UCL
INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS
NHS Foundation Trust

Division of Research and Innovation

JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

NON-COMMERCIAL CLINICAL TRIALS OF IMP (CTIMPs) SPONSORSHIP (SINGLE/MULTICENTRE TRIALS)

Document Number: GOSH/ICH/05/CT01/V11		Version Number: 11
Title: NON-COMMERCIAL CLINICAL TRIALS OF IMP (CTIMPs) SPONSORSHIP (SINGLE/MULTICENTRE TRIALS)		
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Superseded Version Number & Date: GOSH/ICH/05/OP11/10 04/09/2015		
Issue Date: 25th of July 2016		Effective from: 10th of August 2016
Valid to: 10th of August 2018		Frequency of Review: 2 years
Approved by: Dr Vanshree Patel		Designation : Head of Governance, Clinical Trials and Contracts
Signature: Vanshree Patel		Date: 27|07|2016

Revision History			
Previous version	Comments	Reviewed by	Date archived
GOSHICH/05/OP11/10	Updated risk assessment form version and risk assessment tool step 4.	Emma Pendleton	09/08/2016
GOSHICH/05/OP11/09	Addition of the	Emma Pendleton	04/09/2015

	Sponsorship Panel in review of CTIMP sponsorship and other changes in the process		
GOSHICH/05/OP11/08	Made the OP specific for non-commercial CTIMPs sponsored by Trust and other changes; addition of role of CRAC in review of CTIMP sponsorship	Dr Lorna Gibson	07/11/2013
GOSHICH/05/OP11/07	Updating sponsorship in line with requirements based on where patients are recruited for CTIMPS	Dr Lorna Gibson	01/06/2012
GOSHICH/05/OP11/06	Updating sponsorship in line with requirements that the CI employer should usually be the sponsor of non-commercial studies.	W Fisher	17/03/2011
GOSHICH/05/OP11/05	See document change request form with master hard copy	Ms Jo Southern	04/08/2010
GOSHICH/05/OP11/04	Annual review; change to abbreviation list	Ms Jo Southern	18/01/2010
GOSHICH/05/OP11/03	Inclusion of specific risk-assessment based decision making for CTIMP and new risk assessment tool;	Prof D Goldblatt	21/07/2009

GOSHICH/05/OP11/02	See document change request form with master hard copy	Prof D Goldblatt	23/06/2008
GOSHICH/05/OP11/01	First Issue	Prof D Goldblatt	03/03/08

1. Scope /Background

This SOP is applicable to all the clinical trials sponsored, 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.

2. Legal basis

The legal basis for this operating procedure is the Department of Health Research Governance Framework for Health and Social Care 2nd Ed., 2005 and The Medicines for Human Use (Clinical Trials) Regulations 2004. 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 authorisation (2) the conduct of the clinical trial and arrangements for ensuring compliance with International Conference on Harmonisation for Good Clinical Practice (GCP) and (3) pharmacovigilence[2].

The Department of Health Research Governance Framework for Health and Social Care (2nd Ed., 2005) 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 any modifications to the protocol or proposal (and, if necessary, ethical and regulatory approval).

3. 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). This

SOP details the procedure for allocating a Sponsor / Co-sponsor clinical trials covered by The Medicines for Human Use (Clinical Trials) Regulations 2004.

4. Definitions

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 EEA (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

The Sponsor is able to delegate responsibilities but still retains overall legal responsibility for the study.

5. Personnel responsible

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, Chair of Sponsorship Panel. Day to 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.

6. 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 the Sponsor and indemnity will be provided under the NHS clinical negligence scheme for Trusts. 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.

6.1 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.

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 the study meets the definition of CTIMP if it is not been done already. If the team is unsure of the classification then 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.

6.2 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 completed during the grant application stage. This assessment will help the research team and the sponsor to assess any cost 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.

6.3 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. Panel would review the response for acceptance. If the Panel agrees with the 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 request any change in the study documentation including risk assessment, then this will be addressed before submission to regulatory body.

6.4 Non Acceptance of Sponsorship

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

6.5 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.

6.6 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.

6.7. Indemnity Arrangements

GOSH sponsored CTIMPs are covered by the NHS Indemnity scheme (Clinical Negligence Scheme for Trusts, CNST2), 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.

Non-negligent harm cover is offered for GOSH sponsored CTIMPS by UCL where GOSH is the only hosting site or sharing patient's care with UCLH as a second site. For a research study to be eligible for this scheme it must meet the following criteria. The CI must have a full or honorary contract with UCL to be eligible for this trial insurance.

7. Associated documents and SOPs*

Document Name	File Path	Author
CTIMP Risk Assessment Form - GOSHICH/08/F42/03	R&D Folders: Available on Request	Praseeda Thaikalloor
CT:SC Terms of Reference	R&D Folders: Available on Request	Emma Pendleton

8. Recommendations

NA

9. References

Department of Health Research Governance Framework for Health and Social Care (2nd Ed 2005) Available from

Research Governance Framework for Health and Social Care - Gov.uk

(Accessed on 27/06/2016)

Health Research Authority website, Available from

http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/

(Accessed on 27/06/2016)

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

(Accessed on 27/06/2016)

10. Appendices

*all these documents are available electronically