

SOP 005 Grant Application

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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2. Definitions of Terms Used / Glossary

ACoRD	Attributing the costs of health and social care Research and Development.
CI	Chief Investigator
CRN	Clinical Research Network
CTIMP	Clinical Trial of an Investigational Medicinal Product
NCTU	Norwich Clinical Trials Unit
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
QI	Quadram Institute
R&D	Research and Development
RGC	Research Grants Coordinator
RIN	Research Innovation Services
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Objectives

This SOP describes the process for NNUH staff writing and submitting a grant application to external funding bodies. UEA has its own internal processes.

4. Scope

This SOP describes the process to be followed by researchers who are intending to submit a grant application for research funding to an external funding body. This SOP applies when the NNUH is the lead organisation or when any NNUH staff, services or patients are involved in the proposed research project.

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5. Purpose

The purpose of this SOP is to ensure that grant applications have been appropriately costed by the R&D department in line with the ACoRD guidance and have the relevant approvals in place prior to submission. This will ensure that if funded, the project will have sufficient funding in place to cover the costs of the resource required to deliver the objectives of the study and that any NNUH research staff on the grant are contracted to the project for the appropriate duration of time. See appendix 1 for a summary of the process.

6. Rules

The R&D department should be contacted as early as possible for assistance at every stage of the application process.

- An intent to write a grant application form (Appendix 3) should be completed and sent to R&D when the idea is being developed.
- Developing a competitive proposal of high quality takes a considerable amount of time. The RGC should ideally be made aware of the proposal at the stage when the idea is being developed. Timings listed below are indicative timings to provide costs for standard applications. For complex applications (e.g. having complex costing, involving multiple collaborators or subcontractors) approximately 3 months should be given.
- For grant applications led by NNUH, the notice period will depend on the complexity of the study but 6 to 12 weeks may be required.
- For grant applications whereby NNUH is requested to sponsor (please see the NNUH Sponsorship Policy) a CTIMP or device study, these are generally complex studies and 3 months' notice may be required.
- For grant applications where NNUH/NHS costs are being requested, but NNUH is not the lead or sponsor the notice period will depend on the complexity of the study but 4 to 8 weeks may be required.
- To allow review / authorisation of submission, the costs and application need to be finalised no later than 5 working days prior to submission (Single stage or Stage 2 applications generally require authorisations from potentially: Sponsor, Head of Department, Administrative Authority or Finance Office, NHS costs nominated signatory, NHS Facilities and Staff Nominated Signatory. The RGC will inform you who will be the nominated people for these roles. If not enough time is allowed for final reviews, authorisations may be declined and you will be unable to submit)








All grant applications led by or involving NNUH staff, services or patients require R&D authorisation prior to submission

- Grant applications made without authorisation might result in the rejection of the award if funded.




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7. Procedure NNUH

7.1 Procedure for when NNUH is the lead organisation or Requested to be Sponsor

      	<p>If the study requires NNUH to be the lead/Sponsor organisation :</p> <ul style="list-style-type: none"> • the CI will contact the Research Grants Coordinator and complete an Intent to write a Grant Application Form (or forward a copy of the UEA Intent to Write form if already completed) (see appendix 3 – Grant Application Form), as early as possible (see Appendix 2 - Proposal Process). • If a funding stream has not been identified the Research Grants Coordinator will be able to help to identify an appropriate source of funding where the project will fit within the funder's remit. • The Research Grants Coordinator will schedule a costing meeting with the researcher(s). Colleagues from UEA RIN (or appropriate University) and NCTU (or alternative CTU choosing by the investigator) will also be invited if their input is required. • At the costing meeting the amount of resource required will be discussed and all of the costs will be identified. • The Research Grants Coordinator will provide the full study costing to the researcher for review. Changes may be made at this point if necessary. If a SoECAT is required that will be prepared and sent to the researcher for review. Then sent to the CRN for authorisation. • When the costs have been finalised the Applicant will seek authorisation for submission from the appropriate person at each participating organisation (5 working days prior to deadline). • When authorisation is in place from NNUH and any other organisation, then the researcher will be notified that the grant has permission to be submitted.
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7.2 Procedure for when NNUH is not the lead organisation

  	<ul style="list-style-type: none"> • If the study involves NNUH staff, services (including Digital Health, Information Governance, R&D, use of the QI Clinical Research facility, the Norwich Research Park Biorepository) or patients, the CI, lead Research Office or CTU will contact the Research Grants Coordinator and complete a Requesting Costs from NNUH for a Grant Application Form or forward a copy of the UEA Intent to Write form if already completed (see Appendix 4 - Requesting Costs from NNUH for a Grant Application) as early as possible (see Appendix 2) • For grants led by UEA or QI, the Research Grants Coordinator will attend the UEA/QI costing meeting where possible so a further costing meeting will not be required • For grants where NNUH staff are co-applicants and/or there are little NHS resources are needed, email correspondence will be sufficient
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- At the costing meeting the amount of resource required will be discussed and all of the costs for NNUH will be identified.
- The Research Grants Coordinator will provide the costs attributed to NNUH staff, services or patients to the researcher for review. Changes may be made at this point if necessary. If a SoECAT is required that will be prepared and sent to the researcher for review and then sent (by the CI, research Team, CTU or Research Grants Coordinator) to the CRN for authorisation.
- When the costs have been finalised the Research Grants Coordinator will seek authorisation for submission from the appropriate person (5 working days prior to deadline).
- The Research Grants Coordinator will notify the researcher and relevant UEA Project Officer when NNUH authorisation is in place. **WARNING: Applications cannot be submitted by the lead applicant until all organisations involved have provided authorisation to do so.**
- It is the responsibility of the lead applicant (or UEA Project Officer for UEA led applications) to send a copy of the submitted application to the Research Grants Coordinator for their records

Funding Outcomes

- It is essential that the R&D office is notified of the outcome of the funding application so that the record can be updated.

8. References and Related Documents


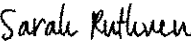
References

ICH GCP E6 / SI 2004/1041

SOP No.	SOP Title
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities

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9. Approval

Author	Michael Sheridan
Role	Research Grants Coordinator
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	<small>DocuSigned by:</small>  <small>4CBAB366CF354A2..</small>
Date	04 November 2022
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	<small>DocuSigned by:</small>  <small>6EB42B4E497249C..</small>
Date	15 November 2022 3:14 GMT

10. Reason for new version and Training Implication

This is a new SOP.

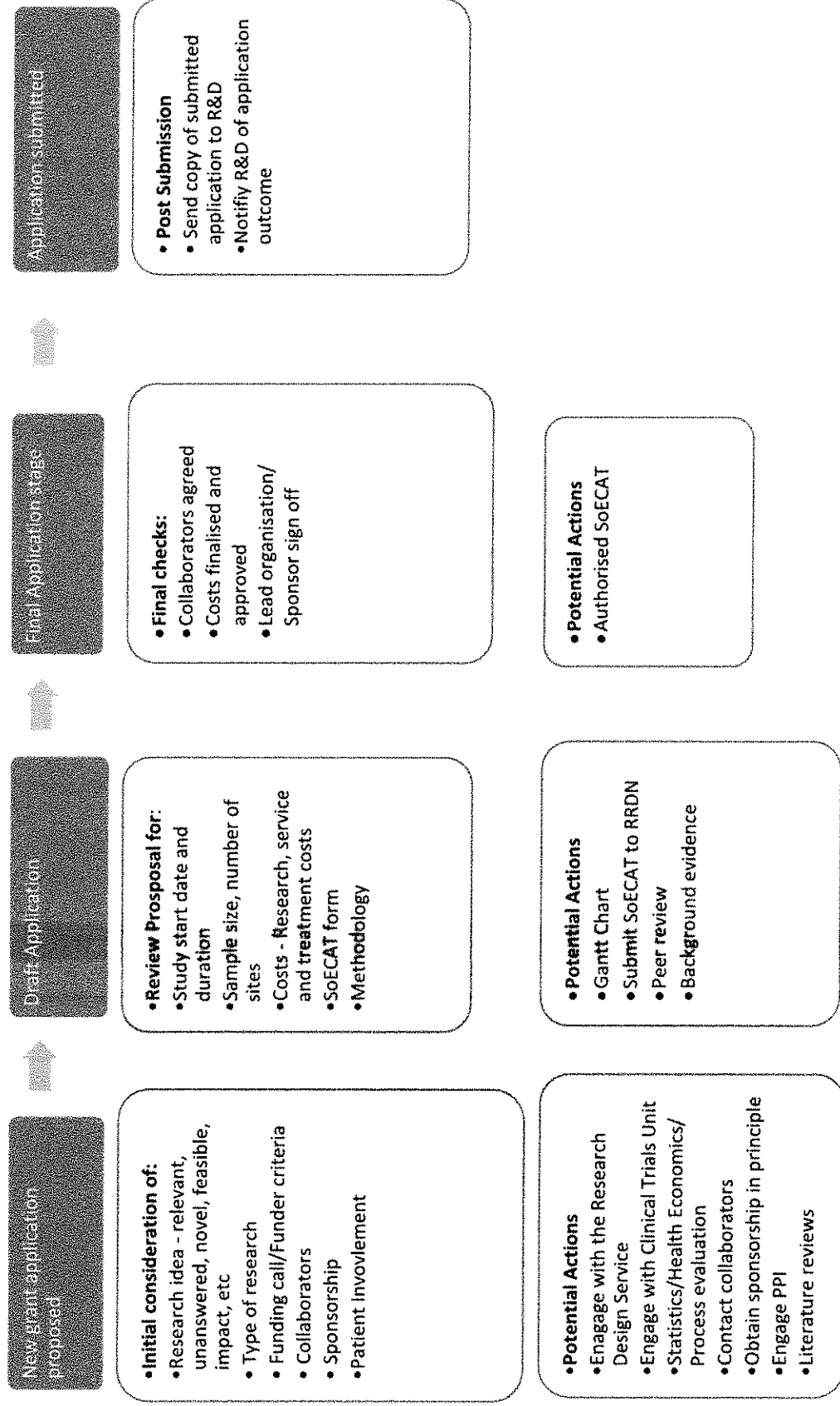
Training Implication	Yes
Actions required	<ul style="list-style-type: none"> • Read to ensure familiarisation with new procedure • Matrix to be updated

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Appendix 1 – NNUH Grant Application Flowchart

NNUH Grant Application Flowchart

Please contact the R&D Office as early as possible for assistance at every stage of the application process



Appendix 2 – Study Outline/Proposal

A proposal must be written by the Research Team prior to applying for any funding. The research proposal is a plan for engaging in systematic inquiry and should demonstrate that:

- the research is worth doing
- the researcher is competent to conduct the study - by providing evidence of the skills and experience of the researcher and their research team
- the results of the study will have validity
- the potential hazards identified in the risk assessment can be mitigated through study design, safety monitoring procedures and project management plans
- the study is carefully planned and can be executed successfully

It is recommended contacting the Research Design Service (RDS) as they can offer advice on all aspects of preparing health and social care research grant applications <https://rds-oe.nihr.ac.uk/>. The application should meet the funder's requirements and strategy.

Before beginning your research proposal you should consider the following points:

- Is it research? <http://www.hra-decisiontools.org.uk/research/#main-content>
- What is your research question
- Why does it matter - FINER (feasible, interesting, novel, ethical, relevant research question)
- Do you have the background information to back up your question
- How will you address this question (i.e. what methods will you use) - PICOT (population, intervention, comparison, outcome, time frame)
- **How important is this activity to the NHS and to service users**
- Is your research question clear
- Are your research methods appropriate
- **What are the identifiable hazards and risks for the participants, investigators and organisations involved**
- **What impact will your research have on the NHS**
- Does your research team add value
- Is it value for money
- What PPI involvement do you have
- Any queries please do contact R&D

Appendix 3

Intent to write a Grant Application Form**For when NNUH request to be Lead Organisation or Sponsor****Proposed Research**

Lead individual for the application:
Lead institution for the application:
Sponsor of the project:
Research Title:
Background/Rationale (what evidence is there that it is needed):
Objectives/Outcomes (max 4):
Participant Group (from what population will they be drawn? How will the group be identified?):
Methodology:
Impact Summary (what benefit to the Trust/Patients/NHS is there?):

Funder

Funder :
Funding Stream (include link):
What stage of application is this? <input type="checkbox"/> Outline Application (or <i>Stage 1</i> , or <i>Expression of Interest</i>) <input type="checkbox"/> Full Application
Application deadline date :
Expected research start date :
Expected research duration (months) :
Is this a re-submission of a previously rejected grant? <input type="checkbox"/> Yes <input type="checkbox"/> No

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Time on the project for application lead (%)?				
Who at NNUH is involved and what is their role?	Will they be named person on the grant	Please state role: (e.g. Co-applicant, Research Nurse, etc.)	Time on project (%/days/weeks)	
Who outside of NNUH will be named on the grant and what is their role? (Name & Contact email)	Organisation	Please state role: (e.g. Co-applicant, RA, CTU etc.)	Time on project (%/days/weeks)	Please confirm that they are aware of their involvement in the application

Involvement

<u>Clinical Trial of an Investigational Medicinal Product (CTIMP):</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
<u>Device Study:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
<u>If Device study, is the device CE marked?:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
<u>Will you involve the Norwich Clinical Trials Unit (NCTU) or another CTU? (if another CTU please name them):</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
<u>If yes, have you already made contact with CTU?</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>Will you use the Norwich Clinical Research Facility (CRF)?:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No

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Will you use the Norwich Biorepository?: <input type="checkbox"/> Yes <input type="checkbox"/> No
What is your participant recruitment target?:
How long is your recruitment period? (months):
Is it a Multicentre study?: <input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, how many sites:
Have you been in contact with the Research Design Service (RDS)?(>): <input type="checkbox"/> Yes <input type="checkbox"/> No
Support departments involved (pathology/radiology/pharmacy/etc):

Costs – please provide detailed list

Investigations (imaging, dispensing, lab tests, ECG, ECHO, etc)	
Consumables required (questionnaire licences, printing, postage, poster, blood tubes, PPE, etc):	
Equipment required (laptop, lab equipment, recorder, etc):	
Staff Recruitment & Training:	
Special Facilities (fridge, freezer, centrifuge, etc)	
Travel/Conferences (quantity, number of attendees, etc)	
Dissemination (events, open access journals, etc):	
TMG/Steering/DMEC/Focus Groups (quantity, number of attendees, location, etc)	
PPI	
Participant Travel and Car Parking (number of visits and duration):	
Other Costs:	

Please return completed form to Michael.sheridan@nnuh.nhs.uk or Office.RD@nnuh.nhs.uk

Appendix 4

Requesting Costs from NNUH for a Grant Application

Proposed Research

Lead individual for the application:
Lead institution for the application:
Sponsor of the project:
Research Title:
Background/Rationale (what evidence is there that it is needed):
Methodology:

Funder

Funder :
Funding Stream :
What stage of application is this? <input type="checkbox"/> Outline Application (or Stage 1, or Expression of Interest) <input type="checkbox"/> Full Application
Funding deadline date :
Expected research start date :
Expected research duration (months) :
Is this a re-submission of a previously rejected grant? <input type="checkbox"/> Yes <input type="checkbox"/> No

Research Team

Who at NNUH is involved and what is their role?	Will they be named person on the grant	Please state role: (e.g. Co-applicant, Research Nurse, etc.)	Time on project (%/days/weeks)	Are they aware of their involvement in the application yet?

SOP 005 Grant Application**Involvement**

<u>Clinical Trial of an Investigational Medicinal Product (CTIMP):</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>Device Study:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>Will you use the Norwich Clinical Research Facility (CRF)?:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>Will you use the Norwich Biorepository?:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>What is your participant recruitment target?:</u>
<u>How long is your recruitment period? (months):</u>
<u>Is it a Multicentre study?:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>If yes, how many sites:</u>

Costs

Investigations (imaging, dispensing, lab tests, ECG, ECHO, etc)	
Consumables required (printing, postage, poster, blood tubes, PPE, etc):	
Equipment required (laptop, lab equipment, recorder, etc):	
Staff Training:	
Special Facilities (fridge, freezer, centrifuge, etc)	
Travel/Conferences (quantity, number of attendees, etc)	
TMG/Steering/DMEC/Focus Groups (quantity, location, etc)	
Participant Travel and Car Parking (number of visits and duration):	
Other Costs:	

Please return completed form to Michael.sheridan@nnuh.nhs.uk or Office.RD@nnuh.nhs.uk

