Gloucestershire Hospitals NHS Foundation Trust

SOP 11: Confirmation of Capacity and Capability

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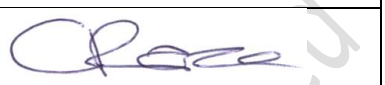
Author:	Gemma Race	
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IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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.

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 13	
2.0	Reviewed and updated to show HRA processes, along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	01/02/2017
3.0	Rebranding to GHNHSFT and updating of contact details and reference documents	31/03/2018
4.0	Inclusion of Finance attributes	Not implemented
5.0	Correction of typographical errors, updating of website links, removing references to statement of activities, removing reference to the Gloucestershire Research Support Service as devolved to GHNHSFT R&D team, removed reference to Gloucestershire Research Consortium, Insertion of a glossary, Insertion of two appendices regarding set up activities, Removal of SOP categories and change of reference codes	30/10/2023
6.0	Departmental name change to R&I from R&D, internet links updated. Inclusion of template C&C email and letter	13/05/2024
7.0	Departmental name change from R&I to RIG, review schedule updated to three years. Clarification on greenlight process for GHNHSFT sponsored studies and process for PIC studies and service evaluations. Other minor amendments	01/09/2025

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

Related Documents:

SOPs	SOP 10: Hosting CTIMPS and other clinical studies
	SOP 13: Monitoring & Oversight of Hosted Studies
	SOP 20: Adverse events and reaction safety reporting
	SOP 38: Monitoring and oversight of sponsored research studies (Non-CTIMPs)
Guidelines	Guidelines 12: Study Setup (Professional Services) Workflow

Glossary

ARSAC	Administration of Radioactive Substances Advisory Committee
aRPM	Assistant Research Portfolio Manager
CPMS	Central Portfolio Management System
CTUM	Commercial Trial Unit Manager
C&C	Capacity and Capability
EoI	Expression of Interest
ETC	Excess Treatment Cost
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRMER	Ionising Radiation (Medical Exposure) Regulations
LCRN	Local Comprehensive Research Network
LIP	Local Information Pack
MHRA	Medicines and Healthcare Products Regulatory Agency
NIHR	National Institute for Health Research
ODP	Open Data Platform
OID	Organisation Information Document
PI	Principal Investigator
RIG	Research, Innovation & Genomics
RPM	Research Portfolio Manager
RO	Research Officer
SEV	Site Evaluation Visit
SIV	Site Initiation Visit
SoE	Schedule of Events
SoECAT	Schedule of Events Cost Attribution Template
SSV	Site Selection Visit
TU	Trials Unit

Contents

1. Introduction, Background and Purpose

This SOP sets out to provide clarity about the process to be followed before Confirmation of Capacity and Capability (C&C) is given to deliver a research study in Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT). Obtaining Confirmation of C&C is an essential precondition to the conduct and delivery of any portfolio or non-portfolio research study where it is noted on the Health Research Authority (HRA) Approval letter, and it is also a local requirement for any project taking place in the Trust e.g. Service Evaluations and Student projects.

HRA Approval is the process for the NHS in England that comprises a review by an NHS Research Ethics Committee (REC) (where required), MHRA (where required), as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as local governance review. This allows NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

HRA Approval applies only to the NHS in England. The HRA has compatibility arrangements in place with the national NHS Permission coordinating function in Northern Ireland, Scotland and Wales that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisations across the UK where applicable. Further information about this can be found at: https://www.hra.nhs.uk/approvals-amendments/

2. Who Should Use This SOP

This SOP should be used by:

- Members of Gloucestershire Hospitals NHS Foundation Trust Research, Innovation and Genomics (RIG) Team
- Research study staff (those staff not directly managed by RIG)

3. When this SOP Should be Used

This SOP should be used when anyone applies for Confirmation of Capacity and Capability to undertake a research study in the Trust. This includes studies sponsored by the Trust as well as studies that are externally sponsored and hosted within the Trust. It also includes GHNHSFT service evaluations and student projects made directly to the GHNHSFT RIG Department.

4. Procedure(s)

The HRA has defined the different stages that sponsors and participating organisations (the Trust) go through on the way to mutually agreeing that the study can open at that organisation (the Trust). These stages can be used to identify time points which the Trust may wish to measure in order to examine where barriers to study set up and delivery occur.

a. **Assessing:** Assessing whether or not the Trust has the capacity and capability to participate in the study.

NB This stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the Trust will participate unless there is a significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires, online surveys or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for on-going clinical care but the responsibility for the research remains with the original Principal Investigator.

b. **Arranging:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study.

c. **Confirming:** Confirming that the Trust has the capacity and capability in place to deliver the study and will deliver the study. This confirmation is given through the mutual agreement of the contents of the Organisation Information Document (OID) and/or sign-off of contract/agreement for non-commercial studies, or sign-off of contract/agreement for commercial studies.

5. Confirmation of Capacity and Capability

5.1 Assess:

- The sponsor/CI/study co-ordinator invites the Trust to assess their local capacity & capability to participate in a study. This invitation will come via the RIG Professional Services in-box or directly from the PI/ research team and will usually consist of:
  - Commercial trial – protocol, industry costing tool and agreement.
  - Non-commercial – protocol, OID/trial agreement and Schedule of Events (SoE)/Schedule of Events Cost Attribution Template (SoECAT).
- If an EoI has been submitted, or feasibility process completed, through the RIG Professional Services team, particularly for commercial studies, much of the assessment will have occurred on submission of the feasibility questionnaire and at the subsequent site evaluation visit (SEV)/site selection visit (SSV).
- The review will only start once there is confirmation GHNHSFT has been accepted as a site and, if required, an amendment has been submitted to the HRA for approval.
- Depending on the study, a Research Portfolio Manager (RPM), or member of the delivery team, will cascade the study documentation to the relevant research team and supporting department research contacts for them to assess, with the support of the RPM, whether the study is feasible. If the research team consider the study feasible to deliver, the RPM will confirm with the Sponsor and request the Local Information Pack (LIP) (see appendix 1).

NB. The Sponsor/CI can send out a LIP once they have received the initial assessment letter from the HRA. The LIP can be declined if received before the RIG Professional Services team are in a position to begin the assessment of C&C, see Appendix 7 for email template

- Concurrently to the above, the Assistant RPM (aRPM) will request the GHNHSFT's involvement in the study on EDGE, if this has not already occurred when the Expression of Interest (EoI) was submitted. This will allow EDGE workflows to be created to collect the information required to perform Capacity and Capability checks.
- If the research team or supporting departments do not have capacity or capability to deliver the study, the RPM will email the sponsor to notify them.
- Consider with the research team and PI when the first patient first visit (FPFV) will take place; discuss and agree the recruitment target with the delivery team and PI. This target should be agreed with the Sponsor/TU.
- All research studies must have at least one Sub-Investigator identified.
- Once confirmed the study is feasible, ensure PI has a signed CV within the last twelve months and a Good Clinical Practice Certificate dated within the last three years before proceeding.

Actions:

- Request involvement for GHNHSFT on EDGE for the study as well as create a new study folder on the RDSU drive. Move KanBan card from 'GHNHSFT EOIs' board to 'GHNHSFT Research Activity' board once selection has been confirmed.
- Obtain the LIP from the sponsor ensuring it is complete (see Appendix 1) which may include requesting the pharmacy and/or laboratory/ Radiology manual(s) as appropriate to the study. Date LIP received will be considered the 'date site selected' for the purposes of EDGE workflows.
- Undertake an assessment of the study agreement/OID and industry costing tool (iCT)/schedule of events/SoECAT.
- Review NHS cost and resource implications. Excess Treatment Costs (ETCs) will be detailed in the SoECAT. The NIHR Open Data Platform (ODP) will specify the

commissioners responsible for the ETCs for a study. Check for up to-date guidance for ETCs on the NIHR website.

- If the study agreement, if applicable, is acceptable, after discussion with PI and lead nurse/coordinator for the trial, localise and return to sponsor. Preferably the sponsor will be asked to sign once local signing has occurred. Where possible, signature by DocuSign or equivalent is requested. Signatures to be arranged as per appendix 6, Signature Flowchart.
- If the OID (if applicable) is acceptable, request a review and signature and hold until issue of Confirmation of Capacity and Capability email. Signatures to be arranged as per appendix 6.
- Request authorisation from the relevant support departments. Emails or meeting notes may be used as confirmation.
- A study sponsor must obtain an ARSAC certificate where the protocol requires administration of radioactive material (for medical purposes), also in cases where the protocol specifies the frequency, activity or processing for an administration that would otherwise be considered standard of care. The study sponsor is responsible for providing the licence to GHNHSFT. If requested by a Sponsor, details of individual licences for GHNHSFT staff can be obtained by contacting the Head of Nuclear Medicine.
- A check of IRMER status/requirements. If a participant is exposed to any ionising radiation after they have consented (even if it would be considered standard) then a Medical Physics expert (MPE) review is required for the overall study and for each individual site. The study details and documents should be sent to the Head of Nuclear Medicine for this review.
- Where staff not employed by GHNHSFT will have contact with patients or staff from GHNHSFT identify (check the Schedule of Events) honorary employment contract / letter of access requirements and ensure that all relevant research passports/honorary contract (or letter of access) application forms and/or copies of NHS substantive contracts are available (or are obtained) (See SOP 18). HRA approval letter will also detail requirements.
- Consider who will be responsible for uploading accruals to EDGE. If the study is being undertaken by one of the Trust's research study staff or delivery teams, it will

be their responsibility. If the study is being undertaken by an external organisation and the Trust's research team are not involved then it will be the RPM responsibility to negotiate how many accruals the Trust will receive, ensure they are notified of accruals and upload them to EDGE.

5.2 Arrange:

Actions

- Clarify with the sponsor and team if there is study specific training required.
- Confirm SIV date and those staff required to attend.
- Confirm IMP delivery date.
- Any other arrangements e.g., Service Level Agreements, freezer, drug cabinet etc
- ARPM to localise study documents in collaboration with delivery team, if not provided by the Sponsor
- Ensure EDGE is updated through the workflows, project site status and date open to recruitment.

5.3 Confirm:

Actions

- Ensure HRA Approval has been received and upload latest versions of documents to the study folder onto the RDSU Drive and EDGE.
- Ensure study agreement is fully executed and/or OID is completed.
- Pharmacy confirmation of readiness has been received (IMP studies).
- Laboratory confirmation of readiness has been received (if relevant).
- Confirmation from any other relevant support departments has been received, if appropriate. All correspondence confirming readiness of support departments should be saved to the electronic R&D folder.
- All required honorary contracts/letter of access ready to issue.
- If the above are confirmed, agree a start date/drug delivery date with the sponsor and issue Confirmation of Capacity and Capability email (Appendix 4) to sponsor, PI, delivery team, research study staff and support departments involved.
- Contract/OID and PI responsibilities letter (Appendix 5) to be sent with Confirmation of C&C email, PI to sign and return to RIG Professional Services team.

- Confirmation of Site greenlight received.
- Lastly, ensure the route for uploading of accruals has been agreed (see last point in **Assess: Actions**).

6. Process for GHNHSFT Sponsored Projects and Low-Risk Projects

Service Evaluations and Student Projects which have been through the Project Review process (RIG SOP 24) will undergo a shortened C&C process using the low-risk review (based on the EDGE workflow), prior to Confirmation of C&C being given. PIC studies and service evaluations not sponsored by the Trust will also undergo a shortened low risk C&C review prior to Confirmation of C&C being given.

Research studies, sponsored by GHNHSFT will be reviewed through a combined C&C and sponsorship review based on the level of risk of the project. Please refer to Guidelines 12 EDGE Study Setup

7. References:

- HRA: Approvals and amendments - Health Research Authority (hra.nhs.uk)
- NIHR : https://www.nihr.ac.uk/
- NIHR ETC information: Excess treatment costs | NIHR
- ODP: https://rdn.uk.qlikcloud.com

Appendix 1: Local Information Package

The sponsor should provide the following information to the site:

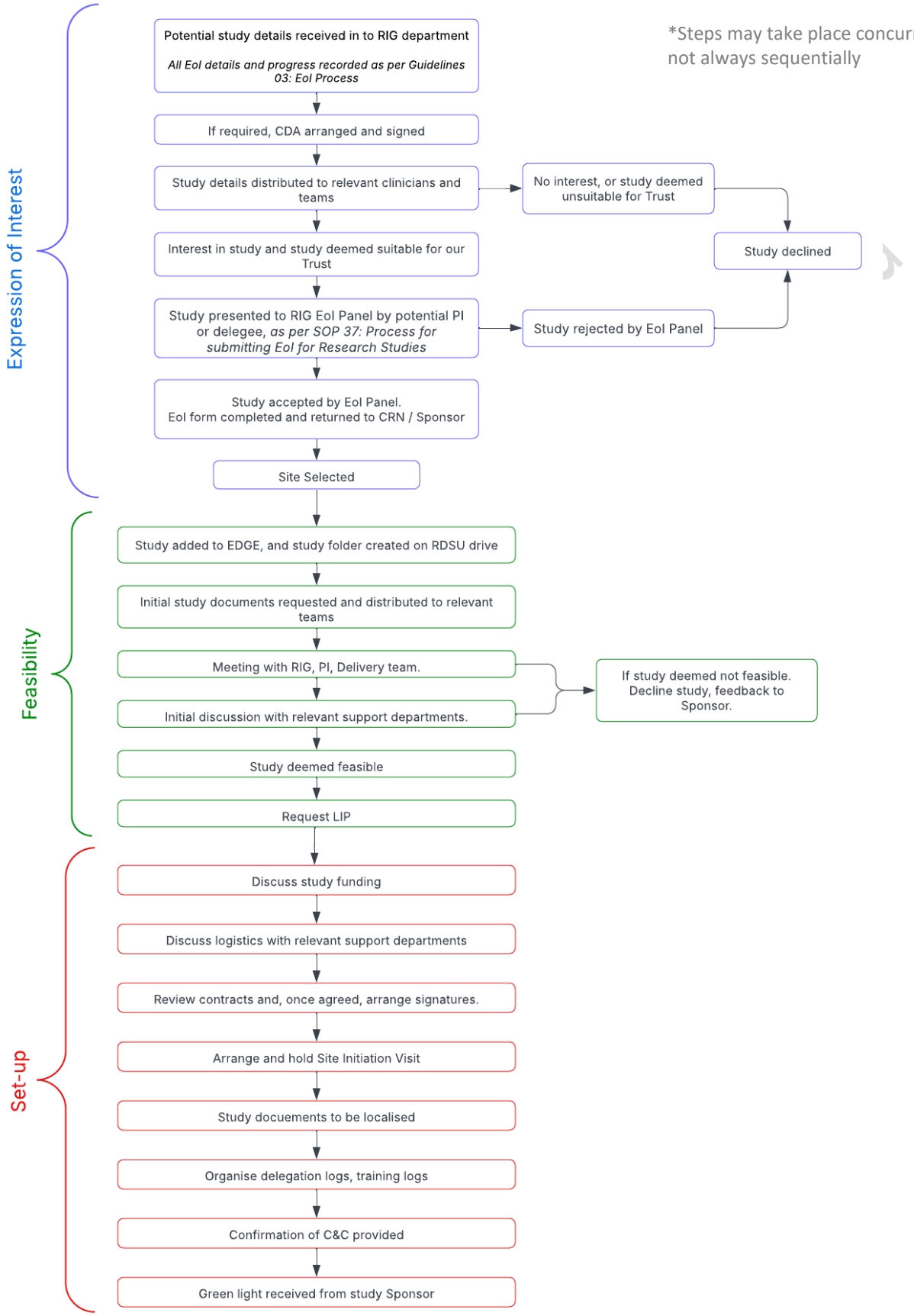
- Copy of the HRA Initial Assessment letter
- Copy of IRAS application form
- Protocol
- Any amendments including the amendment confirming that GHNHSFT is a site if not part of the original IRAS application (HRA approvals and amendment tools)
- Participant Information, consent documents, GP letters
- Relevant model agreement (where applicable)
- Access to the NIHR Costing template – commercial studies
- SoECAT- non-commercial studies
- Schedule of Events – non-commercial studies
- OID– non-commercial studies
- To be provided once available:
  HRA Approval letter and final document versions

Appendix 2: Study Set-up Activities – roles and responsibilities

Activity	Senior RPM/CTUM	RPM	Assistant RPM	Delivery team	PI
Distribute EoI details			X		
Complete EoI form			X	X	X
Request access on EDGE		X	X		
Create study folder			X		
Check GHNFT on IRAS or amendment			X		
Check correct PI listed on IRAS or amendment			X		
Check relevant approvals (HRA/MHRA etc)	X	X	X		
Initial contact with PI	X	X		X	
Contact support departments with study details and request any relevant licenses	X	X		X	
Discuss support Department logistics				X	
Add and update study set-up workflow	x	X		X	
Organise SIV	X	X	X	X	
Funding review	X	X			
ETC check	X	X			
Negotiate Contracts	X	X			
Attend SIV	X	X		X	X
Localise documents			X	X	
Delegation log				X	
Check CVs and GCPs			X	X	
Request CVs and GCPs	X	X		X	
Add EDGE forms	x	X			
Add patients to EDGE				X	
Close down activities				X	
Prepare documents for archiving		X	X	X	
Invoicing	X	X	X		
Patient Expenses reimbursement				X	
Organising amendments and localising new documents		X			
Review Category A amendments		X		X	
Update EDGE status and dates (at both site levels if sponsor)	X	X	X		
Request analysis code	X	X			
SAE reporting				X	

Those highlighted in green are part of the Assess stage of study C&C, the responsibility for these activities depends on the type of study and capacity within the teams. If the study does not need Delivery Team support, then a member of the Professional Services Team (aRPM/RPM/senior RPM/CTUM) will complete these tasks. If the Delivery Team are involved a discussion between teams is required to discuss who has capacity to complete them.

Appendix 3: Setup flow chart*



Appendix 4: Template Confirmation of C&C email

Enc: Document Log, contract/OID and PI responsibilities letter

To: Sponsor/TU contact; PI

CC: Other Sponsor/TU contacts, Sub-Is, Research Matron, Delivery team, relevant support departments

Subject: IRAS: – - Confirmation of Capacity and Capability at Gloucestershire Hospitals NHS Foundation Trust

Dear xxxx,

Local RIG Number:

Full Study Title:

This email confirms that Gloucestershire Hospitals NHS Foundation Trust has the capacity and capability to deliver the above referenced study. Please see attached the PI responsibilities letter, a current document log and the fully executed contract / OID.

We agree to start this study on a date to be agreed when you as sponsor give the green light to begin approaching patients. Please can you ensure that the green light activation e-mail is sent to all staff copied into this e-mail.

If you have any queries, please do not hesitate to contact me.

Appendix 5: PI responsibilities letter

Research, Innovation & Genomics Department
Professional Services Team
Leadon House
Gloucestershire Royal Hospital
Great Western Road
Gloucester,
GL1 3NN
email: ghn-tr.glos.riprofessionalservices@nhs.net

Date xxx

Dear xxx Principal Investigator

Insert study title: xxx
Local RIG number:
Insert REC reference: xxx

The Research, Innovation& Genomics (RIG) Professional Services Team has reviewed the information provided on the above study and note that the study has received full HRA approval. It has been confirmed that Gloucestershire Hospitals NHS Foundation Trust has the capacity and capability to undertake this study and that you aim to recruit XXXXX participants before the end of recruitment date XX/XX/XXXX. The documents approved for use in this study are those approved by HRA; these are detailed at the end of this letter.

Please read this letter detailing your responsibilities as Principal Investigator for this study that will be undertaken within the Trust. At the bottom of the letter please sign and date where indicated to demonstrate that you understand and accept these responsibilities, and return a signed copy to the RIG team ghn-tr.glos.riprofessionalservices@nhs.net.

As named Investigator for this research, it is your responsibility to manage and conduct this study in accordance with the following, as applicable:

- **ICH-GCP (Good Clinical Practice)** – It is mandatory for CIs, PIs of Clinical Trials and also those taking consent in Clinical Trials, to have undertaken GCP training before the study opens (and for them to update their Certificate every three years unless Sponsor requires sooner).
- The requirements of the **UK Policy Framework for Health and Social Care Research (2017)** and **Medicines for Human Use (Clinical Trials) Regulations 2004** (if applicable).
- The **Human Tissue Act 2004** and the **EU Tissue and Cells Directive (2006)** for research involving human tissue.
- The **Data Protection Act 2018**, the UK's implementation of the **General Data Protection Regulation (GDPR)** which details the seven principles of 'good information handling'.
- **RIG Standard Operating Procedures** (SOPs), available on the Trust website https://www.gloshospitals.nhs.uk/about-us/get-involved/support-our-trust/research-our-

hospitals/standard-operating-procedures-sops/, and **Trust policies** available on the Trust intranet site https://intranet.gloshospitals.nhs.uk/policies-and-guidelines/

As Principal Investigator for this research, you are required to ensure study specific duties are appropriately delegated and clearly documented on the study Delegation Log. This guarantees clarity of roles and must be signed and dated by each individual on the study and yourself as Principal Investigator.

Safety Reporting

Guidance on the classification of Adverse Events/Reactions (AEs/ARs) / Serious Adverse Events/Reactions (SAEs/SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) and the requirements for reporting to the sponsor will be found in the study protocol. For GHNHSFT sponsored trials, SAEs or SUSARs must be reported to RIG within 24 hours of becoming aware of the event, using the appropriate Trust RIG template which can be found within RIG SOP 20: Adverse Event and Reaction Safety Reporting. For Trust hosted trials the safety event requires reporting to RIG through EDGE Clinical Trials IT system on the conclusion of the event or at the end of the reporting requirements, as defined in the study protocol.

EDGE and Progress Reporting

All research studies taking place within the Trust are recorded on the EDGE study management system. As PI, you or a delegee, will be responsible for ensuring that all recruitment to the study is recorded on EDGE and that the study site status is updated throughout the study as required. Please get in touch with the RIG department if you require training on the use of EDGE.

As Principal Investigator you are required to respond to progress reporting requests from the RIG Department.

Monitoring and Audit

Your study may be monitored by the RIG team in accordance with the RIG Monitoring and Oversight SOPs (SOP 13: Hosted studies and SOP 38: Sponsored studies), by the Sponsor and Regulatory Authorities at any time. The team involved in conducting this research must ensure full co-operation with any requests from any of these bodies. Action may be taken to suspend research if it is found to not be conducted in accordance with the protocol and all applicable regulations.

All monitoring reports received from external study Sponsors must be sent to the RIG team (ghn-tr.glos.riprofessionalservices@nhs.net) when received.

Completion of study

Upon completion of this Research, the study must be archived appropriately, as described in the study protocol and in accordance with the applicable law.

Prior to any publications arising from the Research conducted at this site, authors should contact the RIG Department using email ghn-tr.commercialadmin@nhs.net, as part of the on-going Research Governance Process.

If you have received an Honorary Contract or Letter of Access in order to conduct the above research at this Trust, it is important that you check the termination date on these documents and, if applicable, contact the RIG Department to extend the document end date.

We wish you every success with your study.

Yours sincerely

Insert e-signature

Insert name:

Principal Investigator declaration:

I have read and understood the responsibilities described in this letter, and agree to act accordingly as Principal Investigator for the above-mentioned study.

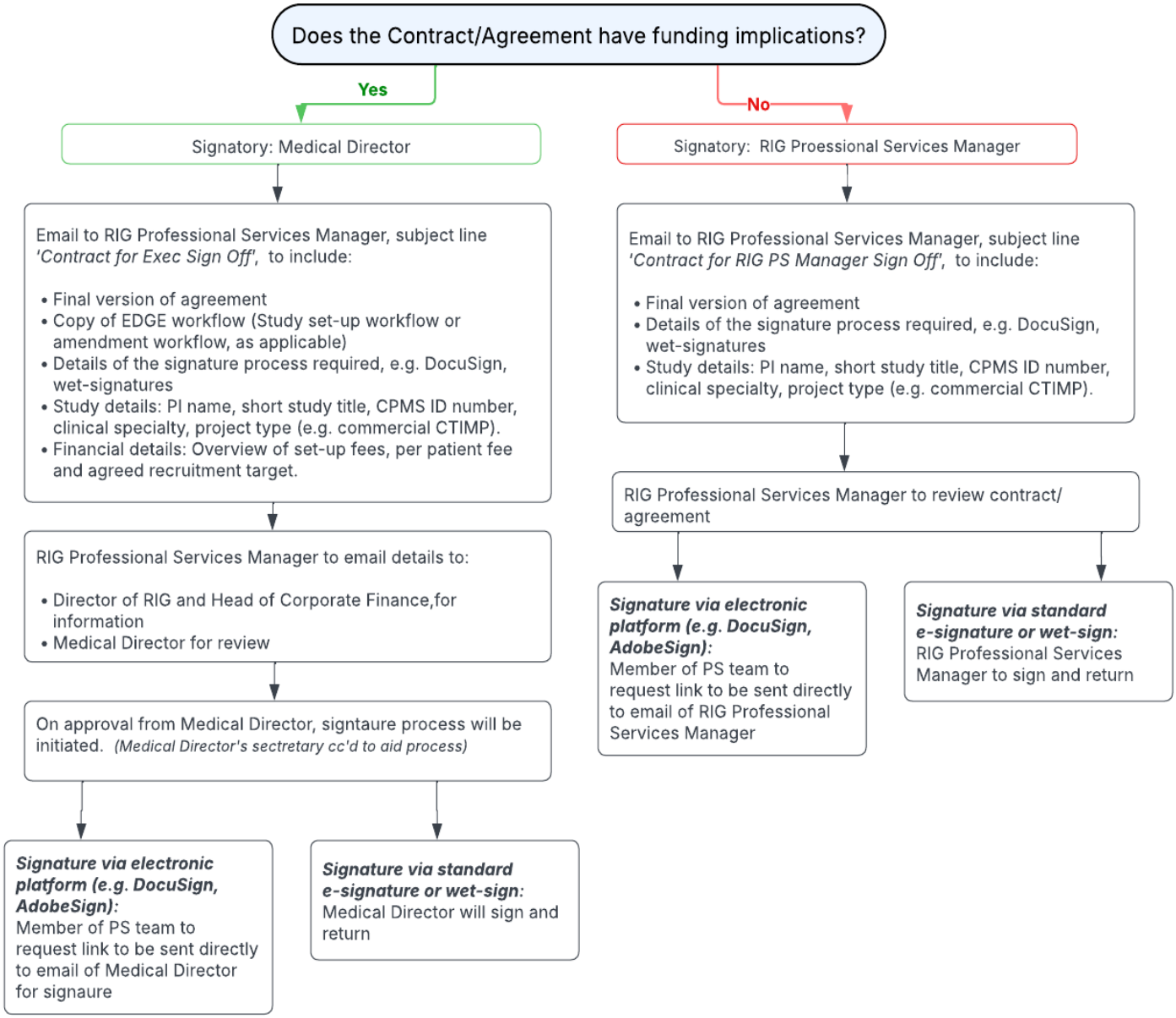
Signed	
Print Name	
Date	

Please return a signed copy of this letter to the RIG department (ghn-tr.glos.riprofessionalservices@nhs.net)

Approved documents:

Current approved document	Date	Version no.

Appendix 6: Signature Flowchart



Appendix 7: LIP Decline Email

To: Email LIP was received from

Cc: PI and any other staff included in LIP email

Subject: Title Acknowledgment

Dear Sponsor,

Thank you for sending through the documents for the XXXXX study.

We are in the process of evaluating the feasibility and timeline of the study at our site with the teams involved, and are, therefore, not in the position to accept the LIP at this time.

We will keep you updated on our progress, and once we are ready to proceed, we will re-request the LIP accordingly.

Please don't hesitate to reach out if you have any questions or concerns.

Email Signature