Gloucestershire Hospitals NHS Foundation Trust

SOP 11: Confirmation of Capacity and Capability

SOP reference:	SOP 11	
Version:	6.0	
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Approved by Commercial Director:	Claire Richardson 08/04/2024	
Implementation date of current version:	13/05/2024	
Date of Review:	13/05/2026	

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

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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

Related Documents:

SOPs
SOP 10 - Hosting CTIMPS and other clinical studies

Glossary

ARSAC	Administration of Radioactive Substances Advisory Committee
CPMS	Central Portfolio Management System
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
NIHR	National Institute for Health Research
ODP	Open Data Platform
OID	Organisation Information Document
PI	Principal Investigator
RPM	Research Portfolio Manager
RO	Research Officer
R&I	Research & Innovation
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 is given to deliver a research study in the Trust for studies receiving HRA Approval. Obtaining Confirmation is an essential precondition to the conduct and delivery of any portfolio or non-portfolio study.

HRA Approval is the process for the NHS in England that comprises a review by a NHS Research Ethics Committee (REC) (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 organisation 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 R&I Team
- Research study staff (those staff not directly managed by R&I)

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 or co-sponsored by the Trust as well as studies that are externally sponsored and hosted within the Trust. It includes applications for non-Portfolio studies, for example GHNHSFT service evaluations and student projects made directly to the GHNHSFT R&I 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, on line 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 confirmation of the contents of the Organisation Information Document (OID) and in some cases a contract for non-commercial studies or sign-off on an agreement/contract 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 Research Governance mailbox or directly from the PI/ research team and will usually consist of:
  - Commercial trial – protocol, industry costing template and agreement.
  - Non-commercial – protocol, OID/trial agreement and Schedule of Events (SoE)/Schedule of Events Cost Attribution Template (SoECAT).
- If a EoI has been submitted through the R&I governance team and 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). If any of these documents are missing request, they should be requested from the sponsor/Trials Unit. The review will only start once there is confirmation GHNHSFT has been accepted as a site and an amendment has been submitted to the HRA for approval.
- A Research Portfolio Manager (RPM) will cascade the 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 (see appendix 1).

  NB The Sponsor/CI can send out a Local Information Pack (LIP) once they have received the initial assessment letter from the HRA. Locally we would not start work on the LIP as the documents provided would not be the final versions until HRA approval is in place. Concurrently to the above, the Research Officer (RO)

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. (See SOP 12). 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.
- 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 a new study folder on the RDSU drive. Add study details to relevant tab on the Capacity & Capability spreadsheet.
- Obtain the Local Information Pack 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 and will be considered the 'date site selected' for the purposes of EDGE workflows.
- Undertake an assessment of the study agreement/OID and industry costing template/schedule of events/SoECAT.
- Review NHS cost and resource implications. Confirmation whether ETC for a study will be provided by the local commissioners' or regional specialist commissioners can be found on the NIHR Open Data Platform (ODP). In the case of the Specialist Commissioners, the Sponsor/TU should be able to provide documentation to confirm the ETC funding has been agreed at a national level for studies since 2019. Where the local commissioners are responsible the ETC payments are made to GHNHSFT from the LCRN. Payments are made on a per participant basis based on recruitment, recorded and confirmed in CPMS.

Payments are subject to the provider threshold applied to GHNHSFT; the threshold is nationally reviewed yearly.

- If the study agreement is acceptable, after discussion with PI and lead nurse/coordinator for the trial, localise and return to sponsor requesting hard copies if appropriate. 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 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 detail of individual licences for GHNHSFT staff can be obtained by contacting the Head of Nuclear Medicine.
- A check of IRMER status/requirements
- 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)
- 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
- RO to localise study documents, 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 (if available) and issue relevant Confirmation of Capacity and Capability email (Appendix 4) to sponsor, PI, delivery team, research study staff and support departments involved, attaching the PI responsibilities letter (Appendix 5)
- Confirmation of Site greenlight received
- Lastly, ensure the route for uploading of accruals has been agreed (see last point in **Actions**).

6. References:

- HRA: Approvals and amendments - Health Research Authority (hra.nhs.uk)

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 (R&D form if pre HRA Approval study (April 2016))
- 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 and consent documents
- 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

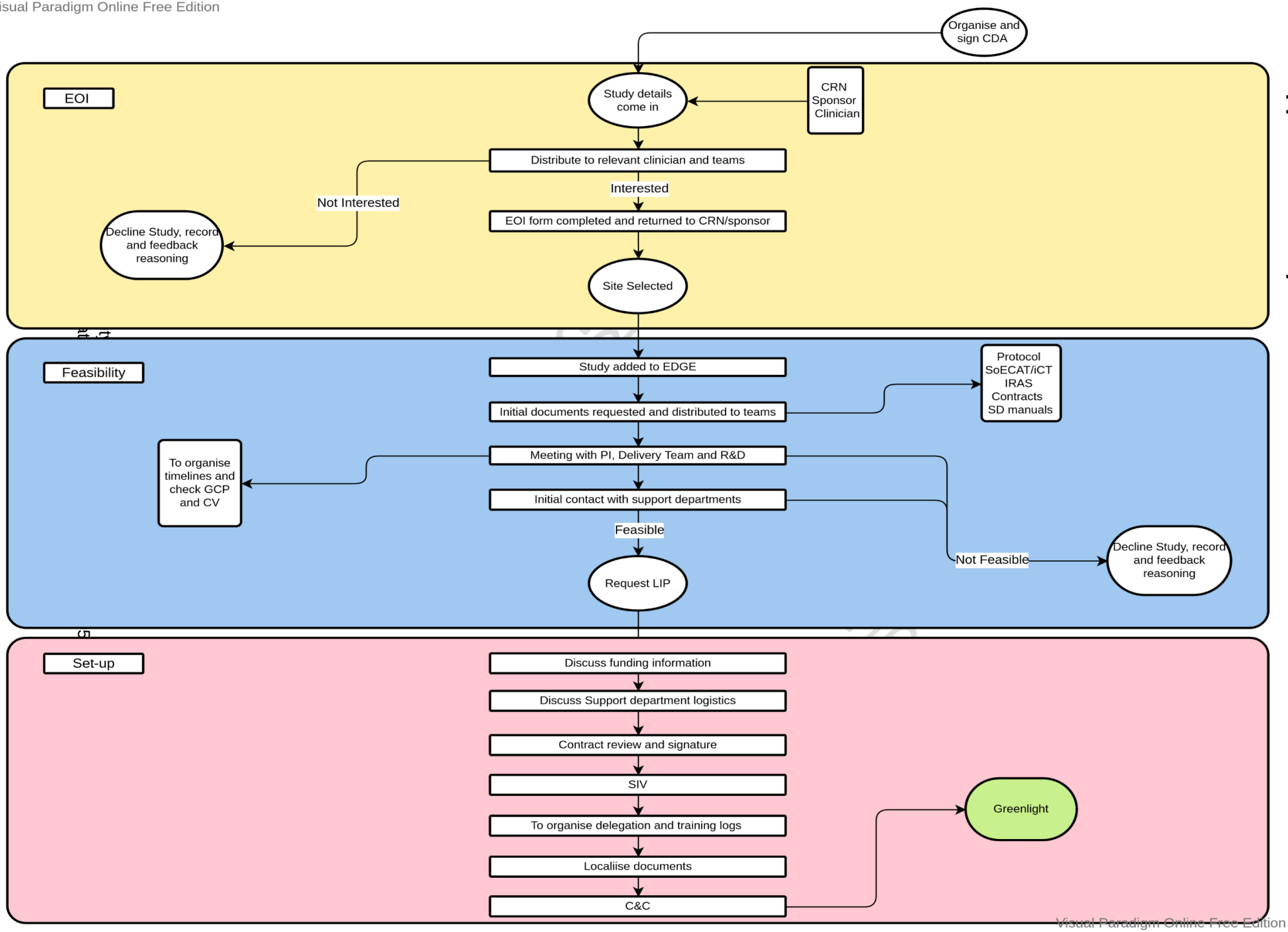
Appendix 2: Study Set-up Activities – roles and responsibilities

Activity	RPM	RO	Delivery team	PI
Distribute EoI details		X		
Complete EoI form		X	X	X
Request access on EDGE	X	X		
Create study folder	(X)	X		
Check GHNFT on IRAS or amendment		X		
Check PI listed		X		
Funding review	X		X (RPM to discuss with coordinator/SDs)	
ETC check	X			
Check relevant approvals (HRA/MHRA etc)	X	X		
Initial contact with PI *****	X		X	
Contact support departments with study details and request any relevant licenses *****	X		X	
Discuss support Department logistics			X	
Negotiate Contracts	X			
Organise SIV	X	X	X	
Attend SIV	(X)		X	X
Localise documents		X	X (check details correct)	
Delegation log			X	
Check CVs and GCPs		X		
Request CVs and GCPs	X		X	
Add and update set-up workflow		X		
Add and update GRSS workflow **+**	X		X	
Add EDGE attributes	X			
Add patients to EDGE			X	
Close down activities			X	
Prepare documents for archiving **$**	X	X	X	
Send boxes off to archive	X	X		
Invoicing (patient expenses included)	X	X		
Patient Expenses reimbursement			X	
Create patient Entity for all patient activities	X		(X) (check details correct)	
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		
Request analysis code	X	X		
SAE reporting			X	

***** Initial contact can be can be dependent on study and study team**+** Completion of workflow is dependent on study team (currently Cancer delivery team will complete certain sections previously agreed – this is to be reviewed within MSRT team)

$ Preparing for archiving currently sits within the delivery team with a plan for this to move within the governance team

Appendix 3: Setup flow chart



Appendix 4: Template Confirmation of C&C email

cc:Research Matrons, xxx Research Team Lead, xxx R&I Research Officer, Delivery Team Research Officer, Lead Pharmacist Clinical Trials (if the study is a CTIMP), Pathology Lead (if relevant) Radiology Lead (if relevant) – add in any supporting services/key people as required re this study.

Enc: Document Log and PI responsibilities letter

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

Dear xxxx,

Local Project 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.

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

Insert Principal Investigator name and department

Date xxx

Dear xxx Principal Investigator

R&D No: xxx
Research and Innovation Department
Leadon House
Gloucestershire Royal Hospital
Great Western Road
Gloucester,
GL1 3NN
Direct Dial: xxx email: ghn-tr.glos.rdsu@nhs.net

Insert study title: xxx
Insert REC reference: xxx

The Research and innovation 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 the 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 on a separate sheet. As named Investigator for this research that is being undertaken at the Gloucestershire Hospitals NHS Foundation Trust, 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'.
- **R&I Standard Operating Procedures** (SOPs) which are available on the Research website https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals/ and **Trust policies** available on the Trust intranet site https://intranet.gloshospitals.nhs.uk/

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 can be found in the study protocol. All safety events

involving Trust patients which require reporting to the Sponsor, must also be reported to the R&I Department. For GHNHSFT sponsored trials events must be reported within 24 hours of becoming aware of the event, using the appropriate Trust R&I template which can be found within SOP 20 Adverse Event and Reaction Safety Reporting. The link to the SOPs is provided above. For Trust hosted trials the safety event requires reporting to R&I 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.

Progress Reporting
As Principal Investigator you are required to respond to progress reporting from the R&I Department.

Monitoring and Audit
Your study may be monitored *in accordance with the Trust R&I Monitoring and Audit SOP (in development March 2024)*, *by* the Sponsor and selected for audit by the R&I Department (where the Trust is not 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.

Archiving
Upon completion of this Research, all studies must be archived appropriately and in accordance with the applicable Law. Any publications arising from the Research conducted at this site must be sent to the R&I Department 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 R&I Department to extend the document end date.

We wish you every success with your study.

Yours sincerely

Insert e-signature

Insert name:
R&I Manager

Appendix 5: Signature Flowchart