is the responsibility of the lead applicant to liaise with the Pre-Award Manager to ensure R&I review the application **at least 8-12 weeks prior to submission**. This ensures relevant parties are involved and provides accurate attribution of costs and the alignment of the correct type of resources to ensure the successful delivery of research proposals.

Due to the input required from both NUH and collaborating parties in formulating a grant application, NUH cannot guarantee that R&I will be able to accommodate applications made after the 8-12 week deadline nor host any research programs which have not been subject to R&I pre-award review and authorisation.

The Lead Applicant who may also be the Principal Investigator (PI) or Chief Investigator (CI) is primarily responsible for managing their research study. This will involve ensuring that all NUH procedures and potential sponsor requirements are adhered to in full.

However as the authorised signatory within R&I, signs the contract with the research funder on behalf of the Trust, R&I will work closely with the CI/PI to ensure that the funds received are managed in accordance with the contracted timelines and recruitment targets.

## Deputy Director of Research and Innovation

Final sign off of grant application both electronically and subsequently a wet signature. This role may be delegated to another NUH Trust authorised signatory. From here on this role will be referred to as the authorised signatory.

## 5. Definitions

ACAT	The Activity Capture and Attribution Template
AMRC	Association of Medical Research Charities
AcoRD	Attributing the costs of health & social care Research & Development
CCG	Clinical Commissioning Groups
CI	Chief Investigator
CTU	Clinical Trials Unit
DH	Department of Health
Documas	A document management system to assist with the management, control and governance of the research and ethics processes covering research and development projects
ETC	Excess Treatment Cost
FEC	Full Economic Cost
HEI	Higher Education Institute
HRA	Health Research Authority
IP	Intellectual Property
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NUH	Nottingham University Hospitals NHS Trust
NIHR	National Institute of Health Research
PCT	Primary Care Trust
pFACT	Project Financial Appraisal and Costing Tool
PI	Principal Investigator
PPI	Patient /Public Involvement
RGF	Research Governance Framework for Health and Social Care: Ed. 2, 2005
RfPB	Research for Patient Benefit
R&I	Research and Innovation
QIPP	Quality, Innovation, Productivity and Prevention
SOP	Standard Operating Procedure
UoN	University of Nottingham

## 6. Procedure

### 6.1 Initial Meeting with Applicant

- Applicants are required to submit the NUH Intention to Apply form (TAFR00301) to the NUH R&I Pre-Award Manager at least 8-12 weeks (depending on type of award) before the application deadline. A funding checklist (Appendix 2) of possible costs will need to be considered by applicants for their application.
- On receipt, the Pre-Award Manager registers the application in Documas as a new grant in formulation and allocates an R&I reference number. The Pre-Award Manager reviews the form and circulates this to relevant colleagues to consider what resources are required to ensure and facilitate a successful and productive meeting with the applicant.
- The Pre-Award Manager will coordinate the first pre-award meeting with the applicant(s) and relevant staff who will support and guide the applicant(s) throughout the development and submission of their application.
- The financial calculations need to be established at a fairly early stage to ensure that the grant applied for covers the costs of the project and demonstrates adequate resources to deliver the proposal.

## 6.2 Sponsorship

- The Pre-Award Manager will advise as to which legal entity is most appropriate to act as the research sponsor for the proposed research.
- The role of research sponsor is central in the governance and delivery of studies. The Department of Health Research Governance Framework for Health and Social Care (RGF) continues to provide the basis for best practice and the Health Research Authority (HRA) has recently clarified its expectations of research sponsors. NUH is able to act as research sponsor in accordance with the HRA guidance.
- For National Institute of Health Research (NIHR) projects and programmes there is a clear expectation (set out in NIHR guidance) regarding host organisations and sponsorship – e.g. for Research for Patient Benefit (RfPB) grants the Trust is always the holder of the grant but the sponsor can be a Higher Education Institute (HEI) or associated body which meets the HRA sponsor guidelines.
- The organisation that employs the CI would normally expect to be the sponsor, however the Trust is happy to act as sponsor in support of CIs with honorary contracts with the Trust while their substantive employment rests with a University, for example.
- It is recognised that it is not always possible to provide NUH R&I with a full protocol and document set prior to an 'in principle' decision to sponsor. Once the funding has been granted a full application for sponsorship is required as part of the governance review.
- The NUH R&I sponsorship review process must be completed before a final decision is made, (refer to SOP-RES-001 Sponsorship).

## 6.3 Identifying Costs for a Grant Application

### 6.3.1 Major Costs

- The major cost in the majority of grant applications is salary costs. NUH R&I finance can help calculate these for NHS staff accurately for the duration of the proposed study. This covers all applicants and participants involved from start to completion, dissemination and in some cases exploitation, depending on the study and award complexity.
- For University staff costs, the applicant must approach the relevant University finance team and request assistance. The University of Nottingham (UoN) calculates the costs using the project financial appraisal and costing tool (pFACT) system; most funding bodies will award 80% of the cost calculated. NHS costs are 100%. The University of Nottingham Finance team supplies a Full Economic Cost (FEC) figure generated from their pFACT to NUH R&I Finance. Finance managers will request access to the application form to complete the form as required. The relevant University manager/finance officer must approve the costs.
- Where there are collaborators from external institutions, the applicant must coordinate the submission of these costs for population within the application. R&I finance captures the finances encapsulating: NHS, HEI, multi-site, Clinical Trials Unit (CTU), Excess Treatment Costs, direct and indirect costs.

### 6.3.2 Indirect and Direct Costs

- NUH R&I provides comprehensive and expert management and support throughout the life cycle of a research study from initial concept through to application, regulatory approvals, study conduct and completion, Patient/Public Involvement (PPI), Intellectual Property (IP) management and dissemination of results. These are legitimate research costs which are calculated transparently and are dependent on the complexity of the research proposal and the extent of NUH involvement.
- The University of Nottingham pFACT software includes University estates and indirect costs (overheads). Some funders allow these costs to be applied for, and some will not pay them. HEIs especially have to agree that they will underwrite their indirect costs when these are not paid by the funder. The NIHR will pay university indirect costs (up to 80% of the FEC) in some but not all of its awards (guidance will be provided by the Pre-Award Manager). (Charities will not pay any indirect costs).

### 6.3.3 Other Costs

- The funding checklist (refer to Appendix 2) prompts applicants to consider other costs which are often not considered.

### 6.4 Attribution of Costs

- There are three types of cost associated with *clinical* research studies in the NHS:
  - i. **"Research"**;
  - ii. **"Support"**; and
  - iii. **"Treatment"**.
- The NIHR and other funders (e.g. Association of Medical Research Charities (AMRC)) will ask for a detailed breakdown of all these costs.
- The Activity Capture and Attribution Template (ACAT) has been developed to support researchers to apply the **AcoRD** guidance to identify fully and attribute correctly the activities being undertaken as part of a research study.
- AcoRD defines the costs as:
  - i. **Research Costs:** the costs of the research and development itself that end where the research ends. They relate to activities that are being undertaken to answer the research question.
  - ii. **NHS Support Costs:** the additional participant care costs associated with the research, which would end once the R&I study in question had stopped, even if the participant care involved continued to be provided.
  - iii. **NHS Treatment Costs:** the participant care costs, which would continue to be incurred if the participant care service in question continued to be provided after the research study had stopped.
  - iv. **Excess Treatment Costs (ETC):** If there are any ETC they must be agreed in principle with the Trust prior to grant submission. For significant ETCs a business case must be submitted to the Clinical Commissioning Groups (CCG) *prior* to any grant submission.
- The early attribution of the costs associated with research enables the Trusts and their commissioners to build these costs into their financial and commissioning plans. The distinction needs to be made between the three categories of costs associated with non-commercial research studies; (Research Costs, NHS Support Costs and Treatment Costs) in liaison with the Trust in advance of submitting full grant proposals.
- By identifying the participant pathway within the research proposal/protocol, the pre-award team will help guide the research applicant as to which costs fall under which category.
- Provider organisations including community provider organisations are expected to fund their own ETCs (as per Department of Health (DH) guidance). If provider organisations cannot fund ETCs for a particular study, they need to submit an application to the commissioners for consideration.
- For any ETCs incurred in primary care or public health, (i.e. incurred in GP practices, community pharmacies, etc.) then an application should be submitted to the CCG for consideration. Health professionals are now much more involved in planning, monitoring and buying the NHS services that people need locally, making sure they are high quality and value for money. These services might be in hospitals, health centres or other community settings.
- Nottingham City CCG has a process in place for reviewing applications; the Prioritisation and Quality, Innovation, Productivity and Prevention (QIPP) Panel meet monthly and make decisions on ETCs. The health services Nottingham City CCG commission, include hospital services run by NUH, mental health and learning disability services run by Nottinghamshire Healthcare Trust and community services provided by Nottingham CityCare Partnership.

### 6.5 Submission of Final Grant Application

- The grant Lead Applicant must familiarise themselves with the submission guidance applicable to the award and coordinate all co-applicants to complete and authorise the application.

- It is advisable that applicants discuss the application briefly with the relevant signatories before they receive these documents for approval as different funding bodies may have unique final processes and timelines.
- Allow sufficient time for this stage of the process to be completed. **Seven working days before the submission deadline** must be allowed for checking and amending as required.
- The pre-award team facilitate the sign off for Trust led applications (see Appendix 3).
- R&I finance review all costs to ensure accuracy and alerts the Pre-Award Manager that the process is complete.
- The Pre-Award Manager subsequently notifies the R&I authorised signatory to expect a request for authorisation from the applicant electronically.
- The applicant is instructed by the Pre-Award manager to proceed to request Trust sign off.
- The authorised signatory electronically authorises the application online and the applicant is alerted that this process has been completed.
- R&I request a PDF copy of the submitted final application plus appendices **within three working days of submission**.
- Post submission, wet signature authorisations signed by the authorised signatory are posted out as per application guidelines.

If NUH is not the lead institution but is a co-applicant on an externally led application then then R&I will request a copy of that final grant proposal for auditing and invoicing purposes. R&I remain responsible for the oversight, financial management and relevant reporting of all co-applicant relevant elements of the award

## 7. References and Associated Documents

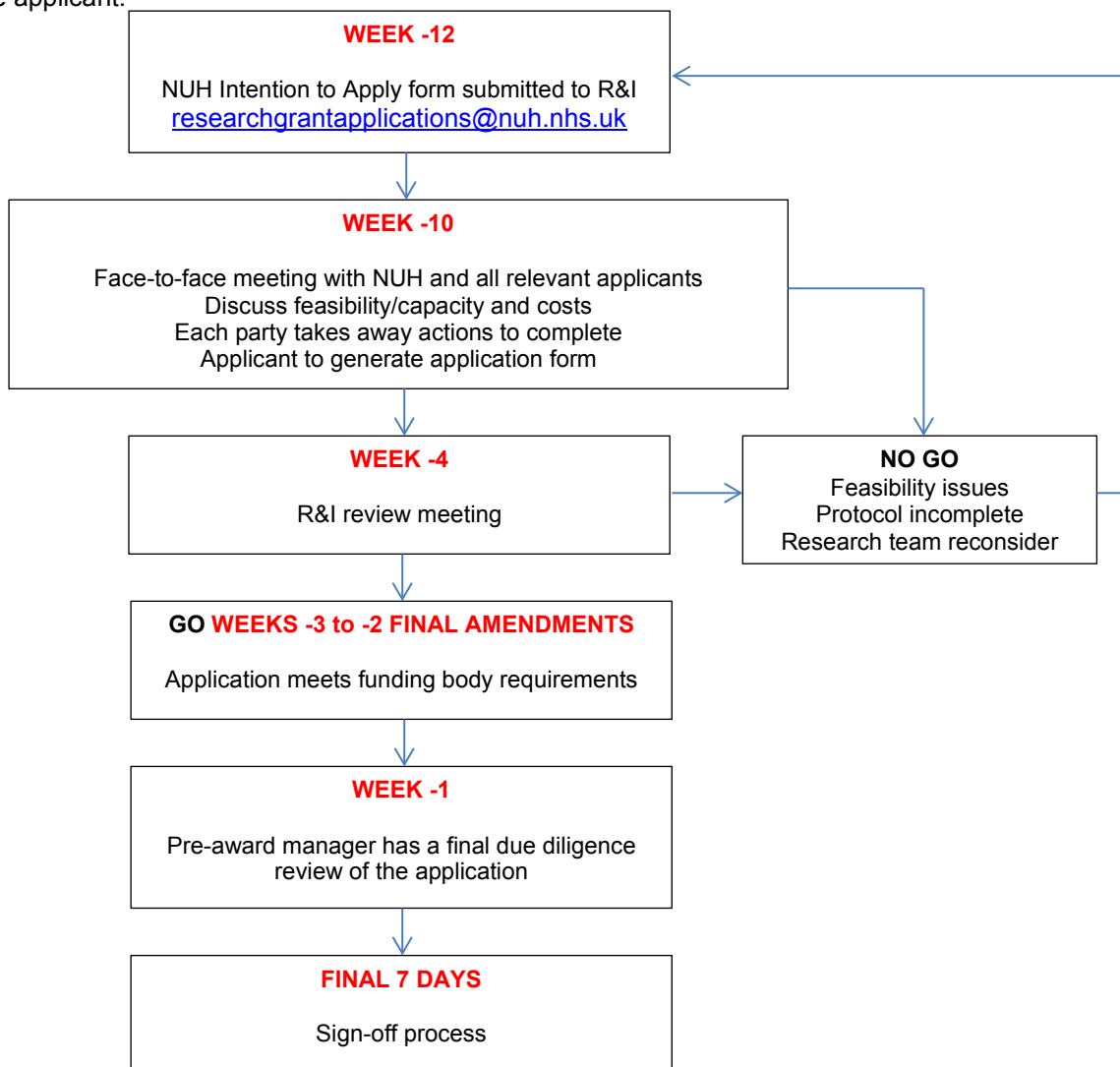
AcoRD: Costs need to be attributed in compliance with AcoRD Annex A: Parts A and B. Please refer to the NIHR website for the guidance  
Guidance on costing attribution, details, documentation, training and costing template for Attributing Costs of Activity (ACAT) are available on the NIHR website  
Research Governance Framework for Health and Social Care: Second Edition, 2005  
NIHR Website

TAFR00301 NUH Intention to Apply Form  
SOP-RES-001 Sponsorship

## 8. Appendices

## Appendix 1. Time-Line for Grant Process

All awards require institutional sign off prior to submission. It is expected that the NUH Intention to Apply form (TAFR00301) is submitted at least 8-12 weeks before the deadline depending on the type of grant. Seven working days before the submission deadline are allowed for checking and amending as required. The Pre-Award Manager operationally oversees the process and is in continual contact with the applicant.



These timelines are a guide to a successful review and a strong application.

(If a HEI is the lead, NUH R&I submit the finances to them and request a copy of the final application on submission).



## **Appendix 2. Funding Checklist - costs to consider**

### **Staff Time – Research Team**

- Basic salary (Band/Scale)
- On-costs of an employee (the true cost including National insurance and Superannuation)
- Increment date and incremental rises
- Inflation (if applicable)
- Whole time equivalent
- Set-up time
- Research related activities
- Time on steering committees
- Time in meetings/training
- Close down time
- Analysis of data
- Write-up
- Dissemination

### **Equipment**

- Computers/tablets/portable devices
- Annual service fee/registration fee
- Specialist software
- Printers
- Specialist lab equipment
- Additional/Specialist diagnostic equipment.

### **Travel and Subsistence (can come under direct costs)**

- PPI: refer to the NIHR INVOLVE COSTING guidance <http://www.invo.org.uk/resource-centre/resource-for-researchers/>
- This will help cost patient/public representative expenses/refreshments, travel expenses for participants
- Research team travel and subsistence
- Travel to and from any meetings for investigators at other sites
- Travel and subsistence for any training events
- Travel and subsistence for any conference

### **Consumables**

- Consumables used for taking/analysing samples
- Stationery/printing costs (relevant study related documents)
- Telephone/fax

### **Other Direct Costs**

- Consultancy fees
- Payments to GPs
- Honorarium for patient/public representative
- Room hire for meetings
- Catering for meetings
- Conference fees
- Furniture
- Licences for software or questionnaires etc.
- Patent fees/maintaining patents
- MHRA fees (annual charges) plus contingency for amendments (£250 each)
- Registry fees
- Journal databases e.g.: Directory of Open Access Journals (DOAJ)~£1200
- Sponsorship fees/project management/QA

- Randomisation
- Database hosting
- Investigation costs (specifically for research and not part of diagnosis/treatment)
- Placebo costs
- Archiving

### **Care Costs**

- Staff identified as Support Cost
- Estimated band basic salary and on-costs (maybe staff employed by a topic specific network)
- Time to review study (local investigator, support department heads etc.)
- Recruitment time/consent process (per participant)
- Time reporting
- Additional outpatient time required for participants
- Additional time as an inpatient for participants
- Additional time in theatre
- Support of other departments for activities over and above routine care
- Pulling medical records
- Pharmacy dispensing
- Additional lab tests for ensuring patient safety
- Administration time (e.g. sending letters)
- Time on study related activities (per participant)
- Time in meetings/training

### **Excess Treatment Costs**

- Drug Costs
- Cost of new clinic or service/patient pathway
- Cost of additional equipment

### **Inflation**

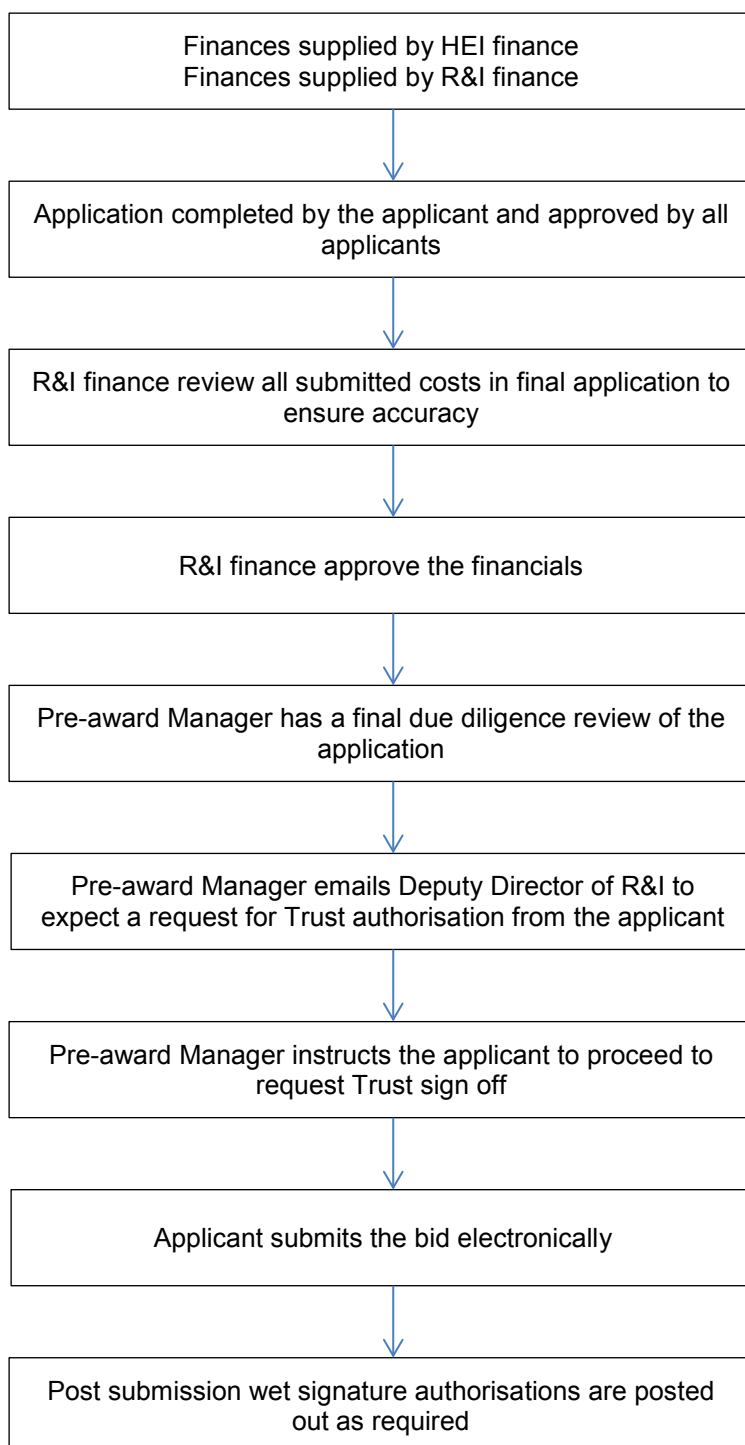
Studies that run for two years or less should have fixed study prices. Studies that will run for longer should have their costs adjusted.

### **Overheads**

Overheads are an integral part of the price to be paid for carrying out research. They ensure that NHS organisations are fully reimbursed for the cost of carrying out research, including those activities that cannot be readily itemised.

### Appendix 3. Sign off Process

All awards require institutional sign off prior to submission. It is expected that 7 working days before the submission deadline are allowed for checking and amending as required. Applicants are advised to alert their relevant directorate/management signatories before they receive the documents for approval and to allow sufficient time for this stage of the process to be completed.



(If a HEI is the lead, NUH R&I submit the financials to them and request a copy of the final application on submission).