



SOP 24: Scientific Peer Review Process

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| SOP reference: | SOP 24 | |
| Version: | 5.0 | |
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| | 29/11/2023 | |
| Implementation date of current version: | 03/01/2024 | |
| Date of Review: | 03/01/2026 | |

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&I website:

[Research at our hospitals \(gloshospitals.nhs.uk\)](https://gloshospitals.nhs.uk)

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol 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 | Review and update along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs | 06/01/2017 |
| 3.0 | Rebranding to GHNHSFT, updating of contact details and reference documents | 31/03/2018 |
| 4.0 | Inclusion of details on the Scientific Review Committee Details of timetables Scientific Review Committee meetings | 01/02/2022 Not implemented |
| 5.0 | Updated references, addition of appendices, Removal of SOP categories and change of reference codes Clarification of SOP title Clarification of processes Changed R&D to R&I | 03/01/2024 |

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

Related Documents:

| SOPs |
|---------------------------------------|
| SOP 04 - Informed Consent in Research |
| SOP 26 – Service Evaluations |
| SOP 27 - Initiating Research |
| SOP 29 - Writing a Protocol |

Glossary

| | |
|----------------|------------------------------------|
| HRA | Health Regulatory Authority |
| R&I | Research and Innovation |
| REC | Research Ethics Committee |
| RPSO | Research Portfolio Support Officer |
| SPRC | Scientific Peer Review Committee |

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1. Introduction, Background and Purpose

All research carried out in Gloucestershire Hospitals NHS Foundation Trust requires scientific peer review by the identified Research Sponsor prior to submission to an NHS Research Ethics Committee (REC). This is a mandatory review for all studies that will be sponsored by the Trust. It is an expectation of the UK Policy Framework for Health and Social Care Research v3, 2017.

Scientific Peer Review will be required so that the Sponsor can confirm “Trust Approval in Principle” which will allow submission to an NHS REC and the Health Research Authority (HRA).

Proposals that do not require NHS REC Review, such as Service Evaluation and Research on NHS Staff will still require Scientific Peer Review prior to Trust Approval. This is to ensure that all projects generated locally are of high quality.

Student Research Projects can be peer reviewed if they involve staff and patients or are members of staff undertaking undergraduate or postgraduate study. Any comments provided by the peer review group for these projects will be advisory.

Audit projects do not require R&I Approval or Scientific Peer Review and should be managed under guidance from the relevant Audit Department of the member of staff leading the project. Audits projects should be submitted to the following email address ghn-tr.clinical.effectiveness@nhs.net.

The flow chart in Appendix 1 summarises the R&I process and highlights the position of Trust Approval in Principle within it.

2. Who should use this SOP?

Local members of staff who are thinking of developing or setting up a project of any description (other than Audit) should read this SOP at the earliest opportunity to understand their requirements under it. It must also be referred to by those members of the Trust who will form part of the Scientific Peer Review Committee.

3. When should this SOP be used?

As soon as an idea for a project is generated, this SOP should be read alongside other relevant SOPs depending on the type of project being planned.

4. Applying for Scientific Peer Review

4.1. Developing an Idea

Before submitting a project proposal for Scientific Peer Review, researchers are advised to contact the R&I Office using the R&I email account, ghn-tr.glos.rdsu@nhs.net for initial guidance on designing a protocol/proposal and for advice around the information that is expected to be included in the submission. An online Scientific Peer Review submission form for researchers is being developed for future use.

Initial methodological advice can also be given and such contact is recommended to ensure Scientific Peer Review is completed with minimal delay. Advice at this stage can also be given in relation to what type of study is being conducted and whether Scientific Peer Review/NHS REC Review and Trust Approval are required. After the initial approach to R&I a standardised email is sent to researchers by the Research Portfolio Support Officers (RPSO) outlining the peer review process. Please see appendix 2.

A proposal should, as a minimum, contain the following information/headings:

- Introduction - Background - what are you researching/evaluating and why? (With references to current publications)

-
- Literature Review
- Aims and Objectives
- Research Questions (if appropriate)
- Methodology
- Analysis
- Costs
- Dissemination plans

4.2. Submitting a Proposal

Once a proposal is in a final draft stage it should be submitted to the R&I office along with all relevant supporting material. Supporting material includes, but is not limited to:

- Participant Information Sheets
- Consent Forms
- GP letters
- Questionnaires
- Rating Scales/Tools
- Interview Schedules
- Data Collection Tools
- Study Lead's CV
- Valid (within 3 years) Good Clinical Practice Certificate
- Written evidence of line manager/departmental head approval for the research project/service evaluation to proceed.

If submitting a student project for peer review, the following needs to be provided as well;

- **Confirmation of student status and course being undertaken**
- **University ethics application and approval notification**

Submissions should be emailed to the Trust R&I Office at ghn-tr.rdsu@nhs.net and marked for the attention of the Scientific Peer Review Committee.

4.3 Scientific Peer Review Administration

4.3.1 Collation of information by SPRC Research Portfolio Support Officer

Once the submission is received by the SPRC, the Research Portfolio Support Officer, will allocate a R&I Reference number to the research project/service evaluation that will be used in all further correspondence with the researcher. The reference number allocation does not mean that Trust approval has been granted at this stage.

The SPRC RPSO will also prepare an electronic file for the study, collating all the information submitted to the SPRC. If any further documentation/information is required, the SPRC RPSO will contact the researcher to request it. The e-folder will be located in the projects section of the RDSU drive, formatted according to the template project folder hierarchy.

Once the required information is present for a SPRC Review, the SPRC RPSO will make copies of the proposal and supporting documents for each member of the SPRC.

4.3.2 Timing of SPRC meetings

The SPRC have a regular meeting on the first Tuesday of the month. All submissions should be received no later than a week before the meeting so that the SPRC can review the proposal before the meeting. In exceptional circumstance, provided the chair of the SPRC agrees, the SPRC RPSO will arrange a date and time for the review outside of this slot and will endeavour to ensure that this is within 1 calendar week of receiving a full submission.

If there are any reasons why a proposal cannot be reviewed at the next SPRC meeting, the SPRC RPSO will contact the project lead to let them know and keep them updated with further information until a date and time for the review can be set.

4.4 Scientific Peer Review

4.4.1 Scientific Peer Review Committee composition

The SPRC will consist of members of the R&I team including, but not limited to:

- Head of R&I
- Associate Professor of Nursing Research Portfolio Manager
- Medical Statistician
- Research Portfolio Support Officer
- Research Matron
- Lead Research Nurses/Coordinators
- Key clinical staff not involved in the research

The chair of the SRC will be appointed by the Head of R&I.

It will be expected that at least 3 members of this group will be required to allow a review to go ahead. If 3 members are not available, then the review

day and time will need to be re-arranged. The SPRC Research Portfolio Support Officer will be present in addition to the 3 members.

Each member, unless on leave, is expected to review the proposals before the meeting. A member may submit comments by email if unable to attend the meeting. The SPRC will review the protocol and supporting documents in relation to the methodology and the science behind the proposal. The SPRC look to ensure that the proposed methodology will meet the aims and objectives of the project and that the project is worthwhile and addressing an identified need, whether research or service evaluation.

The SPRC comments will be collated by the SPRC RPSO and checked by the chair or the Head of R&I, a copy will be placed in the study file and a copy forwarded to the researcher/ project lead to ensure there is a single point of contact for all studies

4.4.2 Feedback from Scientific Peer Review Committee

Comments from the SPRC will be forwarded to the researcher/ project lead within 2 working days of the review using the template found in appendix 3 by the RPSO.SPRC. The comments will be authorised by the SPRC chair or the Head of R&I before sending. The Head of R&I and the medical statistician should be copied into the email reply

The SPRC comments and suggestions are for advice and the researcher/ project lead is under no obligation to follow them. However, if there are any continuing concerns over the design of the study, it may not be possible to progress to the next stage of Governance, whether NHS Ethical Review/HRA or Trust R&I review and approval.

In the event that the SPRC feels it is unable to comment on a study they will refer to two peers, employed within the sponsoring trust that have knowledge of the subject area, but no direct involvement in the study

4.5 Responding to the SPRC

The project lead will be required to respond to the SPRC comments and make corrections as they see fit. If corrections are not to be made, then further details or justification should be provided to the SPRC.

If this further information is still not sufficient, the SPRC can provide further comments on the project.

If agreement cannot be reached following a third submission, Trust Approval in Principle and Agreement to Sponsor the study will not be given and further advice on design should be sought from the R&I Office as per section 4.1 before further submission to the SPRC is undertaken. Referral to independent peers may also be considered in this event – as per section 4.4.2.

4.6 Following SPRC Review

Following the review and any necessary responses, when the SPRC is satisfied that the study is of high quality, the SPRC RPSOr will provide correspondence confirming Trust Approval in Principle and Agreement to Sponsor – see text in Appendix 4 for CTIMPs. An email will be sent out for non-CTIMPs.

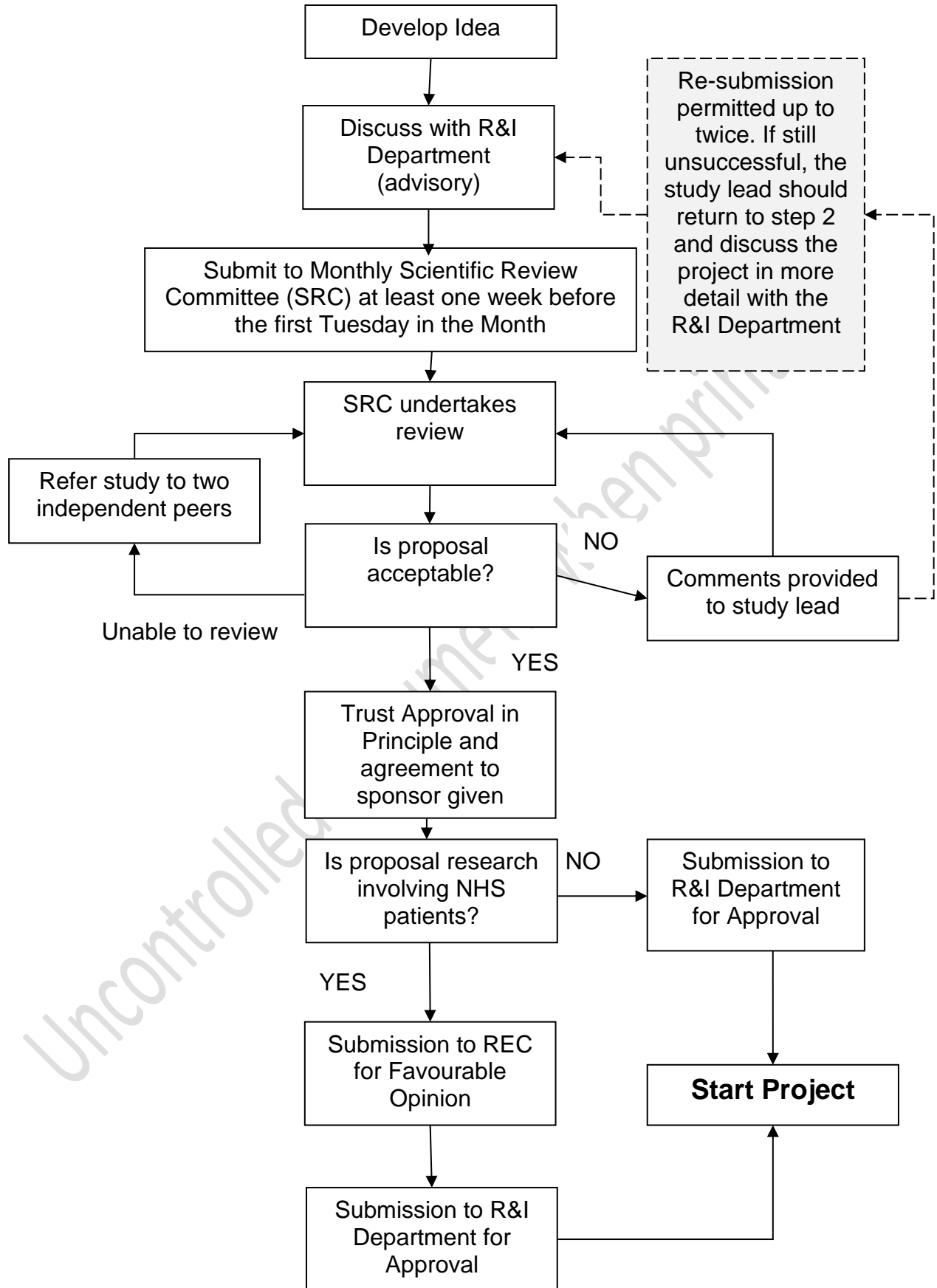
If the study requires NHS REC review, the researcher can then contact the R&I Office for further advice about making an NHS REC application.

If the study does not require NHS REC review (service evaluation, staff-based research) GHNHST approval review will commence. The RPSO involved in the administration of the peer review process will complete a workflow on EDGE. The workflow will document the peer review process and all relevant related documentation will be saved to the R&I folder and

uploaded to EDGE. GHNHSFT approval will be provided in writing using the template in appendix 5.

APPENDIX 1 – Flow Chart of Scientific Review Process

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**APPENDIX 2 –
- Standard Template Email to Researchers submitting studies for Scientific
Peer Review version 2.0 dated 02/12/2022**

Dear.....

Thank you for contacting the Research and Innovation Department about your study proposal.

Our Scientific Peer Review Chair has initially reviewed your study and has confirmed that this is a **Service Evaluation/Research Project**. {delete as appropriate}.

If the Trust is to act as sponsor to your research project/service evaluation it will need to be peer reviewed by the GHNHSFT R&I Scientific Peer Review Panel.

I have outlined the process for Scientific peer review as below.

The peer review panel meets the first Tuesday in the month, but exceptions may be made. Our next peer review meeting will be on 00/00/00.

Please provide a copy of the following documents:

- The Study Proposal version controlled and dated for example; Version 1.0 dated 23.02.2022
- Participant Information Sheets/Consent Forms/Questionnaires as appropriate.
- CV (signed and dated). An electronic signature and date will suffice. I have attached a copy of the template CV that R&I recommend as used by the Heath Research Authority.
- Good Clinical Practice Certificate Introduction or Refresher as appropriate.
- Written evidence of your line manager/ department head's support for the SE or RP to go ahead within your department.

Please forward to ghn-tr.glos.rdsu@nhs.net as soon as possible upon deciding to undertake your service evaluation (SE) or (RP) to access support in designing it.

Please submit at least 7 days before the review date so that reviewers have ample time to review the proposal.

To help you I would recommend adding the following information into the study proposal.

Background - what are you researching/evaluating and why? (With references to current publications) If you have a literature review at hand that would be helpful to include the paper that you forwarded to R&I.

Data to be collected - from whose records. (Diagnoses, earliest and latest dates, any restrictions, such as 18+only?)

What data? (List of data items, where is each to be found, and who will extract it). How the data will be kept (if in a spread sheet, how will patient anonymity be assured?)

How and by whom the data will be analysed?

What are the plans for dissemination? Local, or is the work expected to lead to a publication.

At this point a local R&I reference will be provided to make it easier to identify RP/SE's (some have very similar titles).

This reference number will be used on all correspondence and does **NOT mean your SE/RP has Trust approval to go ahead.**

You will receive written feedback from the Peer Review Meeting, it may be possible to give Trust Approval at this point, or there may be some points requiring clarification or amendment.

It may also be the case that the study requires submission to the Health Research Authority for approval and we as sponsor can provide guidance on this.

When queries have been resolved Trust approval will come out in the form on an email.

In this email will be the details of how to keep R&I informed on the progress of your SE/RP and the requirement to provide the final version of any report/ dissertation/ published journal article on the completion of your SE/RP.

I hope this helps but please don't hesitate to contact me if you have any queries about this.

If you need to meet with one of the R&I team to discuss your study prior to submission for peer review please let me know and I can arrange a meeting via Microsoft Teams or on site as appropriate.

APPENDIX 3- Template Scientific Peer Review Template -Letter of Comments



GHNHSFT Research and Innovation Department
First Floor, Leadon House
Gloucestershire Royal Hospital
Great Western Road
Gloucester, GL1 3NN

Insert recipient's name and address

Date

Dear.....
Local R&I Ref:
Study Title:

The Scientific Peer Review Group were: {list those in attendance at the Peer Review Meeting

Thank you for forwarding details of your study proposal to the Scientific Peer Review Group. The Scientific Review Group reviewed your study on **insert date and time.**

The group agree that this is a very worthwhile project and presented to a high standard. However, there are some areas that require clarification.

Please take the opportunity to read through the comments as below.

Provide main summary of comments

Before we are able to complete the peer review process and then review for Local Trust Approval, we would need to see evidence of a response to our queries.

If documentation is required to be updated, please could you forward R&I copies of this with updated version control date and version number.

I hope you find these comments useful but please do not hesitate to contact the R&I office if you have any questions about the above.

With Best Wishes

[Research Portfolio Support Officer](#)

GHNHSFT Research and Innovation Department

Cc: Chair of GHNHSFT Research and Innovation Department Scientific Peer Review Group

Appendix 4

Sample text for Trust Approval in Principle Correspondence for studies that require REC/HRA approval

Dear XXXXXXXX,

Study Title:

REC Ref:

R&I Ref:

Thank you for submitting details of your Research Project to the Research and Innovation Department at Gloucestershire Hospitals NHS Foundation Trust and for following up on the questions raised by the GHNHSFT Scientific Peer Review Committee.

I can confirm that the peer review process is now complete and I am able to confirm Trust Approval in Principle from Gloucestershire Hospitals NHS Foundation Trust for the above study. This approval also confirms agreement from the Trust to act as Sponsor under the UK Policy Framework for Health and Social Care Research 2017. This does not mean you have Trust Approval for your project to proceed.

Your study requires submission to an NHS Research Ethics Committee, this application can now be made through the Integrated Research Application Service (IRAS). Advice about the application can also be requested from the R&I Office. Following a receipt of a NHS Favourable Ethical Opinion, you will need to apply to the R&I Office for full Trust Approval before commencing your study.

Your project will now be recorded on EDGE including the details below

- Title:
- Chief Investigator:
- Sponsoring Organisation:
- Host Trust:

- Type of Study, i

Thank you for your application. Please contact the R&I Department on 0300 422 5467 if you have any questions about the next stages of the NHS ethics review.

Yours sincerely

Head of R&I/Senior Research Manager

Appendix 5 – Template Letter of Local Trust Approval for a study that does not require NHS REC review (service evaluation, staff-based research)

Dear

Local R&I Reference Number:

Title of Study:

Type of Project: e.g.: Student Project/MSc/Service Evaluation/Staff Survey
Lead Investigator:

Thank you for submitting details of your SE/RP to the Research and Innovation Department at Gloucestershire Hospitals NHS Foundation Trust and for following up on the questions raised by the GHNHSFT Scientific Peer Review Committee on the 00/00/0000.

Please accept this email as confirmation that the paperwork reviewed by the Trust Research and Innovation Department has been accepted and Trust Approval is given for you to begin your Service Evaluation.

Please accept this email as confirmation that the paperwork has been reviewed by the following bodies: [LIST RELEVANT BODIES, for example, Scientific Peer Review Committee dated 00/00/0000 and Gloucestershire Hospitals NHS foundation Trust Research and Innovation Department for Local Trust Approval dated 00/00/0000}

This has been reviewed by the Trust Research and Innovation Department as a Service Evaluation/Research Project. [delete as appropriate}

The Local Trust Approval is for Gloucestershire Hospitals NHS Foundation Trust only.

Documentation Received by R&I and Approved as of date 00/00/0000

List all documentation received as part of the final approval {including the researcher's CV and Study protocol}.

If you need to make any alterations to any of your documentation during your project, please submit them to the R&I inbox, using the R&I reference number above, for approval prior to use.

Please keep us informed of the annual progress (if applicable) of the project, and provide a copy of the findings upon completion, by emailing the R&I inbox ghn-tr.glos.rdsu@nhs.net.

Please could you confirm receipt of this local Trust Approval email.

Finally, may I take this opportunity to wish you all the best with your study.

Thank you,