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-36-02	**Effective Date: 10/08/22**
Version Number: 2.0	**Review Date:** 3 years (or as required)

1.0 BACKGROUND

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

All research conducted within the NHS has to comply with the requirements of the UK Policy Framework for Health and Social Care and, if applicable the Medicines for Human Use (Clinical Trials) Regulations and the Medical Devices Regulations. Other research such as that involving social care sites and prisons are also covered by HRA Research Governance.

The UK Framework for Health and Social Care states there must be a sponsor for:

- All research in England involving NHS or Social Care participants or participant data and in some cases staff (usually if it impacts clinical practice).
- All clinical trials involving a medicine or medical device.
- Research involving the Human Tissue Act or the Mental Capacity Act.
- This framework does not generally encompass children's social care research in England or Scotland, except where the project also involves health research, adult social care research or children's social care research in Northern Ireland or Wales.

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.

- 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.

2.0 PURPOSE

This SOP describes the activities undertaken to ensure all research studies requiring UH sponsorship follow the correct process.

3.0 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.

4.0 RESPONSIBILITIES

4.1 The Sponsor:

- Identify and address poorly designed or planned research and poor-quality research proposals, protocols or applications and ensure that research proposals and protocols:
  a) take into account systematic reviews of relevant existing research evidence and other relevant research in progress,
  b) make appropriate use of patient, service user and public involvement, and
  c) 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.
- Satisfy itself that the investigators, research team and research sites are suitable.
- Ensure that roles and responsibilities of the involved parties and any delegation by the sponsor of its tasks are agreed and documented.
- Ensure 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.
- Ensure 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).
- Agree appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished.
- Ensure arrangements for information about the findings of the research to be made available, including, where appropriate, to participants.

- Ensure that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins.
- Verify that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner.
- Put and keep in place arrangements for adequate finance and management of the research project including its competent risk management and data management.
- Ensure that effective procedures and arrangements are kept in place and adhered to for reporting and 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.

4.2 Clinical Trials Support Network (CTSN):

- Provide advice and assistance to staff and students (as well as NHS clinicians and researchers) in all aspects of the management and conduct of research studies.
- Assisting with obtaining sponsorship if the study has been adopted or is supported by the CTSN.

4.3 Chief Investigator (CI) / Principal Investigator (PI):

- Submit the appropriate ethics (e.g., EC1D and ECDA) and sponsorship forms (e.g., SP1, SP3, SP4) when applying for University of Hertfordshire sponsorship.

5.0 PROCEDURE

Sponsorship should be sought at grant application stage and when the grant has been obtained.

5.1 Applying for Sponsorship at Grant Application Stage

I. 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 case, complete the SP4 and submit it to research-sponsorship@herts.ac.uk.

II. If the initial administrative check indicates applicable for sponsorship, an academic review will be conducted by Associate Dean of Research (ADR) and/or other members of the Advisory Group on Research Governance for Clinical Studies (AGRGCS). 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.

III. If you are working in partnership with another organisation, then you will need to have confirmation from them.

IV. University approval for submission of your grant application cannot be given without this.

V. If your grant application is successful, you will need to complete the EC1D and SP1 forms as above.

5.2 Applying for University Sponsorship for a study requiring HRA/REC approval:

I. Complete the EC1D form and submit to the relevant Ethics Committee with Delegated Authority (ECDA):
   a. Health, Science, Engineering and Technology (hsetecda@herts.ac.uk)
   OR
   b. Social Sciences, Arts and Humanities (ssahecda@herts.ac.uk) .

II. Receive acknowledgement from ECDA.

III. Complete and sign (electronically) the internal SP1 form and email to research-sponsorship@herts.ac.uk together with supporting documentation specified. Note: A risk assessment should have been completed if the study is a clinical trial of an intervention.

IV. If review outcome is favourable, receive letter of sponsorship in principle. 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.

V. Complete online IRAS form and request sponsor authorisation. Once authorised, submit IRAS application.

VI. Once approvals are granted, UH research sponsorship are notified of approvals and ECDA are advised a UH protocol number is issued and a letter of confirmation of sponsorship in full is issued.

VII. 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 (gSOP-09).

5.3 Applying for University Sponsorship for a study NOT requiring HRA/REC ethical approval:

I. Complete UH EC1A form and submit to ECDA.

II. If your research study does not require HRA NHS/Social care ethical approval but requires HRA approval for the purposes of site permissions or confirmations of capacity and capability complete and sign (electronically) the SP3 form.

III. ECDA clerk provides protocol number and submits for consideration.

IV. If approval granted, ECDA clerk sends approval notification.

5.4 Applying for Sponsorship where an NHS Trust is sponsor/co-sponsor/collaborator

I. 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.

II. The Associate Director, R&D will make an assessment of whether it will be able to act as sponsor/co-sponsor/collaborator for your project.

III. 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.

6. REFERENCES and LINKS TO OTHER SOPS AND DOCUMENTS

- gSOP-33 Risk Assessment
- gSOP-13 Research Applications
- gSOP-09 Amendments
- University of Hertfordshire Research Sponsorship Guidance on HertsHub
- EC1D Form
- EC1A Form
- SP1 Form
- SP3 Form
- SP4 Form

7. APPENDICES

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

8. AUTHORSHIP & APPROVAL

Author

Signature  **Date 23/07/2022**

Pro Vice-Chancellor (Research & Enterprise) Approval
Professor J M Senior

Signature  **Date 08/08/2022**

9. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change
2.0	**10/08/22**	Review

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-036-02) and accept to follow University policies implementing it.

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

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