SOP 24: Project Review Process – Research Projects

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

All staff should regularly check the Research, Innovation & Genomics 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 RIG website:

[Research at our hospitals (gloshospitals.nhs.uk)](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.

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 RIG	03/01/2024
6.0	Update to Committee membership Update to, and addition of further appendices. Addition of sponsorship agreement process Peer Review renamed Project Review Service evaluations removed from scope of SOP, PRC pre-meets added to process.	12/02/2026

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

Related Documents:

SOPs
SOP 02 – Research Documentation and File Management
SOP 03: Training
SOP 26 – Service Evaluations
SOP 27 - Obtaining Sponsorship for non-CTIMP and CE marked Medical Device Studies
SOP 29 - Writing a Protocol
SOP 34 – Licence for publication
SOP 42 – Grant Applications

Glossary

EDI	Equality Diversity and Inclusion
GHC	Gloucestershire Health and Care NHS Foundation Trust
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	Health Regulatory Authority
IRAS	Integrated Research Application System
PPI	Patient and Public Involvement
PRC	Project Review Committee
PS	Professional Services
QA	Quality Assurance
QI	Quality Improvement
RIG	Research, Innovation & Genomics
RPM	Research Portfolio Manager
REC	Research Ethics Committee
UoG	University of Gloucestershire

Contents

1. Introduction, Background and Purpose

The UK Policy Framework for Health and Social Care Research describes responsibilities for study sponsors – that is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. These responsibilities include ensuring that research protocols are well designed and are of good quality.

This SOP describes the Project Review process that will be followed within Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) Research, Innovation & Genomics (RIG) Department for any study applying for GHNHSFT sponsorship. Following a successful process, RIG will confirm Trust 'agreement to sponsor', which will allow submission to an NHS Research Ethics Committee (REC) and the Health Research Authority (HRA).

All local research projects require Project Review before the RIG department can issue Trust approval to proceed, this includes those projects not requiring submission through IRAS. This is to ensure all projects generated locally are of high quality.

Student Research Projects (projects which are primarily for the purpose of obtaining an educational qualification) will be sponsored, and peer reviewed, by the relevant academic institution, but must be reviewed within the Trust if they involve staff and patients or where GHNHSFT members of staff undertaking undergraduate or postgraduate study. Research undertaken by Healthcare Science Trainees as part of their Scientific Training Programme and Higher Scientific Specialist Training programmes will be sponsored by GHNHSFT.

Service evaluations (including student service evaluations) follow a shortened project review process prior to RIG approval – please refer to SOP 26: Service Evaluations for details of the governance process for Service Evaluations.

Audit or quality improvement projects do not require RIG Approval or Project Review. GHNHSFT staff planning an audit or quality improvement project should first contact their QI Specialty Lead.   Further information and relevant contact details for the Leads can be found on the [Trust Intranet](#).

The flow chart in Appendix 1 summarises the RIG process.

2. Who should use this SOP?

Local members of staff who are thinking of developing or setting up a research project should read this SOP at the earliest opportunity to understand their responsibilities. It must also be referred to by those members of the Trust who will form part of the Project Review Committee.

3. When should this SOP be used?

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

4. Applying for Project Review

4.1. Developing an idea

Before submitting a project proposal for Project Review, project leads are advised to contact the RIG Professional Services (PS) Office using the Project Review email account, ghn-tr.RIGprojectreview@nhs.net, to discuss their project and draft documents and receive guidance on what is expected to be included in the submission. The RIG PS team will link the project lead with appropriate colleagues for further guidance, for example, on designing a protocol/proposal, methodologies, statistics, PPI (patient and public involvement) or EDI (Equality, Diversity and Inclusion).

Project leads will be directed towards RIG SOP 29: Writing a Protocol, for guidance. As per SOP 29, project leads will be expected to use HRA protocol templates if applicable for their project, or if not, the protocol template included as an appendix to SOP 29. The HRA decision tool can help project leads determine if their project is classed as research, service evaluation or audit.

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

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

- Literature Review

- Aims and Objectives

- Research Questions (if appropriate)

- Methodology

- Proposed analysis

- Costs and funding

- Dissemination plans

See Appendix 3 for guidance template that will be provided to project leads.

4.2   Submitting a proposal

Once a proposal is in a final draft stage, it should be submitted to the RIG 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

  ***N.B** All project documents must have a version number and date*

- Written evidence of line manager/departmental head approval for the research project/service evaluation to proceed.

- The submission should clearly state who is acting as sponsor for the project or whether the researcher is requesting sponsorship from the Trust.
- Study Lead's CV, signed and dated
- A valid (within 3 years) Good Clinical Practice Certificate for person making submission (SOP 03: Training)

If submitting a student project for project review, the following needs to be provided in addition;

- Confirmation of student status and course being undertaken
- University ethics application and approval notification, if received.

Submissions should be emailed to the RIG Office at ghn-tr.RIGprojectreview@nhs.net and marked for the attention of the Project Review Committee.

4.3   Requesting sponsorship prior to external grant application

Researchers require confirmation of sponsorship from the Trust prior to submitting grant applications. In these circumstances researchers should follow SOP 27: Obtaining Sponsorship for non-CTIMP and CE marked Medical Device Research Studies and SOP 42: Grant Applications.

Following a successful grant application, any patient-facing documents, for example, consent forms, patient information sheets, will require proportionate review by the PRC. Researchers should submit their documents to the RIG Office at ghn-tr.RIGprojectreview@nhs.net and marked for the attention of the Project Review Committee.

5 Project Review Administration

5.1   Collation of information for Project Review

Once the submission is received by the RIG Project Support Team, a RIG Reference number will be allocated to the research project that will be used in

all further correspondence with the project lead. The reference number allocation does not mean that Trust approval has been granted.

All projects submitted for PRC review will be recorded on the PRC Tracker stored on the RDSU Drive. Research projects will also be recorded on EDGE and the Project Review EDGE workflow started. Projects recorded on the log will be managed as per the PRC Tracker Guidelines (Guidelines 21).

The RIG Project Support team will also prepare an electronic file for the project, collating all the information submitted to the PRC. The e-folder will be located in the projects section of the RDSU drive, formatted according to the template project folder hierarchy (as per SOP 02).

5.2 PRC Pre-meet

The project lead will be invited to a pre-meet with three members of the PRC (to include a statistician) prior to their study being submitted to the PRC for full review. This is an opportunity for RIG to offer additional support to project leads, with the aim to increase the efficiency of the Project Review process, avoiding the need for repeat submissions.

Following the pre-meet, advice and comments will be forwarded to the project lead (see appendix 2), Once any amendments have been made, the project lead should send all updated documents to RIG (ghn-tr.RIGprojectreview@nhs.net). The submission will be reviewed for completeness by a member of the RIG Project Support Team. Any further documentation/information required will be requested as applicable.

Once the required information has been received, the project will be added to the agenda of the next PRC meeting.

5.3 Timing of PRC meetings

The PRC have a regular meeting in the second week of the month. All submissions should be received no later than five working days before the meeting so that the PRC can review the proposal before the meeting.

If there are any reasons why a proposal cannot be reviewed at the next PRC meeting, the RIG Project Support Team 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.

6 Project Review Process

6.1   Project Review Committee composition

The PRC will consist of members of the RIG team including, but not limited to:

- RIG Professional Services Manager (Chair)
- Medical Statistician
- Research Portfolio Manager (RPM)/Senior RPM (rotating)
- Quality Assurance (QA) Manager (Deputy Chair)
- Commercial Trial Unit Manager
- Academic Services Manager (Deputy Chair)
- Gloucestershire Health and Care NHS Foundation Trust (GHC) Research Team Representative
- Research Matron
- Lead Research Nurses/Coordinators (rotating)
- Team member from Cobalt Imaging (rotating)
- Key clinical staff not involved in the project
- Member of RIG Project Support Team (for administrative support)
- Invitees from other relevant organisations e.g. University of Gloucestershire (UoG)

Meetings will require attendance of at least 5 members of this group (including the Chair or deputy, at least two of the following: Medical Statistician, Commercial Trial Unit Manager, or a Senior RPM and, if the project involves

patient contact, either the Research Matron or a Lead Research Nurse/Coordinator) to be quorate and to enable a review to go ahead. If 5 members are not available, then the review day and time will need to be re-arranged. A member of the RIG Project Support team will be present in addition to the 5 members for administration purposes.

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. Members submitting comments in absence, are not counted towards the 5 core members required for the group to be quorate.

The PRC will review the protocol and supporting documents in relation to the methodology and the science behind the proposal. The PRC look to ensure that the proposed methodology will meet the aims and objectives of the project. The Project Review Matrix (Appendix 6) should be used by members of the PRC to assist their review of the project.

For projects that come to the PRC following a successful grant application, the PRC will review the patient-facing documents only. The project protocol will have been peer reviewed as part of the grant application process.

The PRC comments will be collated by a member of the RIG Project Support Team and checked by the chair or deputy, a copy will be placed in the project file and uploaded to the project record on EDGE if applicable. The comments will be sent to the project lead as described below.

6.2 Feedback from Project Review Committee

Comments from the PRC will be forwarded to the Project Lead, with the RIG Professional Services Manager copied in, within 5 working days of the review using the template found in Appendix 4 for non-student projects, or Appendix 5 for student projects, by a member of the RIG Project Support Team. A meeting

with relevant members of the PRC, to discuss the written comments, may be suggested to the project lead if deemed necessary by the group.

The PRC comments and suggestions are for advice and the project lead is under no obligation to follow them. However, if there are any continuing concerns over the design of the project, it may not be possible to progress to the next stage of governance, whether this be Trust agreement to sponsor, NHS REC Review/HRA review or Trust RIG review and approval.

In the event that the PRC feels it is unable to comment on a project e.g. due to a lack of specialist knowledge in the subject area, they will refer to two peers. These peers must be employed within the Trust, have knowledge of the subject area/work within the department from which the project is arising, but no direct involvement in the project. If there are concerns around sponsorship or risk, the PRC will refer to the Director of RIG and RIG Business Manager for advice.

6.3 Responding to the PRC

6.3.1 Non-Student Projects

For non-student projects, the project lead will be required to respond to the PRC 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 PRC. If the project lead requires a delay or extension to the timelines detailed in the feedback letter, they can request this via email (ghn-tr.RIGprojectreview@nhs.net).

All responses received and document revisions will be reviewed by the PRC at the next meeting; unless these are very minor revisions, when the PRC will comment collectively via email, or where it was agreed at the PRC meeting that the project did not need further review by PRC once minor revisions were made. All documents amended must be updated to a new version number and date, and amendments shown in tracked changes.

Following the second submission, if the further information or amendments are still not sufficient to satisfy the PRC, the PRC can provide further comments on the project via a second feedback letter

6.3.2 Student Projects

Comments from the PRC for student projects are for advisory purposes only, and amendments/updates to project documents based on these do not require resubmission to the PRC. However, if the PRC feel that amendments are essential to assure the integrity of the project, confirmation that these have been made will be required before Trust approval could be given. The project lead should follow direction in their feedback letter (Appendix 5) for the next steps for their project.

7 Following PRC Review for Non-Student Projects

If agreement cannot be reached by the PRC following a third submission, progress to RIG approval, or Agreement to Sponsor the project, will not be possible at this stage and further advice on design should be sought from the RIG PS Office as per section 4.1 before further submission to the PRC is undertaken. Referral to independent peers may also be considered in this event – as per section 6.2.

7.1 Confirming completion of Project Review Process

The PRC process will be considered complete once any necessary responses have been received and reviewed, and the PRC is satisfied that the project is of high quality.

7.1.1 Projects requesting Trust Sponsorship

Once the PRC process is complete, the RIG Professional Services Manager will confirm to the Chair/Deputy Chair of the Sponsorship Panel that the project has been through the PRC (and peer evaluation as part of grant process, if applicable) for information. If the PRC or Chair has any concerns over the Trust's ability to sponsor a project, this will be discussed with the RIG Director

and/or Business Manager. If Sponsorship is denied comments will be fed back to the project lead, with advice for next steps for their project.
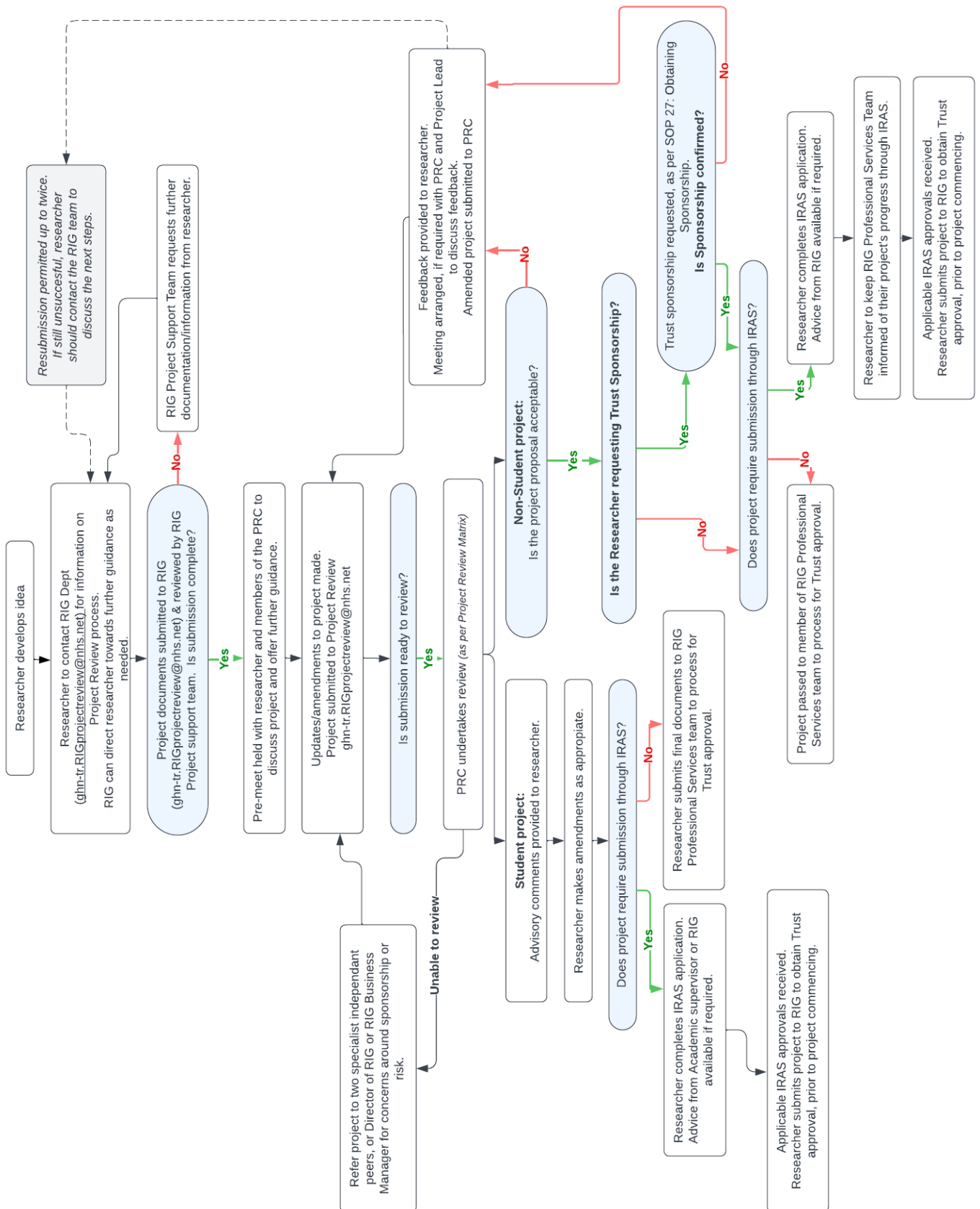
8 References

[HRA protocol templates](#)
[HRA decision tool](#)

Appendix 1: Flow Chart of Project Review Process

Resubmission permitted up to twice. If still unsuccessful, researcher should contact the RIG team to discuss the next steps.

Researcher develops idea

Researcher to contact RIG Dept (ghn-tr.RIGprojectreview@nhs.net) for information on Project Review process. RIG can direct researcher towards further guidance as needed.

Project documents submitted to RIG (ghn-tr.RIGprojectreview@nhs.net) & reviewed by RIG Project support team. Is submission complete?

Yes

No — RIG Project Support Team requests further documentation/information from researcher.

Pre-meet held with researcher and members of the PRC to discuss project and offer further guidance.

Updates/amendments to project made. Project submitted to Project Review ghn-tr.RIGprojectreview@nhs.net

Is submission ready to review?

Yes

PRC undertakes review *(as per Project Review Matrix)*

Unable to review — Refer project to two specialist independant peers, or Director of RIG or RIG Business Manager for concerns around sponsorship or risk.

Feedback provided to researcher. Meeting arranged, if required with PRC and Project Lead to discuss feedback. Amended project submitted to PRC

No

Non-Student project: Is the project proposal acceptable?

Yes

Is the Researcher requesting Trust Sponsorship?

Yes — Trust sponsorship requested, as per SOP 27: Obtaining Sponsorship. **Is Sponsorship confirmed?**

No

Yes — Does project require submission through IRAS?

No — Project passed to member of RIG Professional Services team to process for Trust approval.

Yes — Researcher completes IRAS application. Advice from RIG available if required.

Researcher to keep RIG Professional Services Team informed of their project's progress through IRAS.

Applicable IRAS approvals received. Researcher submits project to RIG to obtain Trust approval, prior to project commencing.

Student project: Advisory comments provided to researcher.

Researcher makes amendments as appropiate.

Does project require submission through IRAS?

No — Researcher submits final documents to RIG Professional Services team to process for Trust approval.

Yes — Researcher completes IRAS application. Advice from Academic supervisor or RIG available if required.

Applicable IRAS approvals received. Researcher submits project to RIG to obtain Trust approval, prior to project commencing.

Appendix 2: Template Email to Project Leads following a PRC pre-meet

Dear……….

Thank you for your time in meeting with members of the Research, Innovation & Genomics (RIG) Project Review Committee about your research project proposal. Please find information below which confirms the process of Project Review and a summary of the comments/suggestions from our meeting.

Comments:

X
X
X

To be conducted within the Trust, and for the Trust to act as sponsor (if applicable), the project will need to be reviewed by the GHNHSFT RIG Project Review Panel. I have outlined the process for Project Review as below.

The Project Review panel meets in the second week in the month. Documents must be submitted to RIG at least 5 days prior to the meeting date so that reviewers have ample time to review the proposal.

Once your project is ready for submission please provide a copy of all project documents, as detailed on the 'Project Review template guidance' document included with this letter, to the RIG department using the email: ghn-tr.RIGprojectreview@nhs.net

A local RIG reference number will be provided to make it easier to identify your project. This reference number will be used on all correspondence but **does NOT mean your project has Trust approval to go ahead.**

You will receive written feedback from the Project Review Meeting detailing the next steps or suggesting amendments or requesting clarifications.

If your project requires submission to the Health Research Authority for approval, we can provide guidance on this following the Project Review process

Please don't hesitate to contact me if you have any queries about this process or if you are requiring any additional advice or support.

Appendix 3: Guidance Template for Project Review Proposals

1. Synopsis

- Provide a brief summary of the project, including the main objectives, design, and significance on first page.

2. Title of the Project

- Provide a concise and descriptive title.

3. Background and Rationale

- Briefly describe the background of the project.
- Explain the significance and rationale for the project.
- Include relevant literature and previous studies.

4. Objectives

- State the primary and secondary objectives of the project.

5. Design

- Describe the project design (e.g., randomized controlled trial, observational study, cohort study, service evaluation).
- Include details on the methodology.
- Describe the Patient and Public Involvement (PPI) in the development of the project and consideration of Equality Diversity and Inclusion (EDI).

6. Population

- Define the project population and inclusion/exclusion criteria.
- Describe the recruitment process.

7. Interventions

- Detail any interventions or treatments to be administered.
- Include information on dosage, frequency, and duration for clinical trials.
- For observational studies or other methodologies, describe the procedures, assessments, or data collection methods.

8. Outcome Measures

- Specify the primary and secondary outcome measures.
- Describe how outcomes will be assessed and measured.

9. Data Collection and Management

- Outline the data collection methods.

- Describe the data management plan, including data storage and confidentiality.
- Describe any IT or digital considerations for the project.

10. Statistical Analysis

- Provide an overview of the statistical methods to be used.
- Include sample size calculation (if applicable) and justification.

11. Ethical Considerations

- Discuss ethical issues related to the project.
- Include information on informed consent and ethical approval.

12. Timeline

- Provide a timeline for the project, including key milestones.

13. Budget

- Outline the budget and funding sources.
- Include a detailed breakdown of costs.
- If external funding has been agreed/applied for please provide all details of funding agreements.

14. References

- List all references cited in the proposal.
- Use a consistent referencing style (e.g., APA, Harvard, Vancouver).

15. Annexes as applicable

- Annex 1: Participant Information Sheet (PIS): Detailed information provided to participants about the project.

* *Please ensure that your patient information includes the necessary GDPR wording, as specified by the HRA – see HRA page for guidance. ***

- Annex 2: Informed Consent Forms (ICF): Copies of all informed consent forms to be used in the project.

- Annex 3: Case Report Forms (CRF)/Data Collection Tools: Examples of questionnaires, surveys, or other data collection tools.

- Annex 4: Letters/Emails of Support: Letters or emails of support from institutions or collaborators.

- Annex 5: Additional Supporting Documents; Any other relevant documents that support the proposal.

- Annex 6: Curriculum Vitae (CV): CVs of key personnel involved in the project.

- Annex 7: Good Clinical Practice (GCP) Certificates: Certificates of GCP training for the research team.

Notes: Please be clear, concise and try to keep world count to less than 4000 words for core protocol, excluding synopsis, references and annexes.

Please also ensure:

- Written evidence of line manager/departmental head approval for the research project to proceed has been included.

- All documents provided are version controlled

- It is clearly stated who is acting as sponsor for the project or whether you are requesting sponsorship for the project from the Trust.

Gloucestershire Hospitals
NHS Foundation Trust

Appendix 4: Template for Project Review feedback/comments for Non-Student Projects

Dear XXXXXXXX,

Project Title:

RIG Ref:

The Project Review Committee were: {list those in attendance at the Project Review Meeting

Thank you for forwarding your project proposal to the Project Review Committee (PRC). The PRC reviewed your project on XX/XX/XXXX.

Please see below the summary of comments of the PRC and areas of the project requiring clarification or improvement. [*We would like to offer you a meeting with the relevant members of the PRC to discuss these comments and provide further guidance. The RIG Project Support Team will arrange this for you]* *delete if not applicable.*

PRC Comments:

X
X

This letter does not mean you have GHNHSFT Trust Approval for your project to proceed at this stage.

Before we are able to complete the Project Review process we require a response to our queries, including any updated project documentation, if applicable. Please ensure updated documentation is version controlled and all changes are visible via document tracking.

The responses and amended documents require review by the committee – the deadline for submission to the next review meeting is dd/mm/yyyy, or dd/mm/yyyy for the following month.   If you require a longer deadline to submit your responses, please contact the Project Review email address to request this.

Please do not hesitate to contact the RIG office if you have any questions about the above.

With Best Wishes

GHNHSFT Research, Innovation & Genomics Department
Cc: Chair of GHNHSFT Research, Innovation & Genomics Department Project Review Group

Appendix 5: Template for Project Review feedback/comments for <u>Student</u> Projects

Dear XXXXXXXX,

Project Title:

RIG Ref:

The Project Review Committee were: {list those in attendance at the Project Review Meeting

Thank you for forwarding your project proposal to the Project Review Committee (PRC). The PRC reviewed your project on XX/XX/XXXX.

Your project is a student project, sponsored by your academic institution, therefore the Committee are providing comments for advisory purposes only. Please see below the summary of comments of the PRC and suggested areas for improvement.

X
X

This letter does not mean you have GHNHSFT Trust Approval for your project to proceed at this stage.

Please discuss these comments with your academic supervisor and make amendments to your project documents as appropriate.

If your project does not require submission through IRAS, to submit your project to RIG for GHNHSFT approval please email all updated and final project documents to the RIG team (ghn-tr.glos.riprofessionalservices@nhs.net), ensuring to quote the above RIG reference.

If your project requires submission through IRAS, please complete this process in collaboration with your academic supervisor. Advice from the RIG team is available if required. Once you have received your necessary approvals through the IRAS process, please submit your project to RIG for Trust approval as described above.

Please do not hesitate to contact the RIG office if you have any questions about the above.

With Best Wishes

GHNHSFT Research, Innovation & Genomics Department

Cc: Chair of GHNHSFT Research, Innovation & Genomics Department Project Review Group

Appendix 6: Project Review Matrix

Project name:	
Local RIG Number:	
PI:	
Student Project:	*Yes / No*
Sponsor *(if applicable)*	

Project addresses a clear research question.	
Comments:	
Background information adequately justifies the project.	
Comments:	
Significance to patients/NHS is clear.	
Comments:	
Appropriate methodology used for the project.	
Comments:	
Sample size sufficient for the project. *** Medical Statistician to complete*	
Comments:	
Are the data analysis plans appropriate to answer the project question? *** Medical Statistician to complete*	
Comments:	
Is the patient recruitment / consent process suitable for the project patient population?	**Yes / No**
Comments:	

Are the project supporting documents e.g. PIS, consent form of a good standard?	**Yes / No**
Comments:	
Is the data handling and storage sufficiently described in the protocol (and supporting documents)?	**Yes / No**
Comments:	
Is the funding clearly described in the protocol and is the funding adequate for entire project activity?	**Yes / No**
Comments:	
Are any risks associated with the project clearly addressed in the protocol and justified by project benefit/significance?	**Yes / No**
Comments:	