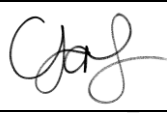



SOP 37 – Process for submitting Expression of Interest for Research Studies

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IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Innovation Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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<https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals>

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol and Western NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

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Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	
2.0	Addition of all research study EOIs using this process, rather than just academic Updating of panel members Updating of scoring sheet	03/07/2025

This SOP will be reviewed every three years unless changes to any relevant legislation require otherwise

Related Documents:

Guidelines
Guidelines 03 EOI Process

Glossary

ARPM	Assistant Research Portfolio Manager
EOI	Expression of Interest
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
PIs	Principal Investigators
RDN	Research Delivery Network
RIG	Research, Innovation and Genomics

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1. Introduction, Background and Purpose

This SOP describes the process for submitting an Expression of Interest (Eoi) in to a Sponsor whether via the South West Central Research Delivery Network (RDN) or through a direct approach for a research study.

This process will provide a robust and measurable method by which research studies will be accepted by the Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) Research, Innovation and Genomics (RIG) Department for Eoi submission.

2. Who should use this SOP?

- All members of the RIG department involved in Eoi submission for research studies
- Potential Principal Investigators (PIs) who wish to express interest in a research study

3. When this SOP should be used

This SOP should be used and referred to, each time an Eoi for a research study is received. This includes both direct approaches and approaches via the RDN.

4. Eoi process

Please refer to the Guidelines 03 EOI process for full details of this.

5. Expression of Interest Panel

Once a prospective PI has confirmed their interest in submitting an Eoi, before this occurs the Eoi panel must review the suitability of the study as per the Guidelines 03.

The prospective PI will be invited to attend the panel meeting by the Assistant Research Portfolio Manager (ARPM) to present the proposed study and the rationale behind why the EOI should be submitted. The EOI submission will not proceed until the prospective PI or their agreed delegee attends a panel meeting. Agreed delegee can be a member of the R&I department that has had sufficient information from the PI or a member of PI's clinical team. If the prospective PI or delegee cannot attend a panel meeting within a two-week period, and still wishes to proceed with an expression of interest, the Sponsor will be contacted and the absolute deadline for submission established.

The panel will consist of the following members;

- Director of Research, Innovation & Genomics
- Research, Innovation & Genomics Business Manager (Chair)
- Research Speciality Lead or Specialist Clinical Research Doctor
- Research Matron
- Delivery Team Lead associated with speciality/study being presented
- R&I Professional Services Manager (Deputy)
- Commercial Unit Trials Manager

Three members need to be in attendance for the panel to convene, please see Appendix 2 Terms of Reference for this meeting. The panel will meet according to need. If practical, the Assistant Research Portfolio Manager or R&I Admin Assistant will attend to record the notes of the meeting or the TEAMS meeting will be recorded. A decision on whether the EOI can be submitted will be reached following the presentation by the prospective PI or delegee using the scoring matrix found in Appendix 1. The decision of the panel will be final.

The prospective PI/delegee will be notified of the panel's decision in writing by the R&I Professional Services Manager or delegee within five working days of the panel meeting. If the panel has agreed the EOI can be submitted, the prospective PI will be informed of the need to complete any outstanding EOI questions in the outcome letter.

6. Accepted Expressions of Interest

Once the panel has accepted an Expression of Interest this will revert to following the pathway described in Guidelines 03 EOI process. Acceptance by the panel does not impact the decision-making process the study Sponsor will follow on accepting Gloucestershire Hospitals Trust as a participating site.

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Appendix 1 – Scoring Matrix

1	Study Impact	Score
	What is the direct patient benefit? How will the study benefit our local patient population? Availability of a medicine/treatment/device/technique not accessible outside of this study? Improve clinical skills within that speciality? Fit with strategic aims of Trust/NIHR	
2	Funding Received for the study	Score
	Explanation of the funding structure and costs for this study or whether a fully funded commercial study Cost savings to the Trust?	
3	Study Timelines	Score
	When is the study predicted to open/is the study already open? If already open, what is the current recruitment versus recruitment target? When is the study predicted to close to recruitment? What is the follow-up schedule?	
4	Recruitment Target	Score
	Predicted recruitment target? >100 in lifetime of the study (high recruiting)	
5	Evidence of patient population	Score
	How has the target been established? (evidence from specific database, etc) Evidence of a screening plan, how would these patients be recruited?	
6	Past/Existing Studies in the Portfolio	Score
	Does this study compete for a patient population with an already open study? Type and range of studies already open, can this further study be supported? Have previous studies achieved recruitment target? (details of actual v predicted recruitment target, RAG notes from EDGE)	
7	PI/Clinical team Experience	Score

	Number of studies previously been PI for and accompanying recruitment to time and target data Confirmation of availability of co-investigators to support PI Confirmation of interest in supporting trial from service lead/ clinical department involved.	
8	Involvement of Supporting Departments	
	Any above standard activity involved Follow-up activity for example dispensing within pharmacy?	
	Total Score	

Each section will be scored as follows:

Demonstrated = 2

Partially Demonstrated = 1

Not Demonstrated = 0

Appendix 2 Terms of Reference for the EOI Acceptance panel meetings

Gloucestershire Hospitals NHS Foundation Trust RIG EOI Acceptance Panel Meetings Terms of Reference

Accountable to	Research & Innovation Heads of Service Meeting/ NIHR Clinical Research Network (CRN) High Level Objectives (HLO)
Chair	Research, Innovation & Genomics Business Manager
Deputy Chair	Professional Services Manager or delegee
Frequency of Meetings	As required
Quorum	At least three core members to include the Chair or Deputy Chair
Approval	April 2025
Review date	April 2027

1. PURPOSE

The purpose of the EOI panel meetings is to consider new study EOIs against the criteria set within this SOP and score these.

2. AUTHORITY

The group is attended by the senior R&I Team and has authority to decide on the outcome of the review.

3. MEMBERSHIP

- a) The Group shall have not less than three members, the core members being:
- Director of Research, Innovation & Genomics
 - Research, Innovation & Genomics Business Manager (Chair)
 - Research Speciality Lead or Specialist Clinical Research Doctor
 - Research Matron
 - Delivery Team Lead associated with speciality/study being presented
 - R&I Professional Services Manager (Deputy)
 - Commercial Trials Unit Manager

4. MEETINGS and QUORUM

- a) Meetings shall be held as required. Any of the core members of the panel may request that a meeting be held if they consider that one is necessary.
- b) A quorum for the Panel shall be a minimum of 3 of the core members and to include either the Chair or Deputy Chair.

- c) Notice of each meeting will be received as soon as practically possible but not less than three working days, an agenda and supporting papers, shall be sent to each member of the Panel not less than two working days before the date of the meeting.
- d) Meetings will normally take place virtually
- e) Outcomes from the Panel meeting will be recorded in writing and sent to the prospective PI/delegee.
- f) An annual schedule of review of panel decisions shall be set and reviewed.

5. ATTENDANCE

- a) Other executive directors, senior managers or senior clinicians of the Trust may be invited to attend Panel meetings.

6. DUTIES

The Panel is responsible for the following main function:
Review of new study EOIs

7. REPORTING

- a) The group will evaluate its membership and performance on a regular basis through an annual review of its activities over the course of the previous year.
- b) The group will undertake an annual audit of compliance with its Terms of Reference.
- c) The group will review and update its terms of reference at each SOP review.