University of Hertfordshire

OBTAINING SPONSORSHIP FOR RESEARCH STUDIES

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for obtaining Sponsorship for research studies

SOP Number: gSOP-36-01	**Effective Date:** 26th April 2018
Version Number: 1.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure. This document sets out the procedures to be followed by all staff seeking sponsorship for research studies.

2. PURPOSE

To ensure all research studies requiring UH sponsorship follow the correct process.

3. APPLICABLE TO

This applies to any UH employee involved with research which requires UH sponsorship including but not limited to: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Managers, Clinical Studies Officers, Data Managers, Research Assistants and Students.

4. RESPONSIBILITIES

To ensure all research staff are familiar with the sponsorship of research studies process and the relevant procedures are followed.

5. PROCEDURE

What is a Sponsor?
A sponsor is an organisation which takes responsibility for the quality and conduct of a research project. All health and social care research is required to have a research sponsor.

The sponsor can be defined in two ways:

- The UK Policy Framework for Health and Social Care Research describes a sponsor as an 'individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project'.
- The Clinical Trials Regulations describes a sponsor, in relation to a clinical trial, as the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

What does a Sponsor do?
A sponsor has overall responsibility for the research including:

a. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:

   - take into account systematic reviews of relevant existing research evidence and other relevant research in progress,
   - make appropriate use of patient, service user and public involvement and
   - are scientifically sound (e.g. through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing.

b. Satisfying itself that the investigators, research team and research sites are suitable;

c. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;

d. ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants

f. ensuring that, where expected or required, the research has approval from

a research ethics committee and any other relevant approval bodies before it begins;

g. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;

h. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;

i. ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

Sponsors of clinical trials of investigational medicinal products have particular legal duties – see www.hra.nhs.uk/resources for details.

Arrangements proposed for the work are consistent with the applicable laws, guidance and regulations, including ICH GCP, Medicines for Human Use (Clinical Trials) Regulations and/or the UK Policy framework for Health and Social Care research.

University or NHS Trust?

The Sponsor is normally expected to be the employer of the Chief Investigator in the case of non-commercial research or the funder in the case of commercial research.

The University should be the sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to take on this role.

How to apply

If applying for University sponsorship:

1. Complete the EC1D form.

If applying for ethics approval from a Health Research Authority REC or Social Care REC via IRAS ('Integrated Research Application System') and needing the University to act as Sponsor for your research study, submit the University Form *EC1D: NHS Protocol Registration Request* to the relevant UH Ethics Committee with Delegated Authority (ECDA); their acknowledgement will be copied to research-sponsorship@herts.ac.uk who will then await the sponsorship application.

2. Complete the SP1 form if the study has funding secured or does not require funding. (If at the stage of applying for funding see information regarding the SP4 form below):

Complete all relevant questions on the form SP1: University approval for sponsorship of a

research study and provide the required supporting documentation and submit to research-sponsorship@herts.ac.uk. Note: A risk assessment should have been completed if the study is a clinical trial of an intervention. If you need the University to act as co-sponsor or an external organisation has agreed to act as sponsor, in addition to all the questions on the form, you must also complete *Annex 2* and provide the additional supporting documentation required.

If study involves an NHS partner:

If you are asking an NHS Trust to be sponsor/co-sponsor/collaborator for your research study you should:
1. Contact the Associate Director, Research & Development within the NHS Trust who will be asked to provide resources or services and where necessary arrange an appointment to discuss what is required.
2. The AD, R&D will make an assessment of whether it will be able to act as sponsor/co-sponsor/collaborator for your project.

If the Trust is to be a co-sponsor, you will need a provisional sponsorship letter/email from the NHS Trust stating they agree in principle to submit with your SP1 form.

If your research study has University Research Ethics Committee (REC) approval but you require sponsorship in order to apply for HRA approval for the purposes of management permissions (R&D confirmation) please use the SP3 form. You will need to provide confirmation of your validated University protocol number which will be given by the University REC.

If the University agrees to act as sponsor or co-sponsor you will receive a sponsorship in principle letter outlining responsibilities. Sponsor authorisation will then be given for submission of your IRAS application.

The University's agreement in principle to act as sponsor is not approval for the study and is conditional on full approval being gained through the normal study regulatory approval processes. Upon receiving NHS REC approval and other approvals/permissions, copy them to the following email address: research-sponsorship@herts.ac.uk. Only once all approvals are in place and all risks and mitigations have been agreed, Research Sponsorship will notify the ECDA so a University protocol number for your study can be issued and University sponsorship confirmed so your research study can commence.

The terms and conditions of University sponsorship require application for approval to notify or submit amendments and reporting as required. Please note guidance for amendments.

If applying at grant application stage:

If UH is to be sponsor or co-sponsor, sponsorship should be applied for at the stage of grant application for a research proposal. In this instance, the EC1D and SP1 form should not be completed at this stage. Instead complete the SP4 and submit it to research-sponsorship@herts.ac.uk. Following internal review by the research office staff, if your request is accepted, you will receive a letter outlining the University's willingness to sponsor your study subject to full review on award. If you are working in partnership with another organisation then you will need to have confirmation from them. University approval for submission of your grant application cannot be given without this. If your grant application is successful, you will need to complete the EC1D and SP1 forms as above.

6. REFERENCES and LINKS TO OTHER SOPS AND DOCUMENTS

- gSOP-033 Risk Assessment
- gSOP-13 Research Applications
- gSOP-09 Amendments

7. APPENDICES

Appendix 1 - Definitions
Appendix 2 - UH Sponsorship and Ethics Approval Flowchart

8. AUTHORSHIP & APPROVAL

Author

Signature **Date**

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature **Date**

9. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

10. AGREEMENT (MOVE ON TO SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-036-01) and accept to follow University policies implementing it.

Recipient
Signature: ……Date: ……..
Name & Position: ……

Please retain copy of the signed form for your reference in your training file

Appendix 1: Definitions

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Clinical Trial of Investigational Medicinal Product (CTIMP) - A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004).

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested, or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation

Principal Investigator (PI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Appendix 2 UH Sponsorship and Ethics Approval Flowchart