DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office

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Title: **SPONSORSHIP APPROVAL FOR GOSH SPONSORED CLINICAL TRIALS**	
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1. Scope

This SOP is applicable to all the clinical trials sponsored or co-sponsored by Great Ormond Street Hospital. The SOP is applicable to Chief Investigators (CI), PIs, and delegated trial team members involved in Trust-sponsored CTIMPs and the Joint R&D Office Clinical Trials Team with responsibility for performing sponsor activities on behalf of the Trust. This SOP is applicable for both single centre and multicentre trials.

The legal basis for this standard operating procedure is The Medicines for Human Use (Clinical Trials) Regulations 2004 and Department of Health UK Policy framework for health and social care research 2017. The Medicines for Human Use (Clinical Trial) Regulations 2004 which implement the EU Directive 2001/20/EC state that all clinical trials involving investigational medicinal products (CTIMP) must have a nominated Sponsor taking on the legal responsibility for (1) obtaining authorization (2) the conduct of the clinical trial and arrangements for ensuring compliance with International Conference on Harmonization for Good Clinical Practice (GCP) and (3) pharmacovigilance.

The Department of Health UK Policy framework for Health and Social Care Research states that all research projects involving NHS patients and/or NHS resources must have a nominated sponsor[1]. The Sponsor must be satisfied there are arrangements in place to (1) ensure each study is conducted according to the current agreed protocol (2) monitor and report on its general progress and (3) require written agreement on behalf of the Sponsor to

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any modifications to the protocol or proposal (and, if necessary, ethical and regulatory approval).

2. Purpose

The purpose of this SOP is to describe the activities undertaken by the Joint R&D Office to grant sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs) and registering for insurance for all research that falls under the Clinical Trials Regulation 2004. This SOP details the procedure for allocating a Sponsor / Co-sponsor clinical trials covered by The Medicines for Human Use (Clinical Trials) Regulations 2004.

This SOP also outlines the process for studies whereby Great Ormond Street Hospital agrees to act as UK Legal Representative on behalf of a sponsor based outside of the UK for CTIMP.

3. Definitions/Abbreviation

Sponsor means an individual or organisation, which accepts the legal responsibility for the initiation, management and financing (or arranging the financing) of a research study alone or as a Co-sponsor.

"Co-sponsor" means one of two or more persons/organisations sharing the Sponsor obligations.
"Sponsor's legal representative" means willing to act as the agent of the sponsor in the event of any legal proceedings instituted in the UK (for example, for service of legal documents) but does not assume any of the legal liabilities of the sponsor(s) for the trial by virtue of that role
GOSH – Great Ormond Street Hospital
REC – Research Ethics Committee
MHRA – Medicine and Healthcare Regulatory Authority
HRA – Health Research Authority
CT: SC – Clinical Trial Sponsorship Committee

4. Responsibilities

Overall legal responsibility for compliance with Sponsor's obligations is with the GOSH Chief Executive. Responsibilities are delegated to the Director of Clinical R&D, Deputy Director of Research & Innovation and Chair of Sponsorship Panel. Day to day management is the responsibility of the Clinical Trials Manager, Clinical Trials Coordinator and Head of Clinical Trials, Governance and Contracts.

It is the responsibility of the chief investigator or delegate to liaise with the Joint R&D Office Clinical trials team prior to submission to REC, HRA and MHRA.
The Sponsor is able to delegate responsibilities but still retains overall legal responsibility for the study.

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5. Procedure

For projects where GOSH patients are involved and the CI has a full or honorary contract with GOSH, GOSH will take on the role of Sponsor and indemnity will be provided under the NHS clinical negligence scheme for Trusts or GOSH clinical trial insurance . All projects registered with the R&D Office as per project registration guidance available from the R&I website and should complete a project registration form.

For sponsorship of a project, the following conditions should be met:

- The CI/PI must have a substantial or honorary employment contract with GOSH
- The funding is granted to GOSH. If funding is granted to ICH, there should be a funding transfer process in place such as an agreement or sub-award
- Sufficient funding to cover the conduct of a trial
- The CI/PI should have an input in the development of the protocol.

5.1 Review of Study Proposal/Draft Protocol

It is important that Chief Investigators contact the Joint R&D Office Clinical Trials Team during the funding application stage of the study. The delay in approaching the trials team may result in denying the sponsorship or further delays in the process. In the early stages/preliminary stage of grant application, clinical trial team will only advice on the different source of funds to consider which is mainly based on protocol synopsis or study overview. The sponsorship agreed at this stage is in principle only.

The formal sponsorship process begins once the funding is granted. The following documentation as a minimum should be provided to the Clinical Trials Manager before sponsorship of CTIMPs can be assessed.

- Draft/final Protocol or trial proposal
- Details of trial funding

The Clinical Trials Manager confirms whether the study meets the definition of CTIMP if it is not been done already. If the team is unsure of the classification then the confirmation should be obtained from the MHRA clinical trial helpline.

Upon receipt of the draft protocol and supporting documents the R&D Office clinical trials team review the documents to ensure the regulatory compliance. The comments will be returned to the investigator for making the changes in the documentation. This process should be continued until consensus between both the CI and the clinical trials team.

5.2 Risk Assessment

A CTIMP risk assessment must be carried out using the risk assessment form (GOSH/ICH/08/F42). The form has two sections, Part 1 and 2. Part 1 should be ideally

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be completed during the grant application stage. This assessment will help the research team and the sponsor to assess any costs that should be included in the grant application.

Part 2 of the risk assessment can be completed after securing the funding. The Clinical Trial Manager will coordinate the risk assessment process with the CI and the trial team. All the relevant teams including pharmacy, radiology, labs and external collaborators should be included in the process as necessary.

The following factors may pose a risk to the conduct of the trial and should be considered but is not an exhaustive list:

- Insufficient funding
- CI's lack of experience
- Multicentre trials
- Design, size and conduct of trial
- Trials that are excluded or restricted in terms of insurance
- Involvement of Advance medicine therapy product
- Complexity of IMP manufacturing process
- Delegation of responsibilities between collaborators
- For CTIMP trial - Involving a medicinal product not licensed in any EU Member State
- Intellectual Property and ownership of trial data
- Capacity to manage the trial

5.3 Sponsorship Panel

Risk Assessment and Protocol will be referred to the Sponsorship Panel. The panel reviews the study according to the Terms of reference (CT:SC Terms of Reference) Clinical Trials Coordinator collates the comments from Panel members and it will be forwarded to the CI for response. The comments from each panel member remain confidential to R&D. Panel would review the response for acceptance. If the Panel agrees to GOSH sponsorship, then the CI will be notified of the confirmation via Declaration of Sponsorship Letter, signed by the Chair of Sponsorship Panel or in his absence the Deputy Director of Research and Innovation. If the panel requests any change in the study documentation including risk assessment, then this will be addressed before submission to regulatory body.

5.4 Non Acceptance of Sponsorship

If the panel members do not reach a consensus on sponsorship, then the Chair of the Sponsorship Panel and/or the Deputy Director of Research Innovation can make a decision to not agree to sponsorship of the trial. The CI will be notified of this decision with reasons for non-acceptance.

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5.5 Sponsor-CI agreement

Once the sponsorship is confirmed, CI will be asked to enter into an agreement with GOSH which will allocate responsibilities to the CI.

5.6 Site Agreements

For multicentre clinical trials of medicinal products falling under the Medicines for Human Use (Clinical Trial) Regulations 2004 where GOSH is the Sponsor or Co-sponsor, each trial site will be asked to enter into an agreement which will allocate responsibilities to the trial sites and Principal Investigator.

5.7 Indemnity Arrangements

GOSH sponsored CTIMPs are covered by the NHS Indemnity scheme (Clinical Negligence Scheme for Trusts, under NHS Resolution), which provides cover for negligent harm but not for non-negligent (no-fault) harm. The NHS Indemnity scheme will apply where researchers who designed the protocol are substantively employed by the NHS or have an honorary contract with GOSH.

Non-negligent harm cover is offered for GOSH sponsored CTIMPS by GOSH trial insurance. This is applicable to both single centre and multicentre trials. This is the primary insurance for all GOSH sponsored studies.

Additional insurance is covered by UCL insurance for studies where the CI has a full or honorary contract with UCL and trial is conducted at GOSH site only. This will serve as a backup insurance. This was agreed and approved by R&I Board in 2018.

The sponsor may need to seek additional insurance advice from the Trust insurer if the trial require:

- Multiple sites
- Adult patients

5.8 Continuous of sponsorship review

Sponsorship is a continuous process and dependent on satisfactory receipt of all approvals, submission of reports in timely manner and following all sponsor's SOPs. In case of non-compliance to any of the aforementioned procedures, the sponsorship will be referred to sponsorship committee for review and further action will be taken.

5.9 Legal Representative

- Should be willing to act as the agent of the sponsor in the event of any legal proceedings instituted in the UK(for example, for service of legal documents)

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- Does not assume any of the legal liabilities of the sponsor(s) for the trial by virtue of the role of legal representative and does not therefore require insurance or indemnity to meet such liabilities, but may in some cases enter into specific contractual arrangements to undertake some of the statutory duties of the sponsor in relation to the trial.

In all trials where GOSH acts as UK legal representative, a contract/written confirmation will be put in place with the sponsor with details of responsibility.

6. Related documents

Document Name	File Path
CTIMP Risk Assessment Form - GOSHICH/08/F42	R&D Folders: Available on Request
CT:SC Terms of Reference	R&D Folders: Available on Request

7. References

https://www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf (Accessed on 03/10/2020)

http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/ (Accessed on 03/10/2020)

The Medicines for Human Use (Clinical Trials) Regulations 2004, Available from **The Medicines for Human Use (Clinical Trials) Regulations 2004**

Terms of Reference of Sponsorship Committee

8. Appendices

N/A