# JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

## Identification and approval of sponsorship for non-CTIMPs

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| GOSH/ICH/11/0P56/02 | Change of procedure reflected in SOP re-write and addition of appendices 1 and 2. | Emma Pendleton | 11/09/2016 |
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## 1. Scope /Background

This SOP sets out the procedure for assessing Sponsorship at Great Ormond Street Hospital (GOSH) and UCL- Institute of Child Health (ICH) for non-CTIMP studies falling under the remit of the Research Governance Framework.

## 2. Legal basis

The legal basis for this Operating Procedure is the Research Governance Framework for Health and Social Care (2nd Ed., 2005) and any other laws or guidelines which are relevant.

## 3. Purpose

The purpose of this SOP is to inform Investigators and study staff on the process of Identification and approval of sponsorship for non-CTIMPs.

## 4. Definitions

Research that falls into the scope of the Research Governance Framework for Health and Social Care 2005, 2nd Ed, (RGF) must have an appropriately identified "Sponsor".

The sponsor in this context is *not the same as the funding body*.

Specifically the Sponsor will be the institution that takes on the responsibility for confirming there are proper arrangements to finance, initiate, manage, conduct and monitor a study.

Research which falls under the Research Governance Framework requires formal confirmation of a designated Sponsor prior to submission for review by a committee of the National Research Ethics Service (NRES), Health Research Authority for HRA approval and/or submission to a host site for confirmation of capacity and capability.

For those studies falling outside the remit of the Research Governance Framework i.e. animal research or computer modelling studies and/or simple laboratory projects not involving direct human tissue sampling, identification and confirmation of a Sponsor (as per the definition above) is not a requirement but for the purposes of the ReDA database, the R&D office will consider identifying a Sponsor.

## 5. Personnel responsible

The overall responsibility as Sponsor is with the GOSH Chief Executive or Director of ICH delegated to the GOSH Director of Clinical R&D, Institute of Child Health Manager and the GOSH Deputy Director of Research and Innovation are the authorised signatory for all Sponsorship declarations.

In practise the RM&G officers and the Head of Governance, Clinical Trials and Contracts under the guidance of the Deputy Director of Research and Innovation and will be able to sign the IRAS form on behalf of the Deputy Director of Research and Innovation. This should be done by logging onto the department's IRAS account research.governance@gosh.nhs.uk and authorising the IRAS form. Specific guidance is outlined in Appendix 2

## 6. Procedure

| ***Who should apply for sponsorship?*** |
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| It is the responsibility of the Chief Investigator (CI) to request sponsorship confirmation from the Joint R&D office but this may be delegated to another member of the research team with sufficient knowledge of the research activity. All sponsorship declarations should be addressed to the CI.<br><br>**Student research:** for MSc level and below, the academic supervisor should be listed as the CI, for PhD level, it may be possible for the student to act as CI however an academic and/or clinical supervisor must be identified prior to sponsorship request. |
| ***When to apply for sponsorship?*** |
| Normally the CI would be expected to formally request confirmation of a Sponsor once research funding has been approved/ granted or approval obtained from the GOSH Clinical Research Applications Committee (CRAC). The CI should liaise with the Joint R&D office as soon as possible after receipt of this information to discuss sponsorship responsibilities for their study.<br><br>Occasionally the funding body requires confirmation of sponsorship prior to a grant submission. This "sponsorship in principle" should be sought from and provided by the Joint R&D Office. This can be in the form of a signature or a letter from the sponsor's representative.<br><br>**Student research:** a request should be sought once the academic and/or clinical |

supervisor has approved the study.

Sponsorship should be confirmed at a minimum ("in principle") before any formal application to the NRES Ethics Committee and/or NHS organisation for confirmation of capacity and capability.

***How to determine the appropriate Sponsor?***

When identifying a sponsor for a research study, please review the information that you have about the study for an indication of:

- Who the CI is
- Who the CI's employer is
- Where the research is to take place
- Who the funder is
- If it is a student project

You may need to request further information such as the research protocol, a copy of the IRAS form and/ or details of any 3rd party involvement in the study from the researcher if the information is not easily accessible from the initial study documents that you have been supplied.

**How to identify a sponsor for a research study?**

*Please also refer to flowchart in Appendix 1*

**GOSH as Sponsor**

GOSH sponsored studies are typically those that have a Chief Investigator (CI) who has a substantive contract of employment with GOSH and who is conducting research involving GOSH patients, their tissue or data.

GOSH will also be the sponsor when:
Studies are conducted by a CI who is an UCL-ICH member of staff who also has an honorary **clinical** contract with GOSH and who is conducting research at GOSH using GOSH patients, tissue or data.

Studies conducted by a CI who has substantive employment at GOSH or has an honorary **clinical** contract with GOSH but is conducting it in a clinical setting other than GOSH.

NB: GOSH honorary research contract (HRC) is issued by this R&D office and is not the same as a GOSH honorary clinical contract (HCC) which would be issued by HR. Confirmation from GOSH HR should be sought that a CI has a GOSH honorary clinical contract before confirming sponsorship.

**UCL (ICH) as Sponsor:**

UCL-ICH sponsored studies are those research studies that are led by a CI who has a substantive employment contract with UCL-ICH and no employment relationship (e.g. honorary clinical contract) with another organisation such as GOSH or another NHS Trust.

These studies may be conducted within UCL-ICH or involve spells at other locations such as GOSH or another NHS Trust.

**Student Research:**

The Sponsor should normally be the academic institution accrediting the degree for which the study forms.

Where students have registered for postgraduate study with UCL-ICH then UCL- will sponsor for their research. Students registered at other institutions will have to seek confirmation of sponsorship from that institution.

In certain circumstances GOSH may act as the Sponsor of clinical student projects however this must be discussed and agreed by the Deputy Director of Research and Innovation.

**Another organisation as Sponsor:**

Studies that are led by CI's who are employed by another organisation (i.e. not GOSH or UCL-ICH) – even where the study is being conducted using GOSH patients, their tissue or data will not be sponsored by GOSH or UCL-ICH.

From time to time exceptions to this rule may occur. Where sponsorship of projects led by employees of other organisations/ students who are not registered at UCL-ICH is considered, approval should be sought from the Deputy Director of Research and Innovation.

**Confirming sponsorship**

Once an assessment has been made that either GOSH or UCL-ICH is the appropriate sponsor, confirmation of sponsorship should be done by electronic signing of the research project's IRAS form. This is done using the research.governance@gosh.nhs.uk IRAS account. The procedure for doing this is outlined in Appendix 2 of this SOP.

The joint R&D office cannot confirm sponsorship/ authorise IRAS forms for projects

led by CI's from other organisations. As a result where another organisation is responsible for sponsoring the project, the CI should approach that organisation to confirm sponsorship.

Where GOSH CI's are leading multi-centre studies (i.e. involving other organisations as hosts of the research) it may be necessary to issue a sponsorship letter. A template for this is available to use from ReDa.

In all instances only those signatories confirmed to provide sponsorship authorisation can do so.

## 7. Associated documents and SOPs*

| Document Name | File Path | Author |
|---|---|---|
| **GOSH and ICH (UCL) non-commercial sponsorship flowchart** | R&D Folders: Available on Request | **Governance team** |
| **Steps to Sponsor's Electronic Authorisation of IRAS form** | R&D Folders: Available on Request | **Governance team** |

## 8. Recommendations

## 9. References

Department of Health: The Research Governance Framework for Health and Social Care 2005 2nd Edition,

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

NRES Guidance on Student Research

http://www.hra.nhs.uk/documents/2013/08/ethical-review-of-student-research-guidance-for-students-supervisors-and-research-ethics-committees.pdf

NRES Standard Operating Procedure v6.1, 2015

http://www.hra.nhs.uk/documents/2015/01/standard-operating-procedures-version-6-1-2.pdf

NRES Ethical review of student research, 20/10/2011 http://www.hra.nhs.uk/documents/2013/08/ethical-review-of-student-research-guidance-for-students-supervisors-and-research-ethics-committees.pdf

## 10. Appendices

*all these documents are available electronically