



SOP 27 - Obtaining Sponsorship for non-CTIMP and CE Marked Medical Device Research Studies

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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 NHS Foundation Trust who gave permission to adapt their templates in the development of these SOPs.

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SOP 27 – Obtaining Sponsorship for non-CTIMP and CE marked Medical Device Research Studies version 1.1 Implementation date: 30/04/2026 Review date: 04/11/2027

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
	This SOP replaces the original SOP 27 Initiating Research v3.3	
1.0	New SOP	4/11/2025
1.1	Update of Appendix 5 list of responsibilities	30/04/2026

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

Related Documents:

SOPs / Guidelines
SOP 11 - Confirmation of Capacity and Capability
SOP 24 - Project Review
SOP 29 - Writing a Protocol
Guidelines 02 - Using the non-CTIMP template protocol
Guidelines XX- Greenlight process (Sponsorship EDGE Workflow)

Glossary

C&C	Capability and Capacity
CI	Chief Investigator
GCP	Good Clinical Practice
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
PI	Principal Investigator
RIG	Research, Innovation and Genomics
REC	Research Ethics Committee

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1. Introduction, Background and Purpose

The UK Policy Framework for Health and Social Care Research v3.3 2017 requires that all health and social care research involving NHS patients, their tissue or information, staff, equipment or other NHS resources, has a sponsor. A sponsor is an organisation which takes ultimate responsibility for the quality and conduct of a research study.

Sponsors are responsible for ensuring that any research undertaken safeguards the rights, safety, dignity and well-being of participants. The sponsor accepts responsibility for securing arrangements to initiate, manage and finance the research. The sponsor ensures that all authorisations have been obtained before commencement of the research and the study will be conducted in accordance with Good Clinical Practice (GCP) and other applicable standards and legislation.

The responsibilities of a sponsor may be delegated and any delegated responsibilities must be documented. Ultimately the sponsor remains accountable for all functions of sponsorship whether delegated or not.

The purpose of this SOP is to explain the process for applying and agreeing GHNHSFT sponsorship in accordance to the expectations of a sponsor's responsibilities.

Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) does not sponsor the following research: - CTIMP studies, research being conducted outside of the UK and research undertaken as part of a qualification (the university at which the student is registered should be the sponsor). Therefore, these types of research are not covered by this SOP. Research undertaken by Healthcare Science Trainees on the Scientific Training Programme and Higher Scientific Specialist Training programmes are exempt from this and their research will be sponsored by GHNHSFT.

2. Who should use this SOP?

All GHNHSFT staff who are involved in the setting up of a research project originating within GHNHSFT.

The RIG Professional Services Team who will facilitate the sponsorship process.

3. When this SOP should be used

This SOP will be referred to as soon as the Research, Innovation and Genomics (RIG) Department, on behalf of GHNHSFT is approached by a prospective researcher. For clarity, this SOP covers non-CTIMP studies and CE Marked Medical Device studies being conducted within the UK.

4. Sponsorship by GHNHSFT

GHNHSFT must be registered with the Department of Health as willing and able to act as a sponsor under the UK Policy Framework for Health and Social Care Research v3.3, 2017. This does not constitute blanket acceptance of sponsorship for all projects requiring a sponsor brought to GHNHSFT RIG department. Investigators should not presume GHNHSFT will automatically assume the role of the Sponsor.

GHNHSFT will consider acting as sponsor where the Chief Investigator (CI) holds a substantive employment contract with GHNHSFT and the proposal:

- Does not pose significant legal, financial or reputational risks to the Trust;
- Is well-designed, peer reviewed and statistically sound

5. Contacting RIG

To apply for sponsorship the prospective researcher must contact the RIG department using the generic email account ghn-tr.glos.riprofessionalservices@nhs.net as early in the process as possible. It is important the documents provided are of a high standard, whether this is a research outline/grant submission, or protocol and accompanying documents. Please refer to [SOP 29](#) Writing a Protocol for details of the details of protocol templates to be used.

6. Process for applying for GHNHSFT Sponsorship

The process for applying for Sponsorship will vary, depending on what stage the project requires confirmation of Trust Sponsorship agreement. It will prevent unnecessary delays if RIG are involved at the earliest possible stage.

Please refer to the flow-charts documenting the whole process at the end of this SOP.

6.1 Projects requiring Sponsorship in Principle for Grant Submission

Researchers preparing grant applications will require 'Sponsorship in principle' from RIG prior to submitting their grant application. Securing this is a requirement for authorisation of the grant submission by the RIG office. Applicants will need to provide a copy of the draft grant application and/or outline of the study and details of study costings to the generic RIG email account to be reviewed by the Sponsorship Review Panel. The Sponsorship Review Panel will consist of the following members;

- Director of Research, Innovation and Genomics (Chair)
- Research, Innovation and Genomics Business Manager (Deputy)
- Research Matron or Delivery Team Lead
- RIG Professional Services Manager

- Quality Assurance Manager
- Commercial Trials Unit Manager
- Head of Corporate Finance
- Assistant Management Accountant (RIG)
- HR Corporate Business Partner
- The Academic Services Manager and/or the Project Lead will attend the panel to present the grant application/provide the background information for the panel.

Three members need to be in attendance for the panel to convene, please see Appendix 1 Terms of Reference for this meeting. The panel will meet according to need.

The Sponsorship Review Panel will review the project and determine whether this project can be issued with a “Sponsorship in Principle” letter. Please see Appendix 2 Confirmation of Sponsorship in Principle.

6.2 Research Projects requiring Sponsorship for HRA and/or REC Submission which are not subject to grant funding

All proposed research projects, not requiring grant funding, but requiring an IRAS application will undergo a Project Review by GHNHSFT RIG department. Please refer to SOP 24 Project Review for full details of the process required, alongside SOP 29 Writing a Protocol.

The Project Review Committee will provide peer evaluation of the protocol and accompanying documents. Once the Project Review Committee have agreed the review is complete, the RIG Professional Services Manager will confirm with the Chair/Deputy Chair of the Sponsorship Panel, the project has been through peer evaluation and seek approval for the project to receive Sponsorship, for IRAS submission.

Once this approval is received, a letter of Sponsorship will be issued. Please see Appendix 3 Confirmation of completion of project review process for studies that require REC/HRA approval.

Confirmation of sponsorship is required for audit and inspection purposes to ensure that the sponsor named on IRAS application has accepted sponsorship and this has not been presumed.

6.3 Research Projects requiring Sponsorship but not requiring HRA and/or REC submission

It is less likely we will be involved in these studies, as any research involving NHS patients, staff, data or facilities must have HRA approval. Not all studies require REC approval, for example research involving staff only or research using previously collected non-identifiable data. Please view the HRA website for full details; the link to the website, the REC decision tool and HRA decision toolkit can be found in the references below. For further guidance, please contact RIG (ghn-tr.glos.riprofessionalservices@nhs.net).

7. Confirmation of Trust Sponsorship from “in Principle”

The following section will describe the process of moving from “Sponsorship in Principle” to confirmed Trust Sponsorship.

7.1 Successful Grant Submissions

Once a research study has received confirmation of a successful funding application, the patient-facing materials will require proportionate peer evaluation through the Project Review Committee. Please refer to SOP 24 Project Review for full details of this process. Once the Project Review Committee has confirmed the review of the patient-facing materials is complete, the RIG Professional Services Manager will

confirm with the Chair/Deputy Chair of the Sponsorship Panel, the patient-facing documents have been through peer evaluation and seek approval for the project to receive confirmation of Sponsorship, for IRAS and/or REC submission.

Once HRA and/or REC approval is received, GHNHST will need to confirm local approval through the Capacity and Capability (C&C) process, before any research activity can occur.

8. Responsibilities

The UK Policy Framework for Health and Social Care Research v3.3, 2017 calls for a clear understanding about responsibility and accountability for the conduct of research. The responsibilities of those involved in research are commonly set out in a contract.

A 'Terms & Conditions of Sponsorship' (see Appendix 4) will be issued by the RIG Professional Services Manager, alongside the "List of Responsibilities for Trust Sponsored Research" once agreement to Sponsor in Principle has been confirmed.

Where GHNHSFT is acting as sponsor, a Delegation of Responsibilities log (see Appendix 6) and CI declaration form (Appendix 7) will also be sent to the CI/PI and must be used. If any of the study activities are to be delegated to other members of the research team, this must be recorded in this log.

9. Receiving Greenlight

Once the project review process is complete, HRA and/or REC approval, and MHRA certificate of no objection obtained, (if required) a C&C review will be conducted, if the study involves GHNHSFT. This review will be based on the risk level of the study and completed by an assigned member of the Professional Services team. These reviews will be documented on EDGE using the appropriate EDGE workflows. Once the C&C

review has completed, sponsorship responsibilities will be assessed and documented on a separate Sponsorship workflow.

If the sponsored study involves a site or sites other than GHNHSFT, the assigned member of the Professional Services team will review those sites using the Sponsorship EDGE workflows.

Once the C&C approval is granted, a greenlight email (Appendix 11) will be issued confirming the research study is approved and open. No research protocol activity can commence until the greenlight email is received.

Please refer to [SOP 11](#) Confirmation of Capacity and Capability and Guidelines for the Greenlight Process.

10. References

[UK policy framework for Health and Social Care Research v3.3, 2017](#)

[Research Support Service Hub | NIHR](#)

[Research passport - Health Research Authority](#)

[IRAS Help - Preparing & submitting applications - HR Good Practice Resource Pack](#)

[HRA Approval - Health Research Authority](#)

[Is my project research? How to determine which projects require review by a Research Ethics Committee - Health Research Authority](#)

[Do I need NHS Ethics approval?](#)

[Transparency wording for all sponsors - Health Research Authority](#)

Appendix 1 Terms of Reference for the Sponsorship Panel meetings

Gloucestershire Hospitals NHS Foundation Trust

RIG Sponsorship Panel Meetings

Terms of Reference

Accountable to	Research & Innovation Heads of Service Meeting
Chair	Research, Innovation & Genomics Director
Deputy Chair	Research, Innovation & Genomics Business Manager
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 Sponsorship panel meetings is to review studies in relation to Sponsorship requirements and decide whether a study can be sponsored by GHNHSFT.

2. AUTHORITY

The group is attended by the senior RIG 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 (Chair)
- Research, Innovation & Genomics Business Manager (Deputy Chair)
- Research Matron or Delivery Team Lead associated with speciality/study being presented
- Head of Corporate Finance
- Assistant Management Accountant (RIG)
- RIG Professional Services Manager
- Quality Assurance Manager
- 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, and will be recorded for audit purposes.
- e) Outcomes from the Panel meeting will be recorded in writing and sent to the prospective PI.

- 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 research studies requesting Trust Sponsorship

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.

Appendix 2 – Confirmation of Sponsorship in Principle for grant funding applications

Dear XXXXXXXX,

Study Title:

RIG Ref:

Thank you for submitting your draft grant application/outline of your Research Project to the Research, Innovation and Genomics Department at Gloucestershire Hospitals NHS Foundation Trust. Your project was reviewed by the GHNHSFT Sponsorship Review Panel on the following dates: dd/mm/yyyy [*and dd/mm/yyyy*], and documents reviewed are detailed at the end of this letter.

I am able to confirm agreement from the Trust to act as Sponsor in Principle for the above referenced project under the UK Policy Framework for Health and Social Care Research 2017. Please find attached the Trust 'Terms and Conditions of Sponsorship' and responsibilities document for your information and perusal.

Your study requires a successful grant submission, followed by a review of any patient-facing documents, by the Project Review Committee, before Sponsorship will be fully agreed and the HRA process can be commenced.

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 RIG Office if required. * (delete as appropriate)

Following receipt of an NHS Favourable Ethical Opinion and/or HRA approval, you will need to apply to the RIG Office for full Trust Approval (Confirmation of Capacity and Capability) before commencing your study.

Your project has been recorded on the EDGE database including the details below

- Title:
- Chief Investigator:

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- Sponsoring Organisation:
- Host Trust:
- Type of Study

Please contact the RIG Department (ghn-tr.glos.riprofessionalservices@nhs.net) if you have any questions about the next stages of the HRA/ethics review.

Yours sincerely

RIG Professional Services Manager

Final documents reviewed:	Version
<i>List all documentation received as part of the final approval {including the researcher's CV and Study protocol}.</i>	

Appendix 3 - Confirmation of Sponsorship for research studies that require HRA and/or REC approval without grant funding

Dear XXXXXXXX,

Study Title:

RIG Ref:

Thank you for submitting your Research Project to the Research, Innovation & Genomics (RIG) Department at Gloucestershire Hospitals NHS Foundation Trust *[and for following up on the questions raised by the GHNHSFT Project Review Committee]*. Your project was reviewed by the GHNHSFT Project Review Committee on the following dates: dd/mm/yyyy *[and dd/mm/yyyy]*, and the final documents reviewed are detailed at the end of this letter.

I can confirm that the Project Review process is now complete, and I am able to confirm agreement from the Trust to act as Sponsor for the above referenced project under the UK Policy Framework for Health and Social Care Research 2017. Please find attached the Trust 'Terms and Conditions of Sponsorship and responsibilities' document for your information and perusal.

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

Your study requires submission through the Integrated Research Application Service (IRAS) platform to obtain Health Research Authority (HRA) *[and NHS Research Ethics Committee (REC)]* approval. Advice about the application can also be requested from the RIG Office if required.

Following receipt of approvals from HRA/REC, you will need to apply to the RIG Office for full Trust Approval (Confirmation of Capacity and Capability) before commencing your study.

Your project has been recorded on the EDGE database including the details below

- Title:
- Chief Investigator:
- Sponsoring Organisation:
- Host Trust:
- Type of Study

Thank you for your application. Please contact the RIG Department (ghn-tr.glos.riprofessionalservices@nhs.net) if you have any questions about the next steps..

Yours sincerely

RIG Professional Services Manager

Final documents reviewed:	Version
<i>List all documentation received as part of the final approval {including the researcher's CV and Study protocol}.</i>	

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Appendix 4 – Terms and Conditions of Sponsorship

Gloucestershire Hospitals NHS Foundation Trust Terms and Conditions of Sponsorship

Gloucestershire Hospitals NHS Foundation Trust agrees to act as sponsor for the above project, subject to the following terms and conditions. Sponsorship may be withdrawn at the Trust's discretion if any of these are breached:

1. The Chief Investigator, Principal Investigator(s) and all members of the research team shall comply with all regulations applicable to the research including, but not limited to:
 - UK Policy Framework for Health and Social Care Research v 3.3 2017;
 - The World Medical Association Declaration of Helsinki (2024);
 - Guideline for good clinical practice E6(R2) (July 2025);
 - Human Tissue Act 2004;
 - Mental Capacity (Amendment) Act 2019;
 - Data Protection Act 2018.
2. The project must be conducted in accordance with the 'List of Responsibilities for Trust Sponsored Research' document [Appendix 2] and any further delegations recorded in the 'Delegation of Responsibilities Log' [Appendix 3].
3. The project **must not** commence at Gloucestershire Hospitals NHS Foundation Trust or any other research site until:
 - A favourable ethical opinion has been obtained from the relevant NHS Research Ethics Committee (REC), if applicable;
 - Confirmation of Capacity and Capability (for HRA approved research) and Trust approval (for non-HRA research) has been granted by the GHNHSFT RIG office and the R&D offices of all other NHS organisations participating in the project and all necessary site agreements are executed;
 - Non-Trust employees having direct contact with patients and/or having a direct bearing on the quality of their care have honorary contracts in place;
 - Arrangements are made for the recovery of associated costs or, if externally funded, financial arrangements are covered by a suitable agreement approved by the Research & Innovation office;
 - In the case of a Clinical Investigation of a Medical Device (CiMD) a Declaration of No Objection has been obtained from the MHRA;
 - Such other regulatory approval(s) require for the research to proceed have been obtained.

Appendix 5 – List of Responsibilities for Trust Sponsored Research

- (1) The UK Policy Framework for Health and Social Care Research v 3.3 2017 and ICH Good Clinical Practice (GCP) Guidelines (E6 R3) requires all research staff to be aware of their responsibilities. Where any responsibilities in the table below are delegated to an individual other than indicated, this must be recorded in a 'Delegation of Responsibilities Log.'
- (2) In the case of a single-centre project, the Chief Investigator (CI) and Principal Investigator (PI) will be the same person.
- (3) Accountabilities are not delegable. Where there is only a symbol for accountability, responsibility will lie also.
- (4) 'TEAM' includes research nurses, research coordinators and other research personnel.
- (5) Key – A = Accountable R = Responsible

Before trial commences					
	Activity	Trust	CI	PI	Delivery Team
1	Develop ethically, scientifically and statistically sound research protocol. For educational research sponsored by the Trust, the scientific validity and quality will also require review from the relevant University ethics committee.	A	R		
2	Prepare Participant Information Sheet(s) (PIS), Consent Form(s) (CF) and other documents including, where applicable, consent for obtaining human tissue, medical data or other material	A	R		
3	Secure funding	A			
4	Present project at Sponsorship Panel		A		
5	Ensure adequate funding in place. Approved at Sponsorship Panel	A			
6	Administer Funding	A			
7	Ensure protocol has undergone independent scientific and statistical review through the Project Review Committee and is compliant with applicable regulations.	A	R		
8	Prepare and submit ethics application	A	R		
9	If applicable ensure favourable opinion in place for each location from the appropriate NHS Research Ethics Committee (REC) and /or HRA	A	R		
10	Prepare documentation for MHRA to receive declaration of no objection	A	R		
11	Obtain certificate of no objection from the MHRA	A	R		

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Before trial commences (continued)					
	Activity	Trust	CI	PI	Delivery Team
12	Obtain NHS R&D approval from each NHS organisation involved in the research	A	R		
13	Prepare approval applications from other relevant bodies (e.g., ARSAC, HTA)	A	R		
14	Obtain approvals from other relevant bodies (e.g., ARSAC, HTA)	A	R		
15	Ensure insurance/indemnity arrangements in place to cover liabilities	A			
16	Register trial with appropriate protocol registration scheme(s)	A	R		
17	Design of case report forms and database	A	R		
18	Ensure training has been conducted on the study either through the SIV or as a separate event. Ensure a SIV has taken place.	A	R		
19	Ensure that no participants are recruited until all necessary approvals have been received	A	R	R	
20	Ensure local Capacity and Capability approval in place	A	R	R	
21	Issue greenlight for location/s once C&C approval checked	A	R		

Conduct of the trial					
	Activity	Trust	CI	PI	Delivery Team
26	Ensure research team are appropriately qualified by education and experience to undertake their role(s) and they have current substantive or honorary employment contracts in place	A	R	R	
27	Ensure students and new researchers are adequately supervised	A	R	R	R
28	Ensure core research team members have completed ICH GCP training (in previous 3 years)	A	R	R	R
29	Ensure applicable legislation is followed	A	R	R	R
30	Put and keep in place arrangements to allow all research staff to conduct the trial in accordance with the Protocol and any agreed contract	A	R	R	
31	Ensure the rights, safety, dignity and well-being of participants are protected and that they receive appropriate medical care whilst participating in the trial		A	R	R
32	Ensure informed consent is received for each participant in accordance with Protocol and approved patient-related documentation		A	R	R
33	Inform, where practicable, health or social care professionals if their patient is a participant in the trial at each trial location		A	A	R
34	Ensure trial is managed, monitored and reported as agreed in the protocol	A	R	R	R
35	Ensure trial data are collected in accordance with the Protocol and ensure integrity and confidentiality of all data collected	A	R	R	R
36	Ensure appropriate analysis of data		A		
37	Ensure trial is conducted in accordance with ICH GCP and applicable legislation	A	R	R	R

Conduct of the trial (continued)					
38	Prepare amendments to HRA/REC/MRHA	A	R		
39	Submit amendments to HRA/REC/MHRA	A			
40	Ensure research team aware of dates of approval and version changes for implementation of amendments	A	R	R	
41	Maintain trial documentation in accordance with regulatory requirements and ICH GCP	A	R	R	R
42	Ensure e/Trial Master File (TMF) (held by the CI) and documentation are complete, accurate and legible	A	R		R
43	Ensure e/Investigator Site File (ISF) and documentation are complete, accurate and legible	A	R	R	R
44	Ensure all data and documentation are available for monitoring, audit or inspection and that appropriate consent has been provided by the Participant	A	R	R	R
45	Maintain detailed records of all Adverse Events (AE) as specified in the Protocol	A	R	R	R
46	Report adverse events as specified in the Protocol and regulatory requirements	A	R	R	R
47	Ensure all Serious Adverse Events (SAE) other than those specified in Protocol as not requiring immediate reporting are recorded, assessed and reported in line with the regulatory requirements and Trust policy	A	R	R	R
48	Ensure all SAEs are reviewed by an appropriate committee for monitoring trial safety (if applicable)	A	R		

Conduct of the trial (continued)					
49	Promptly inform REC/MHRA and investigators at the trial location and other locations of any urgent safety measures taken to protect participants	A	R	R	R
50	Ensure all investigators are, at all times, in possession of the current relevant safety information for the trial	A	R		
51	Periodic reporting to regulatory authorities as per SOP 19. Copies provided to the RIG office	A	R	R	
52	Maintain a record of patient recruitment and report recruitment on EDGE in line with Trust policy	A	R	R	R
53	Report suspected breaches of protocol, ICH GCP and research misconduct and fraud	A	R	R	R

Suspension, termination and completion of the trial					
	Activity	Trust	CI	PI	Team
54	Notify regulatory authority(ies) and relevant REC of Trial if suspended or terminates early	A	R	R	
55	Notify regulatory authority(ies) of the end of the Trial	A	R		
56	Ensure all trial records are archived appropriately on conclusion of the Trial and retained in accordance with regulatory requirements and protocol	A	R	R	
57	Initiate and coordinate review and submission of abstracts, posters and publications	A	R		
58	Close down and archiving procedures	A	R	R	

Appendix 7 – CI Declaration Form

Chief Investigator Declaration Form

GHNHSFT Sponsorship is subject to the following provisions:

- The Chief Investigator has overall responsibility for ensuring that the study is conducted in accordance with all applicable regulations and in accordance with GHNHSFT SOPs available on the GHNHSFT website at: [Standard Operating Procedures \(SOPs\)](#).
- The Chief Investigator must agree to the [GHNHSFT List of Responsibilities for Trust Sponsored Research](#) and to accept their delegated responsibilities in accordance with the [Delegation of Responsibilities Log](#), as outlined in the SOP 27: [Applying Obtaining Sponsorship for non-CTIMP and CE marked Medical Device Research Studies](#).
- The Chief Investigator is accountable to the Sponsor.
- Sponsorship may be withdrawn where the Chief Investigator fails to comply with the GHNHSFT List of Responsibilities for Trust Sponsored Research.
- The Chief Investigator undertakes CI/PI training at least every 3 years*

If you agree to the above, please sign and return this declaration form. Alternatively, please return the form via email, confirming that you accept the following terms (this must be sent from your professional email account).

Declaration:

I have read and agree to the [GHNHSFT List of Responsibilities for Trust Sponsored Research Terms](#) and to accept my delegated responsibilities in accordance with the [Delegation of Responsibilities log](#), as outlined in the SOP on [Obtaining Sponsorship for non-CTIMP and CE marked Medical Device Research Studies](#).

I agree to ensure that the study is conducted in accordance with all applicable regulations and in accordance with GHNHSFT SOPs available on the GHNHSFT website at: [Standard Operating Procedures \(SOPs\)](#)

Chief Investigator Name: _____

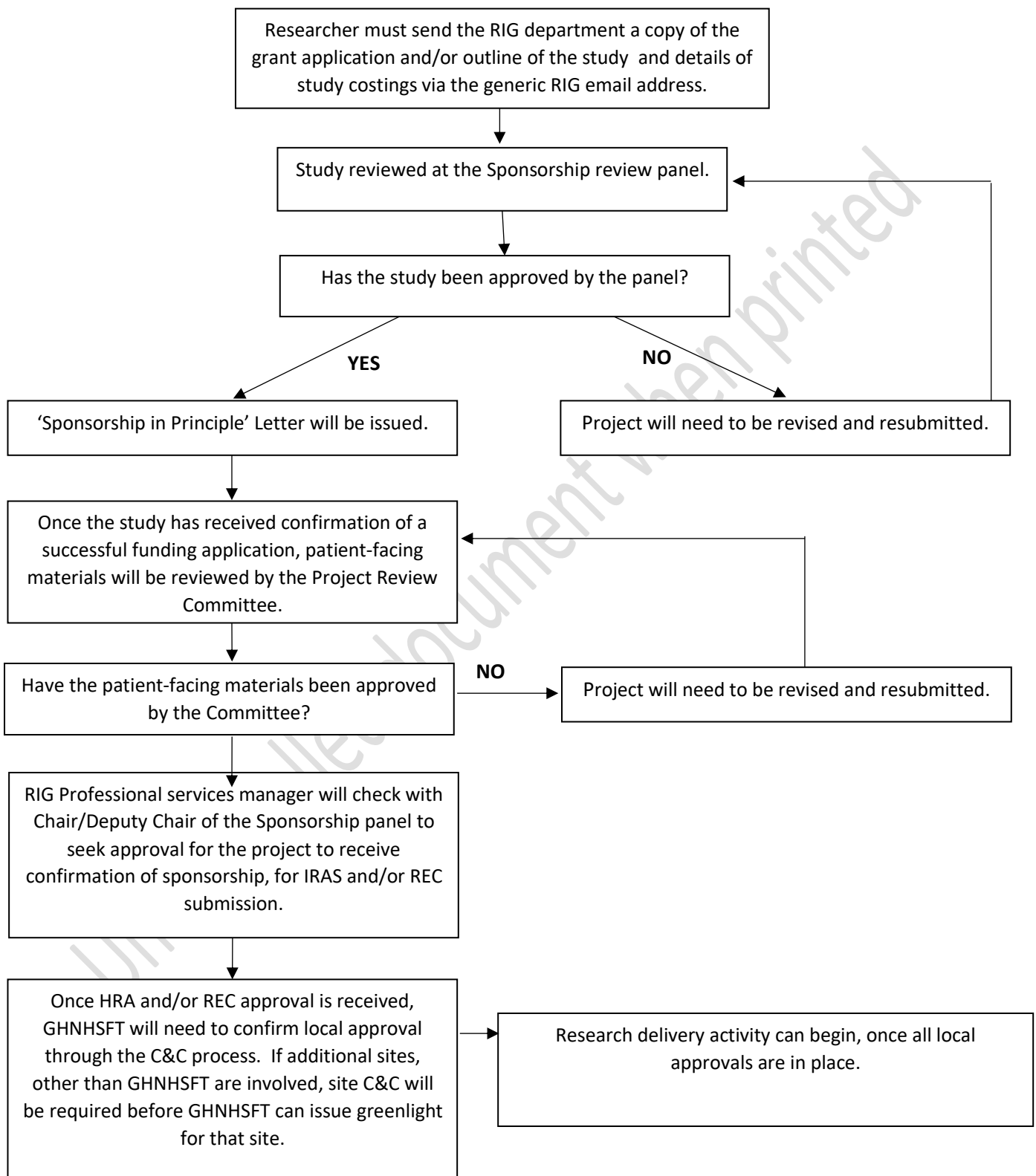
Chief Investigator Signature: _____

Date: _____

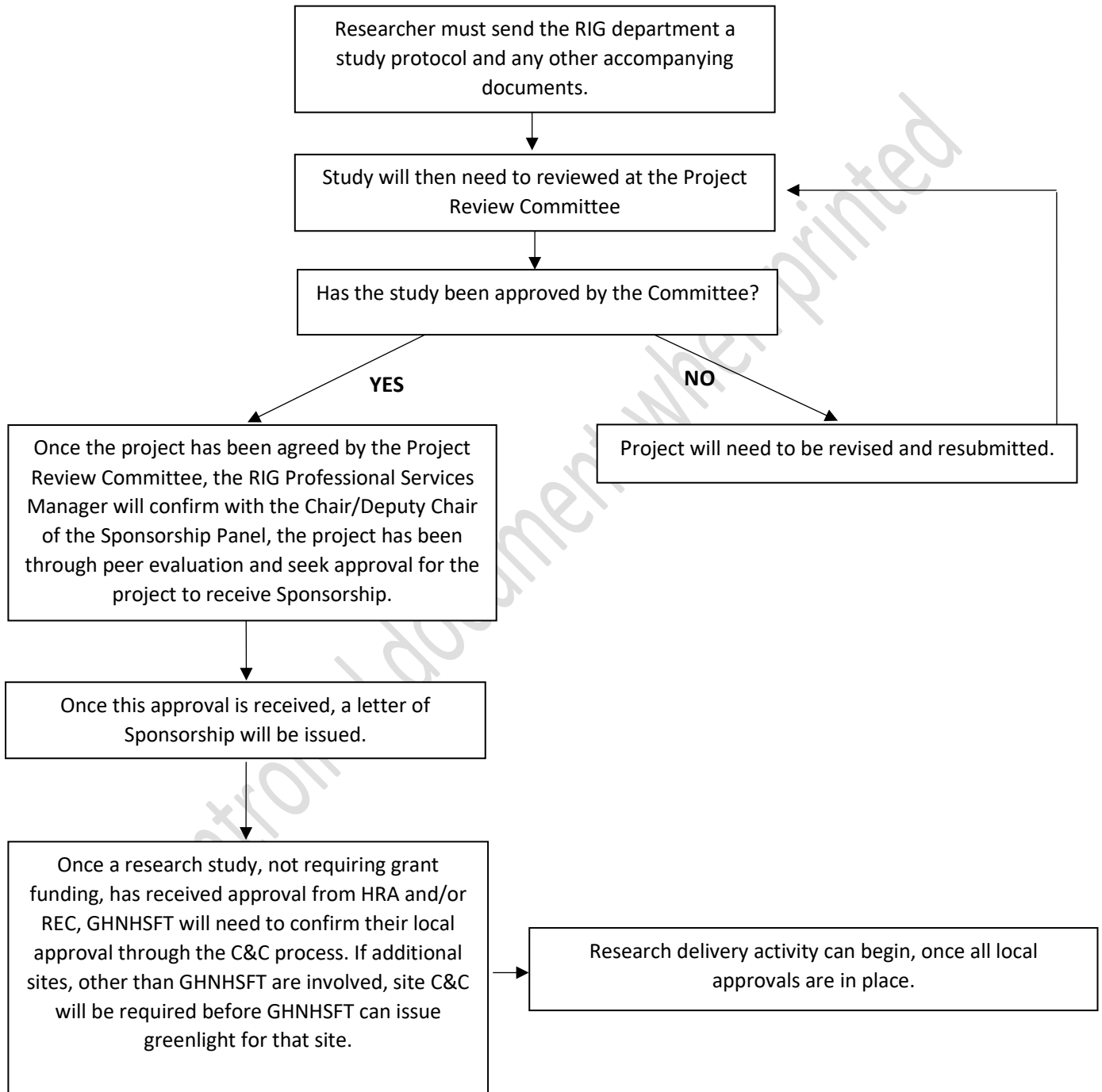
* or more frequently depending on sponsor decision from monitoring and breach outcomes.

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Appendix 8 – Flow Chart for Projects requiring Sponsorship in Principle for Grant Submission



Appendix 9 - Flow Chart for Projects requiring Sponsorship for HRA and/or REC Submission which are not subject to grant funding



Appendix 10 – Pro forma to be used at Sponsorship Panel

Study name/Grant involved:	
Project Lead:	

Notall questions will be applicable to each project	
Confirm the Trust is the most appropriate organisation to Sponsor and that the project aligns with current SOP on Sponsorship	
Comments:	
Bid application/ study outline addresses a clear question/need.	
Comments:	
Background information adequately justifies the project.	
Comments:	
Significance to patients/NHS is clear.	
Comments:	
Appropriate methodology used for the project.	
Comments:	
Ensure Trust support departments and/or supporting partners of the bid have been informed and have agreed to support the application/project. Confirm there are adequate facilities, resources and support to conduct the project	
Comments:	
Confirm the project lead, and other team members if applicable, have adequate skills and experience to deliver the project	
Comments:	

Ensure statistical input has occurred, for sample size and data analysis plan		Yes / No
Comments:		
Is the patient recruitment / consent process suitable for the study patient population?		Yes / No
Comments:		
Has PPI/E been considered? Explanation of PPI/E involvement with the project development and plans for continued PPI/E involvement in the oversight of the delivery of the project		Yes / No
Comments:		
Has data handling and storage been sufficiently described		Yes / No
Comments:		
Has the SoECAT/schedule of events been approved by the Research Finance team and confirmed the funding covers all aspects of the project		Yes / No
Comments:		
Are any risks associated with the study clearly addressed in the bid/study outline and justified ethically by study benefit/significance?		
Comments:		

Review Outcome:		
Outcome:	Project can be Sponsored and grant submitted once Trust finance approval received	<input type="checkbox"/>
	Decision deferred pending further information	<input type="checkbox"/>
	Unable to Sponsor and further advice given	<input type="checkbox"/>

Date of Review:	
Sponsorship panel members present:	

Appendix 11 – Greenlight template

Email Template:

Dear *PI name*,

Please find attached the Greenlight Letter for your site for the *xxxxxx* Study. This confirms that, as of *today date*, your site is now activated and you may begin recruitment.

Please ensure this is filed within your ISF.

Many thanks for all the work you and your team have put in to get your site activated.

Best wishes

Greenlight letter template

The image shows a template for a Greenlight letter. It features the NHS Gloucestershire Hospitals logo at the top right, with the text 'NHS Gloucestershire Hospitals NHS Foundation Trust'. Below the logo is the contact information for Research and Innovation: 'Research and Innovation, Leadon House, Gloucestershire Royal Hospital, Great Western Road, Gloucester, GL1 3NN, ghn-tr.glos.riprofessionalservices@nhs.net'. A red 'Date' label is positioned to the right of the contact information. On the left side, there are five red placeholder labels: 'PI name', 'PI Address', 'PI Address', 'PI Address', and 'PI Address'. Below these is a redacted area for the 'RE:' field, with a table structure: 'Study: Study Name' and 'Greenlight for site: Name of site.'. The main body of the letter contains the following text: 'Dear PI name,', 'Following completion of your site initiation visit on date of SIV, I can confirm that all necessary documentation and actions have been completed.', 'Therefore, I am pleased to inform you that, as of today's date, your site is now activated.', 'Your primary contact will be Name and email.', and 'Please ensure this letter is filed in your Investigator site file.'. The letter concludes with 'Yours sincerely' and a redacted signature area with 'Name' and 'Title' labels. A blue circular graphic at the bottom left contains the text 'Research, Innovation and Genomics'. A large, faint watermark 'Not printed' is visible across the right side of the template.