Gloucestershire Hospitals
NHS Foundation Trust

Initiating Research 01 – Sponsorship

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

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive 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 R&D webpage:

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

SOP reference:	**IR01**	
Version:	3.0	
Author:	Janet Forkes	signature
Reviewed by Assistant Director of Research and Development	Julie Hapeshi 27/03/2018	signature
Implementation date of current version:	31 / 03 / 2018	
Date of Review:	01 / 07 / 2019	

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	13/05/2015
2.0	Update of HRA terminology and EDGE processes. Addition of section 8.1 'staff and student projects'	18/05/2017
3.0	Rebranding to GHNHSFT, updating of contact details and reference documents	31/03/2018

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

Contents

1. Introduction, Background and Purpose

The UK Policy Framework for Health and Social Care Research v3 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.

For clinical trials of Investigational Medicinal Products (CTIMPs), the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) makes it a criminal offence to conduct a CTIMP without a sponsor and the MHRA requires evidence that a sponsor has accepted the role before they will issue approval (Clinical Trials Authorisation).

The purpose of this SOP is to explain who may/should act as sponsor and the nature of their legal status. Guidance is also provided on the roles and responsibilities of those involved in research sponsored by the Trust.

2. Who should use this SOP?

Trust staff who are involved in the setting up of a clinical trial originating within the Trust.

3. When this SOP should be used

This SOP will be referred to as soon as the Trust is approached by a prospective researcher.

4. Sponsorship functions

Sponsors are responsible for ensuring that any research undertaken safeguards the rights, safety, dignity and well-being of participants.

In doing so the sponsor will accept responsibility for securing arrangements to initiate, manage and finance the research. They will also ensure that all authorisations have been obtained before commencement of the research and that it will be conducted in accordance with Good Clinical Practice (GCP) and other applicable standards and legislation.

5. Capacity to act as sponsor

Any organisation that is a legal entity and which funds, initiates, hosts or employs staff involved in research may act as sponsor. The sponsor should not be confused with the funder of the research, although they may often be one and the same entity.

It is possible for an individual to act as sponsor for a research project; although is not recommended owing to the risks and legal liabilities involved. The Trust will not indemnify research conducted under the sponsorship of one of its employees nor another named individual.

The Sponsor will usually be one of the organisations taking the lead for particular aspects of the arrangements of the study or the Chief Investigator's (CI) employing organisation, the lead organisation providing health or social care services to participants or the primary funder.

6. Joint sponsorship

Where two or more organisations share a significant interest in a research project (e.g. one as employer of the CI and another as the host institution), they may choose to act as co-sponsors and delegate the responsibilities of sponsorship between them.

For CTIMPs, the Regulations state that joint sponsors may:

- Take joint responsibility for carrying out the function of the sponsor of the trial; or
- Allocate responsibility for carrying out the function of the sponsor of the trial.

Any delegation of responsibilities at sponsor level will depend on the expertise and capacity of the respective parties to discharge them, in relation to the risk posed by the research. An agreement will be put in place between the parties to ensure that each party is clear on their responsibilities for the research.

7. Non-commercial sponsorship

Non-commercial organisations that may sponsor research include universities, charities, research councils or NHS organisations. The protocol will usually be designed by the CI and the results and Intellectual Property Rights (IPRs) arising from the research owned by the non-commercial sponsor.

Non-commercial sponsors may also fund research. However sometimes a commercial company will fund research with a non-commercial sponsor. In these circumstances the research is known as 'non-commercial industry-funded research'.

8. Sponsorship by Trust

The Trust 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, 2017. This does not constitute blanket acceptance of sponsorship for all projects requiring a sponsor brought to the Trust R&D department.

The Trust will consider acting as sponsor where the CI holds a substantive employment contract with the Trust and the proposal:

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

All proposed trials will undergo a Scientific Peer Review by the Trust. (see R&D SOP RDVL 01)

The Trust's acceptance of sponsorship applies only to research conducted in the UK. If the Trust is being asked to act as sponsor for research outside of the UK, this must be made clear at the time of application.

To make a request for the Trust to act as sponsor, the protocol and any other available documentation should be emailed to the R&D office ghn-tr.rdsu@nhs.net with 'Sponsorship request' in the subject line, before submitting to the Research Ethics Committee. Electronic authorisation will be provided on the combined NHS REC and R&D Form in IRAS.

A 'Terms & Conditions of Sponsorship' (see Appendix B) will be issued once approval has been given.

8.1 Student / Staff projects

If a member of staff or a student who is employed by the Trust is undertaking a project as part of their professional development the Trust will consider undertaking the role as Sponsor if the educational establishment they are attending refuse to undertake the role of Sponsor.

If a student is not employed by the Trust, the Trust will not normally act as Sponsor. Students are advised to contact R&D office as soon as possible to seek advise on how to progress their project.

9. Confirmation of sponsorship

Investigators should not presume that their employer, funder or host organisation will automatically assume the role of the Sponsor.

Confirmation of sponsorship is required for audit and inspection purposes to ensure that the sponsor named on the NHS Research Ethics Committee (REC) application has accepted sponsorship and this has not been presumed. In most cases, the sponsor's authorisation on the NHS R&D form completed via the Integrated Research Application System (IRAS) will be sufficient.

Where the Trust agrees to sponsor a research project, confirmation will be provided by email as well as authorisation of the NHS REC form in IRAS. A letter of confirmation (see Appendix 1) will be provided upon request which may be produced to other relevant bodies and organisations.

10. Responsibilities

The UK Policy Framework for Health and Social Care Research v3, 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 comprising a 'delegation of responsibilities' schedule.

Where the Trust is acting as sponsor, the Delegation of Responsibilities document (see Appendix 3) will be sent to the CI/PI and must be followed. If any of the responsibilities are to be delegated to other members of the research team, this must be recorded in a 'Delegation of Responsibilities Log' (see Appendix 4).

12. Related SOPs and other documents

R&D SOP RDVL 01 Scientific Peer Review

NIHR research passport and streamlined human resources arrangements

https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm#HRGoodPracticeresourcepack

The Research Passport pack contains

- The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks
- Research Passport form
- Research Passport form appendix

- NHS to NHS confirmation of pre-engagement checks
- Instructions for completing the Research Passport form
- CV template

Appendix 1 NHS Trust Confirmation of Sponsorship Letter

[DATE]

Dear Sir/Madam

Confirmation of Sponsorship by Gloucestershire Hospitals NHS FoundationTrust

[Project/Trial Full Title]

We can confirm that Gloucestershire Hospitals NHS Foundation Trust will act as sponsor for the above project under the UK Policy Framework for Health and Social Care Research v3 2017 and the Medicines for Human Use (Clinical Trials) Regulations 2004 (for clinical trials of Investigational Medicinal Products: delete as appropriate).

Sponsorship will remain in place until completion of the research as approved by the applicable NHS Research Ethics Committee (REC) and any other regulatory authority(ies).

Our sponsorship may be withdrawn where the Investigator has failed to comply with our Terms & Conditions of Sponsorship.

This letter does not give permission for the project to commence. No aspect of the project should start at any of the participating sites until all approvals and agreements are in place.

If you have any further questions, please do not hesitate to contact us.

Yours faithfully

……..,

……..

Appendix 2

Gloucestershire Hospitals NHS Foundation Trust Terms & 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:
   i. UK Policy Framework for Health and Social Care Research v 3 2017;
   ii. The World Medical Association Declaration of Helsinki (2000);
   iii. Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended);
   iv. ICH Guidelines for Good Clinical Practice(GCP) (Step 5 Version July 2002);
   v. Human Tissue Act 2004;
   vi. Mental Capacity Act 2005;
   vii. Data Protection Act 1998.

2. The project must be conducted in accordance with the 'Delegation of Responsibilities' document and any further delegations recorded in the 'Delegation of Responsibilities Log'.

3. The project **must not** commence at Gloucestershire Hospitals NHS Foundation Trust or any other research site until:
   i. A favourable ethical opinion has been obtained from the relevant NHS Research Ethics Committee (REC);
   ii. Confirmation of Capacity and Capability (for HRA approved research) and Trust approval (for non-HRA research) has been granted by the GHNHSFT R&D office and the R&D offices of all other NHS organisations participating in the project and all necessary site agreements are executed;
   iii. 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;
   iv. 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;
   v. In the case of a clinical trial of an Investigational Medicinal Product (ctIMPs) Clinical Trial Authorisation has been obtained from the MHRA (or Competent Authorities);
   vi. In the case of a clinical investigation of a Medical Device (ciMD) a Declaration of No Objection has been obtained from the MHRA;
   vii. Such other regulatory approval(s) require for the research to proceed have been obtained.

Appendix 3 Delegation of Responsibilities for Research Sponsored by Trust

Version 2.0 (March 2018) NOTES:

(1) The UK Policy Framework for Health and Social Care Research v 3 2017 and ICH Good Clinical Practice (GCP) Guidelines (E6 R1) 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 administrators, data monitors and other research personnel.

(5) Key ● = Accountable
⊙ = Responsible

Before trial commences					
	Activity	**Trust**	**CI**	**PI**	**Team**
1	Develop ethically, scientifically and statistically sound research protocol		●		
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		●		
3	Secure funding	●	⊙		
4	Ensure adequate funding in place	●			
5	Administer Funding	●			
6	Ensure protocol has undergone independent scientific and statistical review and is compliant with applicable regulations	●	⊙		
7	Prepare and submit ethics application		●		
8	Ensure favourable opinion in place for each site from the appropriate NHS Research Ethics Committee (REC)	●	⊙		
9	Prepare MHRA approval application (Clinical Trial Authorisation)		●		
10	Obtain MHRA approval (Clinical Trial Authorisation)	●	⊙		
11	Obtain HRA approval	●	⊙		
12	Obtain NHS R&D approval from each NHS organisation involved in the research	●	⊙		
13	Prepare approval applications from other relevant bodies (e.g. ARSAC, HTA)		●		
14	Obtain approvals from other relevant bodies (e.g. ARSAC, HTA)	●	⊙		

Before trial commences (continued)					
	Activity	**Trust**	**CI**	**PI**	**Team**
16	Identify supply of Investigational Medicinal Product(s) (IMPs)	●	◉		
17	Ensure familiarity with appropriate use of IMP as described in protocol and other product information		●	◉	
18	Coordinate with Trust support departments involved in the research and obtain relevant authorisations (Pharmacy, Radiology, Laboratories)	●		◉	
19	Ensure relevant authorisations are in place with Trust support departments		●	◉	
20	Ensure adequate facilities, resources and support are available to conduct the trial at the trial site		●	◉	
21	Ensure appropriate contractual arrangements and technical agreements in place	●			
22	Ensure insurance/indemnity arrangements in place to cover liabilities	●			
23	Notify employers/managers of research staff members' participation in the research		●	◉	◉
24	Register trial with appropriate protocol registration scheme(s)	●	◉		
25	Design of case report forms and database		●		
26	Develop trial-specific standard operating procedures		●	◉	
27	Train research team in use of trial-specific standard operating procedures		●	◉	
Conduct of the trial					
	Activity	**Trust**	**CI**	**PI**	**Team**
28	Ensure that no participants are recruited until all necessary approvals have been received	●	◉	◉	
29	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	●	◉	◉	
30	Ensure students and new researchers are adequately supervised	●	◉	◉	◉

Conduct of the trial (continued)					
	Activity	**Trust**	**CI**	**PI**	**Team**
31	Ensure core research team members have completed ICH GCP training (in previous 3 years)	●	◉	◉	◉
32	Ensure applicable legislation is followed	●	◉	◉	◉
33	Put and keep in place arrangements to allow all research staff to conduct the trial in accordance with the Protocol and any agreed contract	●	◉		
34	Ensure the rights, safety, dignity and well-being of participants are protected and that they receive appropriate medical care whilst participating in the trial	●	◉	◉	◉
35	Ensure informed consent is taken for each participant in accordance with Protocol and approved patient-related documentation		●	◉	◉
36	Inform, where practicable, health or social care professionals if their patient is a participant in the trial			●	◉
37	Ensure trial is managed, monitored and reported as agreed in the protocol	●	◉	◉	◉
38	Ensure trial data are collected in accordance with the Protocol and ensure integrity and confidentiality of all data collected		●	◉	◉
39	Ensure appropriate analysis of data		●		
40	Ensure trial is conducted in accordance with ICH GCP and applicable legislation	●	◉	◉	◉
41	Prepare and submit substantial amendments to the MHRA, REC and GRSS/ R&D office		●	◉	
42	Prepare and submit non-substantial amendments to the MHRA, REC and GRSS / R&D office where necessary		●	◉	
43	Ensure research team aware of dates of approval and version changes for implementation of amendments		●	◉	
44	Maintain trial documentation in accordance with regulatory requirements and ICH GCP		●	◉	◉
45	Ensure Trial Master File (TMF) (held by the CI) and documentation are complete, accurate and legible	●	◉		◉

Conduct of the trial (continued)					
	Activity	**Trust**	**CI**	**PI**	**Team**
46	Ensure Investigator Site File (ISF) and documentation are complete, accurate and legible	●	◉	◉	
47	Ensure all data and documentation are available for monitoring, audit or inspection and that appropriate consent has been provided by the Participant	●	◉	◉	◉
48	Ensure procedures are in place for emergency unblinding of the randomisation code	●	◉	◉	
49	Maintain detailed records of all Adverse Events (AE) as specified in the Protocol	●	◉	◉	◉
50	Report adverse events as specified in the Protocol and regulatory requirements	●	◉	◉	◉
51	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	●	◉	◉	◉
52	Ensure all SAEs are reviewed by an appropriate committee for monitoring trial safety (if applicable)	●	◉		
53	Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSARs) are recorded, assessed and reported to the MHRA, REC and R&D office in accordance with the regulatory requirements and Trust policy	●	◉	◉	◉
54	Ensure that investigators at the site and at other sites are aware of any SUSARs occurring in relation to IMP	●	◉		
55	Promptly inform the MHRA, REC, GRSS/ R&D office and investigators at the site and other sites of any urgent safety measures taken to protect participants	●	◉	◉	◉
56	Ensure all investigators are, at all times, in possession of the current relevant safety information for the trial	●	◉		
57	Ensure Annual Safety Reports (ASRs) and progress reports are submitted to the MHRA and REC within the required timescales and copies provided to the R&D office	●	◉	◉	

Conduct of the trial (continued)					
	Activity	**Trust**	**CI**	**PI**	**Team**
58	Maintain a record of patient recruitment and report recruitment to the R&D office in line with Trust policy		●	◉	◉
59	Ensure IMP is provided and labelled in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004	●	◉	◉	
60	Ensure Investigational Medicinal Product (IMP) not used for any purposes other than trial and in strict accordance with the Protocol	●	◉	◉	
61	Report suspected breaches of protocol, ICH GCP and research misconduct and fraud	●	◉	◉	◉
Suspension, termination and completion of the trial					
	Activity	**Trust**	**CI**	**PI**	**Team**
62	Notify regulatory authority(ies) and relevant REC of Trial if suspended or terminates early	●	◉	◉	
63	Notify regulatory authority(ies) of the end of the Trial	●	◉		
64	Ensure all trial records are archived appropriately on conclusion of the Trial and retained in accordance with regulatory requirements and protocol	●	◉	◉	
65	Initiate and coordinate review and submission of abstracts, posters and publications	●	◉		
66	Close down and archiving procedures	●	◉	◉	

Appendix 4 Delegation of Responsibilities Log

PLEASE SEE OVERLEAF

Trust logo

Delegation of Responsibilities Log

PLEASE NOTE:
(1) A printed copy of this document must be retained on the Trial Master File/Investigator Site File/Project File for all projects.
(2) Failure to maintain this log may lead to noncompliance with the research protocol and/or the ICH Good Clinical Practice (GCP) Guidelines.
(3) Accountabilities set out in any Delegation of Responsibilities cannot be delegated.
(4) Certain activities may not be delegated in accordance with the protocol, for example taking informed consent.
(5) More than one sheet may be used where necessary

Responsibility	Delegating member	Delegated member	Delegate trained (tick as appropriate)		CI/PI signature	Start Date	Finish Date
			Yes	No		DD/MM/YYYY	DD/MM/YYYY