Gloucestershire Hospitals
NHS Foundation Trust

Research Development 01 – Scientific Review

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Author:	Janet Forkes	signature
Reviewed by Associate Director of R&D	Julie Hapeshi	signature
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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.

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

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

Contents

1. Introduction, Background and Purpose

All research requires scientific 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 Review will be required so that the Sponsor can confirm "Trust Approval in Principle" which will allow submission to an NHS REC and the HRA.

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

Audit projects do not require R&D Approval or Scientific Review and should be managed under guidance from the relevant Audit Department of the member of staff leading the project.

The flow chart in Appendix 1 summarises the R&D 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.

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 Review

4.1. Developing an Idea

Before submitting a project proposal for Scientific Review, researchers should contact the R&D Office for initial guidance for designing a protocol/proposal and for advice around the information that is expected to be included.

Initial methodological advice can also be given and such contact is recommended to ensure Scientific 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 Review/NHS REC Review and Trust Approval are required.

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

- Introduction
- 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&D 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

The submissions should be sent to the Scientific Review Committee(SRC) at:

R&D Office
Leadon House
Gloucestershire Royal Hospital
Great Western Road
Gloucester
GL1 3NN

Alternatively, submissions can be emailed to the Trust R&D Office at ghn-tr.rdsu@nhs.net and marked for the attention of the Scientific Review Committee.

4.3 Scientific Review Administration

Once received by the SRC Research Support Officer, the study will be logged and given an R&D Reference number that will be sent back to the researcher for future reference.

The SRC Research Support Officer will also prepare an electronic file for the study, collating all the information submitted to the SRC. If any further documentation/information is required, the SRC Research Support Officer will contact the researcher to request it.

Once the required information is present for a SRC Review, the SRC Research Support Officer will make copies of the proposal and supporting documents for each member of the SRC.

The SRC Research Support Officer will arrange a date and time for the review and will endeavour to ensure that this is within 1 calendar week of receiving a full submission.

If there are any reasons why the proposal cannot be reviewed within 1 calendar week, the SRC Research Support Officer 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 Review

4.4.1 Scientific Review Committee composition

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

- Associate Director of R&D
- Senior R&D Manager
- R&D Manager
- Medical Statistician
- Commercial Trial Facilitator
- Research Officer
- Research Support Officer
- CI /project lead/ researcher may be invited

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 SRC Research Support Officer will be present in addition to the 3 members.

The SRC will review the protocol and supporting documents in relation to the methodology and the science behind the proposal. The SRC 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 SRC comments will be collated by the SRC Research Support Officer and checked by a member of the SRC, 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 Review Committee

The comments from the SRC will be forwarded to the researcher/ project lead within 2 working days of the review by the SRC (usually the SRC Research Support Officer).

The SRC 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 or Trust R&D review and approval.

In the event that the SRC 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 SRC

The project lead will be required to respond to the SRC 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 SRC.

If this further information is still not sufficient, the SRC 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&D Office as per section 4.1 before further submission to the SRC is undertaken. Referral to independent peers may also be considered in this event – as per section 4.4.2.

4.6 Following SRC Review

Following the review and any necessary responses, when the SRC is satisfied that the study is of high quality, the SRC Support Officer will provide correspondence confirming Trust Approval in Principle and Agreement to Sponsor – see text in Appendix 2 for CTIMPs. An email will be sent out for non-CTIMPs.

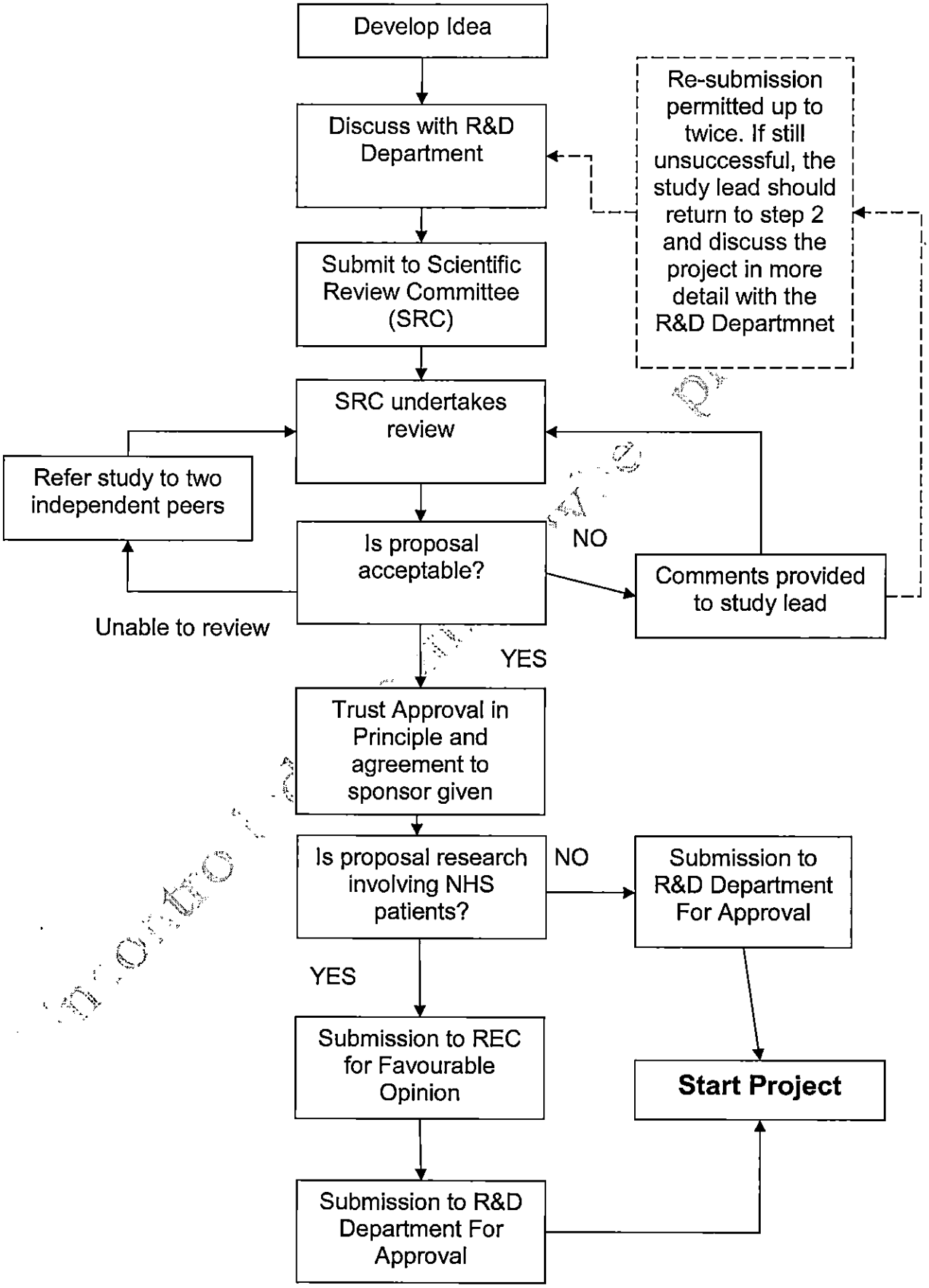
If the study requires NHS REC review, the researcher can then contact the R&D Office for further advice about making an NHS REC application.

If the study does not require NHS REC review (service evaluation, staff-based research) the R&D Managers will proceed with the R&D Approval review.

5 Related SOPs and Documents

R&D SOP IR 03 Writing a Protocol

APPENDIX 1 – Flow Chart of Scientific Review Process



APPENDIX 2 –
Sample text for Trust Approval in Principle Correspondence

Dear XXXXXXXX,

Study Title:
REC Ref:
R&D Ref:

I am writing 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.

If your study requires submission to a 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&D Office. Following a Favourable Ethical Opinion you will need to apply to the R&D Office for full Trust Approval before commencing your study.

If your study does not require NHS REC Review (such as service evaluations and staff research), you will need to apply to the R&D Office for full Trust Approval before commencing the study.

Your project will now be added as a pending application to the Trust Research Register which will hold full details of your study, including:

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

Thank you for your application. Please contact the R&D Department on 0300 422 5463 if you have any questions about the next stages of the R&D review.

Yours sincerely